PTO/AIA/15 (03-13)
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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	13211-713.303
First Named Inventor	Adam BOWEN
Title	NICOTINE SALT FORMULATIONS FOR ...
Express Mail Label No.	FILED VIA EFS ON 10/28/2015

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☐ **Fee Transmittal Form** (PTO/SB/17 or equivalent)
2. ☐ **Applicant asserts small entity status.** See 37 CFR 1.27
3. ☐ **Applicant certifies micro entity status.** See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.
4. ☑ **Specification** [*Total Pages* 93] Both the claims and abstract must start on a new page. *(See MPEP § 608.01(a) for information on the preferred arrangement)*
5. ☑ **Drawing(s)** (35 U.S.C. 113) [*Total Sheets* 8]
6. **Inventor's Oath or Declaration** [*Total Pages* 2] *(including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e))*
   a. ☐ Newly executed (original or copy)
   b. ☑ A copy from a prior application (37 CFR 1.63(d))
7. ☑ **Application Data Sheet** ** See note below.* See 37 CFR 1.76 (PTO/AIA/14 or equivalent)
8. **CD-ROM or CD-R** in duplicate, large table, or Computer Program (*Appendix*)
   ☐ Landscape Table on CD
9. **Nucleotide and/or Amino Acid Sequence Submission** (*if applicable, items a. – c. are required*)
   a. ☐ Computer Readable Form (CRF)
   b. ☐ Specification Sequence Listing on:
      i. ☐ CD-ROM or CD-R (2 copies); *or*
      ii. ☐ Paper
   c. ☐ Statements verifying identity of above copies

ADDRESS TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**

ACCOMPANYING APPLICATION PAPERS

10. ☐ **Assignment Papers** (cover sheet & document(s)) Name of Assignee _____
11. ☐ **37 CFR 3.73(c) Statement** (*when there is an assignee*) ☐ **Power of Attorney**
12. ☐ **English Translation Document** (*if applicable*)
13. ☐ **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    ☐ Copies of citations attached
14. ☐ **Preliminary Amendment**
15. ☐ **Return Receipt Postcard** (*MPEP § 503*) (*Should be specifically itemized*)
16. ☐ **Certified Copy of Priority Document(s)** (*if foreign priority is claimed*)
17. ☐ **Nonpublication Request** Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
18. ☑ **Other:** Certification and Request for Prioritized Examination (Track 1), Fee Transmittal

*Note: (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 **must** be included in an Application Data Sheet (ADS).
(2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).

19. CORRESPONDENCE ADDRESS

☑ The address associated with Customer Number: 66854 **OR** ☐ Correspondence address below

Name					
Address					
City		State		Zip Code	
Country		Telephone		Email	

Signature		Date	October 28, 2015
Name (Print/Type)	Richard D. Shoop	Registration No. (Attorney/Agent)	45,763

This collection of information is required by 37 CFR 1.53(b). 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: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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EX1033
NJOY v. JUUL
IPR2026-00161

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (04-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Adam BOWEN	Nonprovisional Application Number (if known):	
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently $0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.
2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.
3. The applicable box is checked below:

I. ☑ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, **or** the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature	Date October 28, 2015
Name (Print/Typed) Richard D. Shoop	Practitioner Registration Number 45,763

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☑ *Total of one forms are submitted.

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on October 28, 2015.

/Jennifer Capizzi/ October 28, 2015
Jennifer Capizzi Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	: Unassigned	Confirmation No.	:	Unassigned
First Named Inventor	: Adam BOWEN			
Filing Date	: Herewith			
Art Unit	: Unassigned			
Examiner	: Unassigned			
Title	: NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF			
Customer No.	: 66854			

FEE TRANSMITTAL

Transmitted herewith are the following fees:

(1) Basic Filing Fee - Utility	$280
(2) Utility Search Fee	$600
(3) Utility Examination Fee	$720
(4) Claims in Excess of 20 (0 x $80)	$0
(5) Independent Claims in Excess of 3 (0 x $420)	$0
(6) Processing fee (1.17(i))	$140
(7) Prioritized Examination Fee (Track 1) (1.17(c))	$4,000
(8) Application Size Fee (0 x $400)	$0
Total	**$5,740**

☒ The above fees have been paid via EFS to Deposit Account No. 50-4050. Please also deduct from or credit to said Deposit Account any other fees attendant with this matter.

Respectfully submitted,

Dated: October 28, 2015 By: _____
Richard D. Shoop, Reg. No. 45,763

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FACSIMILE: 650.212.7562

SG Docket No.: 13211-713.303

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF

As the below named inventor, I hereby declare that:

This declaration is directed to:

- ☐ The attached application, or
- ■ United States application or PCT international application number 14/271,071 filed on May 6, 2014.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Adam Bowen Date (Optional): 5/14/14

Signature: [signature]

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1 minute 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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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

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As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

■ United States application or PCT international application number 14/271,071 filed on May 6, 2014.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

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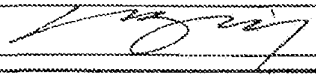
LEGAL NAME OF INVENTOR

Inventor: Chenyue Xing Date (Optional): 05/19/14

Signature: 

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1 minute 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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UNITED STATES PATENT APPLICATION

NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF

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/Jennifer Capizzi/ October 28, 2015
Jennifer Capizzi Date

SG Docket No.: 13211-713.303

NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF

CROSS REFERENCE

[0001] This application is a continuation of U.S. Patent Application No. 14/512,311, filed October 10, 2014, titled "NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF," now U.S. Patent Application Publication No. 2015-0020824-A1, which is a continuation of U.S. Patent Application No. 14/271,071, filed May 6, 2014, titled "NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF," now U.S. Patent Application Publication No. 2014-0345631-A1, which claims the benefit of U.S. Provisional Patent Application No. 61/820,128, filed May 6, 2013, and U.S. Provisional Patent Application No. 61/912,507, filed December 5, 2013, all of which are incorporated herein by reference in their entirety.

SUMMARY OF THE INVENTION

[0002] Provided herein is a method of delivering nicotine to a user comprising operating an electronic cigarette to a user wherein the electronic cigarette comprises a nicotine salt formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200 °C, and inhaling an aerosol generated from the nicotine salt formulation heated by the electronic cigarette.

[0003] Provided herein is a method of delivering nicotine to a user comprising operating an electronic cigarette to a user wherein the electronic cigarette comprises a nicotine salt formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200 °C, and inhaling an aerosol generated from the nicotine salt formulation heated by the electronic cigarette.

[0004] Provided herein is a method of delivering nicotine to a user comprising operating an electronic cigarette wherein the electronic cigarette comprises a nicotine salt formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160 °C, a boiling point >160 °C,

and at least a 50-degree difference between the melting point and the boiling point, and inhaling an aerosol generated from the nicotine salt formulation heated by the electronic cigarette.

[0005] Provided herein is a method of delivering nicotine to a user comprising providing an electronic cigarette to a user wherein the electronic cigarette comprises a nicotine salt formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point, and inhaling an aerosol generated from the nicotine salt formulation heated by the electronic cigarette.

[0006] Provided herein is a method of delivering nicotine to the blood of a user, said method comprising providing an aerosol that is inhaled by the user from an electronic cigarette that comprises a nicotine salt formulation wherein providing the aerosol comprises the electronic cigarette heating the formulation thereby generating the aerosol, wherein the aerosol is effective in delivering a level of nicotine in the blood of the user that is at least 5ng/mL at about 1.5 minutes after a first puff of ten puffs of the aerosol, each puff taken at 30 second intervals.

[0007] Provided herein is a nicotine salt liquid formulation in an electronic cigarette for generating an inhalable aerosol upon heating in the electronic cigarette, the formulation in the cigarette comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200 ^{o}C.

[0008] Provided herein is a nicotine salt liquid formulation in an electronic cigarette for generating an inhalable aerosol upon heating in the electronic cigarette, the formulation in the cigarette comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200 ^{o}C.

[0009] Provided herein is a nicotine salt liquid formulation in an electronic cigarette for generating an inhalable aerosol upon heating in the electronic cigarette, the formulation in the cigarette comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160 °C, a boiling point >160 °C, and at least a 50-degree difference between the melting point and the boiling point.

[0010] Provided herein is a nicotine salt liquid formulation in an electronic cigarette for generating an inhalable aerosol upon heating in the electronic cigarette, the formulation in the cigarette comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point.

[0011] Provided herein is a nicotine salt liquid formulation for generating an inhalable aerosol upon heating in the electronic cigarette, the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200 °C.

[0012] Provided herein is a nicotine salt liquid formulation for generating an inhalable aerosol upon heating in the electronic cigarette, the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200 °C.

[0013] Provided herein is a nicotine salt liquid formulation for generating an inhalable aerosol upon heating in the electronic cigarette, the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160 °C, a boiling point >160 °C, and at least a 50-degree difference between the melting point and the boiling point.

[0014] Provided herein is a nicotine salt liquid formulation for generating an inhalable aerosol upon heating in the electronic cigarette, the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point.

[0015] Provided herein is a nicotine salt liquid formulation for use in an electronic cigarette the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200 °C.

[0016] Provided herein is a nicotine salt liquid formulation for use in an electronic cigarette the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200 °C.

[0017] Provided herein is a nicotine salt liquid formulation for use in an electronic cigarette the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160 °C, a boiling point >160 °C, and at least a 50-degree difference between the melting point and the boiling point.

[0018] Provided herein is a nicotine salt liquid formulation for use in an electronic cigarette the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point.

[0019] Provided herein is a use of a nicotine salt formulation for delivery of nicotine to a user from an electronic cigarette wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200 °C, and the nicotine salt formulation is heated by the electronic cigarette to generate an aerosol inhalable by the user.

[0020] Provided herein is a use of a nicotine salt formulation for delivery of nicotine to a user from an electronic cigarette wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200 °C, and the nicotine salt formulation is heated by the electronic cigarette to generate an aerosol inhalable by the user.

[0021] Provided herein is a use of a nicotine salt formulation for delivery of nicotine to a user from an electronic cigarette wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160 °C, a boiling point >160 °C, and at least a 50-degree difference between the melting point and the boiling point, and the nicotine salt formulation is heated by the electronic cigarette to generate an aerosol inhalable by the user.

[0022] Provided herein is a use of a nicotine salt formulation for delivery of nicotine to the blood of a user from an electronic cigarette, wherein the nicotine salt formulation in the electronic cigarette is heated to form an aerosol which delivers a level of nicotine in the blood of the user that is at least 5 ng/mL at about 1.5 minutes after a first puff of ten puffs of the aerosol, each puff taken at 30 second intervals.

[0023] Provided herein is a use of a nicotine salt formulation for delivery of nicotine to a user from an electronic cigarette wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point, and the nicotine salt formulation is heated by the electronic cigarette to generate an aerosol inhalable by the user.

[0024] Provided herein is a cartomizer for an electronic cigarette comprising:

a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200 °C;

an atomizer comprising a heating element in fluid communication with the nicotine salt liquid formulation; and

a fluid storage compartment that stores the nicotine salt liquid formulation.

[0025] Provided herein is a cartomizer for an electronic cigarette comprising:

a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200 °C;

an atomizer comprising a heating element in fluid communication with the nicotine salt liquid formulation; and

a fluid storage compartment that stores the nicotine salt liquid formulation.

[0026] Provided herein is a cartomizer for an electronic cigarette comprising:

a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further

characterized by a melting point <160 °C, a boiling point >160 °C, and at least a 50-degree difference between the melting point and the boiling point;

an atomizer comprising a heating element in fluid communication with the nicotine salt liquid formulation; and

a fluid storage compartment that stores the nicotine salt liquid formulation.

[0027] Provided herein is a cartomizer for an electronic cigarette comprising:

a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point;

an atomizer comprising a heating element in fluid communication with the nicotine salt liquid formulation; and

a fluid storage compartment that stores the nicotine salt liquid formulation.

[0028] Provided herein is an electronic cigarette for generating an inhalable aerosol comprising:

a fluid storage compartment;

a heater; and

a nicotine salt liquid formulation in the fluid storage compartment, the liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200 °C;

a battery; and

a mouthpiece.

[0029] Provided herein is an electronic cigarette for generating an inhalable aerosol comprising:

a fluid storage compartment;

a heater; and

a nicotine salt liquid formulation in the fluid storage compartment, the liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200 °C;

a battery; and

a mouthpiece.

[0030] Provided herein is an electronic cigarette for generating an inhalable aerosol comprising:

a fluid storage compartment;

a heater; and

a nicotine salt liquid formulation in the fluid storage compartment, the liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160 °C, a boiling point >160 °C, and at least a 50-degree difference between the melting point and the boiling point;

a battery; and

a mouthpiece.

[0031] Provided herein is an electronic cigarette for generating an inhalable aerosol comprising:

a fluid storage compartment;

a heater; and

a nicotine salt liquid formulation in the fluid storage compartment, the liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point;

a battery; and

a mouthpiece.

[0032] Provided herein is a cartridge in an electronic cigarette comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200 °C.

[0033] Provided herein is a cartridge in an electronic cigarette comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation

comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200 °C.

[0034] Provided herein is a cartridge in an electronic cigarette comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160 °C, a boiling point >160 °C, and at least a 50-degree difference between the melting point and the boiling point.

[0035] Provided herein is a cartridge in an electronic cigarette comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point.

[0036] Provided herein is a kit comprising:

(a) an electronic cigarette for generating an inhalable aerosol comprising

i. a device body comprising a cartridge receptacle;

ii. a cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200 °C;

iii. a heater;

iv. a battery; and

v. a mouthpiece; and

(b) instructions for using the electronic cigarette to generate an inhalable aerosol.

[0037] Provided herein is a kit comprising:

(c) an electronic cigarette for generating an inhalable aerosol comprising

i. a device body comprising a cartridge receptacle;

ii. a cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a

nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200 °C;

iii. a heater;

iv. a battery; and

v. a mouthpiece; and

(d) instructions for using the electronic cigarette to generate an inhalable aerosol.

[0038] Provided herein is a kit comprising:

(e) an electronic cigarette for generating an inhalable aerosol comprising

i. a device body comprising a cartridge receptacle;

ii. a cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160 °C, a boiling point >160 °C, and at least a 50-degree difference between the melting point and the boiling point;

iii. a heater;

iv. a battery; and

v. a mouthpiece; and

(f) instructions for using the electronic cigarette to generate an inhalable aerosol.

[0039] Provided herein is a kit comprising:

(g) an electronic cigarette for generating an inhalable aerosol comprising

i. a device body comprising a cartridge receptacle;

ii. a cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point;

iii. a heater;

iv. a battery; and

v. a mouthpiece; and

(h) instructions for using the electronic cigarette to generate an inhalable aerosol.

INCORPORATION BY REFERENCE

[0040] All publications, patents and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0041] A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are used, and the accompanying drawings of which:

[0042] **Figure 1** illustrates results of heart rate data measured for six minutes from start of puffing. Y-axis is heart rate (bpm) and X-axis represent duration of the test (-60 to 180 seconds);

[0043] **Figure 2** illustrates results of heart rate data measured for ten minutes from start of puffing. Y-axis is heart rate (bpm) and X-axis represents duration of the test (0 to 10 minutes);

[0044] **Figure 3** illustrates the calculated vapor pressures of various acids relative to nicotine;

[0045] **Figure 4** illustrates the pharmacokinetic profiles for eight test articles in a blood plasma study;

[0046] **Figure 5** illustrates the comparison of C_{max} and T_{max} for eight test articles in a blood plasma study;

[0047] **Figure 6** illustrates the comparison of C_{max} and AUC for eight test articles in a blood plasma study;

[0048] **Figure 7** depicts an example embodiment of an electronic cigarette having a fluid storage compartment comprising an embodiment nicotine salt formulation described herein; and

[0049] **Figure 8** depicts an example embodiment of an electronic cigarette cartomizer having a fluid storage compartment, a heater, and comprising an embodiment nicotine salt formulation described herein.

DETAILED DESCRIPTION OF THE INVENTION

[0050] Nicotine is a chemical stimulant and increases heart rate and blood pressure when provided to an individual or animal. Nicotine transfer to an individual is associated with a feeling of physical and/or emotional satisfaction. Conflicting reports have been published regarding the transfer efficiency of free base nicotine in comparison to mono- or di-protonated nicotine salts. Studies on the transfer efficiency of free base nicotine and nicotine salts are complex and have yielded unpredictable results. Further, such transfer efficiency studies have been performed under extremely high temperature conditions, comparable to smoking; therefore, they offer scant guidance on the transfer efficiency of free base nicotine and nicotine salts under low-temperature vaporization conditions. Some reports have posited that nicotine free base should give rise to a greater satisfaction in a user than any corresponding nicotine salt.

[0051] It has been unexpectedly discovered herein that certain nicotine salt formulations provide satisfaction in an individual superior to that of free base nicotine, and more comparable to the satisfaction in an individual smoking a traditional cigarette. The satisfaction effect is consistent with an efficient transfer of nicotine to the lungs of an individual and a rapid rise of nicotine absorption in the plasma as shown, for non-limiting example, in Example 8, at least. It has also been unexpectedly discovered herein that certain nicotine salt formulations provide greater satisfaction than other nicotine salt formulations, and such effect has been shown in blood plasma levels of example nicotine salt formulations herein, for non-limiting example, in Example 8, at least. These results show a difference in rate of nicotine uptake in the blood that is higher for some nicotine salt formulations aerosolized by an electronic cigarette than for other nicotine salt formulations, and likewise higher than nicotine freebase formulations, while the peak concentration of the nictoine in the blood and total amount of nicotine delivered appears comparable to a traditional cigarette, and do not appear to vary significantly between the various nicotine formulations. Therefore, described herein are nicotine salt formulations for use in an electronic cigarette, or the like, that provide a general satisfaction effect consistent with an efficient transfer of nicotine to the lungs of an individual and a rapid rise of nicotine absorption in the plasma. Provided herein, therefore, are devices, formulation of nicotine salts, systems, cartomizers, kits and methods that are used to inhale an aerosol generated from a nicotine salt

liquid formulation through the mouth or nose as described herein or as would be obvious to one of skill in the art upon reading the disclosure herein.

[0052] Consistent with these satisfaction effects, it has unexpectedly been found herein that there is a difference between the C_{max} (maximum concentration) and T_{max} (time at which the maximum concentration is measured) when measuring blood plasma nicotine levels of freebase nicotine formulations inhaled using a low temperature vaporization device, i.e. electronic cigarette, as compared to the C_{max} and T_{max} (similarly measuring blood plasma nicotine levels) of a traditional cigarette. Also consistent with these satisfaction effects, it has unexpectedly been found herein that there is a difference between the C_{max} (maximum concentration) and T_{max} (time at which the maximum concentration is measured) when measuring blood plasma nicotine levels of freebase nicotine formulations inhaled using a low temperature vaporization device, i.e. electronic cigarette, as compared to the C_{max} and T_{max} (similarly measuring blood plasma nicotine levels) of nicotine salt formulations inhaled using a low temperature vaporization device, i.e. electronic cigarette. Additionally, it has unexpectedly been found that there is a difference between the rate of nicotine uptake in the plasma of users inhaling freebase nicotine formulations using a low temperature vaporization device, i.e. electronic cigarette, as compared to the rate of nicotine uptake in the plasma of users inhaling smoke of a traditional cigarette. Furthermore, it has unexpectedly been found that there is a difference between the rate of nicotine uptake in the plasma of users inhaling freebase nicotine formulations using a low temperature vaporization device, i.e. electronic cigarette, as compared to the rate of nicotine uptake in the plasma of users inhaling nicotine salt formulations using a low temperature vaporization device, i.e. electronic cigarette.

[0053] Thus, looking at freebase nicotine as a source of nicotine in compositions used in e-cigarettes, freebase nicotine compositions' delivery of nicotine to blood when inhaled using is not necessarily comparable in blood plasma levels (C_{max} and T_{max}) to a traditional cigarette's nicotine delivery to blood when inhaled. Freebase nicotine compositions' delivery of nicotine to blood when inhaled using is not necessarily comparable in blood plasma levels (C_{max} and T_{max}) to nicotine salt formulations' nicotine delivery to blood when inhaled. Freebase nicotine compositions' delivery of nicotine to blood when inhaled using is not necessarily comparable in blood plasma levels when measuring the rate of nicotine uptake in the blood within the first 0-5 minutes to a traditional cigarette's nicotine delivery to blood when inhaled. Freebase nicotine

compositions' delivery of nicotine to blood when inhaled using necessarily is not comparable in blood plasma levels when measuring the rate of nicotine uptake in the blood within the first 0-5 minutes to nicotine salt formulations' nicotine delivery to blood when inhaled.

[0054] Also consistent with these satisfaction effects, it has unexpectedly been found herein that while there appears to be comparable C_{max} and T_{max} values (measuring blood plasma nicotine levels) of nicotine salt formulations inhaled using a low temperature vaporization device, i.e. electronic cigarette, as compared to the C_{max} and T_{max} (similarly measuring blood plasma nicotine levels) of a traditional cigarette, there is a demonstrable difference between the rate of nicotine uptake in the plasma of users inhaling certain nicotine salt formulations using a low temperature vaporization device, i.e. electronic cigarette, as compared to the rate of nicotine uptake in the plasma of users inhaling other nicotine salt formulations using a low temperature vaporization device, i.e. electronic cigarette. It is also unexpected that while the C_{max} and T_{max} values are comparable to those of a traditional cigarette, (or are approaching that of a traditional cigarette), the rate of nicotine uptake in the plasma of blood of users is higher in certain nicotine salt formulations than that of the traditional cigarette. The nicotine salt formulations which demonstrate the quickest rate of nicotine uptake in the plasma were more preferred in satisfaction evaluations, and were rated more equivalent to cigarette satisfaction than the nicotine salt formulations showing the slowest rates of rise of nicotine in the subjects' blood plasma. In addition, doubling the concentration of the nicotine salt in the formulation may not necessarily impact the rate of absorption of nicotine in the blood (see, for non-limiting example Example 8, nicotine benzoate tested in 4% and 2% concentrations).

[0055] Thus, looking at nicotine salt formulations used in e-cigarettes, nicotine salt formulations delivered using an e-cigarette appear comparable in C_{max} and T_{max} values (measuring blood plasma nicotine levels), however, not all nicotine salts perform similarly to each other or to a traditional cigarette with respect to the rate of nicotine uptake in the blood at early time periods (0-1.5 minutes). These results are unexpected. Nicotine salt formulations made using acids having a Vapor Pressure between 20 – 300 mmHg @ 200 °C, or Vapor Pressure > 20 mmHg @ 200 °C, or a Vapor Pressure from 20 to 300 mmHg @ 200 °C, or a Vapor Pressure from 20 to 200 mmHg @ 200 °C, a Vapor Pressure between 20 and 300 mmHg @ 200 °C appear to have a higher rate of nicotine uptake in the blood at early time periods (0-1.5 minutes, 0-3 minutes, 0-2 minutes, 0-4 minutes for non-limiting example) than other nicotine

salt formulations, however, they also provide satisfaction comparable to a traditional cigarette or closer to a traditional cigarette (as compared to other nicotine salt formulations or as compared to nicotine freebase formulations). For non-limiting example, acids that meet one or more criteria of the prior sentence include salicylic acid, sorbic acid, benzoic acid, lauric acid, and levulinic acid. Nicotine salt formulations made using acids that have a difference between boiling point and melting point of at least 50 °C, and a boiling point greater than 160 °C, and a melting point less than 160 °C appear to have a higher rate of nicotine uptake in the blood at early time periods (0-1.5 minutes, 0-3 minutes, 0-2 minutes, 0-4 minutes for non-limiting example) than other nicotine salt formulations, however, they also provide satisfaction comparable to a traditional cigarette or closer to a traditional cigarette (as compared to other nicotine salt formulations or as compared to nicotine freebase formulations). For non-limiting example, acids that meet the criteria of the prior sentence include salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid. Nicotine salt formulations made using acids that have a difference between boiling point and melting point of at least 50 °C, and a boiling point at most 40 °C less than operating temperature, and a melting point at least 40 °C lower than operating temperature appear to have a higher rate of nicotine uptake in the blood at early time periods (0-1.5 minutes, 0-3 minutes, 0-2 minutes, 0-4 minutes for non-limiting example) than other nicotine salt formulations, however, they also provide satisfaction comparable to a traditional cigarette or closer to a traditional cigarette (as compared to other nicotine salt formulations or as compared to nicotine freebase formulations). Operating temperature can be 100 °C to 300°C, or about 200°C, about 150°C to about 250°C, 180C to 220°C, about 180°C to about 220°C, 185°C to 215°C, about 185°C to about 215°C, about 190°C to about 210°C, 190°C to 210°C, 195°C to 205°C, or about 195°C to about 205°C. For non-limiting example, acids that meet the criteria of the prior sentence include salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid. Combinations of these criteria for preference of certain nicotine salt formulations are contemplated herein.

[0056] Other reasons for excluding certain acids from formulations may be unrelated to the rate of nicotine uptake, however. For example, an acid may be inappropriate for use with the device materials (corrosive or otherwise incompatible). Sulfuric acid is an example of this, which may be inappropriate for the e-cigarette device. An acid may be inappropriate for use in inhalation or for toxicity reasons – thus not be compatible for human consumption, ingestion, or

inhalation. Sulfuric acid again is an example of this, which may be inappropriate for a user of an e-cigarette device, depending on the embodiment of the composition. An acid that is bitter or otherwise bad-tasting may also provide a reason for exclusion, such as acetic acid in some embodiments. Acids that oxidize at room temperature or at operating temperature may be inappropriate for certain embodiments, for example, sorbic acid, as this indicates a decomposition or reaction or instability that may be undesirable in the formulation. Decomposition of acids at room or operating temperatures may also indicate that the acid is inappropriate for use in the embodiment formulations. For example, citric acid decomposes at 175°C, and malic acid decomposes at 140°C, thus for a device operating at 200°C, these acids may not be appropriate. Acids that have poor solubility in the composition constituents may be inappropriate for use in certain embodiments of the compositions herein. For example, nicotine bitartrate with a composition of nicotine and tartaric acid as 1:2 molar ratio will not produce a solution at a concentration of 0.5%(w/w) nicotine or higher and 0.9%(w/w) tartaric acid or higher in propylene glycol (PG) or vegetable glycerin (VG) or any mixture of PG and VG at ambient conditions. As used herein, weight percentage (w/w) refers to the weight of the individual component over the weight of the total formulation.

[0057] As used in this specification and the claims, the singular forms "a," "an," and "the" include plural referents unless the context clearly dictates otherwise.

[0058] The term "organic acid" as used herein, refers to an organic compound with acidic properties (e.g., by Brønsted-Lowry definition, or Lewis definition). A common organic acid is the carboxylic acids, whose acidity is associated with their carboxyl group –COOH. A dicarboxylic acid possesses two carboxylic acid groups. The relative acidity of an organic is measured by its pK_a value and one of skill in the art knows how to determine the acidity of an organic acid based on its given pKa value. The term "keto acid" as used herein, refers to organic compounds that contain a carboxylic acid group and a ketone group. Common types of keto acids include alpha-keto acids, or 2-oxoacids, such as pyruvic acid or oxaloacetic acid, having the keto group adjacent to the carboxylic acid; beta-keto acids, or 3-oxoacids, such as acetoacetic acid, having the ketone group at the second carbon from the carboxylic acid; gamma-keto acids, or 4-oxoacids, such as levulinic acid, having the ketone group at the third carbon from the carboxylic acid.

[0059] The term "electronic cigarette" or "e-cigarette" or "low temperature vaporization device" as used herein, refers to an electronic inhaler that vaporizes a liquid solution into an aerosol mist, simulating the act of tobacco smoking. The liquid solution comprises a formulation comprising nicotine. There are many electronic cigarettes which do not resemble conventional cigarettes at all. The amount of nicotine contained can be chosen by the user via the inhalation. In general, an electronic cigarette contains three essential components: a plastic cartridge that serves as a mouthpiece and a reservoir for liquid, an "atomizer" that vaporizes the liquid, and a battery. Other embodiment electronic cigarettes include a combined atomizer and reservoir, called a "cartomizer" that may or may not be disposable, a mouthpiece that may be integrated with the cartomizer or not, and a battery.

[0060] As used in this specification and the claims, unless otherwise stated, the term "about" refers to variations of 1%, 2%, 3%, 4%, 5%, 10%, 15%, or 25%, depending on the embodiment.

[0061] Suitable carriers (e.g.., a liquid solvent) for the nicotine salts described herein include a medium in which a nicotine salt is soluble at ambient conditions, such that the nicotine salt does not form a solid precipitate. Examples include, but are not limited to, glycerol, propylene glycol, trimethylene glycol, water, ethanol and the like, as well as combinations thereof. In some embodiments, the liquid carrier comprises 0% to 100% of propylene glycol and 100% to 0% of vegetable glycerin. In some embodiments, the liquid carrier comprises 10% to 70% of propylene glycol and 90% to 30% of vegetable glycerin. In some embodiments, the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin. In some embodiments, the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

[0062] The formulations described herein vary in concentration. In some formulations, a dilute concentration of the nicotine salt in the carrier is utilized. In some formulations, a less dilute concentration of the nicotine salt in the carrier is utilized. In some formulations the concentration of nicotine in the nicotine salt formulation is about 1% (w/w) to about 25% (w/w). In some formulations the concentration of nicotine in the nicotine salt formulation is about 1% (w/w) to about 20% (w/w). In some formulations the concentration of nicotine in the nicotine salt formulation is about 1% (w/w) to about 18% (w/w). In some embodiments the concentration of nicotine in the nicotine salt formulation is about 1% (w/w) to about 15% (w/w). In some formulations the concentration of nicotine in the nicotine salt formulation is about 4% (w/w) to about 12% (w/w). In some formulations the concentration of nicotine in the nicotine salt

formulation is about 4% (w/w). In some embodiments the concentration of nicotine in the nicotine salt formulation is about 2% (w/w). In some formulations the concentration of nicotine in the nicotine salt formulation is 1% (w/w) to 25% (w/w). In some formulations the concentration of nicotine in the nicotine salt formulation is 1% (w/w) to 20% (w/w). In some formulations the concentration of nicotine in the nicotine salt formulation is 1% (w/w) to 18% (w/w). In some formulations the concentration of nicotine in the nicotine salt formulation is 1% (w/w) to 15% (w/w). In some formulations the concentration of nicotine in the nicotine salt formulation is 4% (w/w) to 12% (w/w). In some formulations the concentration of nicotine in the nicotine salt formulation is 4% (w/w). In some formulations the concentration of nicotine in the nicotine salt formulation is 2% (w/w). In some formulations, a less dilute concentration of one nicotine salt is used in conjunction with a more dilute concentration of a second nicotine salt. In some formulations, the concentration of nicotine in the first nicotine salt formulation is about 1% to about 20%, and is combined with a second nicotine salt formulation having a concentration of nicotine therein from about 1% to about 20% or any range or concentration therein. In some formulations, the concentration of nicotine in the first nicotine salt formulation is 1% to 20%, and is combined with a second nicotine salt formulation having a concentration of nicotine therein from 1% to 20% or any range or concentration therein. As used with respect to concentrations of nicotine in the nicotine salt formulations, the term "about" refers to ranges of 0.05% (i.e. if the concentration is about 2%, the range is 1.95%-2.05%), 0.1 (i.e. if the concentration is about 2%, the range is 1.9%-2.1%), 0.25 (i.e. if the concentration is about 2%, the range is 1.75%-2.25%), 0.5 (i.e. if the concentration is about 2%, the range is 1.5%-2.5%), or 1 (i.e. if the concentration is about 4%, the range is 3%-5%), depending on the embodiment.

[0063] Nicotine salts are formed by the addition of a suitable acid, including organic or inorganic acids. In some formulations provided herein, suitable organic acids are carboxylic acids. Examples of organic carboxylic acids disclosed herein are monocarboxylic acids, dicarboxylic acids (organic acid containing two carboxylic acid groups), carboxylic acids containing an aromatic group such as benzoic acids, hydroxycarboxylic acids, heterocyclic carboxylic acids, terpenoid acids, sugar acids; such as the pectic acids, amino acids, cycloaliphatic acids, aliphatic carboxylic acids, keto carboxylic acids, and the like. In some formulations provided herein, the organic acids used herein are monocarboxylic acids. Nicotine salts are formed from the addition of a suitable acid to nicotine. In some formulations provided

herein, the stoichiometric ratios of the nicotine to acid (nicotine:acid) are 1:1, 1:2, 1:3, 1:4, 2:3, 2:5, 2:7, 3:4, 3:5, 3:7, 3:8, 3:10, 3:11, 4:5, 4:7, 4:9, 4:10, 4:11, 4:13, 4:14, 4:15, 5:6, 5:7, 5:8, 5:9, 5:11, 5:12, 5:13, 5:14, 5:16, 5:17, 5:18, or 5:19. In some formulations provided herein, the stoichiometric ratios of the nicotine to acid are 1:1, 1:2, 1:3, or 1:4 (nicotine:acid).

[0064] Nicotine is an alkaloid molecule that comprises two basic nitrogens. It may occur in different states of protonation. For example, if no protonation exists, nicotine is referred to as the "free base." If one nitrogen is protonated, then the nicotine would be "mono-protonated."

[0065] Nicotine salt formulations may be formed by adding a suitable acid to nicotine, stirring the neat mixture at ambient temperature or at elevated temperature, and then diluting the neat mixture with a carrier mixture, such as a mixture of propylene glycol and glycerin. In some embodiments, the suitable acid is completely dissolved by the nicotine prior to dilution. The suitable acid may not completely dissolved by the nicotine prior to dilution. The addition of the suitable acid to the nicotine to form a neat mixture may cause an exothermic reaction. The addition of the suitable acid to the nicotine to form a neat mixture may be conducted at 55 °C. The addition of the suitable acid to the nicotine to form a neat mixture may be conducted at 90 °C. The neat mixture may be cooled to ambient temperature prior to dilution. The dilution may be carried out at elevated temperature.

[0066] Nicotine salt formulations may be prepared by combining nicotine and a suitable acid in a carrier mixture, such as a mixture of propylene glycol and glycerin. The mixture of nicotine and a first carrier mixture is combined with a mixture of a suitable acid in a second carrier mixture. In some embodiments, the first and second carrier mixtures are identical in composition. In some embodiments, the first and second carrier mixtures are not identical in composition. In some embodiments, heating of nicotine/acid/carrier mixture is required to facilitate complete dissolution.

[0067] In some embodiments, nicotine salt formulations may be prepared and added to a solution of 3:7 ratio by weight of propylene glycol (PG)/vegetable glycerin (VG), and mixed thoroughly. While described herein as producing 10g of each of the formulations, all procedures noted *infra* are scalable. Other manners of formulation may also be employed form the formulations noted infra, without departing from the disclosure herein, and as would be known to one of skill in the art upon reading the disclosure herein.

[0068] The optimal nicotine salt formulation may be determined by the vapor pressure of the constituent acid. In some embodiments, the nicotine salt formulations comprise an acid with a vapor pressure that is similar to the vapor pressure of free base nicotine. In some embodiments, the nicotine salt formulations are formed from an acid with a vapor pressure that is similar to the vapor pressure of free base nicotine at the heating temperature of the device. Figure 3 illustrates this trend. Nicotine salts formed from nicotine and benzoic acid; nicotine and salicylic acid; or nicotine and levulinic acid are salts that produce a satisfaction in an individual user consistent with efficient transfer of nicotine and a rapid rise in nicotine plasma levels. This pattern may be due to the mechanism of action during heating of the nicotine salt formulation. The nicotine salt may disassociate at, or just below, the heating temperature of the device, resulting in a mixture of free base nicotine and the individual acid. At that point, if both the nicotine and acid have similar vapor pressures, they may aerosolize at the same time, giving rise to a transfer of both free base nicotine and the constituent acid to the user.

[0069] The nicotine salt liquid formulation for generating an inhalable aerosol upon heating in an electronic cigarette may comprise a nicotine salt in a biologically acceptable liquid carrier; wherein the acid used to form said nicotine salt is characterized by a vapor pressure between 20 – 4000 mmHg at 200 °C. In some embodiments, the acid used to form the nicotine salt is characterized by vapor pressure between 20 – 2000 mmHg at 200 °C. In some embodiments, the acid used to form the nicotine salt is characterized by vapor pressure between 100 – 300 mmHg at 200 °C.

[0070] Unexpectedly, different nicotine salt formulations produced varying degrees of satisfaction in an individual. In some embodiments, the extent of protonation of the nicotine salt affected satisfaction, such that more protonation was less satisfying as compared to less protonation. The nicotine salt formed may be monoprotonated. The nicotine salt formed may be diprotonated. The nicotine salt may exist in more than one protonation state, e.g., an equilibrium of mono-protonated and di-protonated nicotine salts. The extent of protonation of the nicotine molecule may be dependent upon the stoichiometric ratio of nicotine:acid used in the salt formation reaction. The extent of protonation of the nicotine molecule may be dependent upon the solvent. The extent of protonation of the nicotine molecule may be unknown. In some embodiments, monoprotonated nicotine salts produced a high degree of satisfaction in the user. For example, nicotine benzoate and nicotine salicylate are mono-protonated nicotine salts and all

produce a high degree of satisfaction in the user. The reason for this trend may be explained by a mechanism of action wherein the nicotine is first deprotonated prior to transfer to the vapor with the constituent acid and then retained and stabilized after re-protonated by the acid going down stream to the lungs of the user. It may be easier to remove one proton versus two protons, thus resulting in better transfer efficiency. In addition, the lack of satisfaction of free base nicotine indicates that a second factor may be important. A nicotine salt may be best performing when it is at its optimal extent of protonation, depending on the salt. For example, nicotine pyruvate is a nicotine salt with 1:2 nicotine:acid ratio. The formulation containing nicotine pyruvate (1:2) may deliver more satisfaction to the user than the one containing same amount of nicotine but only half amount of pyruvic acid, i.e. nicotine pyruvate (1:1). This may be explained as 1 mole of nicotine produces a salt with 2 moles of pyruvic acid. When there is not enough pyruvic acid to associate with all nicotine molecules, the free base nicotine left unprotonated in the formulation may reduce the satisfaction the formulation provides.

[0071] The flavor of the constituent acid used in the salt formation may be a consideration in choosing the acid. A suitable acid may have minimal or no toxicity to humans in the concentrations used. A suitable acid may be compatible with the electronic cigarette components it contacts or could contact at the concentrations used. That is, such acid does not degrade or otherwise react with the electronic cigarette components it contacts or could contact. The odor of the constituent acid used in the salt formation may be a consideration in choosing a suitable acid. The concentration of the nicotine salt in the carrier may affect the satisfaction in the individual user. In some embodiments, the flavor of the formulation is adjusted by changing the acid. In some embodiments, the flavor of the formulation is adjusted by adding exogenous flavorants. In some embodiments, an unpleasant tasting or smelling acid is used in minimal quantities to mitigate such characteristics. In some embodiments, exogenous pleasant smelling or tasting acid is added to the formulation. Examples of salts which can provide flavor and aroma to the mainstream aerosol at certain levels include nicotine acetate, nicotine oxalate, nicotine malate, nicotine isovalerate, nicotine lactate, nicotine citrate, nicotine phenylacetate and nicotine myristate.

[0072] Nicotine salt formulations may generate an inhalable aerosol upon heating in an electronic cigarette. The amount of nicotine or nicotine salt aerosol inhaled may be user-

determined. The user may, for example, modify the amount of nicotine or nicotine salt inhaled by adjusting his inhalation strength.

[0073] Formulations are described herein comprising two or more nicotine salts. In some embodiments, wherein a formulation comprises two or more nicotine salts, each individual nicotine salt is formed as described herein.

[0074] Nicotine salt formulations, as used herein, refer to a single or mixture of nicotine salts with other suitable chemical components used for e-cigarette, such as carriers, stabilizers, diluents, dispersing agents, suspending agents, thickening agents, and/or excipients. In certain embodiments, the nicotine salt formulation is stirred at ambient conditions for 20 minutes. In certain embodiments, the nicotine salt formulation is heated and stirred at 55C for 20 minutes. In certain embodiments, the nicotine salt formulation is heated and stirred at 90C for 60 minutes. In certain embodiments, the formulation facilitates administration of nicotine to an organism (e.g., lung).

[0075] The nicotine of nicotine salt formulations provided herein is either naturally occurring nicotine (e.g., from extract of nicotineous species such as tobacco), or synthetic nicotine. In some embodiments, the nicotine is (-)-nicotine, (+)-nicotine, or a mixture thereof. In some embodiments, the nicotine is employed in relatively pure form (e.g., greater than about 80% pure, 85% pure, 90% pure, 95% pure, or 99 % pure). In some embodiments, the nicotine for nicotine salt formulation provided herein is "water clear" in appearance in order to avoid or minimize the formation of tarry residues during the subsequent salt formation steps.

[0076] Nicotine salt formulations used for e-cigarettes described herein, in some embodiments, have a nicotine concentration of about 0.5% (w/w) to about 20% (w/w), wherein the concentration is of nicotine weight to total solution weight, i.e. (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 1% (w/w) to about 20% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 1% (w/w) to about 18% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 1% (w/w) to about 15% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 4% (w/w) to about 12% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 1% (w/w) to about 18% (w/w), about 3% (w/w) to about 15% (w/w), or about 4% (w/w) to about

12% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 0.5% (w/w) to about 10% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 0.5% (w/w) to about 5% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 0.5% (w/w) to about 4% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 0.5% (w/w) to about 3% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 0.5% (w/w) to about 2% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 0.5% (w/w) to about 1% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 1% (w/w) to about 10% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 1% (w/w) to about 5% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 1% (w/w) to about 4% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 1% (w/w) to about 3% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 1% (w/w) to about 2% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 2% (w/w) to about 10% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 2% (w/w) to about 5% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 2% (w/w) to about 4% (w/w). Certain embodiments provide a nicotine salt formulation having a nicotine concentration of about 0.5%, 0.6%, 0.7%, 0.8%, 0.9%, 1.0%, 1.1%, 1.2%, 1.3%, 1.4%, 1.5%, 1.6%, 1.7%, 1.8%, 1.9%, 2.0%, 2.1%, 2.2%, 2.3%, 2.4%, 2.5%, 2.6%, 2.7%, 2.8%, 2.9%, 3.0%, 3.1%, 3.2%, 3.3%, 3.4%, 3.5%, 3.6%, 3.7%, 3.8%, 3.9%, 4.0%, 4.5%, 5.0%, 5.5%, 6.0%, 6.5%, 7.0%, 7.5%, 8.0%, 8.5%, 9.0%, 9.5%, 10%, 11%, 12%, 13%, 14%, 15%, 16%, 17%, 18%, 19%, or 20% (w/w), or more, including any increments therein. Certain embodiments provide a nicotine salt formulation having a nicotine concentration of about 5% (w/w). Certain embodiments provide a nicotine salt formulation having a nicotine concentration of about 4% (w/w). Certain embodiments provide a nicotine salt formulation having a nicotine concentration of about 3% (w/w). Certain embodiments provide a nicotine salt formulation having a nicotine concentration

of about 2% (w/w). Certain embodiments provide a nicotine salt formulation having a nicotine concentration of about 1% (w/w). Certain embodiments provide a nicotine salt formulation having a nicotine concentration of about 0.5% (w/w).

[0077] The formulation further may comprise one or more flavorants.

[0078] Thee suitable acid for the nicotine salt formulation may have a vapor pressure >20 mmHg at 200 °C and is non-corrosive to the electronic cigarette or is non-toxic to humans. In some embodiments, the suitable acid for nicotine salt formation is selected from the group consisting of salicylic acid, formic acid, sorbic acid, acetic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

[0079] Thee suitable acid for the nicotine salt formulation may have a vapor pressure of about 20 to 200 mmHg at 200 °C and is non-corrosive to the electronic cigarette or is non-toxic to humans. In some embodiments, the suitable acid for nicotine salt formation is selected from the group consisting of salicylic acid, benzoic acid, lauric acid, and levulinic acid.

[0080] Thee suitable acid for the nicotine salt formulation may have a melting point <160 °C, a boiling point >160 °C, at least a 50-degree difference between the melting point and the boiling point, and is non-corrosive to the electronic cigarette or is non-toxic to humans. In some embodiments, the suitable acid for nicotine salt formation has a melting point at least 40 degrees lower than the operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, at least a 50-degree difference between the melting point and the boiling point, and is non-corrosive to the electronic cigarette or is non-toxic to humans; wherein the operating temperature is 200 °C. In some embodiments, the suitable acid for nicotine salt formation is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

[0081] Thee suitable acid for the nicotine salt formulation does not decompose at the operating temperature of the electronic cigarette. In some embodiments, the suitable acid for nicotine salt formation does not oxidize at the operating temperature of the electronic cigarette. In some embodiments, the suitable acid for nicotine salt formation does not oxidize at room temperature. In some embodiments, the suitable acid for nicotine salt formation does not provide an unpleasant taste. In some embodiments, the suitable acid for nicotine salt formation has good solubility in a liquid formulation for use in an electronic cigarette.

[0082] Provided herein is an electronic cigarette 2 having a fluid storage compartment 4 comprising an embodiment nicotine salt formulation of any embodiment described herein within the fluid storage compartment described herein. An embodiment is shown in FIG. 7. The electronic cigarette 2 of FIG. 7 includes a mouth end 6, and a charging end 8. The mouth-end 6 includes a mouthpiece 10. The charging end 8 may connect to a battery or a charger or both, wherein the battery is within a body of the electronic cigarette, and the charger is separate from the battery and couples to the body or the battery to charge the battery. In some embodiments the electronic cigarette comprises a rechargeable battery within a body 14 of the electronic cigarette and the charge end 8 comprises a connection 12 for charging the rechargeable battery. In some embodiments, the electronic cigarette comprises a cartomizer that comprises the fluid storage compartment and an atomizer. In some embodiments, the atomizer comprises a heater. In some embodiments the fluid storage compartment 4 is separable from an atomizer. In some embodiments the fluid storage compartment 4 is replaceable as part of a replaceable cartridge. In some embodiments the fluid storage compartment 4 is refillable. In some embodiments, the mouthpiece 10 is replaceable.

[0083] Provided herein is a cartomizer 18 for an electronic cigarette 2 having a fluid storage compartment 4 comprising an embodiment nicotine salt formulation of any embodiment described herein within the fluid storage compartment described herein. The cartomizer 18 embodiment of FIG. 8 includes a mouth end 6, and a connection end 16. The connection end 16 in the embodiment of FIG. 8 couples the cartomizer 14 to a body of an electronic cigarette, or to a battery of the electronic cigarette, or both. The mouth end 6 includes a mouthpiece 10. In some embodiments, the cartomizer does not include a mouthpiece, and in such embodiments, the cartomizer can be coupled to a mouthpiece of an electronic cigarette, or the cartomizer can be coupled to a battery or body of an electronic cigarette, while the mouthpiece is also coupled to the battery or the body of the electronic cigarette. In some embodiments, the mouthpiece is integral with the body of the electronic cigarette. In some embodiments, including the embodiment of FIG. 8, the cartomizer 18 comprises the fluid storage compartment 4 and an atomizer (not shown). In some embodiments, the atomizer comprises a heater (not shown).

Examples

Example 1: Preparation of Nicotine salt Formulations

[0084] Various nicotine formulations were prepared and added to a solution of 3:7 ratio by weight of propylene glycol (PG)/vegetable glycerin (VG), and mixed thoroughly. The examples shown below were used to make 10g of each of the formulations. All procedures are scalable.

[0085] For example, in order to make nicotine formulations with a final nicotine free base equivalent concentration of 2% (w/w), the following procedures were applied to each individual formulation.

- Nicotine benzoate salt formulation: 0.15g benzoic acid was added to a beaker followed by adding 0.2g nicotine to the same beaker. The mixture was stirred at 55 °C for 20 minutes until benzoic acid was completely dissolved and an orange oily mixture was formed. The mixture was cooled down to ambient conditions. 9.65g PG/VG (3:7) solution was added to the orange nicotine benzoate salt and the mixture was stirred until a visually homogenous formulation solution was achieved.
- Nicotine benzoate salt formulation can also be made by adding 0.15g benzoic acid to a beaker followed by adding 0.2g nicotine and 9.65g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 55 °C for 20 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.
- Nicotine citrate salt formulation was made by adding 0.47g citric acid to a beaker followed by adding 0.2g nicotine and 9.33g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 90 °C for 60 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.
- Nicotine malate salt formulation was made by adding 0.33g L-malic acid to a beaker followed by adding 0.2g nicotine and 9.47g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 90 °C for 60 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.
- Nicotine succinate salt formulation was made by adding 0.29g succinic acid to a beaker followed by adding 0.2g nicotine and 9.51g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 90 °C for 60 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.

- Nicotine salicylate salt formulation was made by adding 0.17g salicylic acid to a beaker followed by adding 0.2g nicotine and 9.63g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 90 °C for 60 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.
- Nicotine salicylate salt formulation can also be made by adding 0.17g salicylic acid to a beaker followed by adding 0.2g nicotine to the same beaker. The mixture was stirred at 90 °C for 60 minutes until salicylic acid was completely dissolved and an orange oily mixture was formed. The mixture was either cooled to ambient conditions or kept at 90 °C when 9.63g PG/VG (3:7) solution was added. The mixture was then stirred at 90 °C until a visually homogenous formulation solution was achieved with no undissolved chemicals.
- Nicotine free base formulation was made by adding 0.2g nicotine to a beaker followed by adding 9.8g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at ambient conditions for 10 minutes until a visually homogenous formulation solution was achieved.

[0086] For example, in order to make nicotine salt formulations with a final nicotine free base equivalent concentration of 3% (w/w), the following procedures were applied to each individual formulation.

- Nicotine benzoate salt formulation: 0.23g benzoic acid was added to a beaker followed by adding 0.3g nicotine to the same beaker. The mixture was stirred at 55 °C for 20 minutes until benzoic acid was completely dissolved and an orange oily mixture was formed. The mixture was cooled down to ambient conditions. 9.47g PG/VG (3:7) solution was added to the orange nicotine benzoate salt and the blend was stirred until a visually homogenous formulation solution was achieved.
- Nicotine benzoate salt formulation can also be made by adding 0.23g benzoic acid to a beaker followed by adding 0.3g nicotine and 9.47g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 55 °C for 20 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.
- Nicotine citrate salt formulation was made by adding 0.71g citric acid to a beaker followed by adding 0.3g nicotine and 8.99g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 90 °C for 60 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.

- Nicotine malate salt formulation was made by adding 0.5g L-malic acid to a beaker followed by adding 0.3g nicotine and 9.2g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 90 °C for 60 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.
- Nicotine levulinate salt formulation was made by adding melted 0.64g levulinic acid to a beaker followed by adding 0.3g nicotine to the same beaker. The mixture was stirred at ambient conditions for 10 minutes. Exothermic reaction took place and oily product was produced. The mixture was allowed to cool down to ambient temperature and 9.06g PG/VG (3:7) solution was added to the same beaker. The mixture was then stirred at ambient conditions for 20 minutes until a visually homogenous formulation solution was achieved.
- Nicotine pyruvate salt formulation was made by adding 0.33g pyruvic acid to a beaker followed by adding 0.3g nicotine to the same beaker. The mixture was stirred at ambient conditions for 10 minutes. Exothermic reaction took place and oily product was produced. The mixture was allowed to cool down to ambient temperature and 9.37g PG/VG (3:7) solution was added to the same beaker. The mixture was then stirred at ambient conditions for 20 minutes until a visually homogenous formulation solution was achieved.
- Nicotine succinate salt formulation was made by adding 0.44g succinic acid to a beaker followed by adding 0.3g nicotine and 9.26g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 90 °C for 60 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.
- Nicotine salicylate salt formulation was made by adding 0.26g salicylic acid to a beaker followed by adding 0.3g nicotine and 9.44g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 90 °C for 60 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.
- Nicotine salicylate salt formulation can also be made by adding 0.26g salicylic acid to a beaker followed by adding 0.3g nicotine to the same beaker. The mixture was stirred at 90 °C for 60 minutes until salicylic acid was completely dissolved and an orange oily mixture was formed. The mixture was either cooled to ambient conditions or kept at 90 °C when 9.44g PG/VG (3:7) solution was added. The blend was then stirred at 90C until a visually homogenous formulation solution was achieved with no undissolved chemicals.

- Nicotine free base formulation was made by adding 0.3g nicotine to a beaker followed by adding 9.7g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at ambient conditions for 10 minutes until a visually homogenous formulation solution was achieved.

[0087] For example, in order to make nicotine salt formulations with a final nicotine free base equivalent concentration of 4% (w/w), the following procedures were applied to each individual formulation.

- Nicotine benzoate salt formulation: 0.3g benzoic acid was added to a beaker followed by adding 0.4g nicotine to the same beaker. The mixture was stirred at 55 °C for 20 minutes until benzoic acid was completely dissolved and an orange oily mixture was formed. The mixture was cooled down to ambient conditions. 9.7g PG/VG (3:7) solution was added to the orange nicotine benzoate salt and the blend was stirred until a visually homogenous formulation solution was achieved.
- Nicotine benzoate salt formulation can also be made by adding 0.3g benzoic acid to a beaker followed by adding 0.4g nicotine and 9.7g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 55 °C for 20 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.

For example, in order to make nicotine salt formulations with a final nicotine free base equivalent concentration of 5% (w/w), the following procedures were applied to each individual formulation.

- Nicotine benzoate salt formulation: 0.38g benzoic acid was added to a beaker followed by adding 0.5g nicotine to the same beaker. The mixture was stirred at 55 °C for 20 minutes until benzoic acid was completely dissolved and an orange oily mixture was formed. The mixture was cooled down to ambient conditions. 9.12g PG/VG (3:7) solution was added to the orange nicotine benzoate salt and the blend was stirred until a visually homogenous formulation solution was achieved.
- Nicotine benzoate salt formulation can also be made by adding 0.38g benzoic acid to a beaker followed by adding 0.5g nicotine and 9.12g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 55 °C for 20 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.
- Nicotine malate salt formulation was made by adding 0.83g L-malic acid to a beaker followed by adding 0.5g nicotine and 8.67g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 90 °C for 60 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.

- Nicotine levulinate salt formulation was made by adding melted 1.07g levulinic acid to a beaker followed by adding 0.5g nicotine to the same beaker. The mixture was stirred at ambient conditions for 10 minutes. Exothermic reaction took place and oily product was produced. The mixture was allowed to cool down to ambient temperature and 8.43g PG/VG (3:7) solution was added to the same beaker. The mixture was then stirred at ambient conditions for 20 minutes until a visually homogenous formulation solution was achieved.
- Nicotine pyruvate salt formulation was made by adding 0.54g pyruvic acid to a beaker followed by adding 0.5g nicotine to the same beaker. The mixture was stirred at ambient conditions for 10 minutes. Exothermic reaction took place and oily product was produced. The mixture was allowed to cool down to ambient temperature and 8.96g PG/VG (3:7) solution was added to the same beaker. The mixture was then stirred at ambient conditions for 20 minutes until a visually homogenous formulation solution was achieved.
- Nicotine succinate salt formulation was made by adding 0.73g succinic acid to a beaker followed by adding 0.5g nicotine and 8.77g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 90 °C for 60 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.
- Nicotine salicylate salt formulation was made by adding 0.43g salicylic acid to a beaker followed by adding 0.5g nicotine and 9.07g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 90 °C for 60 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.
- Nicotine salicylate salt formulation can also be made by adding 0.43g salicylic acid to a beaker followed by adding 0.5g nicotine to the same beaker. The mixture was stirred at 90 °C for 60 minutes until salicylic acid was completely dissolved and an orange oily mixture was formed. The mixture was either cooled to ambient conditions or kept at 90C when 9.07g PG/VG (3:7) solution was added. The blend was then stirred at 90 °C until a visually homogenous formulation solution was achieved with no undissolved chemicals.
- Nicotine free base formulation was made by adding 0.5g nicotine to a beaker followed by adding 9.5g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at ambient conditions for 10 minutes until a visually homogenous formulation solution was achieved.

[0088] Various formulations comprising different nicotine salts can be prepared similarly, or different concentrations of the above-noted nicotine formulations or other nicotine salt

formulations can be prepared as one of skill in the art would know to do upon reading the disclosure herein.

[0089] Various formulations comprising two or more nicotine salts can be prepared similarly in a solution of 3:7 ratio of propylene glycol (PG)/vegetable glycerin (VG). For example, 0.43g (2.5% w/w nicotine) of nicotine levulinate salt and 0.34 g (2.5% w/w nicotine) of nicotine acetate salt are added to 9.23g of PG/VG solution, to achieve a 5% w/w nicotine formulation.

[0090] Also provided is another exemplary formulation. For example, 0.23g (1.33% w/w nicotine) of nicotine benzoate salt (molar ratio 1:1 nicotine/benzoic acid), 0.25g (1.33% w/w nicotine) of nicotine salicylate salt(molar ratio 1:1 nicotine/salicylic acid) and 0.28 g (1.34% w/w nicotine) of nicotine pyruvate salt (molar ratio 1:2 nicotine/pyruvic acid) are added to 9.25g of PG/VG solution, to achieve a 5% w/w nicotine formulation.

Example 2: Heart rate study of nicotine solutions via e-cigarette

[0091] Exemplary formulations of nicotine levulinate, nicotine benzoate, nicotine succinate, nicotine salicylate, nicotine malate, nicotine pyruvate, nicotine citrate, nicotine freebase, and a control of propylene glycol were prepared as noted in Example 1 in 3% w/w solutions and were administered in the same fashion by an electronic cigarette to the same human subject. About 0.5 mL of each solution was loaded into an "eRoll" cartridge atomizer (joyetech.com) to be used in the study. The atomizer was then attached to an "eRoll" e-cigarette (same manufacturer). The operating temperature was from about 150°C to about 250 °C, or from about 180°C to about 220 °C.

[0092] Heart rate measurements were taken for 6 minutes; from 1 minute before start of puffing, for 3 minutes during puffing, and continuing until 2 minutes after end of puffing. The test participant took 10 puffs over 3 minutes in each case. The base heart rate was the average heart rate over the first 1 minute before start of puffing. Heart rate after puffing started was averaged over 20-second intervals. Puffing (inhalation) occurred every 20 seconds for a total of 3 minutes. Normalized heart rate was defined as the ratio between individual heart rate data point and the base heart rate. Final results were presented as normalized heart rate, shown for the first 4 minutes in FIG. 1.

[0093] FIG. 1 summarizes results from heart rate measurements taken for a variety of nicotine salt formulations. For ease of reference in reviewing FIG. 1, at the 180-second

timepoint, from top to bottom (highest normalized heart rate to lowest normalized heart rate), the nicotine formulations are as follows: nicotine salicylate formulation, nicotine malate formulation, nicotine levulinate formulation (nearly identical to nicotine malate formulation at 180 seconds, thus, as a second reference point: the nicotine malate formulation curve is lower than the nicotine levulinate formulation curve at the 160-second time point), nicotine pyruvate formulation, nicotine benzoate formulation, nicotine citrate formulation, nicotine succinate formulation, and nicotine free base formulation. The bottom curve (lowest normalized heart rate) at the 180-second timepoint is associated with the placebo (100% propylene glycol). The test formulations comprising a nicotine salt cause a faster and more significant rise in heart rate than the placebo. The test formulations comprising a nicotine salt also cause faster and more significant rise when compared with a nicotine freebase formulation with the same amount of nicotine by weight. In addition, the nicotine salts (e.g., nicotine benzoate and nicotine pyruvate) prepared from the acids having calculated vapor pressures between 20 - 200 mmHg at 200 °C (benzoic acid (171.66 mmHg), with the exception of pyruvic acid (having a boiling point of 165C), respectively) cause a faster rise in heart rate than the rest. The nicotine salts (e.g., nicotine levulinate, nicotine benzoate, and nicotine salicylate) prepared from the acids (benzoic acid, levulinic acid and salicylic acid, respectively) also cause a more significant heart rate increase. Thus, other suitable nicotine salts formed by the acids with the similar vapor pressure and/or similar boiling point may be used in accordance with the practice of the present invention. This experience of increased heart rate theoretically approaching or theoretically comparable to that of a traditional burned cigarette has not been demonstrated or identified in other electronic cigarette devices. Nor has it been demonstrated or identified in low temperature tobacco vaporization devices (electronic cigarettes) that do not burn the tobacco, even when a nicotine salt was used (a solution of 20% (w/w) or more of nicotine salt) as an additive to the tobacco. Thus the results from this experiment are surprising and unexpected.

Example 3: Satisfaction Study of Nicotine salt Solution via e-cigarette

[0094] In addition to the heart rate study shown in Example 2, nicotine formulations (using 3% w/w nicotine formulations as described in Example 1) were used to conduct a satisfaction study in a single test participant. The test participant, an e-cigarette and/or traditional cigarette user, was required to have no nicotine intake for at least 12 hours before the test. The participant

took 10 puffs using an e-cigarette (same as used in Example 2) over 3 minutes in each case, and then was asked to rate the level of physical and emotional satisfaction he or she felt on a scale of 0 - 10, with 0 being no physical or emotional satisfaction. The results indicated that the least satisfying compound was the nicotine free base. Nicotine benzoate, nicotine salicylate, and nicotine succinate all performed well, followed by nicotine pyruvate, nicotine citrate, and nicotine pyruvate.

[0095] Based on the Satisfaction Study, the nicotine salts formulations with acids having vapor pressure ranges between >20 mmHg @ 200 °C, or 20-200 mmHg @ 200 °C, or 100 – 300 mmHg @ 200 °C provide more satisfaction than the rest (except the pyruvic acid which has boiling point of 165 °C). For reference, it has been determined that salicylic acid has a vapor pressure of about 135.7 mmHg @ 200 °C, benzoic acid has a vapor pressure of about 171.7 mmHg @ 200 °C, lauric acid has a vapor pressure of about 38 mmHg @ 200 °C, and levulinic acid has a vapor pressure of about 149 mmHg @ 200 °C.

Example 4: Test formulation 1 (TF1):

[0096] A solution of nicotine levulinate in glycerol comprising nicotine salt used: 1.26g (12.6% w/w) of 1:3 nicotine levulinate 8.74g (87.4% w/w) of glycerol - Total weight 10.0g.

[0097] Neat nicotine levulinate was added to the glycerol, and mixed thoroughly. L-Nicotine has a molar mass of 162.2g, and levulinic acid molar mass is 116.1g. In a 1:3 molar ratio, the percentage of nicotine in nicotine levulinate by weight is given by: 162.2g / (162.2g + (3 x 116.1g)) = 31.8% (w/w).

Example 5: Test formulation 2 (TF2):

[0098] A solution of free base nicotine in glycerol comprising 0.40g (4.00% w/w) of L-nicotine was dissolved in 9.60g (96.0% w/w) of glycerol and mixed thoroughly.

Example 6: Heart rate study of nicotine solutions via e-cigarette:

[0099] Both formulations (TF1 and TF2) were administered in the same fashion by an electronic cigarette to the same human subject: about 0.6 mL of each solution was loaded into "eGo-C" cartridge atomizer (joyetech.com). The atomizer was then attached to an "eVic" e-cigarette (same manufacturer). This model of e-cigarette allows for adjustable voltage, and

therefore wattage, through the atomizer. The operating temperature of the e-cigarette is from about 150°C to about 250 °C, or from about 180°C to about 220 °C.

[00100] The atomizer in both cases has resistance 2.4ohms, and the e-cigarette was set to 4.24V, resulting in 7.49W of power. (**P = V^2 / R**)

[00101] Heart rate was measured in a 30-second interval for ten minutes from start of puffing. Test participants took 10 puffs over 3 minutes in each case (solid line (2^{nd} highest peak): cigarette, dark dotted line (highest peak): test formulation 1 (TF1-nicotine salt formulation), light dotted line: test formulation 2 (TF2 — nicotine formulation). Comparison between cigarette, TF1, and TF2 is shown in FIG. 2.

[00102] It is clearly shown in FIG. 2 that the test formulation with nicotine levulinate (TF1) causes a faster rise in heart rate than just nicotine (TF2). Also, TF1 more closely resembles the rate of increase for a cigarette. Other salts were tried and also found to increase heart rate relative to a pure nicotine solution. Thus, other suitable nicotine salts that cause the similar effect may be used in accordance with the practice of the present invention. For example, other keto acids (alpha-keto acids, beta-keto acids, gamma-keto acids, and the like) such as pyruvic acid, oxaloacetic acid, acetoacetic acid, and the like. This experience of increased heart rate comparable to that of a traditional burned cigarette has not been demonstrated or identified in other electronic cigarette devices, nor has it been demonstrated or identified in low temperature tobacco vaporization devices that do not burn the tobacco, even when a nicotine salt was used (a solution of 20% (W/W) or more of nicotine salt) as an additive to the tobacco. Thus the results from this experiment are surprising and unexpected.

[00103] In addition, the data appears to correlate well with the previous findings shown in FIG. 2.

[00104] As previously noted in the Satisfaction Study, the nicotine salts formulations with acids having vapor pressures between 20 – 300 mmHg @ 200 °C provide more satisfaction than the rest, with the exception of the nicotine salt formulation made with pyruvic acid, which has a boiling point of 165 °C, as noted in FIG. 3. Based on the findings herein, it was anticipated that these nicotine salt formulations having either:

- a Vapor Pressure between 20 – 300 mmHg @ 200 °C,
- a Vapor Pressure > 20 mmHg @ 200 °C,

- a difference between boiling point and melting point of at least 50 °C, and a boiling point greater than 160 °C, and a melting point less than 160 °C,
- a difference between boiling point and melting point of at least 50 °C, and a boiling point greater than 160 °C, and a melting point less than 160 °C,
- a difference between boiling point and melting point of at least 50 °C, and a boiling point at most 40 °C less than operating temperature, and a melting point at least 40 °C lower than operating temperature, or
- a combination thereof produce one or more of the following effects:

[00105] T_{max} – Time to maximum blood concentration: Based on the results established herein, a user of an e-cigarette comprising the nicotine salt formulation will experience a comparable rate of physical and emotional satisfaction from using a formulation comprising a mixture of nicotine salts prepared with an appropriate acid at least 1.2X to 3X faster than using a formulation comprising a freebase nicotine. As illustrated in FIG. 1: Nicotine from a nicotine salts formulation appears to generate a heartbeat that is nearly 1.2 times that of a normal heart rate for an individual approximately 40 seconds after the commencement of puffing; whereas the nicotine from a nicotine freebase formulation appears to generate a heartbeat that is nearly 1.2 times that of a normal heart rate for an individual approximately 110 seconds after the commencement of puffing; a 2.75 X difference in time to achieve a comparable initial satisfaction level.

[00106] Again this would not be inconsistent with the data from FIG. 2, where the data illustrated that at approximately 120 seconds (2 minutes), the heart rate of test participants reached a maximum of 105 – 110 bpm with either a regular cigarette or a nicotine salt formulation (TF1); whereas those same participants heart rates only reached a maximum of approximately 86 bpm at approximately 7 minutes with a nicotine freebase formulation (TF2); also a difference in effect of 1.2 times greater with nicotine salts (and regular cigarettes) versus freebase nicotine.

[00107] Further, when considering peak satisfaction levels (achieved at approximately 120 seconds from the initiation of puffing (time =0) and looking at the slope of the line for a normalized heart rate, the approximate slope of those nicotine salt formulations that exceeded the freebase nicotine formulation range between 0.0054 hr_n/sec and 0.0025 hr_n/sec. By comparison, the slope of the line for the freebase nicotine formulation is about 0.002. This would suggest that

the concentration of available nicotine will be delivered to the user at a rate that is between 1.25 and 2.7 times faster than a freebase formulation.

[00108] In another measure of performance; C_{max} – Maximum blood nicotine concentration; it is anticipated that similar rates of increase will be measured in blood nicotine concentration, as those illustrated above. That is, it was anticipated based on the findings herein, and unexpected based on the art known to date, that there would be comparable C_{max} between the common cigarette and certain nicotine salt formulations, but with a lower C_{max} in a freebase nicotine solution.

[00109] Similarly, anticipated based on the findings herein, and unexpected based on the art known to date, that certain nicotine salt formulations would have higher rate of nicotine uptake levels in the blood at early time periods. Indeed, Example 8 presents data for multiple salt formulations consistent with these predictions which were made based on the findings and tests noted herein, and unexpected compared to the art available to date.

Example 7: Heart rate study of nicotine solutions via e-cigarette

[00110] Exemplary formulations of nicotine levulinate, nicotine benzoate, nicotine succinate, nicotine salicylate, nicotine malate, nicotine pyruvate, nicotine citrate, nicotine sorbate, nicotine laurate, nicotine freebase, and a control of propylene glycol are prepared as noted in Example 1 and are administered in the same fashion by an electronic cigarette to the same human subject. About 0.5 mL of each solution is loaded into an "eRoll" cartridge atomizer (joyetech.com) to be used in the study. The atomizer is then attached to an "eRoll" e-cigarette (same manufacturer). The operating temperature of the e-cigarette is from about 150°C to about 250 °C, or from about 180°C to about 220 °C.

[00111] Heart rate measurements are taken for 6 minutes; from 1 minute before start of puffing, for 3 minutes during puffing, and continuing until 2 minutes after end of puffing. The test participant takes 10 puffs over 3 minutes in each case. The base heart rate is the average heart rate over the first 1 minute before start of puffing. Heart rate after puffing started is averaged over 20-second intervals. Normalized heart rate is defined as the ratio between individual heart rate data point and the base heart rate. Final results are presented as normalized heart rate.

Example 8: Blood Plasma testing

[00112] Blood plasma testing was conducted on three subjects (n = 3). Eight test articles were used in this study: one reference cigarette and seven blends used in an e-cigarette device having an operating temperature of the e-cigarette from about 150°C to about 250 °C, or from about 180°C to about 220 °C. The reference cigarette was Pall Mall (New Zealand). Seven blends were tested in the e-cigarette: 2% free base, 2% benzoate, 4% benzoate, 2% citrate, 2% malate, 2% salicylate, and 2% succinate. Except for 2% succinate (n = 1), all other blends have n = 3. The seven blends were liquid formulations prepared as described in Example 1.

[00113] The concentration of nicotine in each of the formulations was confirmed using UV spectrophotometer (Cary 60, manufactured by Agilent). The sample solutions for UV analysis were made by dissolving 20mg of each of the formulations in 20mL 0.3% HCl in water. The sample solutions were then scanned in UV spectrophotometer and the characteristic nicotine peak at 259nm was used to quantify nicotine in the sample against a standard solution of 19.8 □g/mL nicotine in the same diluent. The standard solution was prepared by first dissolving 19.8mg nicotine in 10mL 0.3% HCl in water followed by a 1:100 dilution with 0.3% HCl in water. Nicotine concentrations reported for all formulations were within the range of 95%-105% of the claimed concentrations

[00114] All subjects were able to consume 30-55 mg of the liquid formulation of each tested blend using the e-cigarette.

[00115] Literature results: C. Bullen et al, Tobacco Control 2010, 19:98-103

Cigarette (5min adlib, n=9): T_{max} = 14.3 (8.8-19.9), C_{max} = 13.4 (6.5-20.3)

1.4% E-cig (5min adlib, n=8): T_{max} = 19.6 (4.9-34.2), C_{max} = 1.3 (0.0-2.6)

Nicorette Inhalator (20mg/20min, n=10): T_{max} = 32.0 (18.7-45.3), C_{max} = 2.1 (1.0-3.1)

[00116] Estimated C_{max} of 2% nicotine blends:

C_{max} = Mass consumed * Strength * Bioavailability / (Vol of Distribution * Body Weight) = 40mg * 2% * 80% / (2.6L/kg * 75kg) = 3.3 ng/mL

[00117] Estimated C_{max} of 4% nicotine blends:

C_{max} = Mass consumed * Strength * Bioavailability / (Vol of Distribution * Body Weight) = 40mg * 4% * 80% / (2.6L/kg * 75kg) = 6.6 ng/mL

[00118] Pharmacokinetic profiles of the blood plasma testing are shown in FIG. 4; showing blood nicotine concentrations (ng/mL) over time after the first puff (inhalation) of the aerosol

from the e-cigarette or the smoke of the Pall Mall. Ten puffs were taken at 30 sec intervals starting at time =0 and continuing for 4.5 minutes. For ease of reference and review of FIG. 4, at the 5-minute timepoint, the curves on the graph show from top to bottom (highest average blood nicotine concentration to lowest average blood nicotine concentration) are 4% benzoate, 2% succinate, 2% salicylate, 2% citrate, Pall Mall cigarette, 2% benzoate, 2% malate, and 2% free base blend. Although noted as highest to lowest at this time point, this is not to say that there is a statistically significant difference between any of the salt formulations, or between any of the salt formulations and the Pall Mall cigarette. However, it is possible there may be a statistically significant difference between the C_{max} of particular salt formulations, and it is also likely based on the data shown in FIG. 4 and in other studies herein that the freebase formulation is statistically different from salt formulations and/or the Pall Mall with respect to C_{max}, since it appears lower than others tested at several time points. One of skill in the art, upon review of the disclosure herein could properly power a test to determine actual statistically-based differences between one or more formulations and the cigarette, or between the formulations themselves in an e-cigarette. For ease of reference Tables 1 & 2 present the amount of nicotine detected (as an average of all users) for each formulation and the Pall Mall, presented in ng/mL, along with C_{max} and T_{max} and AUC. Data from these tables, along with the raw data therefore, was used to generate FIG. 4, 5, and 6.

Table 1

Time	Pall Mall	2% Freebase	2% Benzoate	4% Benzoate
-2	0.46	0.03	0.09	0.05
0	-0.46	-0.03	-0.09	-0.05
1.5	1.54	0.08	5.67	6.02
3	9.98	1.19	8.60	11.47
5	11.65	1.70	11.44	15.06
7.5	11.34	3.09	6.43	12.12
10	9.24	3.42	5.03	11.08
12.5	8.85	3.35	4.68	10.10
15	8.40	2.81	4.47	8.57
30	5.51	1.74	2.72	5.56

60	3.39	0.79	1.19	3.60
T_{max} (min)	**5.17**	**10.00**	**6.67**	**5.83**
C_{max} (ng/mL)	**11.65**	**3.42**	**11.44**	**15.06**
AUC (ng*min/mL)	**367.5**	**106.2**	**207.8**	**400.2**

Table 2

Time	**2% Citrate**	**2% Malate**	**2% Salicylate**	**2% Succinate**
-2	0.06	-0.17	-0.19	-0.06
0	-0.06	0.17	0.19	0.06
1.5	4.80	1.09	6.14	2.10
3	8.33	5.30	12.04	10.81
5	12.09	10.02	13.46	13.81
7.5	6.93	5.93	5.21	5.15
10	6.01	4.85	4.60	5.18
12.5	5.34	4.17	3.83	4.17
15	4.72	3.79	3.52	3.41
30	3.40	1.56	2.19	2.01
60	1.70	0.46	0.55	1.00
T_{max} (min)	**5.83**	**5.00**	**4.33**	**5.00**
C_{max} (ng/mL)	**12.09**	**10.02**	**13.46**	**13.81**
AUC (ng*min/mL)	**238.0**	**146.1**	**182.9**	**179.5**

[00119] Comparison of T_{max} and C_{max} of the seven blends and reference cigarette are shown in FIG. 5. Comparison of C_{max} and AUC of the seven blends and reference cigarette are shown in FIG. 6. Due to the time limit of the wash-period, baseline blood nicotine concentration (at t=-2 and t=0 min) was higher for samples consumed at a later time on the test day. The data in FIGS. 4-6 show corrected blood nicotine concentration values (i.e. apparent blood nicotine concentration at each time point minus baseline nicotine concentration of the same sample).

[00120] Rates of nicotine uptake in the blood of the users of each sample within the first 90 seconds are shown in Table 3.

Table 3

Sample	Rate of nicotine uptake (ng/mL/min)
2% Salicylate	4.09
2% Benzoate	3.78
2% Citrate	3.20
2% Succinate	1.40
Pall Mall (reference)	1.03
2% Malate	0.73
2% Freebase	0.05
4% Benzoate	4.01

[00121] Although the T_{max} and C_{max} values are comparable between the tested blends and the reference cigarette (with the exception of the 2% free base blend), the rates of nicotine absorption within the first 90 seconds differed among the test articles. In particular, four blends (2% salicylate, 2% benzoate, 4% benzoate, and 2% citrate) showed markedly higher rates of absorption within the first 90 seconds compared to the other blends and with the reference cigarette. These four blends contain salts (salicylate, benzoate, and citrate) which performed well in the Satisfaction Study of Example 3. Moreover, 2% benzoate and 4% benzoate had comparable rates of absorption, suggesting that a lower concentration of nicotinic salt may not adversely impact the rate of absorption.

Example 9: Blood Plasma testing

[00122] Blood plasma testing is conducted on 24 subjects (n = 24). Eight test articles are used in this study: one reference cigarette and seven blends delivered to a user in an e-cigarette as an aerosol. The operating temperature of the e-cigarette is from about 150°C to about 250 °C, or from about 180°C to about 220 °C. The reference cigarette is Pall Mall (New Zealand). Seven blends are tested: 2% free base, 2% benzoate, 4% benzoate, 2% citrate, 2% malate, 2% salicylate, and 2% succinate. The seven blends are liquid formulations prepared according to protocols similar to that described *infra* and in Example 1.

[00123] All subjects are to consume 30-55 mg of the liquid formulation of each tested blend. Ten puffs are to be taken at 30 sec intervals starting at time =0 and continuing for 4.5 minutes. Blood plasma testing is to occur for at least 60 minutes from the first puff (t=0) Pharmacokinetic data (e.g., C_{max}, T_{max}, AUC) for nicotine in the plasma of users are obtained at various time periods during those 60 minutes, along with rates of nicotine absorption within the first 90 seconds for each test article.

Example 10: Blood Plasma testing

[00124] Blood plasma testing is conducted on twenty-four subjects (n = 24). Eleven test articles are used in this study: one reference cigarette and ten blends delivered to a user in an e-cigarette as an aerosol. The reference cigarette is Pall Mall (New Zealand). The operating temperature of the e-cigarette is from about 150°C to about 250 °C, or from about 180°C to about 220 °C. Ten blends are tested: 2% free base, 2% benzoate, 2% sorbate, 2% pyruvate, 2% laurate, 2% levulinate, 2% citrate, 2% malate, 2% salicylate, and 2% succinate. The ten blends are liquid formulations prepared according to protocols similar to that described *infra* and in Example 1.

[00125] All subjects are to consume 30-55 mg of the liquid formulation of each tested blend. Ten puffs are to be taken at 30 sec intervals starting at time =0 and continuing for 4.5 minutes. Blood plasma testing is to occur for at least 60 minutes from the first puff (t=0) . Pharmacokinetic data (e.g., C_{max}, T_{max}, AUC) for nicotine in the plasma of users are obtained at various time periods during those 60 minutes, along with rates of nicotine absorption within the first 90 seconds for each test article.

Example 11: Blood Plasma testing

[00126] Blood plasma testing is conducted on twenty-four subjects (n = 24). Twenty-one test articles are used in this study: one reference cigarette and twenty blends delivered to a user in an e-cigarette as an aerosol. The reference cigarette is Pall Mall (New Zealand). The operating temperature of the e-cigarette is from about 150°C to about 250 °C, or from about 180°C to about 220 °C. Twenty blends are tested: 2% free base, 4% free base, 2% benzoate, 4% benzoate, 2% sorbate, 4% sorbate, 2% pyruvate, 4% pyruvate, 2% laurate, 4% laurate, 2% levulinate, 4% levulinate, 2% citrate, 4% citrate, 2% malate, 4% malate, 2% salicylate, 4% salicylate, 2%

succinate, and 4% succinate. The twenty blends are liquid formulations prepared according to protocols similar to that described *infra* and in Example 1.

[00127] All subjects are to consume 30-55 mg of the liquid formulation of each tested blend. Ten puffs are to be taken at 30 sec intervals starting at time =0 and continuing for 4.5 minutes. Blood plasma testing is to occur for at least 60 minutes from the first puff (t=0) . Pharmacokinetic data (e.g., C_{max}, T_{max}, AUC) for nicotine in the plasma of users are obtained at various time periods during those 60 minutes, along with rates of nicotine absorption within the first 90 seconds for each test article.

Example 12: Blood Plasma testing

[00128] Blood plasma testing is conducted on twenty-four subjects (n = 24). Twenty-one test articles are used in this study: one reference cigarette and twenty blends delivered to a user in an e-cigarette as an aerosol. The reference cigarette is Pall Mall (New Zealand). The operating temperature of the e-cigarette is from about 150°C to about 250 °C, or from about 180°C to about 220 °C. Twenty blends are tested: 2% free base, 1% free base, 2% benzoate, 1% benzoate, 2% sorbate, 1% sorbate, 2% pyruvate, 1% pyruvate, 2% laurate, 1% laurate, 2% levulinate, 1% levulinate, 2% citrate, 1% citrate, 2% malate, 1% malate, 2% salicylate, 1% salicylate, 2% succinate, and 1% succinate. The twenty blends are liquid formulations prepared according to protocols similar to that described *infra* and in Example 1.

[00129] All subjects are to consume 30-55 mg of the liquid formulation of each tested blend. Ten puffs are to be taken at 30 sec intervals starting at time =0 and continuing for 4.5 minutes. Blood plasma testing is to occur for at least 60 minutes from the first puff (t=0) . Pharmacokinetic data (e.g., C_{max}, T_{max}, AUC) for nicotine in the plasma of users are obtained at various time periods during those 60 minutes, along with rates of nicotine absorption within the first 90 seconds for each test article.

[00130] Further understanding may be gained through contemplation of the numbered embodiments below.

2. A method of delivering nicotine to a user comprising operating an electronic cigarette to a user wherein the electronic cigarette comprises a nicotine salt formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine

salt is characterized by vapor pressure >20 mmHg at 200 °C, and inhaling an aerosol generated from the nicotine salt formulation heated by the electronic cigarette.

3. A method of delivering nicotine to a user comprising operating an electronic cigarette to a user wherein the electronic cigarette comprises a nicotine salt formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200 °C, and inhaling an aerosol generated from the nicotine salt formulation heated by the electronic cigarette.

4. A method of delivering nicotine to a user comprising operating an electronic cigarette wherein the electronic cigarette comprises a nicotine salt formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160 °C, a boiling point >160 °C, and at least a 50-degree difference between the melting point and the boiling point, and inhaling an aerosol generated from the nicotine salt formulation heated by the electronic cigarette.

5. A method of delivering nicotine to a user comprising providing an electronic cigarette to a user wherein the electronic cigarette comprises a nicotine salt formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point, and inhaling an aerosol generated from the nicotine salt formulation heated by the electronic cigarette.

6. The method of any one of embodiments 1-3, wherein an operating temperature is from 150 °C to 250 °C.

7. The method of any one of embodiments 1-3, wherein an operating temperature is from 180 °C to 220 °C.

8. The method any one of embodiments 1-3, wherein an operating temperature is about 200 °C.

9. The method of embodiment 4, wherein the operating temperature is from 150 °C to 250 °C.

10. The method of embodiment 4, wherein the operating temperature is from 180 °C to 220 °C.

11. The method of embodiment 4, wherein the operating temperature is about 200 °C.

12. The method any one of embodiments 1-10, wherein the aerosol comprises condensate of the nicotine salt.

13. The method any one of embodiments 1-10, wherein the aerosol comprises condensate of freebase nicotine.

14. The method any one of embodiments 1-10, wherein the aerosol comprises condensate of freebase nicotine and condensate of the carrier.

15. The method any one of embodiments 1-10, wherein the aerosol comprises condensate of freebase nicotine and condensate of the acid.

16. The method any one of embodiments 1-14, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 5 microns.

17. The method any one of embodiments 1-14, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 1 or 2 microns.

18. The method any one of embodiments 1-14, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 0.7 microns.

19. The method any one of embodiments 1-14, wherein the aerosol comprises condensate in particle sizes from about 0.3 microns to about 0.4 microns.

20. The method any one of embodiments 1-18, wherein the acid is a carboxylic acid.

21. The method of any one of embodiments 1-18, wherein the acid used to form said nicotine salt is an organic acid.

22. The method of embodiment 20, wherein the organic acid is monocarboxylic acid, aromatic acid, or keto acid.

23. The method of embodiment 20, wherein the organic acid is formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, phenylacetic acid, benzoic acid, pyruvic acid, levulinic acid, tartaric acid, lactic acid, malonic acid, succinic acid, fumaric acid, finnaric acid, gluconic acid, saccharic acid, salicylic acid, sorbic acid, malonic acid, or malic acid.

24. The method of any one of embodiments 1-18, wherein the acid used to form the nicotine salt is salicylic acid.

25. The method of any one of embodiments 1-18, wherein the acid used to form the nicotine salt is benzoic acid.

26. The method of any one of embodiments 1-18, wherein the acid used to form the nicotine salt is pyruvic acid.

27. The method of any one of embodiments 1-18, wherein the acid used to form the nicotine salt is sorbic acid.

28. The method of any one of embodiments 1-18, wherein the acid used to form the nicotine salt is lauric acid.

29. The method of any one of embodiments 1-18, wherein the acid used to form the nicotine salt is levulinic acid.

30. The method of any one of embodiments 1-18, wherein said nicotine salt comprises nicotine pyruvate.

31. The method of any one of embodiments 1-18, wherein said nicotine salt comprises nicotine salicylate.

32. The method of any one of embodiments 1-18, wherein said nicotine salt comprises nicotine sorbate.

33. The method of any one of embodiments 1-18, wherein said nicotine salt comprises nicotine laurate.

34. The method of any one of embodiments 1-18, wherein said nicotine salt comprises nicotine levulinate.

35. The method of any one of embodiments 1-18, wherein said nicotine salt comprises nicotine benzoate.

36. The method of any one of embodiments 1-34, wherein the liquid carrier comprises glycerol, propylene glycol, trimethylene glycol, water, ethanol or combinations thereof.

37. The method of any one of embodiments 1-34, wherein the liquid carrier comprises propylene glycol and vegetable glycerin.

38. The method of any one of embodiments 1-34, wherein the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

39. The method of any one of embodiments 1-34, wherein the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

40. The method of any one of embodiments 1-38, wherein the nicotine salt is in an amount that forms about 0.5% to about 20% nicotine in the inhalable aerosol.

41. The method of any one of embodiments 1-38, wherein the nicotine salt is in an amount that forms about 1% to about 20% nicotine in the inhalable aerosol.

42. The method of any one of embodiments 1-40, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 25% (w/w).

43. The method of any one of embodiments 1-40, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 20% (w/w).

44. The method of any one of embodiments 1-40, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 18% (w/w).

45. The method of any one of embodiments 1-40, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 15% (w/w).

46. The method of any one of embodiments 1-40, wherein the liquid formulation has a nicotine concentration of about 4% (w/w) to about 12% (w/w).

47. The method of any one of embodiments 1-40, wherein the liquid formulation has a nicotine concentration of about 4% (w/w).

48. The method of any one of embodiments 1-40, wherein the liquid formulation has a nicotine concentration of about 2% (w/w).

49. The method of any one of embodiments 1-47, wherein the formulation further comprises a flavorant.

50. The method of any one of embodiments 1-48, wherein the formulation is non-corrosive to an electronic cigarette.

51. The method of any one of embodiments 1-49, wherein the acid is stable at and below operating temperature or about 200 °C.

52. The method of any one of embodiments 1-50, wherein the acid does not decompose at and below operating temperature or about 200 °C.

53. The method of any one of embodiments 1-51, wherein the acid does not oxidize at and below operating temperature or about 200 °C.

54. The method of any one of embodiments 1-52, wherein the formulation is non-corrosive to the electronic cigarette.

55. The method of any one of embodiments 1-53, wherein the formulation is non-toxic to a user of the electronic cigarette.

56. The method of any one of embodiments 1-54, wherein the formulation further comprises one or more additional nicotine salts in a biologically acceptable liquid carrier suitable for generating the inhalable aerosol upon heating.

57. The method of embodiment 55, wherein a second acid used to form the additional nicotine salt is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

58. A method of delivering nicotine to the blood of a user, said method comprising providing an aerosol that is inhaled by the user from an electronic cigarette that comprises a nicotine salt formulation wherein providing the aerosol comprises the electronic cigarette heating the formulation thereby generating the aerosol, wherein the aerosol is effective in delivering a level of nicotine in the blood of the user that is at least 5ng/mL at about 1.5 minutes after a first puff of ten puffs of the aerosol, each puff taken at 30 second intervals.

59. The method of embodiment 54, wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200 °C.

60. The method of embodiment 54, wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200 °C.

61. The method of embodiment 54, wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160 °C, a boiling point >160 °C, and at least a 50-degree difference between the melting point and the boiling point.

62. The method of any one of embodiments 57-60, wherein the heating of the formulation is at a temperature from 150 °C to 250 °C.

63. The method of any one of embodiments 57-60, wherein the heating of the formulation is at a temperature from 180 °C to 220 °C.

64. The method of any one of embodiments 57-60, wherein the heating of the formulation is at a temperature of about 200 °C.

65. The method of embodiment 54, wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than the operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point; and the operating temperature is 200 °C.

66. The method of any one of embodiments 57-64, wherein the Cmax is over 10 ng/mL on average.

67. The method of any one of embodiments 57-64, wherein the Cmax is over 11 ng/mL on average.

68. The method of any one of embodiments 57-64, wherein the Cmax is between 10 ng/mL and 16 ng/mL on average.

69. The method of any one of embodiments 57-64, wherein the Cmax is between 11 ng/mL and 15 ng/mL on average.

70. The method of any one of embodiments 57-64, wherein the Cmax is between 11 ng/mL and 14 ng/mL on average.

71. The method of any one of embodiments 57-69, wherein the Tmax under 10 minutes on average.

72. The method of any one of embodiments 57-69, wherein the Tmax is under 9 minutes on average.

73. The method of any one of embodiments 57-69, wherein the Tmax is under 8 minutes on average.

74. The method of any one of embodiments 57-69, wherein the Tmax is under 7 minutes on average.

75. The method of any one of embodiments 54-63, wherein the Tmax is from 3 minutes to 10 minutes on average.

76. The method of any one of embodiments 57-69, wherein the Tmax is from 3 minutes to 7.5 minutes on average.

77. The method of any one of embodiments 57-75, wherein the aerosol comprises condensate of the nicotine salt.

78. The method of any one of embodiments 57-75, wherein the aerosol comprises condensate of freebase nicotine.

79. The method of any one of embodiments 57-75, wherein the aerosol comprises condensate of freebase nicotine and condensate of the carrier.

80. The method of any one of embodiments 57-75, wherein the aerosol comprises condensate of freebase nicotine and condensate of the acid.

81. The method of any one of embodiments 57-79, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 5 microns.

82. The method of any one of embodiments 57-79, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 1 or 2 microns.

83. The method of any one of embodiments 57-79, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 0.7 microns.

84. The method of any one of embodiments 57-79, wherein the aerosol comprises condensate in particle sizes from about 0.3 microns to about 0.4 microns.

85. The method of any one of embodiments 57-83, wherein the acid is a carboxylic acid.

86. The method of any one of embodiments 57-83, wherein the acid used to form said nicotine salt is an organic acid.

87. The method of embodiment 85, wherein the organic acid is monocarboxylic acid, aromatic acid, or keto acid.

88. The method of embodiment 85, wherein the organic acid is formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, phenylacetic acid, benzoic acid, pyruvic acid, levulinic acid, tartaric acid, lactic acid, malonic acid, succinic acid, fumaric acid, finnaric acid, gluconic acid, saccharic acid, salicylic acid, sorbic acid, malonic acid, or malic acid.

89. The method of any one of embodiments 57-83, wherein the acid used to form the nicotine salt is salicylic acid.

90. The method of any one of embodiments 57-83, wherein the acid used to form the nicotine salt is benzoic acid.

91. The method of any one of embodiments 57-83, wherein the acid used to form the nicotine salt is pyruvic acid.

92. The method of any one of embodiments 57-83, wherein the acid used to form the nicotine salt is sorbic acid.

93. The method of any one of embodiments 57-83, wherein the acid used to form the nicotine salt is lauric acid.

94. The method of any one of embodiments 57-83, wherein the acid used to form the nicotine salt is levulinic acid.

95. The method of any one of embodiments 57-83, wherein said nicotine salt comprises nicotine pyruvate.

96. The method of any one of embodiments 57-83, wherein said nicotine salt comprises nicotine salicylate.

97. The method of any one of embodiments 57-83, wherein said nicotine salt comprises nicotine sorbate.

98. The method of any one of embodiments 57-83, wherein said nicotine salt comprises nicotine laurate.

99. The method of any one of embodiments 57-83, wherein said nicotine salt comprises nicotine levulinate.

100. The method of any one of embodiments 57-83, wherein said nicotine salt comprises nicotine benzoate.

101. The method of any one of embodiments 57-99, wherein the liquid carrier comprises glycerol, propylene glycol, trimethylene glycol, water, ethanol or combinations thereof.

102. The method of any one of embodiments 57-99, wherein the liquid carrier comprises propylene glycol and vegetable glycerin.

103. The method of any one of embodiments 57-99, wherein the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

104. The method of any one of embodiments 57-99, wherein the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

105. The method of any one of embodiments 57-103, wherein the nicotine salt is in an amount that forms about 0.5% to about 20% nicotine in the inhalable aerosol.

106. The method of any one of embodiments 57-103, wherein the nicotine salt is in an amount that forms about 1% to about 20% nicotine in the inhalable aerosol.

107. The method of any one of embodiments 57-105, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 25% (w/w).

108. The method of any one of embodiments 57-105, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 20% (w/w).

109. The method of any one of embodiments 57-105, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 18% (w/w).

110. The method of any one of embodiments 57-105, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 15% (w/w).

111. The method of any one of embodiments 57-105, wherein the liquid formulation has a nicotine concentration of about 4% (w/w) to about 12% (w/w).

112. The method of any one of embodiments 57-105, wherein the liquid formulation has a nicotine concentration of about 4% (w/w).

113. The method of any one of embodiments 57-105, wherein the liquid formulation has a nicotine concentration of about 2% (w/w).

114. The method of any one of embodiments 57-112, wherein the formulation further comprises a flavorant.

115. The method of any one of embodiments 57-113, wherein the formulation is non-corrosive to an electronic cigarette.

116. The method of any one of embodiments 57-114, wherein the acid is stable at and below operating temperature or about 200 °C.

117. The method of any one of embodiments 57-115, wherein the acid does not decompose at and below operating temperature or about 200 °C.

118. The method of any one of embodiments 57-116, wherein the acid does not oxidize at and below operating temperature or about 200 °C.

119. The method of any one of embodiments 57-117, wherein the formulation is non-corrosive to the electronic cigarette.

120. The method of any one of embodiments 57-118, wherein the formulation is non-toxic to a user of the electronic cigarette.

121. The method of any one of embodiments 57-119, wherein the formulation further comprises one or more additional nicotine salts in a biologically acceptable liquid carrier suitable for generating the inhalable aerosol upon heating.

122. The method of embodiment 120, wherein a second acid used to form the additional nicotine salt is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

123. A nicotine salt liquid formulation in an electronic cigarette for generating an inhalable aerosol upon heating in the electronic cigarette, the formulation in the cigarette comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200 °C.

124. A nicotine salt liquid formulation in an electronic cigarette for generating an inhalable aerosol upon heating in the electronic cigarette, the formulation in the cigarette comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200 °C.

125. A nicotine salt liquid formulation in an electronic cigarette for generating an inhalable aerosol upon heating in the electronic cigarette, the formulation in the cigarette comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160 °C, a boiling point >160 °C, and at least a 50-degree difference between the melting point and the boiling point.

126. A nicotine salt liquid formulation in an electronic cigarette for generating an inhalable aerosol upon heating in the electronic cigarette, the formulation in the cigarette comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point.

127. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-124, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature from 150 °C to 250 °C.

128. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-124, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature from 180 °C to 220 °C.

129. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-124, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature of about 200 °C.

130. The nicotine salt liquid formulation in the electronic cigarette of embodiment 125, wherein the operating temperature is from 150 °C to 250 °C.

131. The nicotine salt liquid formulation in the electronic cigarette of embodiment 125, wherein the operating temperature is from 180 °C to 220 °C.

132. The nicotine salt liquid formulation in the electronic cigarette of embodiment 125, wherein the operating temperature is about 200 °C.

133. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein the acid is a carboxylic acid.

134. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein the acid used to form said nicotine salt is an organic acid.

135. The nicotine salt liquid formulation in the electronic cigarette of embodiment 133, wherein the organic acid is monocarboxylic acid, aromatic acid, or keto acid.

136. The nicotine salt liquid formulation in the electronic cigarette of embodiment 133, wherein the organic acid is formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, phenylacetic acid, benzoic acid, pyruvic acid, levulinic acid, tartaric acid, lactic acid, malonic acid, succinic acid, fumaric acid, finnaric acid, gluconic acid, saccharic acid, salicylic acid, sorbic acid, malonic acid, or malic acid.

137. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein the acid used to form the nicotine salt is salicylic acid.

138. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein the acid used to form the nicotine salt is benzoic acid.

139. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein the acid used to form the nicotine salt is pyruvic acid.

140. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein the acid used to form the nicotine salt is sorbic acid.

141. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein the acid used to form the nicotine salt is lauric acid.

142. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein the acid used to form the nicotine salt is levulinic acid.

143. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein said nicotine salt comprises nicotine pyruvate.

144. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein said nicotine salt comprises nicotine salicylate.

145. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein said nicotine salt comprises nicotine sorbate.

146. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein said nicotine salt comprises nicotine laurate.

147. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein said nicotine salt comprises nicotine levulinate.

148. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein said nicotine salt comprises nicotine benzoate.

149. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-147, wherein the liquid carrier comprises glycerol, propylene glycol, trimethylene glycol, water, ethanol or combinations thereof.

150. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-147, wherein the liquid carrier comprises propylene glycol and vegetable glycerin.

151. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-147, wherein the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

152. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-147, wherein the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

153. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-151, wherein the nicotine salt is in an amount that forms about 0.5% to about 20% nicotine in the inhalable aerosol.

154. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-151, wherein the nicotine salt is in an amount that forms about 1% to about 20% nicotine in the inhalable aerosol.

155. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-153, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 25% (w/w).

156. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-153, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 20% (w/w).

157. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-153, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 18% (w/w).

158. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-153, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 15% (w/w).

159. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-153, wherein the liquid formulation has a nicotine concentration of about 4% (w/w) to about 12% (w/w).

160. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-153, wherein the liquid formulation has a nicotine concentration of about 4% (w/w).

161. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-153, wherein the liquid formulation has a nicotine concentration of about 2% (w/w).

162. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-160, wherein the formulation further comprises a flavorant.

163. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-161, wherein the formulation is non-corrosive to an electronic cigarette.

164. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-162, wherein the acid is stable at and below operating temperature or about 200 °C.

165. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-163, wherein the acid does not decompose at and below operating temperature or about 200 °C.

166. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-164, wherein the acid does not oxidize at and below operating temperature or about 200 °C.

167. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-165, wherein the formulation is non-corrosive to the electronic cigarette.

168. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-166, wherein the formulation is non-toxic to a user of the electronic cigarette.

169. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-167 further comprising one or more additional nicotine salts in a biologically acceptable liquid carrier suitable for generating the inhalable aerosol upon heating.

170. The nicotine salt liquid formulation in the electronic cigarette of embodiment 168, wherein a second acid used to form the additional nicotine salt is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

171. A nicotine salt liquid formulation for generating an inhalable aerosol upon heating in the electronic cigarette, the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200 °C.

172. A nicotine salt liquid formulation for generating an inhalable aerosol upon heating in the electronic cigarette, the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200 °C.

173. A nicotine salt liquid formulation for generating an inhalable aerosol upon heating in the electronic cigarette, the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160 °C, a boiling point >160 °C, and at least a 50-degree difference between the melting point and the boiling point.

174. A nicotine salt liquid formulation for generating an inhalable aerosol upon heating in the electronic cigarette, the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point.

175. The nicotine salt liquid formulation of any one of embodiments 170-172, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature from 150 °C to 250 °C.

176. The nicotine salt liquid formulation of any one of embodiments 170-172, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature from 180 °C to 220 °C.

177. The nicotine salt liquid formulation of any one of embodiments 170-172, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature of about 200 °C.

178. The nicotine salt liquid formulation of embodiment 173, wherein the operating temperature is from 150 °C to 250 °C.

179. The nicotine salt liquid formulation of embodiment 173, wherein the operating temperature is from 180 °C to 220 °C.

180. The nicotine salt liquid formulation of embodiment 173, wherein the operating temperature is about 200 °C.

181. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein the acid is a carboxylic acid.

182. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein the acid used to form said nicotine salt is an organic acid.

183. The nicotine salt liquid formulation of embodiment 181, wherein the organic acid is monocarboxylic acid, aromatic acid, or keto acid.

184. The nicotine salt liquid formulation of embodiment 181, wherein the organic acid is formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid, linoleic

acid, linolenic acid, phenylacetic acid, benzoic acid, pyruvic acid, levulinic acid, tartaric acid, lactic acid, malonic acid, succinic acid, fumaric acid, finnaric acid, gluconic acid, saccharic acid, salicylic acid, sorbic acid, malonic acid, or malic acid.

185. The liquid formulation of any one of embodiments 170-179, wherein the acid used to form the nicotine salt is salicylic acid.

186. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein the acid used to form the nicotine salt is benzoic acid.

187. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein the acid used to form the nicotine salt is pyruvic acid.

188. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein the acid used to form the nicotine salt is sorbic acid.

189. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein the acid used to form the nicotine salt is lauric acid.

190. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein the acid used to form the nicotine salt is levulinic acid.

191. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein said nicotine salt comprises nicotine pyruvate.

192. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein said nicotine salt comprises nicotine salicylate.

193. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein said nicotine salt comprises nicotine sorbate.

194. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein said nicotine salt comprises nicotine laurate.

195. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein said nicotine salt comprises nicotine levulinate.

196. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein said nicotine salt comprises nicotine benzoate.

197. The nicotine salt liquid formulation of any one of embodiments 170-195, wherein the liquid carrier comprises glycerol, propylene glycol, trimethylene glycol, water, ethanol or combinations thereof.

198. The nicotine salt liquid formulation of any one of embodiments 170-195, wherein the liquid carrier comprises propylene glycol and vegetable glycerin.

199. The nicotine salt liquid formulation of any one of embodiments 170-195, wherein the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

200. The nicotine salt liquid formulation of any one of embodiments 170-195, wherein the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

201. The nicotine salt liquid formulation of any one of embodiments 170-199, wherein the nicotine salt is in an amount that forms about 0.5% to about 20% nicotine in the inhalable aerosol.

202. The nicotine salt liquid formulation of any one of embodiments 170-199, wherein the nicotine salt is in an amount that forms about 1% to about 20% nicotine in the inhalable aerosol.

203. The nicotine salt liquid formulation of any one of embodiments 170-201, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 25% (w/w).

204. The nicotine salt liquid formulation of any one of embodiments 170-201, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 20% (w/w).

205. The nicotine salt liquid formulation of any one of embodiments 170-201, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 18% (w/w).

206. The nicotine salt liquid formulation of any one of embodiments 170-201, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 15% (w/w).

207. The nicotine salt liquid formulation of any one of embodiments 170-201, wherein the liquid formulation has a nicotine concentration of about 4% (w/w) to about 12% (w/w).

208. The nicotine salt liquid formulation of any one of embodiments 170-201, wherein the liquid formulation has a nicotine concentration of about 4% (w/w).

209. The nicotine salt liquid formulation of any one of embodiments 170-201, wherein the liquid formulation has a nicotine concentration of about 2% (w/w).

210. The nicotine salt liquid formulation of any one of embodiments 170-208, wherein the formulation further comprises a flavorant.

211. The nicotine salt liquid formulation of any one of embodiments 170-209, wherein the formulation is non-corrosive to an electronic cigarette.

212. The nicotine salt liquid formulation of any one of embodiments 170-210, wherein the acid is stable at and below operating temperature or about 200 °C.

213. The nicotine salt liquid formulation of any one of embodiments 170-211, wherein the acid does not decompose at and below operating temperature or about 200 °C.

214. The nicotine salt liquid formulation of any one of embodiments 170-212, wherein the acid does not oxidize at and below operating temperature or about 200 °C.

215. The nicotine salt liquid formulation of any one of embodiments 170-213, wherein the formulation is non-corrosive to the electronic cigarette.

216. The nicotine salt liquid formulation of any one of embodiments 170-214, wherein the formulation is non-toxic to a user of the electronic cigarette.

217. The nicotine salt liquid formulation of any one of embodiments 170-215, further comprising one or more additional nicotine salts in a biologically acceptable liquid carrier suitable for generating the inhalable aerosol upon heating.

218. The nicotine salt liquid formulation of embodiment 216, wherein a second acid used to form the additional nicotine salt is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

219. A nicotine salt liquid formulation for use in an electronic cigarette the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200 °C.

220. A nicotine salt liquid formulation for use in an electronic cigarette the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200 °C.

221. A nicotine salt liquid formulation for use in an electronic cigarette the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160 °C, a boiling point >160 °C, and at least a 50-degree difference between the melting point and the boiling point.

222. A nicotine salt liquid formulation for use in an electronic cigarette the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more

than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point.

223. The nicotine salt liquid formulation of any one of embodiments 218-220, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature from 150 °C to 250 °C.

224. The nicotine salt liquid formulation of any one of embodiments 218-220, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature from 180 °C to 220 °C.

225. The nicotine salt liquid formulation of any one of embodiments 218-220, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature of about 200 °C.

226. The nicotine salt liquid formulation of embodiment 221, wherein the operating temperature is from 150 °C to 250 °C.

227. The nicotine salt liquid formulation of embodiment 221, wherein the operating temperature is from 180 °C to 220 °C.

228. The nicotine salt liquid formulation of embodiment 221, wherein the operating temperature is about 200 °C.

229. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein the acid is a carboxylic acid.

230. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein the acid used to form said nicotine salt is an organic acid.

231. The nicotine salt liquid formulation of embodiment 229, wherein the organic acid is monocarboxylic acid, aromatic acid, or keto acid.

232. The nicotine salt liquid formulation of embodiment 229, wherein the organic acid is formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, phenylacetic acid, benzoic acid, pyruvic acid, levulinic acid, tartaric acid, lactic acid, malonic acid, succinic acid, fumaric acid, finnaric acid, gluconic acid, saccharic acid, salicylic acid, sorbic acid, malonic acid, or malic acid.

233. The liquid formulation of any one of embodiments 218-227, wherein the acid used to form the nicotine salt is salicylic acid.

234. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein the acid used to form the nicotine salt is benzoic acid.

235. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein the acid used to form the nicotine salt is pyruvic acid.

236. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein the acid used to form the nicotine salt is sorbic acid.

237. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein the acid used to form the nicotine salt is lauric acid.

238. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein the acid used to form the nicotine salt is levulinic acid.

239. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein said nicotine salt comprises nicotine pyruvate.

240. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein said nicotine salt comprises nicotine salicylate.

241. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein said nicotine salt comprises nicotine sorbate.

242. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein said nicotine salt comprises nicotine laurate.

243. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein said nicotine salt comprises nicotine levulinate.

244. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein said nicotine salt comprises nicotine benzoate.

245. The nicotine salt liquid formulation of any one of embodiments 218-243, wherein the liquid carrier comprises glycerol, propylene glycol, trimethylene glycol, water, ethanol or combinations thereof.

246. The nicotine salt liquid formulation of any one of embodiments 218-243, wherein the liquid carrier comprises propylene glycol and vegetable glycerin.

247. The nicotine salt liquid formulation of any one of embodiments 218-243, wherein the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

248. The nicotine salt liquid formulation of any one of embodiments 218-243, wherein the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

249. The nicotine salt liquid formulation of any one of embodiments 218-247, wherein the nicotine salt is in an amount that forms about 0.5% to about 20% nicotine in the inhalable aerosol.

250. The nicotine salt liquid formulation of any one of embodiments 218-247, wherein the nicotine salt is in an amount that forms about 1% to about 20% nicotine in the inhalable aerosol.

251. The nicotine salt liquid formulation of any one of embodiments 218-247, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 25% (w/w).

252. The nicotine salt liquid formulation of any one of embodiments 218-247, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 20% (w/w).

253. The nicotine salt liquid formulation of any one of embodiments 218-247, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 18% (w/w).

254. The nicotine salt liquid formulation of any one of embodiments 218-247, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 15% (w/w).

255. The nicotine salt liquid formulation of any one of embodiments 218-247, wherein the liquid formulation has a nicotine concentration of about 4% (w/w) to about 12% (w/w).

256. The nicotine salt liquid formulation of any one of embodiments 218-247, wherein the liquid formulation has a nicotine concentration of about 4% (w/w).

257. The nicotine salt liquid formulation of any one of embodiments 218-247, wherein the liquid formulation has a nicotine concentration of about 2% (w/w).

258. The nicotine salt liquid formulation of any one of embodiments 218-256, wherein the formulation further comprises a flavorant.

259. The nicotine salt liquid formulation of any one of embodiments 218-257, wherein the formulation is non-corrosive to an electronic cigarette.

260. The nicotine salt liquid formulation of any one of embodiments 218-258, wherein the acid is stable at and below operating temperature or about 200 °C.

261. The nicotine salt liquid formulation of any one of embodiments 218-259, wherein the acid does not decompose at and below operating temperature or about 200 °C.

262. The nicotine salt liquid formulation of any one of embodiments 218-260, wherein the acid does not oxidize at and below operating temperature or about 200 °C.

263. The nicotine salt liquid formulation of any one of embodiments 218-261, wherein the formulation is non-corrosive to the electronic cigarette.

264. The nicotine salt liquid formulation of any one of embodiments 218-262, wherein the formulation is non-toxic to a user of the electronic cigarette.

265. The nicotine salt liquid formulation of any one of embodiments 218-263, further comprising one or more additional nicotine salts in a biologically acceptable liquid carrier suitable for generating the inhalable aerosol upon heating.

266. The nicotine salt liquid formulation of embodiment 264, wherein a second acid used to form the additional nicotine salt is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

267. Use of a nicotine salt formulation for delivery of nicotine to a user from an electronic cigarette wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200 °C, and the nicotine salt formulation is heated by the electronic cigarette to generate an aerosol inhalable by the user.

268. Use of a nicotine salt formulation for delivery of nicotine to a user from an electronic cigarette wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200 °C, and the nicotine salt formulation is heated by the electronic cigarette to generate an aerosol inhalable by the user.

269. Use of a nicotine salt formulation for delivery of nicotine to a user from an electronic cigarette wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160 °C, a boiling point >160 °C, and at least a 50-degree difference between the melting point and the boiling point, and the nicotine salt formulation is heated by the electronic cigarette to generate an aerosol inhalable by the user.

270. Use of a nicotine salt formulation for delivery of nicotine to the blood of a user from an electronic cigarette, wherein the nicotine salt formulation in the electronic cigarette is heated to form an aerosol which delivers a level of nicotine in the blood of the user that is at least 5 ng/mL at about 1.5 minutes after a first puff of ten puffs of the aerosol, each puff taken at 30 second intervals.

271. Use of a nicotine salt formulation for delivery of nicotine to a user from an electronic cigarette wherein the nicotine salt formulation comprises a nicotine salt in a biologically

acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point, and the nicotine salt formulation is heated by the electronic cigarette to generate an aerosol inhalable by the user.

272. The use of any one of embodiments 266-269, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature is from 150 °C to 250 °C.

273. The use of any one of embodiments 266-269, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature is from 180 °C to 220 °C.

274. The use of any one of embodiments 266-269, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature is about 200 °C.

275. The use of embodiment 270, wherein the operating temperature is from 150 °C to 250 °C.

276. The use of embodiment 270, wherein the operating temperature is from 180 °C to 220 °C.

277. The use of embodiment 270, wherein the operating temperature is about 200 °C.

278. The use of any one of embodiments 266-276, wherein the aerosol comprises condensate of the nicotine salt.

279. The use of any one of embodiments 266-276, wherein the aerosol comprises condensate of freebase nicotine.

280. The use of any one of embodiments 266-276, wherein the aerosol comprises condensate of freebase nicotine and condensate of the carrier.

281. The use of any one of embodiments 266-276, wherein the aerosol comprises condensate of freebase nicotine and condensate of the acid.

282. The use of any one of embodiments 266-280, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 5 microns.

283. The use of any one of embodiments 266-280, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 1 or 2 microns.

284. The use of any one of embodiments 266-280, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 0.7 microns.

285. The use of any one of embodiments 266-280, wherein the aerosol comprises condensate in particle sizes from about 0.3 microns to about 0.4 microns.

286. The use of any one of embodiments 266-284, wherein the acid is a carboxylic acid.

287. The use of any one of embodiments 266-284, wherein the acid used to form said nicotine salt is an organic acid.

288. The use of embodiment 286, wherein the organic acid is monocarboxylic acid, aromatic acid, or keto acid.

289. The use of embodiment 286, wherein the organic acid is formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, phenylacetic acid, benzoic acid, pyruvic acid, levulinic acid, tartaric acid, lactic acid, malonic acid, succinic acid, fumaric acid, finnaric acid, gluconic acid, saccharic acid, salicylic acid, sorbic acid, malonic acid, or malic acid.

290. The use of any one of embodiments 266-284, wherein the acid used to form the nicotine salt is salicylic acid.

291. The use of any one of embodiments 266-284, wherein the acid used to form the nicotine salt is benzoic acid.

292. The use of any one of embodiments 266-284, wherein the acid used to form the nicotine salt is pyruvic acid.

293. The use of any one of embodiments 266-284, wherein the acid used to form the nicotine salt is sorbic acid.

294. The use of any one of embodiments 266-284, wherein the acid used to form the nicotine salt is lauric acid.

295. The use of any one of embodiments 266-284, wherein the acid used to form the nicotine salt is levulinic acid.

296. The use of any one of embodiments 266-284, wherein said nicotine salt comprises nicotine pyruvate.

297. The use of any one of embodiments 266-284, wherein said nicotine salt comprises nicotine salicylate.

298. The use of any one of embodiments 266-284, wherein said nicotine salt comprises nicotine sorbate.

299. The use of any one of embodiments 266-284, wherein said nicotine salt comprises nicotine laurate.

300. The use of any one of embodiments 266-284, wherein said nicotine salt comprises nicotine levulinate.

301. The use of any one of embodiments 266-284, wherein said nicotine salt comprises nicotine benzoate.

302. The use of any one of embodiments 266-300, wherein the liquid carrier comprises glycerol, propylene glycol, trimethylene glycol, water, ethanol or combinations thereof.

303. The use of any one of embodiments 266-300, wherein the liquid carrier comprises propylene glycol and vegetable glycerin.

304. The use of any one of embodiments 266-300, wherein the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

305. The use of any one of embodiments 266-300, wherein the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

306. The use of any one of embodiments 266-304, wherein the nicotine salt is in an amount that forms about 0.5% to about 20% nicotine in the inhalable aerosol.

307. The use of any one of embodiments 266-304, wherein the nicotine salt is in an amount that forms about 1% to about 20% nicotine in the inhalable aerosol.

308. The use of any one of embodiments 266-306, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 25% (w/w).

309. The use of any one of embodiments 266-306, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 20% (w/w).

310. The use of any one of embodiments 266-306, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 18% (w/w).

311. The use of any one of embodiments 266-306, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 15% (w/w).

312. The use of any one of embodiments 266-306, wherein the liquid formulation has a nicotine concentration of about 4% (w/w) to about 12% (w/w).

313. The use of any one of embodiments 266-306, wherein the liquid formulation has a nicotine concentration of about 4% (w/w).

314. The use of any one of embodiments 266-306, wherein the liquid formulation has a nicotine concentration of about 2% (w/w).

315. The use of any one of embodiments 266-313, wherein the formulation further comprises a flavorant.

316. The use of any one of embodiments 266-314, wherein the formulation is non-corrosive to an electronic cigarette.

317. The use of any one of embodiments 266-315, wherein the acid is stable at and below operating temperature or about 200 °C.

318. The use of any one of embodiments 266-316, wherein the acid does not decompose at and below operating temperature or about 200 °C.

319. The use of any one of embodiments 266-317, wherein the acid does not oxidize at and below operating temperature or about 200 °C.

320. The use of any one of embodiments 266-318, wherein the formulation is non-corrosive to the electronic cigarette.

321. The use of any one of embodiments 266-319, wherein the formulation is non-toxic to a user of the electronic cigarette.

322. The use of any one of embodiments 266-320, wherein the formulation further comprises one or more additional nicotine salts in a biologically acceptable liquid carrier suitable for generating the inhalable aerosol upon heating.

323. The use of embodiment 321, wherein a second acid used to form the additional nicotine salt is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid

324. A cartomizer for an electronic cigarette comprising:

a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200 °C;

an atomizer comprising a heating element in fluid communication with the nicotine salt liquid formulation; and

a fluid storage compartment that stores the nicotine salt liquid formulation.

325. A cartomizer for an electronic cigarette comprising:

a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200 °C;

an atomizer comprising a heating element in fluid communication with the nicotine salt liquid formulation; and

a fluid storage compartment that stores the nicotine salt liquid formulation.

326. A cartomizer for an electronic cigarette comprising:

a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160 °C, a boiling point >160 °C, and at least a 50-degree difference between the melting point and the boiling point;

an atomizer comprising a heating element in fluid communication with the nicotine salt liquid formulation; and

a fluid storage compartment that stores the nicotine salt liquid formulation.

327. A cartomizer for an electronic cigarette comprising:

a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point;

an atomizer comprising a heating element in fluid communication with the nicotine salt liquid formulation; and

a fluid storage compartment that stores the nicotine salt liquid formulation.

328. The cartomizer of any one of embodiments 323-325, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature from 150 °C to 250 °C.

329. The cartomizer of any one of embodiments 323-325, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature from 180 °C to 220 °C.

330. The cartomizer of any one of embodiments 323-325, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature of about 200 °C.

331. The cartomizer of embodiment 326, wherein the operating temperature is from 150 °C to 250 °C.

332. The cartomizer of embodiment 326, wherein the operating temperature is from 180 °C to 220 °C.

333. The cartomizer of embodiment 326, wherein the operating temperature is about 200 °C.

334. The cartomizer of any one of embodiments 323-332, wherein the cartomizer further comprises a mouthpiece.

335. The cartomizer of any one of embodiments 323-333, wherein the acid is a carboxylic acid.

336. The cartomizer of any one of embodiments 323-333, wherein the acid used to form said nicotine salt is an organic acid.

337. The cartomizer of embodiment 335, wherein the organic acid is monocarboxylic acid, aromatic acid, or keto acid.

338. The cartomizer of embodiment 335, wherein the organic acid is formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, phenylacetic acid, benzoic acid, pyruvic acid, levulinic acid, tartaric acid, lactic acid, malonic acid, succinic acid, fumaric acid, finnaric acid, gluconic acid, saccharic acid, salicylic acid, sorbic acid, malonic acid, or malic acid.

339. The cartomizer of any one of embodiments 323-333, wherein the acid used to form the nicotine salt is salicylic acid.

340. The cartomizer of any one of embodiments 323-333, wherein the acid used to form the nicotine salt is benzoic acid.

341. The cartomizer of any one of embodiments 323-333, wherein the acid used to form the nicotine salt is pyruvic acid.

342. The cartomizer of any one of embodiments 323-333, wherein the acid used to form the nicotine salt is sorbic acid.

343. The cartomizer of any one of embodiments 323-333, wherein the acid used to form the nicotine salt is lauric acid.

344. The cartomizer of any one of embodiments 323-333, wherein the acid used to form the nicotine salt is levulinic acid.

345. The cartomizer of any one of embodiments 323-333, wherein said nicotine salt comprises nicotine pyruvate.

346. The cartomizer of any one of embodiments 323-333, wherein said nicotine salt comprises nicotine salicylate.

347. The cartomizer of any one of embodiments 323-333, wherein said nicotine salt comprises nicotine sorbate.

348. The cartomizer of any one of embodiments 323-333, wherein said nicotine salt comprises nicotine laurate.

349. The cartomizer of any one of embodiments 323-333, wherein said nicotine salt comprises nicotine levulinate.

350. The cartomizer of any one of embodiments 323-333, wherein said nicotine salt comprises nicotine benzoate.

351. The cartomizer of any one of embodiments 323-349, wherein the liquid carrier comprises glycerol, propylene glycol, trimethylene glycol, water, ethanol or combinations thereof.

352. The cartomizer of any one of embodiments 323-349, wherein the liquid carrier comprises propylene glycol and vegetable glycerin.

353. The cartomizer of any one of embodiments 323-349, wherein the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

354. The cartomizer of any one of embodiments 323-349, wherein the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

355. The cartomizer of any one of embodiments 323-353, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 25% (w/w).

356. The cartomizer of any one of embodiments 323-353, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 20% (w/w).

357. The cartomizer of any one of embodiments 323-353, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 18% (w/w).

358. The cartomizer of any one of embodiments 323-353, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 15% (w/w).

359. The cartomizer of any one of embodiments 323-353, wherein the liquid formulation has a nicotine concentration of about 4% (w/w) to about 12% (w/w).

360. The cartomizer of any one of embodiments 323-353, wherein the liquid formulation has a nicotine concentration of about 4% (w/w).

361. The cartomizer of any one of embodiments 323-353, wherein the liquid formulation has a nicotine concentration of about 2% (w/w).

362. The cartomizer of any one of embodiments 323-360, wherein the electronic cigarette is configured to generate an aerosol inhalable by a user.

363. The cartomizer of embodiment 361, wherein the aerosol comprises condensate of the nicotine salt.

364. The cartomizer of embodiment 361, wherein the aerosol comprises condensate of freebase nicotine.

365. The cartomizer of embodiment 361, wherein the aerosol comprises condensate of freebase nicotine and condensate of the carrier.

366. The cartomizer of embodiment 361, wherein the aerosol comprises condensate of freebase nicotine and condensate of the acid.

367. The cartomizer of any one of embodiments 361-365, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 5 microns.

368. The cartomizer of any one of embodiments 361-365, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 1 or 2 microns.

369. The cartomizer of any one of embodiments 361-365, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 0.7 microns.

370. The cartomizer of any one of embodiments 361-365, wherein the aerosol comprises condensate in particle sizes from about 0.3 microns to about 0.4 microns.

371. The cartomizer of any one of embodiments 361-369, wherein the nicotine salt is in an amount that forms about 0.5% to about 20% nicotine in the inhalable aerosol.

372. The cartomizer of any one of embodiments 361-369, wherein the nicotine salt is in an amount that forms about 1% to about 20% nicotine in the inhalable aerosol.

373. The cartomizer of any one of embodiments 323-371, wherein the formulation further comprises a flavorant.

374. The cartomizer of any one of embodiments 323-372, wherein the formulation is non-corrosive to an electronic cigarette.

375. The cartomizer of any one of embodiments 323-373, wherein the acid is stable at and below operating temperature or about 200 °C.

376. The cartomizer of any one of embodiments 323-374, wherein the acid does not decompose at and below operating temperature or about 200 °C.

377. The cartomizer of any one of embodiments 323-375, wherein the acid does not oxidize at and below operating temperature or about 200 °C.

378. The cartomizer of any one of embodiments 323-376, wherein the formulation is non-corrosive to the electronic cigarette.

379. The cartomizer of any one of embodiments 323-377, wherein the formulation is non-toxic to a user of the electronic cigarette.

380. The cartomizer of any one of embodiments 323-378, wherein the formulation further comprises one or more additional nicotine salts in a biologically acceptable liquid carrier suitable for generating the inhalable aerosol upon heating.

381. The cartomizer of embodiment 379, wherein a second acid used to form the additional nicotine salt is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

382. An electronic cigarette for generating an inhalable aerosol comprising

a fluid storage compartment;

a heater; and

a nicotine salt liquid formulation in the fluid storage compartment, the liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200 °C;

a battery; and

a mouthpiece.

383. An electronic cigarette for generating an inhalable aerosol comprising

a fluid storage compartment;

a heater; and

a nicotine salt liquid formulation in the fluid storage compartment, the liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used

to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200 °C;

a battery; and

a mouthpiece.

384. An electronic cigarette for generating an inhalable aerosol comprising

a fluid storage compartment;

a heater; and

a nicotine salt liquid formulation in the fluid storage compartment, the liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160 °C, a boiling point >160 °C, and at least a 50-degree difference between the melting point and the boiling point;

a battery; and

a mouthpiece.

385. An electronic cigarette for generating an inhalable aerosol comprising

a fluid storage compartment;

a heater; and

a nicotine salt liquid formulation in the fluid storage compartment, the liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point;

a battery; and

a mouthpiece.

386. The electronic cigarette of any one of embodiments 381-384, wherein the heater comprises a heater chamber, a fluid wick, and a resistive heating element in contact with the fluid wick.

387. The electronic cigarette of any one of embodiments 381-384, wherein the mouthpiece, the heater and the fluid storage compartment form a cartomizer separable from the battery.

388. The electronic cigarette of any one of embodiments 381-384, wherein the heater and the fluid storage compartment form a cartomizer separable from the battery and the mouthpiece.

389. The electronic cigarette of any one of embodiments 381-384, wherein the fluid storage compartment is separable from the heater, the battery and the mouthpiece.

390. The electronic cigarette of any one of embodiments 381-383, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature from 150 °C to 250 °C.

391. The electronic cigarette of any one of embodiments 381-383, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature from 180 °C to 220 °C.

392. The electronic cigarette of any one of embodiments 381-383, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature of about 200 °C.

393. The electronic cigarette of embodiment 384, wherein the operating temperature is from 150 °C to 250 °C.

394. The electronic cigarette of embodiment 384, wherein the operating temperature is from 180 °C to 220 °C.

395. The electronic cigarette of embodiment 384, wherein the operating temperature is about 200 °C.

396. The electronic cigarette of any one of embodiments 381-394, wherein the aerosol comprises condensate of the nicotine salt.

397. The electronic cigarette of any one of embodiments 381-394, wherein the aerosol comprises condensate of freebase nicotine.

398. The electronic cigarette of any one of embodiments 381-394, wherein the aerosol comprises condensate of freebase nicotine and condensate of the carrier.

399. The electronic cigarette of any one of embodiments 381-394, wherein the aerosol comprises condensate of freebase nicotine and condensate of the acid.

400. The electronic cigarette of any one of embodiments 381-398, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 5 microns.

401. The electronic cigarette of any one of embodiments 381-398, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 1 or 2 microns.

402. The electronic cigarette of any one of embodiments 381-398, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 0.7 microns.

403. The electronic cigarette of any one of embodiments 381-398, wherein the aerosol comprises condensate in particle sizes from about 0.3 microns to about 0.4 microns.

404. The electronic cigarette of any one of embodiments 381-402, wherein the acid is a carboxylic acid.

405. The electronic cigarette of any one of embodiments 381-402, wherein the acid used to form said nicotine salt is an organic acid.

406. The electronic cigarette of embodiment 404, wherein the organic acid is monocarboxylic acid, aromatic acid, or keto acid.

407. The electronic cigarette of embodiment 404, wherein the organic acid is formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, phenylacetic acid, benzoic acid, pyruvic acid, levulinic acid, tartaric acid, lactic acid, malonic acid, succinic acid, fumaric acid, finnaric acid, gluconic acid, saccharic acid, salicylic acid, sorbic acid, malonic acid, or malic acid.

408. The electronic cigarette of any one of embodiments 381-402, wherein the acid used to form the nicotine salt is salicylic acid.

409. The electronic cigarette of any one of embodiments 381-402, wherein the acid used to form the nicotine salt is benzoic acid.

410. The electronic cigarette of any one of embodiments 381-402, wherein the acid used to form the nicotine salt is pyruvic acid.

411. The electronic cigarette of any one of embodiments 381-402, wherein the acid used to form the nicotine salt is sorbic acid.

412. The electronic cigarette of any one of embodiments 381-402, wherein the acid used to form the nicotine salt is lauric acid.

413. The electronic cigarette of any one of embodiments 381-402, wherein the acid used to form the nicotine salt is levulinic acid.

414. The electronic cigarette of any one of embodiments 381-402, wherein said nicotine salt comprises nicotine pyruvate.

415. The electronic cigarette of any one of embodiments 381-402, wherein said nicotine salt comprises nicotine salicylate.

416. The electronic cigarette of any one of embodiments 381-402, wherein said nicotine salt comprises nicotine sorbate.

417. The electronic cigarette of any one of embodiments 381-402, wherein said nicotine salt comprises nicotine laurate.

418. The electronic cigarette of any one of embodiments 381-402, wherein said nicotine salt comprises nicotine levulinate.

419. The electronic cigarette of any one of embodiments 381-402, wherein said nicotine salt comprises nicotine benzoate.

420. The electronic cigarette of any one of embodiments 381-419, wherein the liquid carrier comprises glycerol, propylene glycol, trimethylene glycol, water, ethanol or combinations thereof.

421. The electronic cigarette of any one of embodiments 381-419, wherein the liquid carrier comprises propylene glycol and vegetable glycerin.

422. The electronic cigarette of any one of embodiments 381-419, wherein the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

423. The electronic cigarette of any one of embodiments 381-419, wherein the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

424. The electronic cigarette of any one of embodiments 381-422, wherein the nicotine salt is in an amount that forms about 0.5% to about 20% nicotine in the inhalable aerosol.

425. The electronic cigarette of any one of embodiments 381-422, wherein the nicotine salt is in an amount that forms about 1% to about 20% nicotine in the inhalable aerosol.

426. The electronic cigarette of any one of embodiments 381-424, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 25% (w/w).

427. The electronic cigarette of any one of embodiments 381-424, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 20% (w/w).

428. The electronic cigarette of any one of embodiments 381-424, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 18% (w/w).

429. The electronic cigarette of any one of embodiments 381-424, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 15% (w/w).

430. The electronic cigarette of any one of embodiments 381-424, wherein the liquid formulation has a nicotine concentration of about 4% (w/w) to about 12% (w/w).

431. The electronic cigarette of any one of embodiments 381-424, wherein the liquid formulation has a nicotine concentration of about 4% (w/w).

432. The electronic cigarette of any one of embodiments 381-424, wherein the liquid formulation has a nicotine concentration of about 2% (w/w).

433. The electronic cigarette of any one of embodiments 381-431, wherein the formulation further comprises a flavorant.

434. The electronic cigarette of any one of embodiments 381-432, wherein the formulation is non-corrosive to an electronic cigarette.

435. The electronic cigarette of any one of embodiments 381-433, wherein the acid is stable at and below operating temperature or about 200 °C.

436. The electronic cigarette of any one of embodiments 381-434, wherein the acid does not decompose at and below operating temperature or about 200 °C.

437. The electronic cigarette of any one of embodiments 381-435, wherein the acid does not oxidize at and below operating temperature or about 200 °C.

438. The electronic cigarette of any one of embodiments 381-436, wherein the formulation is non-corrosive to the electronic cigarette.

439. The electronic cigarette of any one of embodiments 381-437, wherein the formulation is non-toxic to a user of the electronic cigarette.

440. The electronic cigarette of any one of embodiments 381-438, wherein the formulation further comprises one or more additional nicotine salts in a biologically acceptable liquid carrier suitable for generating the inhalable aerosol upon heating.

441. The electronic cigarette of embodiment 439, wherein a second acid used to form the additional nicotine salt is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

442. A cartridge in an electronic cigarette comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200 °C.

443. A cartridge in an electronic cigarette comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a

nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200 °C.

444. A cartridge in an electronic cigarette comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160 °C, a boiling point >160 °C, and at least a 50-degree difference between the melting point and the boiling point.

445. A cartridge in an electronic cigarette comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point.

446. The cartridge of any one of embodiments 441-444, wherein the cartridge is separable from the electronic cigarette.

447. The cartridge of any one of embodiments 441-445, wherein the acid is a carboxylic acid.

448. The cartridge of any one of embodiments 441-445, wherein the acid used to form said nicotine salt is an organic acid.

449. The cartridge of embodiment 447, wherein the organic acid is monocarboxylic acid, aromatic acid, or keto acid.

450. The cartridge of embodiment 447, wherein the organic acid is formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, phenylacetic acid, benzoic acid, pyruvic acid, levulinic acid, tartaric acid, lactic acid, malonic acid, succinic acid, fumaric acid, finnaric acid, gluconic acid, saccharic acid, salicylic acid, sorbic acid, malonic acid, or malic acid.

451. The cartridge of any one of embodiments 441-445, wherein the acid used to form the nicotine salt is salicylic acid.

452. The cartridge of any one of embodiments 441-445, wherein the acid used to form the nicotine salt is benzoic acid.

453. The cartridge of any one of embodiments 441-445, wherein the acid used to form the nicotine salt is pyruvic acid.

454. The cartridge of any one of embodiments 441-445, wherein the acid used to form the nicotine salt is sorbic acid.

455. The cartridge of any one of embodiments 441-445, wherein the acid used to form the nicotine salt is lauric acid.

456. The cartridge of any one of embodiments 441-445, wherein the acid used to form the nicotine salt is levulinic acid.

457. The cartridge of any one of embodiments 441-445, wherein said nicotine salt comprises nicotine pyruvate.

458. The cartridge of any one of embodiments 441-445, wherein said nicotine salt comprises nicotine salicylate.

459. The cartridge of any one of embodiments 441-445, wherein said nicotine salt comprises nicotine sorbate.

460. The cartridge of any one of embodiments 441-445, wherein said nicotine salt comprises nicotine laurate.

461. The cartridge of any one of embodiments 441-445, wherein said nicotine salt comprises nicotine levulinate.

462. The cartridge of any one of embodiments 441-445, wherein said nicotine salt comprises nicotine benzoate.

463. The cartridge of any one of embodiments 441-461, wherein the liquid carrier comprises glycerol, propylene glycol, trimethylene glycol, water, ethanol or combinations thereof.

464. The cartridge of any one of embodiments 441-461, wherein the liquid carrier comprises propylene glycol and vegetable glycerin.

465. The cartridge of any one of embodiments 441-461, wherein the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

466. The cartridge of any one of embodiments 441-461, wherein the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

467. The cartridge of any one of embodiments 441-465, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 25% (w/w).

468. The cartridge of any one of embodiments 441-465, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 20% (w/w).

469. The cartridge of any one of embodiments 441-465, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 18% (w/w).

470. The cartridge of any one of embodiments 441-465, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 15% (w/w).

471. The cartridge of any one of embodiments 441-465, wherein the liquid formulation has a nicotine concentration of about 4% (w/w) to about 12% (w/w).

472. The cartridge of any one of embodiments 441-465, wherein the liquid formulation has a nicotine concentration of about 4% (w/w).

473. The cartridge of any one of embodiments 441-465, wherein the liquid formulation has a nicotine concentration of about 2% (w/w).

474. The cartridge of any one of embodiments 441-472, wherein the formulation further comprises a flavorant.

475. The cartridge of any one of embodiments 441-473, wherein the formulation is non-corrosive to an electronic cigarette.

476. The cartridge of any one of embodiments 441-474, wherein the acid is stable at and below operating temperature or about 200 °C.

477. The cartridge of any one of embodiments 441-475, wherein the acid does not decompose at and below operating temperature or about 200 °C.

478. The cartridge of any one of embodiments 441-476, wherein the acid does not oxidize at and below operating temperature or about 200 °C.

479. The cartridge of any one of embodiments 441-477, wherein the formulation is non-corrosive to the electronic cigarette.

480. The cartridge of any one of embodiments 441-478, wherein the formulation is non-toxic to a user of the electronic cigarette.

481. The cartridge of any one of embodiments 441-479, wherein the formulation further comprises one or more additional nicotine salts in a biologically acceptable liquid carrier suitable for generating the inhalable aerosol upon heating.

482. The cartridge of embodiment 480, wherein a second acid used to form the additional nicotine salt is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

483. A kit comprising:

(a) an electronic cigarette for generating an inhalable aerosol comprising

i. a device body comprising a cartridge receptacle;

ii. a cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200 ^{o}C;

iii. a heater;

iv. a battery; and

v. a mouthpiece; and

(b) instructions for using the electronic cigarette to generate an inhalable aerosol.

484. A kit comprising:

(a) an electronic cigarette for generating an inhalable aerosol comprising

i. a device body comprising a cartridge receptacle;

ii. a cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200 ^{o}C;

iii. a heater;

iv. a battery; and

v. a mouthpiece; and

(b) instructions for using the electronic cigarette to generate an inhalable aerosol.

485. A kit comprising:

(a) an electronic cigarette for generating an inhalable aerosol comprising

i. a device body comprising a cartridge receptacle;

ii. a cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is

further characterized by a melting point <160 °C, a boiling point >160 °C, and at least a 50-degree difference between the melting point and the boiling point;

iii. a heater;

iv. a battery; and

v. a mouthpiece; and

(b) instructions for using the electronic cigarette to generate an inhalable aerosol.

486. A kit comprising:

(a) an electronic cigarette for generating an inhalable aerosol comprising

i. a device body comprising a cartridge receptacle;

ii. a cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point;

iii. a heater;

iv. a battery; and

v. a mouthpiece; and

(b) instructions for using the electronic cigarette to generate an inhalable aerosol.

487. The kit of any one of embodiments 482-485, wherein the acid is a carboxylic acid.

488. The kit of any one of embodiments 482-485, wherein the acid used to form said nicotine salt is an organic acid.

489. The kit of embodiment 487, wherein the organic acid is monocarboxylic acid, aromatic acid, or keto acid.

490. The kit of embodiment 487, wherein the organic acid is formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, phenylacetic acid, benzoic acid, pyruvic acid, levulinic acid, tartaric acid, lactic acid, malonic acid, succinic acid, fumaric acid, finnaric acid, gluconic acid, saccharic acid, salicylic acid, sorbic acid, malonic acid, or malic acid.

491. The kit of any one of embodiments 482-485, wherein the acid used to form the nicotine salt is salicylic acid.

492. The kit of any one of embodiments 482-485, wherein the acid used to form the nicotine salt is benzoic acid.

493. The kit of any one of embodiments 482-485, wherein the acid used to form the nicotine salt is pyruvic acid.

494. The kit of any one of embodiments 482-485, wherein the acid used to form the nicotine salt is sorbic acid.

495. The kit of any one of embodiments 482-485, wherein the acid used to form the nicotine salt is lauric acid.

496. The kit of any one of embodiments 482-485, wherein the acid used to form the nicotine salt is levulinic acid.

497. The kit of any one of embodiments 482-485, wherein said nicotine salt comprises nicotine pyruvate.

498. The kit of any one of embodiments 482-485, wherein said nicotine salt comprises nicotine salicylate.

499. The kit of any one of embodiments 482-485, wherein said nicotine salt comprises nicotine sorbate.

500. The kit of any one of embodiments 482-485, wherein said nicotine salt comprises nicotine laurate.

501. The kit of any one of embodiments 482-485, wherein said nicotine salt comprises nicotine levulinate.

502. The kit of any one of embodiments 482-485, wherein said nicotine salt comprises nicotine benzoate.

503. The kit of any one of embodiments 482-501, wherein the liquid carrier comprises glycerol, propylene glycol, trimethylene glycol, water, ethanol or combinations thereof.

504. The kit of any one of embodiments 482-501, wherein the liquid carrier comprises propylene glycol and vegetable glycerin.

505. The kit of any one of embodiments 482-501, wherein the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

506. The kit of any one of embodiments 482-501, wherein the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

507. The kit of any one of embodiments 482-505, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 25% (w/w).

508. The kit of any one of embodiments 482-505, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 20% (w/w).

509. The kit of any one of embodiments 482-505, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 18% (w/w).

510. The kit of any one of embodiments 482-505, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 15% (w/w).

511. The kit of any one of embodiments 482-505, wherein the liquid formulation has a nicotine concentration of about 4% (w/w) to about 12% (w/w).

512. The kit of any one of embodiments 482-505, wherein the liquid formulation has a nicotine concentration of about 4% (w/w).

513. The kit of any one of embodiments 482-505, wherein the liquid formulation has a nicotine concentration of about 2% (w/w).

514. The kit of any one of embodiments 482-512, wherein the formulation further comprises a flavorant.

515. The kit of any one of embodiments 482-513, wherein the formulation is non-corrosive to an electronic cigarette.

516. The kit of any one of embodiments 482-514, wherein the acid is stable at and below operating temperature or about 200 ^{o}C.

517. The kit of any one of embodiments 482-515, wherein the acid does not decompose at and below operating temperature or about 200 ^{o}C.

518. The kit of any one of embodiments 482-516, wherein the acid does not oxidize at and below operating temperature or about 200 ^{o}C.

519. The kit of any one of embodiments 482-517, wherein the formulation is non-corrosive to the electronic cigarette.

520. The kit of any one of embodiments 482-518, wherein the formulation is non-toxic to a user of the electronic cigarette.

521. The kit of any one of embodiments 482-519, wherein the formulation further comprises one or more additional nicotine salts in a biologically acceptable liquid carrier suitable for generating the inhalable aerosol upon heating.

522. The kit of embodiment 520, wherein a second acid used to form the additional nicotine salt is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

523. A cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200 °C.

524. A cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200 °C.

525. A cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160 °C, a boiling point >160 °C, and at least a 50-degree difference between the melting point and the boiling point.

526. A cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point.

527. The cartridge of any one of embodiments 523-526, wherein the cartridge can be connected to an electronic cigarette.

528. The cartridge of any one of embodiments 523-527, wherein the acid is a carboxylic acid.

529. The cartridge of any one of embodiments 523-527, wherein the acid used to form said nicotine salt is an organic acid.

530. The cartridge of embodiment 529, wherein the organic acid is monocarboxylic acid, aromatic acid, or keto acid.

531. The cartridge of embodiment 529, wherein the organic acid is formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, phenylacetic acid, benzoic acid, pyruvic acid, levulinic acid, tartaric acid, lactic acid, malonic acid, succinic acid, fumaric acid, finnaric acid, gluconic acid, saccharic acid, salicylic acid, sorbic acid, malonic acid, or malic acid.

532. The cartridge of any one of embodiments 523-527, wherein the acid used to form the nicotine salt is salicylic acid.

533. The cartridge of any one of embodiments 523-527, wherein the acid used to form the nicotine salt is benzoic acid.

534. The cartridge of any one of embodiments 523-527, wherein the acid used to form the nicotine salt is pyruvic acid.

535. The cartridge of any one of embodiments 523-527, wherein the acid used to form the nicotine salt is sorbic acid.

536. The cartridge of any one of embodiments 523-527, wherein the acid used to form the nicotine salt is lauric acid.

537. The cartridge of any one of embodiments 523-527, wherein the acid used to form the nicotine salt is levulinic acid.

538. The cartridge of any one of embodiments 523-527, wherein said nicotine salt comprises nicotine pyruvate.

539. The cartridge of any one of embodiments 523-527, wherein said nicotine salt comprises nicotine salicylate.

540. The cartridge of any one of embodiments 523-527, wherein said nicotine salt comprises nicotine sorbate.

541. The cartridge of any one of embodiments 523-527, wherein said nicotine salt comprises nicotine laurate.

542. The cartridge of any one of embodiments 523-527, wherein said nicotine salt comprises nicotine levulinate.

543. The cartridge of any one of embodiments 523-527, wherein said nicotine salt comprises nicotine benzoate.

544. The cartridge of any one of embodiments 523-543, wherein the liquid carrier comprises glycerol, propylene glycol, trimethylene glycol, water, ethanol or combinations thereof.

545. The cartridge of any one of embodiments 523-543, wherein the liquid carrier comprises propylene glycol and vegetable glycerin.

546. The cartridge of any one of embodiments 523-543, wherein the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

547. The cartridge of any one of embodiments 523-543, wherein the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

548. The cartridge of any one of embodiments 523-547, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 25% (w/w).

549. The cartridge of any one of embodiments 523-547, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 20% (w/w).

550. The cartridge of any one of embodiments 523-547, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 18% (w/w).

551. The cartridge of any one of embodiments 523-547, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 15% (w/w).

552. The cartridge of any one of embodiments 523-547, wherein the liquid formulation has a nicotine concentration of about 4% (w/w) to about 12% (w/w).

553. The cartridge of any one of embodiments 523-547, wherein the liquid formulation has a nicotine concentration of about 4% (w/w).

554. The cartridge of any one of embodiments 523-547, wherein the liquid formulation has a nicotine concentration of about 2% (w/w).

555. The cartridge of any one of embodiments 523-553, wherein the formulation further comprises a flavorant.

556. The cartridge of any one of embodiments 523-554, wherein the formulation is non-corrosive to an electronic cigarette.

557. The cartridge of any one of embodiments 523-555, wherein the acid is stable at and below operating temperature or about 200 °C.

558. The cartridge of any one of embodiments 523-556, wherein the acid does not decompose at and below operating temperature or about 200 °C.

559. The cartridge of any one of embodiments 523-557, wherein the acid does not oxidize at and below operating temperature or about 200 °C.

560. The cartridge of any one of embodiments 523-558, wherein the formulation is non-corrosive to the electronic cigarette.

561. The cartridge of any one of embodiments 523-559, wherein the formulation is non-toxic to a user of the electronic cigarette.

562. The cartridge of any one of embodiments 523-560, wherein the formulation further comprises one or more additional nicotine salts in a biologically acceptable liquid carrier suitable for generating the inhalable aerosol upon heating.

563. The cartridge of embodiment 561, wherein a second acid used to form the additional nicotine salt is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

[00131] Although preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein can be employed in practicing the invention. It is intended that the following embodiments define the scope of the invention and that methods and structures within the scope of these embodiments and their equivalents be covered thereby.

CLAIMS

What is claimed is:

1. A method of delivering nicotine to a user comprising:
deploying an electronic cigarette comprising a nicotine formulation that comprises nicotine, an organic acid, and a biologically acceptable liquid carrier, wherein:
   a. the nicotine concentration is from about 0.5% (w/w) to about 20% (w/w);
   b. the nicotine formulation comprises nicotine lactate;
   c. the biologically acceptable liquid carrier comprises propylene glycol and glycerol; and
   d. operation of the electronic cigarette comprises heating at least a portion of the nicotine formulation to generate an inhalable aerosol.

2. The method of claim 1, wherein a molar ratio of nicotine to organic acid is between about 1:1 and 1:3.

3. The method of claim 1, wherein the nicotine formulation further comprises at least one flavorant.

4. The method of claim 1, wherein the nicotine concentration is about 4.5%.

5. The method of claim 1, wherein inhalation of the aerosol into the user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 min to about 8 min.

6. The method of claim 1, wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns.

7. A method of delivering nicotine to a user comprising:
deploying an electronic cigarette comprising a nicotine formulation that comprises nicotine, a carboxylic acid, wherein the carboxylic acid comprises lactic acid, and a biologically acceptable liquid carrier, wherein:
   a. the nicotine concentration is from about 0.5% (w/w) to about 20% (w/w);
   b. the nicotine formulation comprises protonated nicotine;

c. the biologically acceptable liquid carrier comprises propylene glycol and glycerol;
d. the acid does not decompose at room temperature and does not decompose at the operating temperature of the electronic cigarette; and
e. operation of the electronic cigarette comprises heating at least a portion of the nicotine formulation to generate an inhalable aerosol.

8. The method of claim 7, wherein a molar ratio of nicotine to organic acid is between 1:1 and 1:3.

9. The method of claim 7, wherein the nicotine formulation further comprises at least one flavorant.

10. The method of claim 7, wherein the nicotine concentration is about 4.5%.

11. The method of claim 7, wherein inhalation of the aerosol into the user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 min to about 8 min.

12. The method of claim 7, wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns.

13. An electronic cigarette, comprising:
a liquid reservoir;
a nicotine formulation within the liquid reservoir, the nicotine formulation comprising:
nicotine lactate;
propylene glycol; and
glycerol;
wherein a concentration of nicotine in the nicotine formulation is from about 0.5% (w/w) to about 20% (w/w);
a vaporizing component configured to produce an aerosol from the nicotine formulation; and
a mouthpiece configured to connect to the reservoir for inhalation of the aerosol.

14. The electronic cigarette of claim 13, further comprises a battery configured to provide power to the vaporizing component.

15. The electronic cigarette of claim 13, wherein a molar ratio of nicotine to organic acid is between 1:1 and 1:3.

16. The electronic cigarette of claim 13, wherein the nicotine formulation further comprises at least one flavorant.

17. The electronic cigarette of claim 13, wherein the vaporizing component comprises a heating element in fluid communication with the nicotine formulation.

18. The electronic cigarette of claim 13, wherein the nicotine concentration is about 4.5%.

19. The electronic cigarette of claim 13, wherein inhalation of the aerosol into the user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 min to about 8 min.

20. The electronic cigarette of claim 13, wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns.

ABSTRACT

A nicotine salt liquid formulation for generating an inhalable aerosol in an electronic cigarette comprising nicotine salt that forms about 0.5% to about 20% nicotine is provided.

FIG. 1

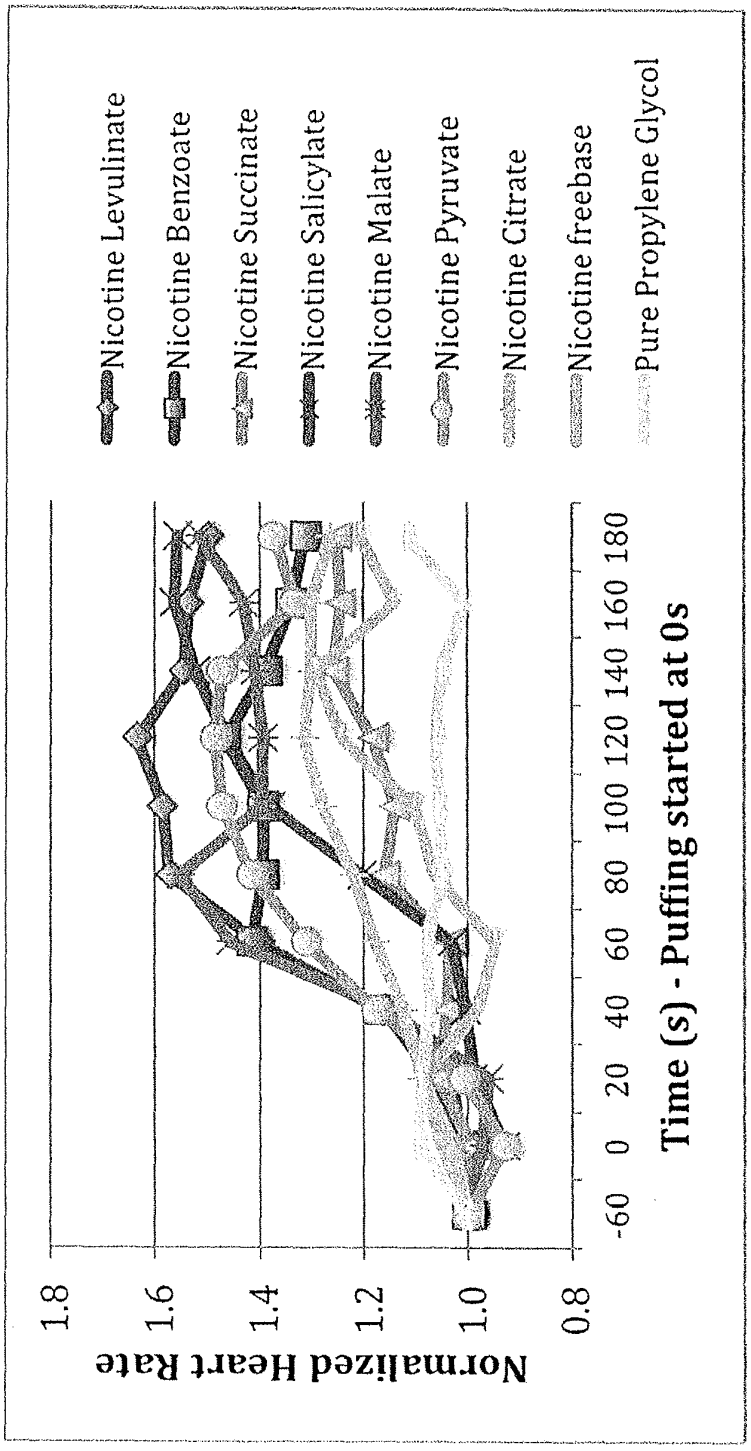

Nicotine Levulinate
Nicotine Benzoate
Nicotine Succinate
Nicotine Salicylate
Nicotine Malate
Nicotine Pyruvate
Nicotine Citrate
Nicotine freebase
Pure Propylene Glycol
Normalized Heart Rate
1.8
1.6
1.4
1.2
1.0
0.8
-60 0 20 40 60 80 100 120 140 160 180
Time (s) - Puffing started at 0s

FIG. 2

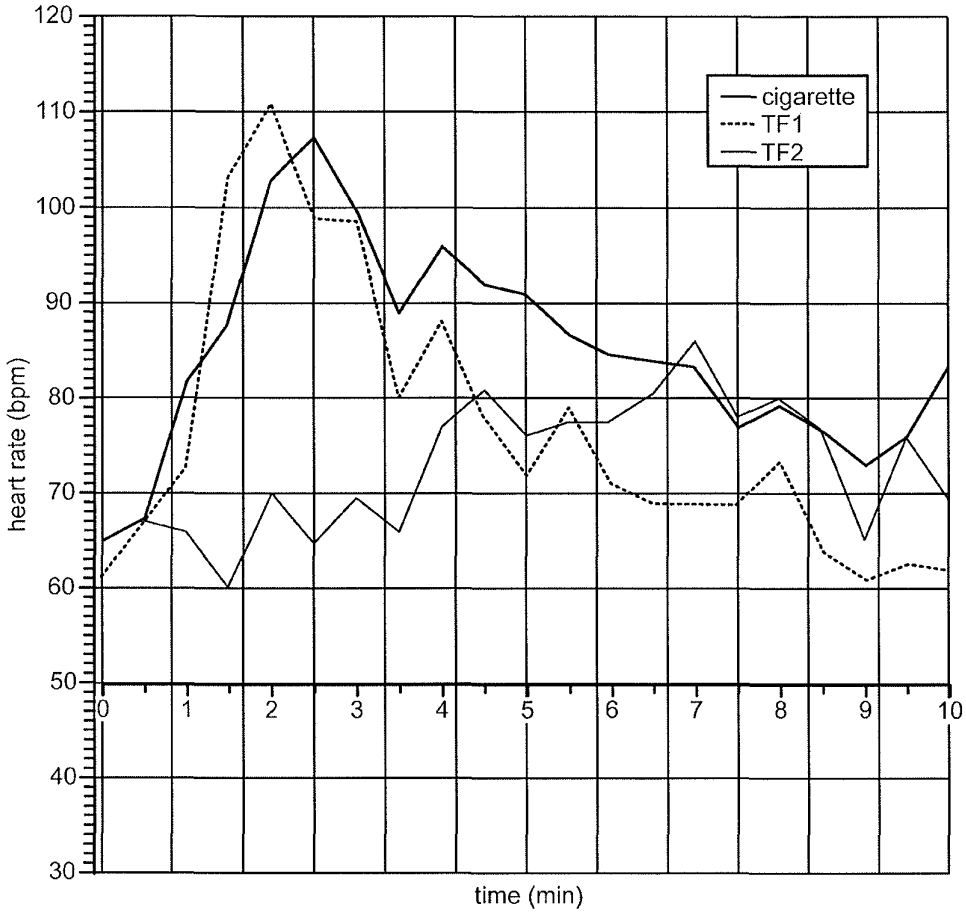

120
110
100
90
80
70
60
50
40
30
heart rate (bpm)
0
1
2
3
4
5
6
7
8
9
10
time (min)
cigarette
TF1
TF2

FIG. 3

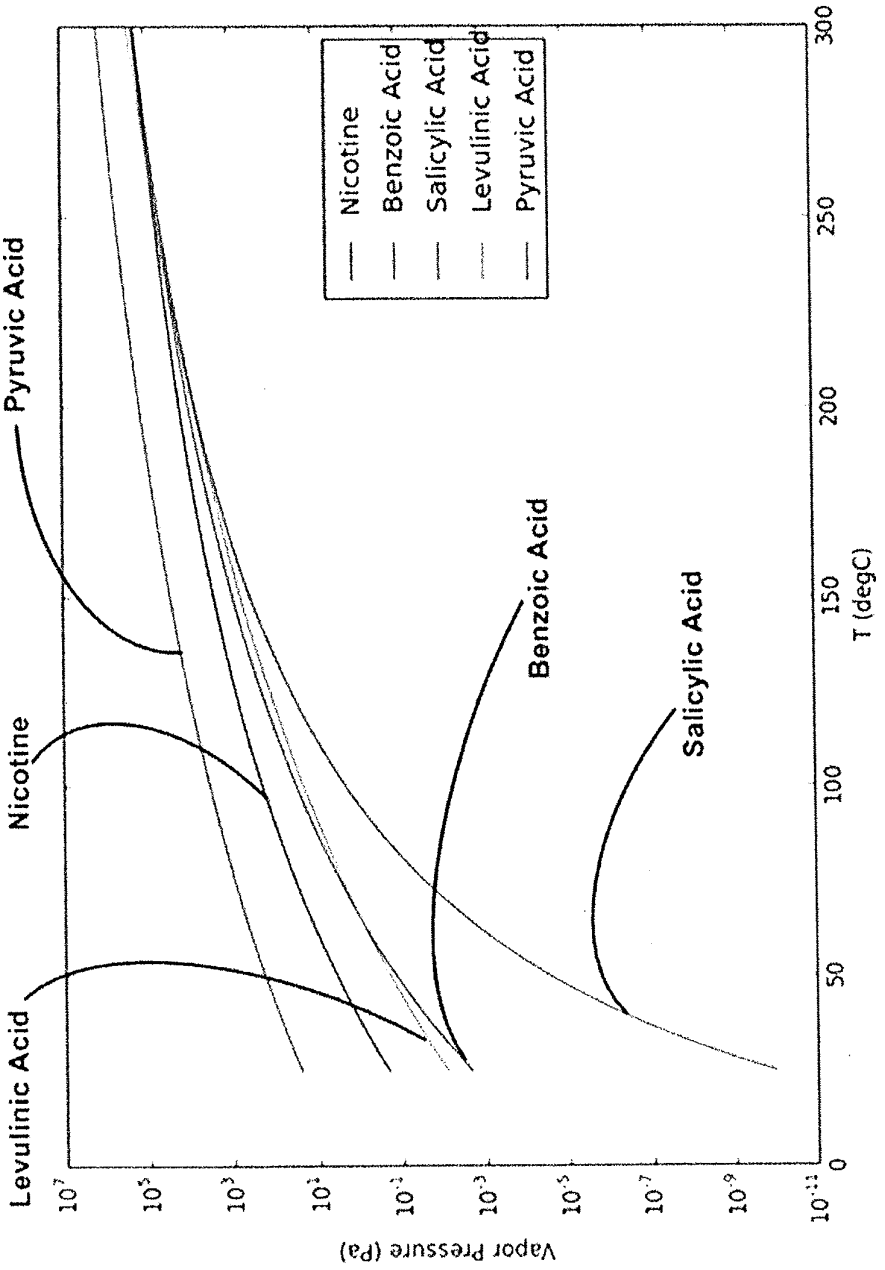

Nicotine
Benzoic Acid
Salicylic Acid
Levulinic Acid
Pyruvic Acid
Pyruvic Acid
Nicotine
Benzoic Acid
Salicylic Acid
Levulinic Acid
Vapor Pressure (Pa)
T (degC)
0
50
100
150
200
250
300

FIG. 4

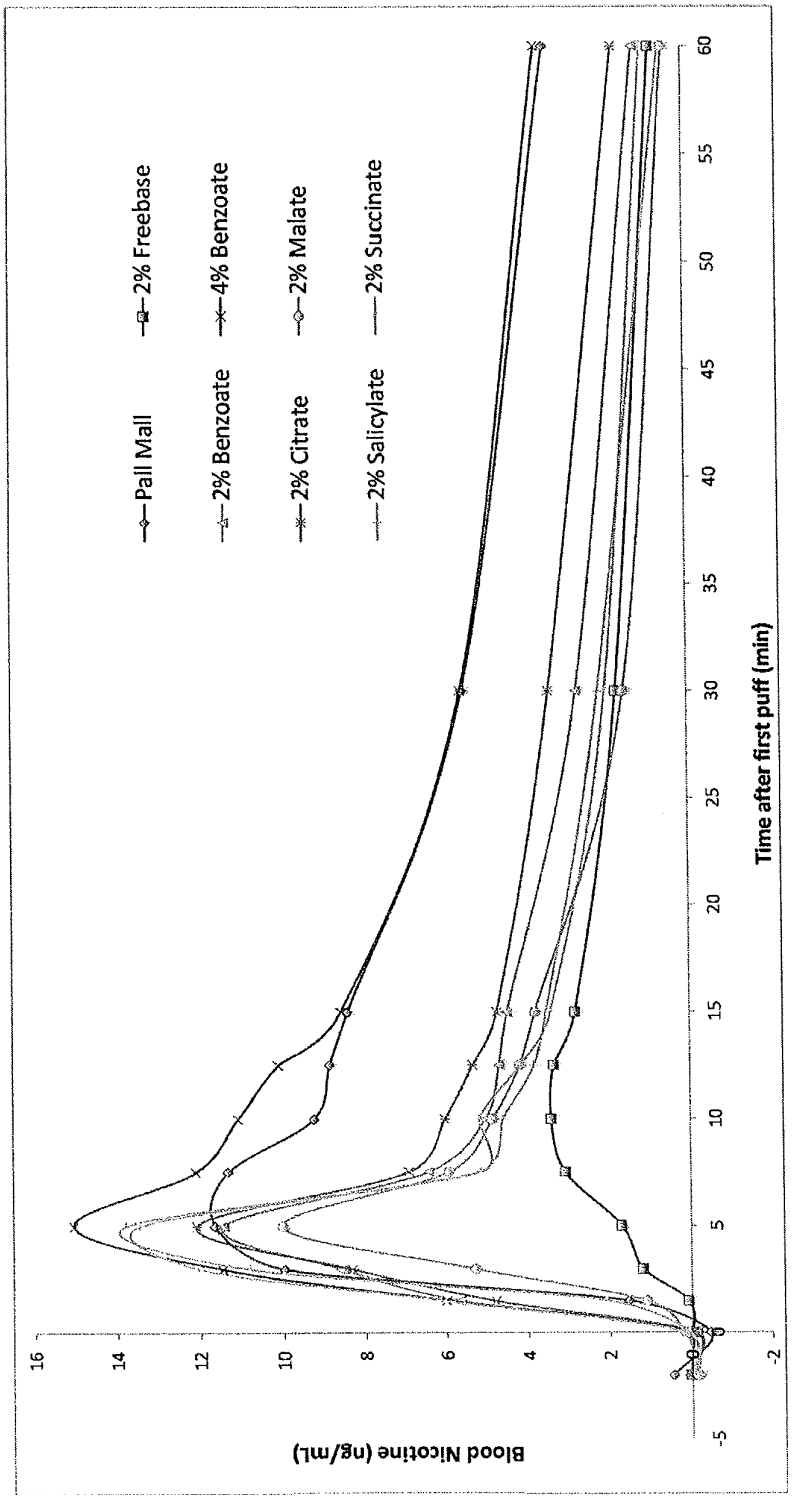

Pall Mall
2% Freebase
2% Benzoate
4% Benzoate
2% Citrate
2% Malate
2% Salicylate
2% Succinate
Blood Nicotine (ng/mL)
Time after first puff (min)
16
14
12
10
8
6
4
2
0
-2
-5
0
5
10
15
20
25
30
35
40
45
50
55
60

FIG. 5

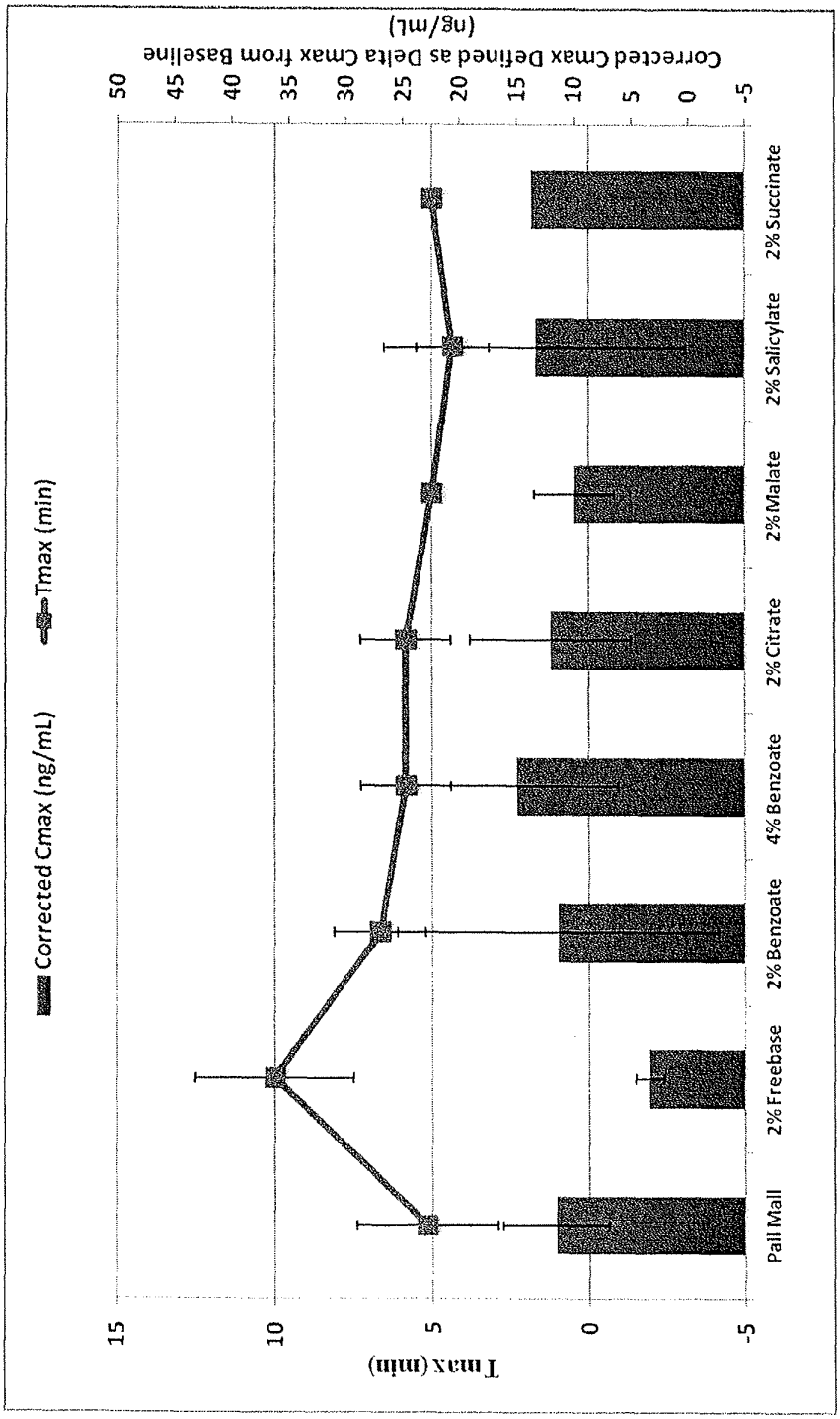

Corrected Cmax (ng/mL)
Tmax (min)
Corrected Cmax Defined as Delta Cmax from Baseline (ng/mL)
Tmax (min)
50
45
40
35
30
25
20
15
10
5
0
-5
15
10
5
0
-5
Pall Mall
2% Freebase
2% Benzoate
4% Benzoate
2% Citrate
2% Malate
2% Salicylate
2% Succinate

FIG. 6

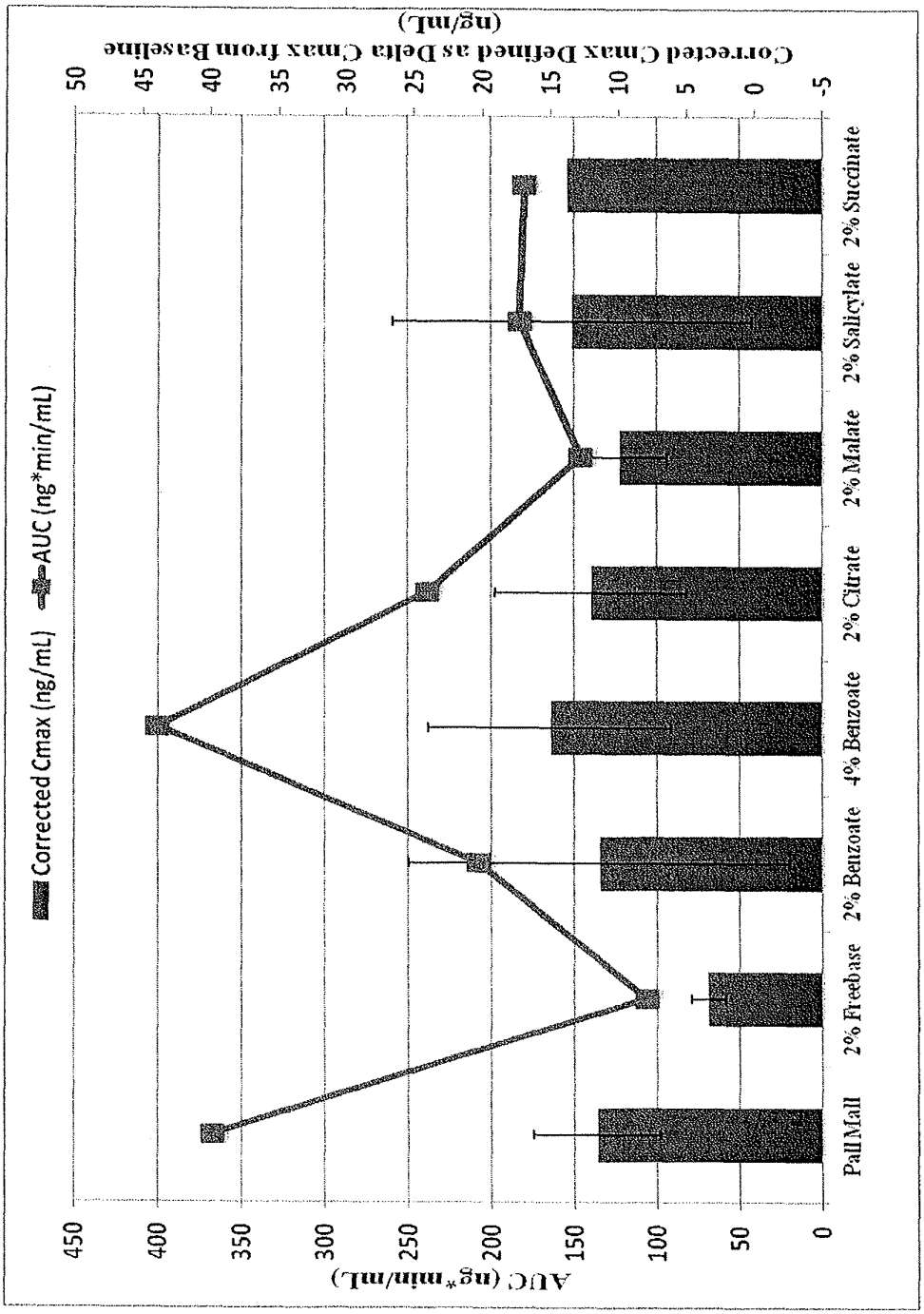

Corrected Cmax (ng/mL)
AUC (ng*min/mL)
AUC (ng*min/mL)
Corrected Cmax Defined as Delta Cmax from Baseline (ng/mL)
0
50
100
150
200
250
300
350
400
450
-5
0
5
10
15
20
25
30
35
40
45
50
PallMall
2% Freebase
2% Benzoate
4% Benzoate
2% Citrate
2% Malate
2% Salicylate
2% Succinate

FIG. 7

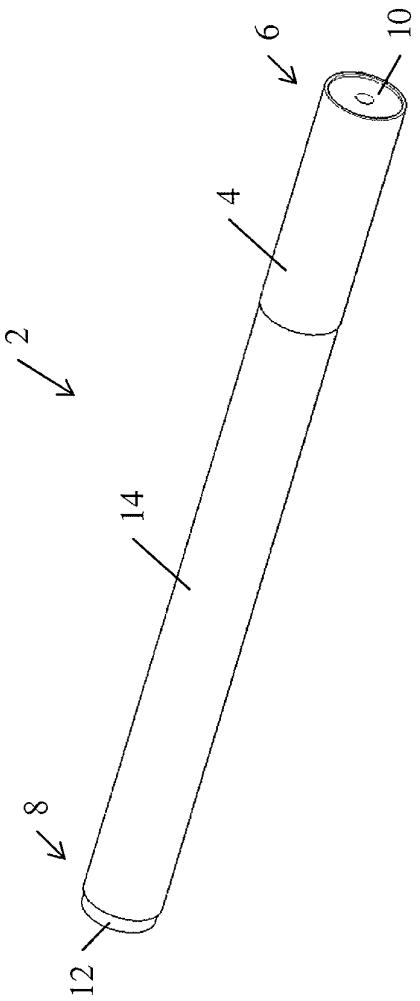
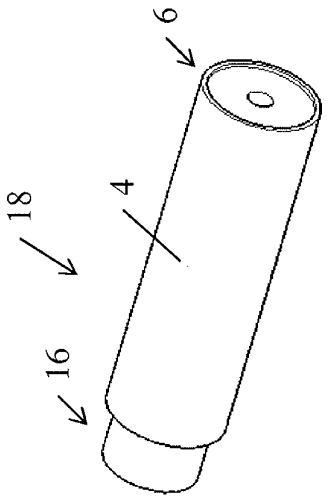


FIG. 8



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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	13211-713.303
	Application Number	
Title of Invention	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF	

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.
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.

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.)

Inventor Information:

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Legal Name

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Correspondence Information:

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For further information see 37 CFR 1.33(a).

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	13211-713.303
	Application Number	
Title of Invention	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF	

☐ An Address is being provided for the correspondence Information of this application.			
Customer Number	66854		
Email Address	info@shayglenn.com	Add Email	Remove Email

Application Information:

Title of the Invention	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF		
Attorney Docket Number	13211-713.303	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	8	**Suggested Figure for Publication (if any)**	

Filing By Reference :

Only compete 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	66854		

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	13211-713.303
	Application Number	
Title of Invention	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF	

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)
	Continuation of	14512311	2014-10-10
Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
14512311	Continuation of	14271071	2014-05-06
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
14271071	Claims benefit of provisional	61820128	2013-05-06
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
14271071	Claims benefit of provisional	61912507	2013-12-05

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) [i] the 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).

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Application Number	Country [i]	Filing Date (YYYY-MM-DD)	Access Code [i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	13211-713.303
	Application Number	
Title of Invention	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF	

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

☐ 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.
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.

Authorization to Permit Access:

☐ Authorization to Permit Access to the Instant Application by the Participating Offices

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.

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.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

Applicant Information:

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.

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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	13211-713.303
	Application Number	
Title of Invention	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF	

Applicant 1 Remove

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.

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. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information:

Address 1			
Address 2			
City		**State/Province**	
Country [i]		Postal Code	
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:

Providing assignment information in this section does not subsitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Assignee 1

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.

Remove

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	13211-713.303
	Application Number	
Title of Invention	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF	

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

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	/Richard D. Shoop/			Date (YYYY-MM-DD)	2015-10-28
First Name	Richard D.	Last Name	Shoop	Registration Number	45763

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.

EFS Web 2.2.10

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Filer:	Richard Douglas Shoop/Jennifer Capizzi
Attorney Docket Number:	13211-713.303

Filed as Large Entity

Filing Fees for Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility application filing	1011	1	280	280
Utility Search Fee	1111	1	600	600
Utility Examination Fee	1311	1	720	720
Request for Prioritized Examination	1817	1	4000	4000
Pages:				
Claims:				
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Publ. Fee- Early, Voluntary, or Normal	1504	1	0	0
PROCESSING FEE, EXCEPT PROV. APPLS.	1830	1	140	140
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**5740**

Electronic Acknowledgement Receipt

EFS ID:	23924095
Application Number:	14925968
International Application Number:	
Confirmation Number:	2707
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Customer Number:	66854
Filer:	Richard Douglas Shoop/Jennifer Capizzi
Filer Authorized By:	Richard Douglas Shoop
Attorney Docket Number:	13211-713.303
Receipt Date:	28-OCT-2015
Filing Date:	
Time Stamp:	23:21:34
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$5740
RAM confirmation Number	9477
Deposit Account	504050
Authorized User	SHOOP, RICHARD D
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		13211-713-303_Application.pdf	5727373 5b047150dc60f0088d9856d9c3ec17f2ccc779a2	yes	106

Multipart Description/PDF files in .zip description

Document Description	Start	End
Transmittal of New Application	1	1
TrackOne Request	2	2
Fee Worksheet (SB06)	3	3
Oath or Declaration filed	4	5
Specification	6	94
Claims	95	97
Abstract	98	98
Drawings-only black and white line drawings	99	106

Warnings:

Information:

2	Application Data Sheet	13211-713-303_ADS.pdf	1561216 e2d175cd560f8aa1dc65469d028c2fd0de44a800	no	7

Warnings:

Information:

3	Fee Worksheet (SB06)	fee-info.pdf	40475 9af2f419221b526f61615f13196ac5aad12a1cc7	no	2

Warnings:

Information:

Total Files Size (in bytes):	7329064

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.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 14/925,968

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	280
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	600
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	720
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	*			OR	x 80 =	0.00
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*				x 420 =	0.00
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).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1600

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	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 found in the appropriate box in column 1.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
14/925,968	10/28/2015	1747	1600	13211-713.303	20	3

CONFIRMATION NO. 2707

66854
SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

FILING RECEIPT

OC000000078568042

Date Mailed: 11/12/2015

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Adam BOWEN, San Francisco, CA;
Chenyue XING, San Francisco, CA;

Applicant(s)

Adam BOWEN, San Francisco, CA;
Chenyue XING, San Francisco, CA;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 14/512,311 10/10/2014
which is a CON of 14/271,071 05/06/2014
which claims benefit of 61/820,128 05/06/2013
and claims benefit of 61/912,507 12/05/2013

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

If Required, Foreign Filing License Granted: 11/09/2015
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/925,968**
Projected Publication Date: 02/18/2016
Non-Publication Request: No
Early Publication Request: No

Title

NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF

Preliminary Class

131

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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UNITED STATES PATENT AND TRADEMARK OFFICE

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

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO CA 94403

MAILED
DEC 09 2015
OFFICE OF PETITIONS

Doc Code: TRACK1.GRANT

Decision Granting Request for Prioritized Examination (Track I or After RCE)	Application No.: 14/925,968

1. THE REQUEST FILED 10/28/15 IS **GRANTED.**

The above-identified application has met the requirements for prioritized examination

A. ☒ for an original nonprovisional application (Track I).
B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination.** The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

A. filing a **petition for extension of time** to extend the time period for filing a reply;
B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims**, or a multiple dependent claim;
C. filing a **request for continued examination**;
D. filing a notice of appeal;
E. filing a request for suspension of action;
F. mailing of a notice of allowance;
G. mailing of a final Office action;
H. completion of examination as defined in 37 CFR 41.102; or
I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to Cheryl Gibson-Baylor at (571)272-3213, Office of Petitions. In his/her absence, calls may be directed to Brian W. Brown, (571)272-5338.

Cheryl Gibson-Baylor
/Cheryl Gibson-Baylor/
[*Signature*]

Petitions Paralegal Specialist
(Title)

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/925,968	10/28/2015	Adam BOWEN	13211-713.303	2707

66854 7590 12/16/2015

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

EXAMINER	
MAYES, DIONNE WALLS	

ART UNIT	PAPER NUMBER
1747	

NOTIFICATION DATE	DELIVERY MODE
12/16/2015	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):

info@shayglenn.com

Office Action Summary	Application No. 14/925,968	Applicant(s) BOWEN ET AL.	
	Examiner DIONNE WALLS MAYES	Art Unit 1747	AIA (First Inventor to File) Status Yes

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/28/2015*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-20* is/are pending in the application.

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

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-20* is/are rejected.

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

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of

activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

3. Claims 1-12 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-15 of Hon '895 (U.S. Patent No. 9,215,895) in view of Gonda (US. Pat. App. Pub. 2014/0261474).

Regarding the instant independent claims 1 and 7, the Hon '895 patent claims recite nearly all that is recited in the instant claims; but, it fails to recite that the nicotine formulation comprises nicotine lactate and/or a propylene glycol/glycerol liquid carrier. However, the Gonda reference teaches that a nicotine formulation, such as a nicotine lactate salt (based on lactic acid) in solution (i.e., glycerin/glycols), can be prepared so as to be inhaled which results in rapid delivery of nicotine (see abstract and paras.[0052],[0078]). Hence, it would have been obvious to one having ordinary skill in the art to have included the nicotine formulation of Gonda in the device of Hon '895 as such is already known in the art.

Regarding dependent claims 2-6 and 8-12, the limitations of these claims are deemed to have been met by, or an obvious modification of, the claims of Hon '895.

4. Claims 1-4, 6-10 and 12 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 105-122 of copending Application No. 14/271,071.

Regarding claims 1-4, 6-10 and 12, while the claims of copending Application No. 14/271,071 are not identical to those of the instant application, they are not patentably distinct therefrom because, collectively, claims 105-122 of Application No. 14/271,071 generally encompass the above-referenced claims of the instant application.

5. Claims 5 and 11 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 105-122 of copending Application No. 14/271,071 in view of Gonda (US. Pat. No. 2014/0261474) and Bowen et al (US. Pat. App. Pub. 2009/0151717).

Regarding claims 5 and 11, claims 105-122 of Application No. 14/271,071 fail to recite that inhalation of the aerosol into the user's lungs takes place over a period of about 5 minutes at a rate of about one inhalation per 30 seconds and results in a nicotine plasma T_{max} from about 3 min to about 8 min. However, Gonda states that adjustments in pH, in combination with changing the particle size of the aerosol, can be carried out to create a different experience for the user. By decreasing the pH of the nicotine formulation, the likelihood of airway irritation and cough is reduced. By decreasing the particle size, the aerosolized particles of nicotine will deposit deeper in the lungs, which increases the rate of absorption of the nicotine and leads to an

increase in peak nicotine plasma levels (see para. [0007],[0033]-[0036], [0052], [0064], [0086]). Further, Gonda states that, during inhalation of aerosolized nicotine formulations, a satisfactory dose of nicotine is achieved in a small number of breaths, spaced by short periods, preferably less than 2 minutes (see para. [0017]). (Note: To this point, the Bowen et al reference further discloses that, typically, when smokers "puff" on cigarettes they may take a puff every 30 seconds (i.e., in an intense smoking regime). Bowen et al then shows that aerosol devices used to inhale a nicotine substance can also be "smoked" in such manner (see para. [0107])). This collective disclosure indicates that the parameters of pH, aerosolized nicotine particle size, and even nicotine concentration in the liquid formulation and inhalation rate, are all "result-effective variables". Note: Once a particular parameter is recognized as a result-effective variable, i.e., a variable which achieves a recognized result, the determination of the optimum or workable ranges of said variable can be characterized by routine experimentation. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) (prior art suggested proportional balancing to achieve desired results in the formation of an alloy). MPEP 2144.05. Hence, it would have been obvious to one having ordinary skill in the art at the time of the invention to have undergone routine experimentation and arrived at the claimed inhalation rate which result in the claimed T_{max} parameters, after determining that these values provided, as close as possible, the same nicotine blood levels achieved by smoking a conventional cigarette - which is the goal of Gonda and Bowen et al.

This is a provisional nonstatutory double patenting rejection.

Claim Rejections - 35 USC § 103

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

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102 of this title, 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.

7. 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.

8. 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.

9. Claims 1-4, 7-10 and 13-18 are rejected under 35 U.S.C. 103 as being unpatentable over Hon (US. Pat. App. Pub. 2006/0196518) in view of Gonda (US. Pat. No. 2014/0261474).

Regarding independent claims 1, 7 and 13, Hon discloses a flameless, battery-operated electronic atomizing cigarette, and a method of using the same, designed to help a smoker wean himself from the tobacco-smoking habit - while still enjoying the nicotine delivery. The cigarette is designed to dispense a liquid nicotine formulation contained in a storage container in aerosolized/vaporized form upon being heated by an electric heater, for inhalation by a user. The nicotine formulation may include anywhere from 0.1-6% nicotine by weight and tobacco essence (see abstract; paras. [0006],[0021],[0028]-[0032])(corresponding to the claimed "a method of delivering nicotine to a user comprising deploying an electronic cigarette comprising a nicotine formulation that comprises nicotine…and a biologically acceptable liquid carrier, wherein…the nicotine concentration is from about 0.5% (w/w) to about 20% (w/w)…operation of the electronic cigarette comprises heating at least a portion of the nicotine formulation to generate an inhalable aerosol”(claims 1,7); and “an electronic cigarette, comprising a liquid reservoir; a nicotine formulation within the liquid reservoir...wherein a concentration of nicotine in the nicotine formulation is from about 0.5% (w/w) to about 20%(w/w); a vaporizing component configured to produce an aerosol form the nicotine formulation; and a mouthpiece configured to connect to the reservoir for inhalation of the aerosol”(claim 13); the “wherein the nicotine formulation further comprises at least one flavorant” recitation of claims 3, 9 and 16; the “wherein

the nicotine concentration is from about 4.5%" recitation of claims 4, 10 and 18; the "further comprises a battery configured to provide power to the vaporizing component" recitation of claim 14; the "wherein the vaporizing component comprises a heating element in fluid communication with the nicotine formulation" recitation of claim 17).

Hon is silent as to whether the nicotine, in its liquid formulation, may be combined with an organic acid (i.e., lactic acid). However, the Gonda reference teaches that administering an aerosolized, liquid nicotine-containing formulation via inhalation (i.e., pulmonary administration) in order to effectuate a peak level of nicotine in the blood plasma after a very short period of time - mimicking that which is typically achieved during actual cigarette smoking - is known. Specifically, Gonda teaches that a nicotine formulation, such as a nicotine lactate salt (based on lactic acid) in solution (i.e., glycerin and glycols), can be prepared so as to be inhaled which results in rapid delivery of nicotine (see abstract and paras.[0052],[0078]). Hence, it would have been obvious to one having ordinary skill in the art to have included the nicotine formulation of Gonda in the device of Hon for the benefits described above (corresponding to the claimed "nicotine, an organic acid/lactic acid, and a biologically acceptable liquid carrier/glycerol"; the "wherein the acid does not decompose at room temperature and does not decompose at the operating temperature of the electronic cigarette"(claim 7)). Hence, the modified Hon/Gonda invention meets all the limitations of the above-referenced claims.

Regarding claims 2, 8 and 15, Gonda doesn't specifically state the molar ratio of nicotine to lactic acid, for example; however, one of ordinary skill in the art would have

optimized said nicotine/acid amounts in order to provide the optimal stoichiometric amounts for nicotine salt formation and, in doing so, undergone routine experimentation and arrived at the claimed ratios (corresponding to the claimed "wherein the molar ratio of nicotine or organic acid is between about 1:1 and 1:3").

10. Claims 5-6, 11-12 and 19-20 are rejected under 35 U.S.C. 103 as being unpatentable over Hon (US. Pat. App. Pub. 2006/0196518) in view of Gonda (US. Pat. No. 2014/0261474) and Bowen et al (US. Pat. App. Pub. 2009/0151717).

The modified Hon/Gonda invention fails to disclose anything about nicotine plasma concentrations; the time period at which the maximum concentration is reached after inhaling nicotine from the electronic cigarette; and micron size of the aerosol generated therefrom, to result in the claimed time period for peak nicotine concentration; however, it does disclose that each of these parameters impact nicotine delivery and absorption in the bloodstream (see paras. [0043],[0092]). Specifically, Gonda states that adjustments in pH, in combination with changing the particle size of the aerosol, can be carried out to create a different experience for the user. By decreasing the pH of the nicotine formulation, the likelihood of airway irritation and cough is reduced. By decreasing the particle size, the aerosolized particles of nicotine will deposit deeper in the lungs, which increases the rate of absorption of the nicotine and leads to an increase in peak nicotine plasma levels (see para. [0007],[0033]-[0036], [0052], [0064], [0086]). Further, Gonda states that, during inhalation of aerosolized nicotine formulations, a satisfactory dose of nicotine is achieved in a small number of breaths, spaced by short periods, preferably less than 2 minutes (see para. [0017]).

(Note: To this point, the Bowen et al reference further discloses that, typically, when smokers "puff" on cigarettes they may take a puff every 30 seconds (i.e., in an intense smoking regime). Bowen et al then shows that aerosol devices used to inhale a nicotine substance can also be "smoked" in such manner (see para. [0107])). This collective disclosure indicates that the parameters of pH, aerosolized nicotine particle size, and even nicotine concentration in the liquid formulation and inhalation rate, are all "result-effective variables". Note: Once a particular parameter is recognized as a result-effective variable, i.e., a variable which achieves a recognized result, the determination of the optimum or workable ranges of said variable can be characterized by routine experimentation. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) (prior art suggested proportional balancing to achieve desired results in the formation of an alloy). MPEP 2144.05. Hence, it would have been obvious to one having ordinary skill in the art at the time of the invention to have undergone routine experimentation and fabricated the nicotine formulation of Hon in the form of a liquid nicotine lactate salt solution and, in so doing, arrived at the claimed particle size, and inhalation rate which result in the claimed T_{max} parameters, after determining that these values provided, as close as possible, the same nicotine blood levels achieved by smoking a conventional cigarette - which is the goal of Hon, Gonda and Bowen et al (corresponding to the claimed "wherein inhalation of the aerosol into the user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma T_{max} from about 3 min to about 8 min" recitation of claim 5, 11 and 19; the "wherein the

inhalable aerosol has a particle size from about 0.1 microns to about 5 microns" recitation of claim 6, 12 and 20).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIONNE WALLS MAYES whose telephone number is (571)272-5836. The examiner can normally be reached on Tuesday and Thursday, 8:00A - 6:30P EST.

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.

/DIONNE WALLS MAYES/
Examiner, Art Unit 1747

Notice of References Cited	Application/Control No. 14/925,968	Applicant(s)/Patent Under Reexamination BOWEN ET AL.	
	Examiner DIONNE WALLS MAYES	Art Unit 1747	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-2014/0261474 A1	09-2014	GONDA	A61M15/06	131/270
*	B	US-2006/0196518 A1	09-2006	HON	A24F47/002	131/360
*	C	US-2009/0151717 A1	06-2009	BOWEN	A61M11/041	128/200.23
	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

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

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BIB DATA SHEET

CONFIRMATION NO. 2707

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
14/925,968	10/28/2015	131	1747	13211-713.303

APPLICANTS

INVENTORS

Adam BOWEN, San Francisco, CA;
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**** CONTINUING DATA ***************************

This application is a CON of 14/512,311 10/10/2014 PAT 9215895
which is a CON of 14/271,071 05/06/2014
which claims benefit of 61/820,128 05/06/2013
and claims benefit of 61/912,507 12/05/2013

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****

11/09/2015

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /DIONNE WALLS MAYES/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		CA	8	20	3

ADDRESS

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UNITED STATES

TITLE

NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF

FILING FEE RECEIVED		
1600	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

BIB (Rev. 05/07).

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	3	(("20060195518") or ("20120256567") or ("20080241255")).PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 11:41
S2	3	(("20060195518") or ("20120255567") or ("20080241255")).PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 11:41
S3	2	(("20120255567") or ("20080241255")).PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 11:42
S4	0	("2006").pn. and (hon).in.	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 11:42
S5	42	(hon).in. and cigarette	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 11:44
S6	25	("131"/$ or "128"/$).ccls. and electronic cigarette and nicotine and plasma	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:06
S7	6	("131"/$ or "128"/$).ccls. and (fuisz).in. and nicotine and plasma	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:06
S8	91	("131"/$ or "128"/$).ccls. and inhal$5 near15 nicotine and plasma	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:15
S9	25	("131"/$ or "128"/$).ccls. and inhal$5 near15 nicotine and plasma and ((max or maxim$3) near25 time)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:16
S10	23	("131"/$ or "128"/$).ccls. and inhal$5 near15 nicotine and (plasma near25 (peak or max or maxim$3) near25 time)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:25
S11	9	("131"/$ or "128"/$).ccls. and inhal$5 same (nicotine same (plasma near25 (peak or max or maxim$3) near25 time))	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:25
S12	9	("131"/$ or "128"/$).ccls. and inhal$5 same (nicotine same (plasma near25 (peak or max or maxim$3) near25 time))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:26
S13	32	("131"/$ or "128"/$).ccls. and inhal$5 and (nicotine same (plasma near25 (peak or max or maxim$3) same time))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:28
S14	2	("131"/$ or "128"/$).ccls. and nicotine benzoate	US-PGPUB; USPAT; USOCR; FPRS;	ADJ	ON	2015/01/20 15:51

			EPO; JPO; DERWENT; IBM_TDB			
S15	2	(vaporiz$3 or electronic cigarette) and nicotine benzoate	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:52
S16	346	("131"/$ or "128"/$).ccls. and (salt near5 nicotine)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:53
S17	230	("131"/$ or "128"/$).ccls. and (salt near5 nicotine) same (acid)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:54
S18	210	("131"/$ or "128"/$).ccls. and (salt near5 nicotine) near35 (acid)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:55
S19	17	("131"/$ or "128"/$).ccls. and (salt near5 nicotine) near35 (carboxylic or citric)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 16:08
S20	1	("2356185").PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 16:32
S21	1	("2356185").PN.	USOCR	OR	OFF	2015/01/20 16:33
S22	4	nicotine benzoate	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 16:38
S23	1	("20010029959").PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 16:43
S24	0	electronic cigarette and inhal$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 16:47
S25	1	nicotine and inhal$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 16:48
S26	1	nicotine and inhal$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR;	ADJ	ON	2015/01/20 16:59

			FPRS; EPO; JPO; DERWENT; IBM_TDB			
S27	53	inhal$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 17:33
S28	222	puff$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 17:37
S29	207	("131"/$ or "128"/$ or cigarette) and puff$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 17:40
S30	179	("131"/$ or "128"/$) and puff$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 17:40
S31	28	(("20070163610") or ("20090293895") or ("20130186416") or ("7832410") or ("8,156,944") or ("8,511,318") or ("20140345631") or ("20140345635") or ("20040191322") or ("20060018840") or ("20060196518") or ("20080241255") or ("20090004249") or ("20100242976") or ("20110268809") or ("20120255567") or ("4,830,028") or ("4,836,224") or ("6,102,036") or ("6,234,169") or ("6,799,576") or ("6,874,507") or ("7,767,698") or ("8,079,371") or ("8,322,350") or ("8,375,957") or ("8,381,739") or ("8,741,348")).PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 20:10
S32	1	(14/512311).APP.	US-PGPUB; USPAT	OR	OFF	2015/03/23 22:03
S33	1	(14/512311).APP.	US-PGPUB; USPAT	OR	OFF	2015/05/14 15:25
S34	1605	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:07
S35	237	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:08
S36	221	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5 or mouth or oral$4)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:08

S37	191	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5 or mouth or oral$4) and (plasma or blood)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:08
S38	163	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5 or mouth or oral$4) and (plasma or blood) and ph	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:09
S39	108	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5 or mouth or oral$4) and (plasma or blood) and ph and ((drop$4 or vapor$4 or aerosol$4 or particle) near25 size)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:10
S40	87	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5 or mouth or oral$4) and (plasma or blood) and ph and ((drop$4 or vapor$4 or aerosol$4 or particle) near25 size) and heat$4	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:11
S41	77	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5) and (plasma or blood) and ph and ((drop$4 or vapor$4 or aerosol$4 or particle) near25 size) and heat$4	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:12
S42	4	("2004076289").PN.	FPRS; EPO; JPO	OR	OFF	2015/05/14 18:13
S43	15	ANDERSSON near3 SVEN-BORJE	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:15
S44	13	ANDERSSON near3 SVEN-BORJE and nicotine	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:15
S45	71	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5) and (plasma or blood) and ph and ((drop$4 or vapor$4 or aerosol$4 or particle) near25 size) and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:26
S46	21	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5) and (plasma or blood) and (ph near5 "7") and ((drop$4 or vapor$4 or aerosol$4 or particle) near25 size) and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:27
S47	26	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5) and (plasma or blood) and (ph near5 "7") and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:28
S48	38	("128"/$ or "131"/$ or "424"/$ or "514"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5) and	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:31

		(plasma or blood) and (ph near5 "7") and heat$4 and lung				
S49	1	("20060196518").PN.	US-PGPUB; USPAT	OR	OFF	2015/05/14 19:32
S50	34	("128"/$ or "131"/$ or "424"/$ or "514"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and (salicylic or sorbic or lauric or levulinic or citric or benzoic or pyruvic) and (inhal$5) and ((plasma or blood or peek or peak) near10 concentration) and (ph near5 "7") and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 08:30
S51	1	("8831739").PN.	US-PGPUB; USPAT	OR	OFF	2015/05/15 08:43
S52	1	("8381739").PN.	US-PGPUB; USPAT	OR	OFF	2015/05/15 08:43
S53	14	(igor near3 gonda) and nicotine and ng/ml	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 10:42
S54	13	(igor near3 gonda) and nicotine near50 concentration near50 ng/ml	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 10:42
S55	0	(igor near3 gonda) and nicotine near50 concentration near50 ng/ml near50 salt	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 10:43
S56	64	(igor near3 gonda) and ((blood or plasma or nicotine) near50 concentration)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 10:46
S57	13	(igor near3 gonda) and ((blood or plasma or nicotine) near50 concentration) same nicotine	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 10:46
S58	1	("20030136404").PN.	US-PGPUB; USPAT	OR	OFF	2015/05/17 15:16
S59	1	(14/512311).APP.	US-PGPUB; USPAT	OR	OFF	2015/07/14 09:12
S60	1	("20140261474").PN.	US-PGPUB; USPAT	OR	OFF	2015/07/14 10:27
S61	1	(14/512311).APP.	US-PGPUB; USPAT	OR	OFF	2015/09/17 14:40
S62	934	(A24F47/008).cpc.	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/09/17 14:46
S63	78	("128"/$ or "131"/$ or "424"/$ or "514"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and acid and (inhal$5) and (plasma or blood) and (ph near5 "7") and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/09/17 14:46
S64	367	("128"/$ or "131"/$ or "424"/$ or "514"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and acid and (inhal$5) and (plasma or blood) and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/09/17 14:47
S65	283	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and (levulinic or pyruvic or salicylic or sorbic or lauric or benzoic) and (inhal$5 or mouth or oral$4) and	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/09/17 14:48

		(plasma or blood)				
S69	2	(("20060196518") or ("20140261474")).PN.	US-PGPUB; USPAT	OR	OFF	2015/12/10 16:09

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S66	723	(A24F47/008).cpc.	US-PGPUB; * No UPAD	ADJ	ON	2015/09/17 14:46
S67	246	("128"/$ or "131"/$ or "424"/$ or "514"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and acid and (inhal$5) and (plasma or blood) and heat$4 and lung	US-PGPUB; * No UPAD	ADJ	ON	2015/09/17 14:47
S68	196	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and (levulinic or pyruvic or salicylic or sorbic or lauric or benzoic) and (inhal$5 or mouth or oral$4) and (plasma or blood)	US-PGPUB; * No UPAD	ADJ	ON	2015/09/17 14:49

12/ 12/ 2015 9:04:04 PM
C:\ Users\ dmayes\ Documents\ EAST\ Workspaces\ 14925968.wsp

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14925968	BOWEN ET AL.
	Examiner	Art Unit
	DIONNE W MAYES	1747

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Search conducted (see attached search strategy)	12/10/2015	DWM
Inventor search conducted	12/10/2015	DWM

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/925,968	10/28/2015	Adam BOWEN	13211-713.303

CONFIRMATION NO. 2707

66854
SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

PUBLICATION NOTICE

OC000000080704214

Title:NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF

Publication No.US-2016-0044968-A1
Publication Date:02/18/2016

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The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

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Sheet 1 of 20

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	US- 374,584	12/13/1887	Cook	
	2	US- 576,653	2/9/1897	Bowlby	
	3	US- 595,070	12/7/1897	Oldenbusch	
	4	US- 720,007	2/10/1903	Dexter	
	5	US- 799,844	9/19/1905	Fuller	
	6	US- 968,160	8/23/1910	Johnson	
	7	US- 969,076	8/30/1910	Pender	
	8	US- 1,067,531	7/15/1913	MacGregor	
	9	US- 1,163,183	12/7/1915	Stoll	
	10	US- 1,299,162	4/1/1919	Fisher	
	11	US- 1,505,748	8/19/1924	Louis	
	12	US- 1,552,877	9/8/1925	Phillipps et al.	
	13	US- 1,632,335	6/14/1927	Hiering	
	14	US- 1,706,244	3/19/1929	Louis	
	15	US- 1,845,340	2/16/1932	Ritz	
	16	US- 1,972,118	9/4/1934	McDill	
	17	US- 1,998,683	4/23/1935	Montgomery	
	18	US- 2,031,363	2/18/1936	Elof	
	19	US- 2,039,559	5/5/1936	Segal	

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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	374	CA2641869A1	5/6/2010	Xia, Hao Ran		
	375	CN101869356A(w/EngTrans)	10/27/2010	Liu Zheqi		
	376	CN102754924A(w/EngTrans)	10/31/2012	Long		
	377	CN1122213A(w/EngAbs)	5/15/1996	Philip Morris Prod Inc		
	378	CN85106876A(w/EngCorres)	9/3/1986	M. J. Luinoziancaogose		
	379	DE19854005A1(w/EngAbs)	5/18/2000	Reemtsma Gmbh		

Examiner Signature		Date Considered	

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Sheet 2 of 20

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

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	20	US- 2,104,266	1/4/1938	McCormick	
	21	US- 2,231,909	2/18/1941	Hempel	
	22	US- 2,327,120	8/17/1943	McCoon	
	23	US- 2,460,427	2/1/1949	Musselman et al.	
	24	US- 2,483,304	9/27/1949	Rudolf	
	25	US- 2,502,561	4/4/1950	Ludwig	
	26	US- 2,765,949	10/9/1956	Swan	
	27	US- 2,830,597	4/15/1958	Jakob	
	28	US- 2,860,638	11/18/1958	Frank	
	29	US- 2,897,958	8/4/1959	Tarleton et al.	
	30	US- 2,935,987	5/10/1960	Ackerbauer	
	31	US- 3,146,937	9/1/1964	Joseph	
	32	US- 3,258,015	6/28/1966	Drummond et al.	
	33	US- 3,292,634	12/20/1966	Beucler	
	34	US- 3,373,915	3/19/1968	Anderson et al.	
	35	US- 3,420,360	1/7/1969	Young	
	36	US- 3,479,561	11/18/1969	Janning	
	37	US- 3,567,014	3/2/1971	Feigelman	
	38	US- 3,707,017	12/26/1972	Paquette	

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	380	DE19854012A1(w/EngTrans)	5/18/2000	Reemtsma Gmbh		
	381	DE4200639A1(w/EngEquiv)	7/23/1992	Brown & Williamson Tob.		
	382	EP0532194A1	3/17/1993	Philip Morris Prod Inc		
	383	EP0535695A2	4/7/1993	Phillips Petroleum Co		
	384	EP1458388A(asWO03/055486)	9/22/2004	McNeil AB		
	385	EP2325093B1	6/20/2012	Imperial Tobacco Ltd		

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	39	US- 3,792,704	2/19/1974	Parker	
	40	US- 3,861,523	1/21/1975	Fountain et al.	
	41	US- 3,941,300	3/2/1976	Troth	
	42	US- 4,020,853	5/3/1977	Nuttall	
	43	US- 4,049,005	9/20/1977	Hernandez et al.	
	44	US- 4,066,088	1/3/1978	Ensor	
	45	US- 4,207,976	6/17/1980	Herman	
	46	US- 4,215,708	8/5/1980	Bron	
	47	US- 4,219,032	8/26/1980	Tabatznik et al.	
	48	US- 4,506,683	3/26/1985	Cantrell et al.	
	49	US- 4,519,319	5/28/1985	Howlett	
	50	US- 4,595,024	6/17/1986	Greene et al.	
	51	US- 4,708,151	11/24/1987	Shelar	
	52	US- 4,735,217	4/5/1988	Gerth et al.	
	53	US- 4,771,796	9/20/1988	Myer	
	54	US- 4,793,365	12/27/1988	Sensabaugh Jr. et al.	
	55	US- 4,794,323	12/27/1988	Zhou et al.	
	56	US- 4,798,310	1/17/1989	Kasai et al.	
	57	US- 4,813,536	3/21/1989	Willis	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	386	EP2609821A1	7/3/2013	Philip Morris Prod S.A		
	390	ES2118034A1(w/EngAbs)	9/1/1998	Nugar Bobinajes Sl		
	391	GB1025630A	4/14/1966	British American Tobacco		
	392	GB1065678A	4/19/1967	Super Temp Corp		
	393	IE-S2005-0051	2/2/2005	Oglesby & Butler R&D Ltd		
	394	IE-S2005-0563	8/24/2005	Oglesby & Butler R&D Ltd		

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 20

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	58	US- 4,819,665	4/11/1989	Roberts et al.	
	59	US- 4,830,028	5/16/1989	Lawson et al.	
	60	US- 4,836,224	6/6/1989	Lawson et al.	
	61	US- 4,846,199	7/11/1989	Rose	
	62	US- 4,848,374	7/18/1989	Chard et al.	
	63	US- 4,848,563	7/18/1989	Robbins	
	64	US- 4,893,639	1/16/1990	White	
	65	US- 4,907,606	3/13/1990	Lilja et al.	
	66	US- 4,941,483	7/17/1990	Ridings et al.	
	67	US- 4,944,317	7/31/1990	Thal	
	68	US- 4,947,874	8/14/1990	Brooks et al.	
	69	US- 4,947,875	8/14/1990	Brooks et al.	
	70	US- 5,005,759	4/9/1991	Bouche	
	71	US- 5,020,548	6/4/1991	Farrier et al.	
	72	US- 5,027,836	7/2/1991	Shannon et al.	
	73	US- 5,050,621	9/24/1991	Creighton et al.	
	74	US- 5,060,671	10/29/1991	Counts et al.	
	75	US- 5,065,776	11/19/1991	Lawson et al.	
	76	US- 5,076,297	12/31/1991	Farrier et al.	

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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	395	IE-S2005-0615	9/19/2005	Oglesby & Butler R&D Ltd		
	396	JP02-145179A(w/EngEquiv)	6/4/1990	Hercules Inc		
	397	JP03-049671(w/EngEquiv)	3/4/1991	Brown & Williamson Tob.		
	398	JP03-180166(w/EngEquiv)	8/6/1991	R J Reynolds Tobacco Co		
	399	JP09-075058(w/EngAbs)	3/25/1997	Nagai, Masaya		
	400	JP11-178563(w/EngAbs)	7/6/1999	Japan Tobacco Inc		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 5 of 20

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

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	77	US- 5,105,831	4/21/1992	Banerjee et al.	
	78	US- 5,105,838	4/21/1992	White et al.	
	79	US- 5,123,530	6/23/1992	Lee	
	80	US- 5,144,962	9/8/1992	Counts et al.	
	81	US- 5,183,062	2/2/1993	Clearman et al.	
	82	US- 5,224,498	7/6/1993	Deevi et al.	
	83	US- 5,249,586	10/5/1993	Morgan et al.	
	84	US- 5,261,424	11/16/1993	Sprinkel Jr.	
	85	US- 5,269,237	12/14/1993	Baker et al.	
	86	US- 5,269,327	12/14/1993	Counts et al.	
	87	US- 5,322,075	6/21/1994	Deevi et al.	
	88	US- 5,324,498	6/28/1994	Streusand et al.	
	89	US- 5,372,148	12/13/1994	McCafferty et al.	
	90	US- 5,388,574	2/14/1995	Ingebrethsen	
	91	US- 5,591,368	1/7/1997	Fleischhauer et al.	
	92	US- 5,605,226	2/25/1997	Hernlein	
	93	US- 5,641,064	6/24/1997	Goserud	
	94	US- 5,649,552	7/22/1997	Cho et al.	
	95	US- 5,666,977	9/16/1997	Higgins et al.	

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	401	JP2000-203639(w/EngAbs)	7/25/2000	S & B Foods Inc		
	402	JP2000-236865A(w/EngAbs)	9/5/2000	Seiko Kogyo KK		
	403	JP2001-165437A(wEngAbs)	6/22/2001	Tsubota Pearl Co Ltd		
	404	JP2005-034021A(w/EngCorres)	2/10/2005	Seiko Epson Corp		
	405	JP2006-504430A(w/EngEquiv)	2/9/2006	R J Reynolds Tobacco Co		
	406	JP62-278975(w/EngAbs)	12/3/1987	Watabe, Isamu		

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 6 of 20

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

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	96	US- 5,666,978	9/16/1997	Counts et al.	
	97	US- 5,708,258	1/13/1998	Counts et al.	
	98	US- 5,730,118	3/24/1998	Hermanson	
	99	US- 5,730,158	3/24/1998	Collins et al.	
	100	US- 5,746,587	5/5/1998	Racine et al.	
	101	US- 5,810,164	9/22/1998	Rennecamp	
	102	US- 5,819,756	10/13/1998	Mielordt	
	103	US- 5,845,649	12/8/1998	Saito et al.	
	104	US- 5,865,185	2/2/1999	Collins et al.	
	105	US- 5,881,884	3/16/1999	Podosek	
	106	US- 5,931,828	8/3/1999	Durkee	
	107	US- 5,934,289	8/10/1999	Watkins et al.	
	108	US- 5,938,018	8/17/1999	Keaveney et al.	
	109	US- 5,944,025	8/31/1999	Cook et al.	
	110	US- 5,954,979	9/21/1999	Counts et al.	
	111	US- 5,967,310	10/19/1999	Hill	
	112	US- 5,975,415	11/2/1999	Zehnal	
	113	US- 5,979,460	11/9/1999	Matsumura	
	114	US- 5,994,025	11/30/1999	Iwasa et al.	

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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	407	JP64-37276A(w/EngEquiv)	2/7/1989	R J Reynolds Tobacco Co		
	408	KR0193885B1(w/EngEquiv)	6/15/1999	Philip Morris Prod Inc		
	409	WO95/01137A1	1/12/1995	Voges Innovation Pty Ltd.		
	410	WO97/12639A1	4/10/1997	Slutsky, Arthur		
	411	WO00/28842A1(EngAbs)	5/25/2000	Reemtsma Gmbh		
	412	WO03/056948A1(EngAbs)	7/17/2003	Japan Tobacco Inc.		

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 7 of 20

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

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	115	US- 5,996,589	12/7/1999	St. Charles	
	116	US- 6,053,176	4/25/2000	Adams et al.	
	118	US- 6,095,153	8/1/2000	Kessler et al.	
	119	US- 6,102,036	8/15/2000	Slutsky et al.	
	120	US- 6,125,853	10/3/2000	Susa et al.	
	121	US- 6,155,268	12/5/2000	Takeuchi	
	122	US- 6,164,287	12/26/2000	White	
	123	US- 6,234,169	5/22/2001	Bulbrook et al.	
	124	US- 6,269,966	8/7/2001	Pallo et al.	
	125	US- 6,349,728	2/26/2002	Pham	
	126	US- 6,381,739	4/30/2002	Breternitz Jr. et al.	
	127	US- 6,386,371	5/14/2002	Parsons	
	128	US- 6,431,363	8/13/2002	Hacker	
	129	US- 6,446,793	9/10/2002	Layshock	
	130	US- 6,510,982	1/28/2003	White et al.	
	131	US- 6,532,965	3/18/2003	Abhulimen et al.	
	132	US- 6,536,442	3/25/2003	St. Charles et al.	
	133	US- 6,557,708	5/6/2003	Polacco	
	134	US- 6,598,607	7/29/2003	Adiga et al.	

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	413	WO03/082031A1	10/9/2003	Steinberg, Dan A.		
	414	WO03/094900A1	11/20/2003	Alexza Molecular Delivery		
	415	WO2004/064548A1	8/5/2004	Netzer, Omry		
	417	WO2005/020726A1	3/10/2005	Lee, Seunghyun		
	418	WO2006/015070A1	2/9/2006	Brown & Williamson Tob.		
	419	WO2007/026131A1	3/8/2007	Acetate Products Ltd		

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Sheet 8 of 20

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Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

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	136	US- 6,615,840	9/9/2003	Fournier et al.	
	137	US- 6,622,867	9/23/2003	Menceles	
	138	US- 6,655,379	12/2/2003	Clark et al.	
	139	US- 6,672,762	1/6/2004	Faircloth et al.	
	140	US- 6,688,313	2/10/2004	Wrenn et al.	
	141	US- 6,726,006	4/27/2004	Funderburk et al.	
	142	US- 6,772,756	8/10/2004	Shayan	
	143	US- 6,799,576	10/5/2004	Farr	
	144	US- 6,803,545	10/12/2004	Blake et al.	
	145	US- 6,805,545	10/19/2004	Slaboden	
	146	US- 6,810,883	11/2/2004	Felter et al.	
	147	US- 6,827,573	12/7/2004	St. Charles et al.	
	148	US- 6,954,979	10/18/2005	Logan	
	149	US- 7,000,775	2/21/2006	Gelardi et al.	
	151	US- 7,488,171	2/10/2009	St. Charles et al.	
	152	US- 7,546,703	6/16/2009	Johnske et al.	
	153	US- 7,621,403	11/24/2009	Althoff et al.	
	154	US- 7,644,823	1/12/2010	Gelardi et al.	

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	421	WO2010/023561A1	3/4/2010	Actavis Group Ptc		
	422	WO2011/033396A2	3/24/2011	Minilogic Device Corp Ltd		
	423	WO2011/117580A2	9/29/2011	Kind Consumer Ltd		
	424	WO2012/021972A1	2/23/2012	Cogestor Inc.		
	425	WO2012/027350A2	3/1/2012	Alelov, Eli		
	426	WO2012/085207A1	6/28/2012	Philip Morris Prod S.A		

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	155	US- 7,767,698	8/3/2010	Warchol et al.	
	156	US- 7,815,332	10/19/2010	Smith	
	157	US- 7,832,410	11/16/2010	Hon	
	158	US- 7,886,507	2/15/2011	McGuinness Jr.	
	159	US- 7,988,034	8/2/2011	Pezzoli	
	160	US- 8,141,701	3/27/2012	Hodges	
	161	US- 8,156,944	4/17/2012	Hon	
	162	US- 8,322,350	12/4/2012	Lipowicz	
	163	US- 8,371,310	2/12/2013	Brenneise	
	164	US- 8,381,739	2/26/2013	Gonda	
	165	US- 8,387,612	3/5/2013	Damani et al.	
	166	US- 8,443,534	5/21/2013	Goodfellow et al.	
	167	US- 8,490,629	7/23/2013	Shenassa et al.	
	168	US- 8,539,959	9/24/2013	Scatterday	
	169	US- 8,541,401	9/24/2013	Mishra et al.	
	170	US- 8,596,460	12/3/2013	Scatterday	
	171	US- 8,671,952	3/18/2014	Winterson et al.	
	172	US- 8,741,348	6/3/2014	Hansson et al.	
	175	US- 8,915,254	12/23/2014	Monsees et al.	

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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	428	WO2013/050934A1	4/11/2013	SIS Resources Ltd.		
	429	WO2013/083635A1	6/13/2013	Philip Morris Prod S.A		
	431	WO2013/098398A2	7/4/2013	Philip Morris Prod S.A		
	432	WO2013/142678A1	9/26/2013	Njoy Inc.		
	434	WO2014/093127A2	6/19/2014	Fuisz, Richard C.		
	436	WO2014/118286A2	8/7/2014	Philip Morris Prod S.A		

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 10 of 20

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

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	176	US- 8,925,555	1/6/2015	Monsees et al.	
	354	US- 2015/0157056**	6/11/2015	Bowen et al.	
	179	US- 9,215,895**	12/22/2015	Bowen et al.	
	180	US- D590990	4/21/2009	Hon	
	181	US- D590991	4/21/2009	Hon	
	182	US- D624238	9/21/2010	Turner	
	183	US- D642330	7/26/2011	Turner	
	184	US- D644375	8/30/2011	Zhou	
	185	US- D653803	2/7/2012	Timmermans	
	186	US- D691324	10/8/2013	Saliman	
	187	US- D695450	12/10/2013	Benassayag et al.	
	188	US- D707389	6/17/2014	Liu	
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	190	US- 2001/0032643	10/25/2001	Hochrainer et al.	
	191	US- 2001/0032795	10/25/2001	Weinstein et al.	
	192	US- 2001/0052480	12/20/2001	Kawaguchi et al.	
	193	US- 2002/0078951	6/27/2002	Nichols et al.	
	194	US- 2002/0175164	11/28/2002	Dees et al.	
	195	US- 2003/0005926	1/9/2003	Jones et al.	

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	437	WO2014/139611A1	9/18/2014	Philip Morris Prod S.A		
	438	WO2014/140087A1	9/18/2014	Philip Morris Prod S.A		
	440	WO2014/187763A1	11/27/2014	Philip Morris Prod S.A		
	441	WO2014/187770A2	11/27/2014	Philip Morris Prod S.A		
	443	WO2015/006652A1	1/15/2015	Alexza Pharm. Inc.		
	445	WO2015/040180A2	3/26/2015	Philip Morris Prod S.A		

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Sheet 11 of 20

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

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	360	US- 2015/0208729**	7/30/2015	Monsees et al.	
	196	US- 2003/0089377	5/15/2003	Hajaligol et al.	
	197	US- 2004/0031495	2/19/2004	Steinberg	
	198	US- 2004/0099266	5/27/2004	Cross et al.	
	199	US- 2004/0149296	8/5/2004	Rostami et al.	
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	201	US- 2004/0173229	9/9/2004	Crooks et al.	
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	203	US- 2004/0221857	11/11/2004	Dominguez	
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	211	US- 2005/0172976	8/11/2005	Newman et al.	
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	448	WO2015/082652A1	6/11/2015	Philip Morris Prod S.A		
	449	WO2015/084544A1	6/11/2015	Pax Labs, Inc.		
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	453	WO2015/124878A1(EngAbs)	8/27/2015	Smokio		
	454	WO2015/148547A1	10/1/2015	Nicotech LLC		
	455	WO2015/175979A1	11/19/2015	Pax Labs, Inc.		

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Sheet 12 of 20

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

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	214	US- 2006/0018840	1/26/2006	Lechuga Ballesteros et al.	
	215	US- 2006/0054676	3/16/2006	Wischusen	
	216	US- 2006/0102175	5/18/2006	Nelson	
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	229	US- 2007/0144514	6/28/2007	Yeates et al.	
	230	US- 2007/0163610	7/19/2007	Lindell et al.	
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Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

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	233	US- 2007/0267033	11/22/2007	Mishra et al.	
	234	US- 2007/0280652	12/6/2007	Williams	
	235	US- 2007/0283972**	12/13/2007	Monsees et al.	
	236	US- 2008/0023003	1/31/2008	Rosenthal	
	237	US- 2008/0029095	2/7/2008	Esser	
	238	US- 2008/0092912	4/24/2008	Robinson et al.	
	239	US- 2008/0149118	6/26/2008	Oglesby et al.	
	240	US- 2008/0216828	9/11/2008	Wensley et al.	
	241	US- 2008/0241255	10/2/2008	Rose et al.	
	242	US- 2008/0257367	10/23/2008	Paterno et al.	
	243	US- 2008/0276947	11/13/2008	Martzel	
	244	US- 2009/0004249	1/1/2009	Gonda	
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	248	US- 2009/0230117	9/17/2009	Fernando et al.	
	249	US- 2009/0255534	10/15/2009	Paterno	
	250	US- 2009/0267252	10/29/2009	Ikeyama	
	251	US- 2009/0272379	11/5/2009	Thorens et al.	

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	253	US- 2009/0288669	11/26/2009	Hutchens	
	254	US- 2009/0293892	12/3/2009	Williams et al.	
	255	US- 2009/0293895	12/3/2009	Axelsson et al.	
	256	US- 2010/0000672	1/7/2010	Fogle	
	257	US- 2010/0006092	1/14/2010	Hale et al.	
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	259	US- 2010/0031968	2/11/2010	Sheikh et al.	
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	261	US- 2010/0163063	7/1/2010	Fernando et al.	
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	265	US- 2010/0242974	9/30/2010	Pan	
	266	US- 2010/0242976	9/30/2010	Katayama et al.	
	267	US- 2010/0275938	11/4/2010	Roth et al.	
	268	US- 2010/0276333	11/4/2010	Couture	
	269	US- 2010/0307116	12/9/2010	Fisher	
	270	US- 2011/0030706	2/10/2011	Gibson et al.	
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Attorney Docket Number	13211-713.303

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Sheet 16 of 20

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

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United States Patent [19]

Sensabaugh, Jr. et al.

[11] **Patent Number: 4,793,365**

[45] **Date of Patent: Dec. 27, 1988**

[54] **SMOKING ARTICLE**

[75] Inventors: **Andrew J. Sensabaugh, Jr.**, Winston-Salem; **Henry T. Ridings**, Lewisville; **John H. Reynolds, IV**, Winston-Salem, all of N.C.

[73] Assignee: **R. J. Reynolds Tobacco Company**, Winston-Salem, N.C.

[21] Appl. No.: **650,604**

[22] Filed: **Sep. 14, 1984**

[51] **Int. Cl.**[4] **A24D 1/00**; A24D 1/02; A24D 1/18; A24F 1/00

[52] **U.S. Cl.** **131/194**; 131/335; 131/360; 131/361; 131/364; 128/202.21

[58] **Field of Search** 131/360, 361, 364, 359, 131/194, 335, 195, 196, 197

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Primary Examiner—V. Millin

Attorney, Agent, or Firm—Grover M. Myers; David G. Conlin

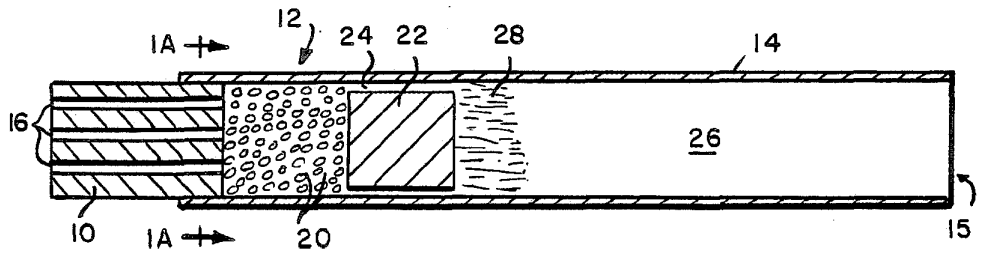
[57] **ABSTRACT**

The present invention relates to a smoking article which produces an aerosol that resembles tobacco smoke, but contains no more than a minimal amount of incomplete combustion or pyrolysis products.

The smoking article of the present invention provides an aerosol "smoke" which is chemically simple, consisting essentially of oxides of carbon, air, water, and the aerosol which carries any desired flavorants or other desired volatile materials, and trace amounts of other materials. The aerosol "smoke" has no significant mutagenic activity as measured by the Ames Test. In addition, the article may be made virtually ashless so that the user does not have to remove any ash during use.

One embodiment of the present smoking article comprises a short combustible carbonaceous fuel element; a short heat stable, preferably carbonaceous substrate bearing an aerosol forming substance, and a relatively long mouthend piece. The fuel element and the substrate are arranged in a heat exchange relationshp, thereby causing aerosol formation without significant degradation of the aerosol former.

50 Claims, 3 Drawing Sheets



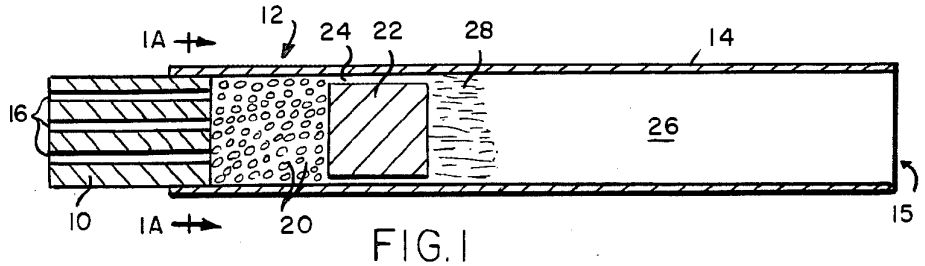


FIG. 1

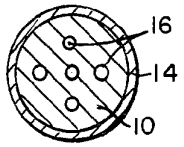


FIG. 1A

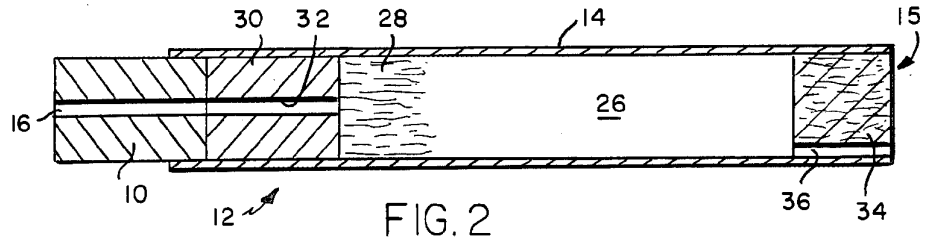


FIG. 2

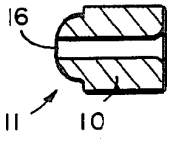


FIG. 2A

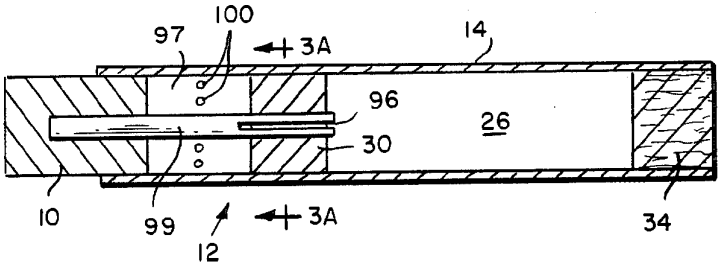


FIG. 3

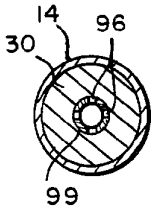


FIG. 3A

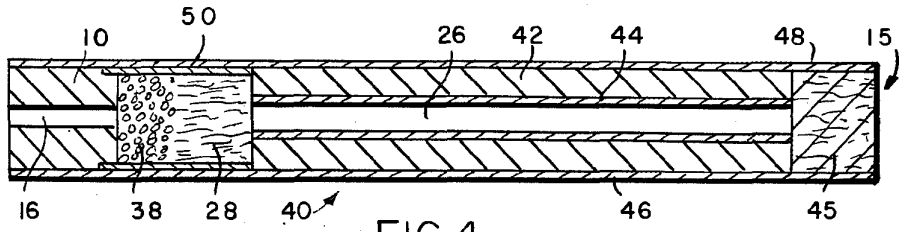


FIG.4

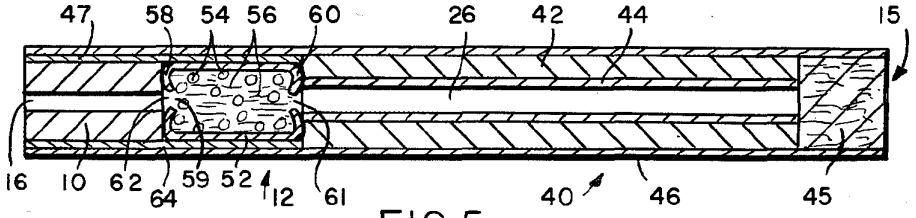


FIG.5

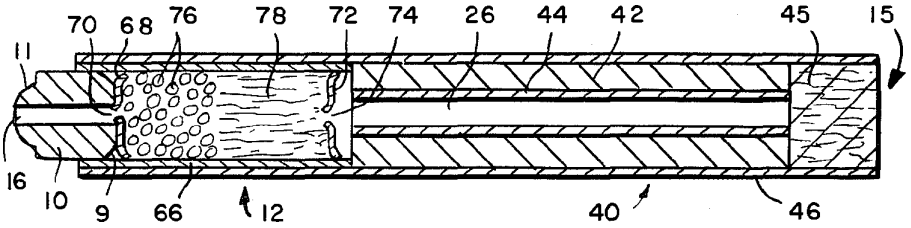


FIG.6

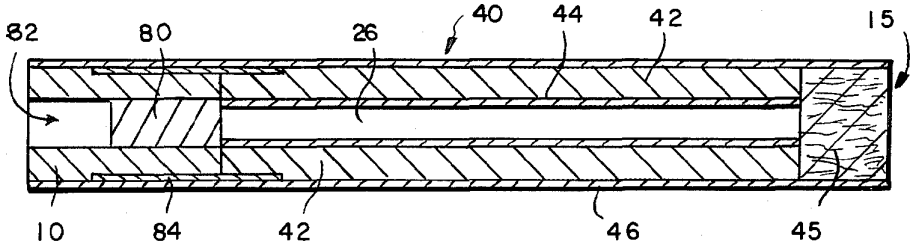


FIG.7

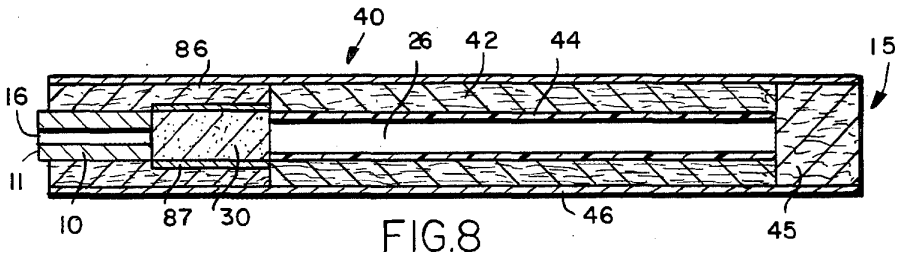


FIG.8

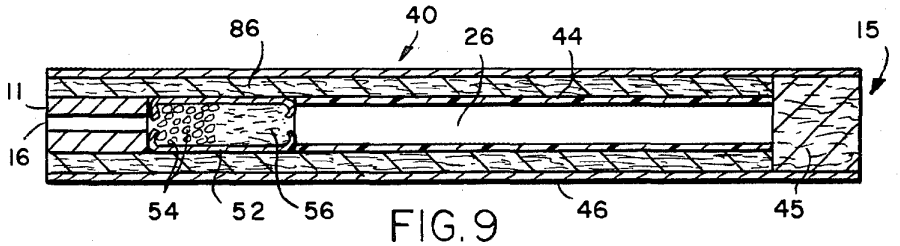


FIG.9

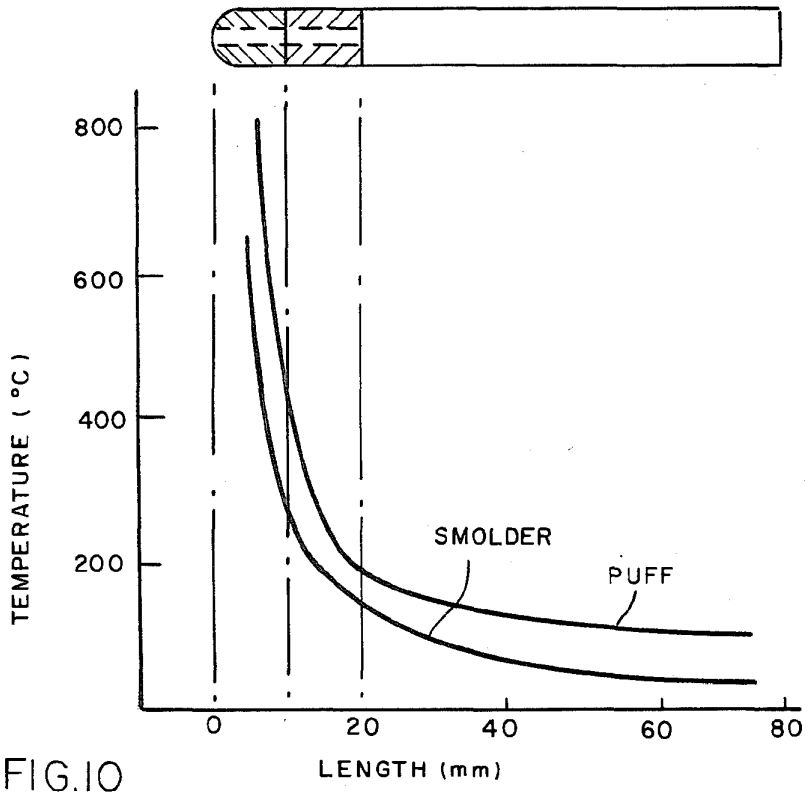


FIG.10

SMOKING ARTICLE

BACKGROUND OF THE INVENTION

The present invention relates to a smoking article which produces an aerosol that resembles tobacco smoke which contains no more than a minimal amount of incomplete combustion or pyrolysis products.

Many smoking articles have been proposed through the years, especially over the last 20 to 30 years. But none of these products has ever realized any commercial success.

Tobacco substitutes have been made from a wide variety of treated and untreated plant material, such as cornstalks, eucalyptus leaves, lettuce leaves, corn leaves, cornsilk, alfalfa, and the like. Numerous patents teach proposed tobacco substitutes made by modifying cellulosic materials, such as by oxidation, by heat treatment, or by the addition of materials to modify the properties of cellulose. One of the most complete lists of these substitutes is found in U.S. Pat. No. 4,079,742 to Rainer et al. Despite these extensive efforts, it is believed that none of these products has been found to be completely satisfactory as a tobacco substitute.

Many proposed smoking articles have been based on the generation of an aerosol or a vapor. Some of these products produce an aerosol or a vapor without heat. See, e.g., U.S. Pat. No. 4,284,089 to Ray. However, the aerosols or vapors from these articles fail to adequately simulate tobacco smoke.

Some proposed aerosol generating smoking articles have used a heat or fuel source in order to produce an aerosol. However, none of these articles has ever achieved any commercial success, and it is believed that none has ever been widely marketed. The absence of such smoking articles from the marketplace is believed to be due to a variety of reasons, including insufficient aerosol generation, both initially and over the life of the product, poor taste, off-taste due to the thermal degradation of the smoke former and/or flavor agents, the presence of substantial pyrolysis products and sidestream smoke, and unsightly appearance.

One of the earliest of these proposed articles was described by Siegel in U.S. Pat. No. 2,907,686. Siegel proposed a cigarette substitute which included an absorbent carbon fuel, preferably a 2½ inch stick of charcoal, which was burnable to produce hot gases, and a flavoring agent carried by the fuel, which was adapted to be distilled off incident to the production of the hot gases. Siegel also proposed that a separate carrier could be used for the flavoring agent, such as a clay, and that a smoke-forming agent, such as glycerol, could be admixed with the flavoring agent. Siegel's proposed cigarette substitute would be coated with a concentrated sugar solution to provide an impervious coat and to force the hot gases and flavoring agents to flow toward the mouth of the user. It is believed that the presence of the flavoring and/or smoke-forming agents in the fuel of Siegel's article would cause substantial thermal degradation of those agents and an attendant off-taste. Moreover, it is believed that the article would end to produce substantial sidestream smoke containing the aforementioned unpleasant thermal degradation products.

Another such article was described by Ellis et al. in U.S. Pat. No. 3,258,015. Ellis et al. proposed a smoking article which has an outer cylinder of fuel having good smoldering characteristics, preferably fine cut tobacco

or reconstituted tobacco, surrounding a metal tube containing tobacco, reconstituted tobacco, or other source of nicotine and water vapor. On smoking, the burning fuel heated the nicotine source material to cause the release of nicotine vapor and potentially aerosol generating material, including water vapor. This was mixed with heated air which entered the open end of the tube. A substantial disadvantage of this article was the ultimate protrusion of the metal tube as the tobacco fuel was consumed. Other apparent disadvantages of this proposed smoking article include the presence of substantial tobacco pyrolysis products, the substantial tobacco sidestream smoke and ash, and the possible pyrolysis of the nicotine source material in the metal tube.

In U.S. Pat. No. 3,356,094, Ellis et al. modified their original design to eliminate the protruding metal tube. This new design employed a tube made out of a material, such as certain inorganic salts or an epoxy bonded ceramic, which became frangible upon heating. This frangible tube was then removed when the smoker eliminated ash from the end of the article. Even though the appearance of the article was very similar to a conventional cigarette, apparently no commercial product was ever marketed.

In U.S. Pat. No. 3,738,374, Bennett proposed the use of carbon or graphite fibers, mat, or cloth associated with an oxidizing agent as a substitute cigarette filler. Flavor was provided by the incorporation of a flavor or fragrance into the mouthend of an optional filter tip.

U.S. Pat. Nos. 3,943,941 and 4,044,777 to Boyd et al. and British Patent No. 1,431,045 proposed the use of a fibrous carbon fuel which was mixed or impregnated with volatile solids or liquids which were capable of distilling or subliming into the smoke stream to provide "smoke" to be inhaled upon burning of the fuel. Among the enumerated smoke producing agents were polyhydric alcohols, such as propylene glycol, glycerol, and 1,3 butylene glycol, and glyceryl esters, such as triacetin. Despite Boyd et al.'s desire that the volatile materials distill without chemical change, it is believed that the mixture of these materials with the fuel would lead to substantial thermal decomposition of the volatile materials and to bitter offtastes. Similar products were proposed in U.S. Pat. No. 4,286,604 to Ehretsmann et al. and in U.S. Pat. No, 4,326,544 to Hardwick et al.

Bolt et al., in U.S. Pat. No. 4,340,072 proposed a smoking article having a fuel rod with a central air passageway and a mouthend chamber containing an aerosol forming agent. Tee fuel rod preferably was a molding or extrusion of reconstituted tobacco and/or tobacco substitute, although the patent also proposed the use of tobacco, a mixture of tobacco substitute material and carbon, or a sodium carboxymethycellulose (SCMC) and carbon mixture. The aerosol forming agent was proposed to be a nicotine source material, or granules or microcapsules of a flavorant in triacetin or benzyl benzoate. Upon burning, air entered the air passage where it was mixed with combustion gases from the burning rod. The flow of these hot gases reportedly ruptured the granules or microcapsules to release the volatile material. This material reportedly formed an aerosol and/or was transferred into the mainstream aerosol. It is believed that the articles of Bolt et al., due in part to the long fuel rod, would produce insufficient aerosol from the aerosol former to be acceptable, especially in the early puffs. The use of microcapsules or granules would further impair aerosol delivery because

of the heat needed to rupture the wall material. Moreover, total aerosol delivery would appear dependent on the use of tobacco or tobacco pyrolysis products and sidestream smoke which would not be desirable in this type smoking article.

U.S. Pat. No. 3,516,417 to Moses proposed a smoking article, with a tobacco fuel, which was identical to the article of Bolt et al., except that Moses used a double density plug of tobacco in lieu of the granular or microencapsulated flavorant of Bolt et al. See FIG. 4, and col. 4, l. 17–35. This article would suffer many of the same problems as the articles proposed by Bolt et al.

Thus, despite decades of interest and effort, there is still no smoking article on the market which provides the benefits and advantages associated with conventional cigarette smoking.

SUMMARY OF THE INVENTION

The present invention relates to a smoking article which is capable of producing substantial quantities of aerosol, both initially and over the useful life of the product, without significant thermal degradation of the aerosol former and without the presence of substantial pyrolysis or incomplete combustion products or sidestream smoke. Thus, the article of the present invention is able to provide the user with the sensations and benefits of cigarette smoking without burning tobacco.

In one aspect of the present invention, the smoking article has a short, combustible carbonaceous fuel element, generally less than about 30 mm long, which is substantially free of volatile organic material. Preferably, the fuel element is less than about 15 mm in length. A physically separate aerosol generating means, such as a substrate or chamber containing an aerosol forming substance, is located in a conductive heat exchange relationship to the fuel element. preferably, the heat exchange relationship is achieved by providing a heat conductive member which efficiently conducts or transfers heat from the burning fuel element to the aerosol generating means. Advantageously, the aerosol generating means is a relatively short body, again generally less than about 30 mm long, which either abuts or is adjacent to the nonlighting end of the fuel element. Preferably, the aerosol generating means is a thermally stable substrate impregnated with one or more aerosol forming substances and is less than about 15 mm in length.

The smoking article of the present invention normally is provided with mouthend piece including means, such as a longitudinal passage, for delivering the volatile material produced by the aerosol generating means to the user. Advantageously, the article has the same overall dimensions as a conventional cigarette, and as a result, the mouthend piece and the aerosol delivery means usually extend over more than one-half the length of the article. Alternatively, the fuel element and the aerosol generating means may be produced without a built-in mouthpiece or aerosol delivery means, for use as a disposable cartridge, with a separate, reusable mouthpiece.

Upon lighting, the fuel element generates heat which is used to volatilize the aerosol forming substance or substances contained in the substrate or chamber. These volatile materials are then drawn toward the mouthend, especially during puffing, and into the user's mouth, akin to the smoke of a conventional cigarette. Because the fuel element is relatively short, the hot, burning fire cone is always close to the aerosol generating body, which maximizes heat transfer to the aerosol generating means and the resultant production of aerosol. The use of a relatively short, low mass aerosol generating body, in close proximity to the short fuel element, also increases aerosol production by minimizing the heat sink effect of the substrate or carrier. Because the aerosol forming substance is physically separate from the fuel element, it is exposed to substantially lower temperatures than are present in the burning fire cone, which minimizes the possibility of thermal degradation of the aerosol former. Moreover, the use of a carbonaceous fuel element which is substantially free of volatile organic material eliminates the presence of substantial pyrolysis or incomplete combustion products and the presence of substantial sidestream smoke.

In another important aspect of the present invention, the smoking article is provided with means for conducting heat from the fuel element to the aerosol generating means other than the mere end to end abutment of the fuel element to the aerosol generating means. Preferably, the heat conducting means is a heat conducting member, such as a metal foil, or a metal rod, which advantageously contacts both the fuel element and the aerosol generating means. Contact of the metal foil is preferably along the external longitudinal surfaces of the fuel element and the aerosol generator. Contact of the metal rod is preferably made by embedding the rod centrally within the fuel element and the aerosol generator.

The use of the heat conducting means of the present invention substantially increases heat transfer to the aerosol generator which, in turn, volatilizes larger quantities of the aerosol former for delivery to the user. This increased heat transfer is, in part, due to the fact that the heat conducting means transfers heat both during a puff and during smolder, whereas convective heat transfer, which is primarily relied upon in most prior art aerosol generating articles, primarily delivers heat only during a puff. This increased heat transfer makes more efficient use of the available fuel energy, reduces the amount of fuel needed, helps deliver aerosol on the initial puffs, and substantially reduces material costs of the fuel. Further, it is believed that conductive heat transfer reduces the carbon fuel combustion temperature and thus greatly reduces the CO/CO_2 ratio.

In a particularly preferred embodiment of the invention, the fuel element is a pressed carbon plug or mass of carbonized fibers, generally about 10 mm or less in length, which is provided with at least one longitudinal passage to aid heat transfer to the aerosol generator. The aerosol generating means is a thermally stable,, preferably carbonaceous substrate about 10 mm or less in length which is impregnated with one or more aerosol forming substances, such as a mixture of glycerol and propylene glycol. This substrate may be provided with an axial passage which may be aligned with an axial passage in the fuel element. This fuel element and substrate are joined by an encircling piece of heat conductive aluminum foil which envelops the longitudinal periphery of the nonlighting end of the fuel element and at least a portion, and preferably all, of the longitudinal periphery of the substrate.

Preferred embodiments of the invention are capable of delivering at least 0.6 mg of aerosol, measured as wet total particulate matter, in the first 3 puffs, when smoked under standard FTC smoking conditions. More preferably, preferred embodiments of the invention are capable of delivering 1.5 mg or more of aerosol in the

first 3 puffs. Most preferably, preferred embodiments of the invention are capable of delivering 3 mg or more of aerosol in the first 3 puffs when smoked under standard FTC smoking conditions. Moreover, preferred embodiments of the invention deliver an average of at least about 0.8 mg of wet total particulate matter per puff under standard FTC smoking conditions.

The smoking article of the present invention also may include a charge or plug of tobacco which is used to add a tobacco flavor to the aerosol. Preferably, the tobacco is placed at the mouthend of the aerosol generating means, or it is mixed with the carrier for the aerosol forming substance. Flavoring agents also may be incorporated into the article to flavor the aerosol delivered to the user.

The smoking article of the present invention also provides an aerosol "smoke" which is chemically simple, consisting essentially of air, oxides of carbon, water, and the aerosol which carries any desired flavorants or other desired volatile materials, and trace amounts of other materials. The aerosol "smoke" has no significant mutagenic activity using the Ames test discussed hereinafter. In addition, the article may be made virtually ashless so that the user does not have to remove any ash during use.

In another important aspect of the invention, the aerosol forming substance may be replaced, in whole or in part, by a volatile, nonaerosol substance, such as a flavoring agent and/or other volatile solid or liquid materials, to deliver flavors and/or other materials to the user, in aerosol or vapor form.

The smoking article of the present invention is described in greater detail in the accompanying drawings and in the detailed description of the invention which follows.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1** through **9** are longitudinal, sectional views of various embodiments of the invention;

FIG. **1A** is a sectional view of the embodiment of FIG. **1**, taken along lines **1A—1A** in FIG. **1**;

FIG. **2A** is a longitudinal view of a modified, tapered fuel element of the embodiment of FIG. **2**;

FIG. **3A** is a sectional view of the embodiment of FIG. **3**, taken along lines **3A—3A** in FIG. **3**; and

FIG. **10** is the average peak temperature profile of the smoking article of Example **5** during use.

DETAILED DESCRIPTION OF THE INVENTION

The embodiment of the invention illustrated in FIG. **1**, which preferably has the diameter of a conventional cigarette, includes a short, combustible carbonaceous fuel element **10**, an abutting aerosol generating means **12**, and a foil lined paper tube **14**, which forms the mouthend **15** of the article. In this embodiment, fuel element **10** is a blow pipe charcoal, a carbonized wood, which is provided with five longitudinally extending holes **16**. See FIG. **1A**. The fuel element **10**, which is about 20 mm long, optionally may be wrapped with cigarette paper to improve lighting of the charcoal fuel. This paper may be treated with known burn additives.

Aerosol generating means **12** includes a plurality of glass beads **20** coated with an aerosol forming substance or substances, such as glycerin. The glass beads are held in place by a porous disc **22**, which may be made of cellulose acetate. This disc may be provided with a series of peripheral grooves **24** which provide passages between the disc and the foil lined tube **14**.

The foil lined paper tube **14**, which forms the mouthend of the article, surrounds aerosol generating means **12** and the rear, non-lighting end of fuel element **10**. The tube also forms an aerosol delivery passage **26** between the aerosol generating means **12** and the mouthend **15** of the article.

The article illustrated in FIG. **1** also includes an optional mass or plug of tobacco **28** to contribute flavor to the aerosol. This tobacco charge **28** may be placed at the mouthend of disc **22**, as shown in FIG. **1**, or it may be placed between glass beads **20** and disc **22**. It also may be placed in passage **26** at a location spaced from aerosol generator **12**.

In the embodiment shown in FIG. **2**, the short fuel element **10** is a pressed carbon rod or plug, about 20 mm long, which is provided with an axial hole **16**. Alternatively, the fuel ma be formed from carbonized fibers and preferably also provided with an axial passageway corresponding to hole **16**. In this embodiment, aerosol generating means **12** includes a thermally stable conductive carbonaceous substrate **30**, such as a plug of porous carbon, which is impregnated with an aerosol forming substance or substances. This substrate may be provided with an optional axial passageway **32**, as is shown in FIG. **2**. This embodiment also includes a mass of tobacco **28** which is preferably placed at the mouthend of substrate **30**. For appearance sake, this article also includes an optional high porosity cellulose acetate filter **34**, which may be provided with peripheral grooves **36** to provide passages for the aerosol forming substance between filter **34** and foil tube **14**. Optionally, as shown in FIG. **2A**, the lighting end **11** of the fuel element may be tapered to improve lightability.

Upon lighting any of the aforesaid embodiments, the carbonaceous fuel element **10** burns, which generates the heat used to volatilize the aerosol forming substance or substances present in aerosol generating means **12**. These volatile materials are then drawn down passage **26** toward the mouthend **15**, especially during puffing, and into the user's mouth, like the smoke of a conventional cigarette. Because the aerosol forming substance is physically separate from the fuel element, it is exposed to substantially lower temperatures than are present in the burning fire cone, which minimizes the possibility of thermal degradation of the aerosol former. This also results in aerosol production during puffing, but little or no aerosol production during smolder. In addition, the use of a carbonaceous fuel element and a physically separate aerosol generator eliminate the presence of substantial pyrolysis or incomplete combustion products and avoid the production of substantial sidestream smoke.

If a charge of tobacco is employed, the hot vapors of the aerosol former are swept through the bed of tobacco to extract and vaporize the volatile components in the tobacco, without the need for tobacco combustion. Thus the user of this smoking article receives an aerosol which contains the qualities and flavors of natural tobacco without the combustion products produced by a conventional cigarette.

Because of the small size and burning characteristics of the carbonaceous fuel elements employed in the present invention, the fuel element usually begins burning over substantially all of its exposed length within a few puffs. Thus, the portion of the fuel element adjacent to the aerosol generator **12** becomes hot quickly, which

significantly increases heat transfer to the aerosol generator, especially during the early and middle puffs. Because the fuel element is so short, there is never a long section of nonburning fuel to act as a heat sink, as in the prior art thermal aerosol articles. Heat transfer, and therefore aerosol delivery, also is enhanced by the use of holes **16** through the fuel, which draw hot gases to the aerosol generator, especially during puffing.

The presence of fill lined tube **14**, which couples the nonlighting end of fuel **10** to aerosol generator **12**, also increases heat transfer to the aerosol generator. The foil also helps to extinguish the fire cone. When only a small amount of the unburned fuel remains, heat loss through the foil acts as a heat sink which helps to extinguish the fire cone.

The foil used in this article is typically an aluminum foil of 0.35 mils (0.0089 mm) in thickness, but the thickness and/or the type of metal employed may be varied to achieve any desired degree of heat transfer. Other types of heat conducting members such as Grafoil, available from Union Carbide, also may be employed.

In the foregoing embodiments of the invention, short fuel element **10**, foil lined tube **14**, and passages **16** in the fuel cooperate with the aerosol generator to provide a system which is capable of producing substantial quantities of aerosol throughout the life of the fuel element, and especially during the early and middle puffs. The close proximity of the fire cone to the aerosol generator after a few puffs, together with the conductive metallic foil, results in heat delivery during puffs and during the relatively long period of smolder between puffs. Standard FTC smoking conditions consist of two second puffs separated by 58 seconds of smolder.) While not wishing to be bound by theory, it is believed that the aerosol generator is maintained at relatively high temperatures between puffs and that the additional heat delivered during puffs, which is significantly increased by the hole or holes **16** in the fuel element, is primarily utilized to vaporize the aerosol forming substance. This increased heat transfer makes more efficient use of the available fuel energy, reduces the amount of fuel needed, and helps deliver aerosol on the initial puffs. Further, the conductive heat transfer utilized in the present invention is believed to reduce the carbon fuel combustion temperature which, it is believed, reduces the CO/CO_2 ratio in the combustion products produced by the feel. See, e.g., C. Hagg, *General Inorganic Chemistry* at p. 592 (John Wiley & Sons, 1969).

The embodiment of the invention illustrated in FIG. **3**, includes a short combustible carbonaceous fuel element **10**, connected to aerosol generating means **12** by a heat conductive rod **99** and by a foil lined paper tube **14**, which also forms the mouthend **15** of the article. In this embodiment, fuel element **10** may be blowpipe charcoal or a pressed or extruded carbon rod or plug or other carbonaceous fuel source.

Aerosol generating means **12** includes a thermally stable carbonaceous substrate **30**, such as a plug of porous carbon, which is impregnated with an aerosol forming substance or substances. This embodiment includes a void space **97** between the fuel element **10** and the substrate **30**. The portion of the foil lined tube **14** surrounding this void space includes a plurality of peripheral holes **100** which permit sufficient air to enter the void space to provide appropriate pressure drop.

As shown in FIGS. **3** and 3A, the heat conducting means includes a conductive rod **99** and the foil lined tube **14**. The rod **99**, preferably formed of aluminum, has at least one, preferably from 2 to 5, peripheral grooves **96** therein, to allow air passage through the substrate The article of FIG. **3** has the advantage that the air introduced into the void space **97** contains less carbon oxidation products because it is not drawn through the burning fuel.

In general, the combustible carbonaceous fuel elements which may be employed in practicing the invention are generally less than about 30 mm long. Advantageously the fuel element is about 20 mm or less in length, preferably about 15 mm or less in length. In most current preferred embodiments, the fuel element is between about 3 mm to about 10 mm in length. These lengths are sufficient to provide fuel for at least about 7 to 10 puffs, the normal number of puffs obtained with a conventional cigarette under FTC smoking conditions. Preferably, the feel is provided with means for passing hot gases to the substrate, such as one or more longitudinally extending holes **16** in FIGS. **1** and **2**. It is believed the holes also aid in decreasing heat transfer in later puffs by increasing in size.

The fuel elements are primarily formed of a carbonaceous material. Preferably, the carbon content of the fuel is at least 80%, most preferably about 90% or more, by weight. High carbon content fuels are preferred because they produce minimal pyrolysis and incomplete combustion products, little or no visible sidestream smoke, minimal ash, and high heat capacity. However, lower carbon content fuel elements are within the scope of this invention, especially where a nonburning inert filler is used.

The carbonaceous materials used in or as the fuel may be derived from virtually any of the numerous carbon sources known to those skilled in the art. Preferably, the carbonaceous material is obtained by the pyrolysis or carbonization of cellulosic materials, such as wood, cotton, rayon, tobacco, coconut, paper, and the like, although carbonaceous materials from other sources may be used.

In most instances, the carbonaceous material should be capable of being ignited by a conventional cigarette lighter without the use of an oxidizing agent. Burning characteristics of this type may generally be obtained from a cellulosic material which has been pyrolyzed at temperatures between about 400° C. to about 1000° C., preferably between about 500° C. to about 950° C., in an inert atmosphere or under a vacuum. The pyrolysis time is not believed to be important, as long as the temperature at the center of the pyrolyzed mass has reached the aforesaid temperature range for at least a few minutes.

While undesirable in most cases, carbonaceous materials which require the use of an oxidizing agent to render them ignitable by a cigarette lighter are within the scope of this invention, as are carbonaceous materials which require the use of a glow retardant or other type of combustion modifying agent. Such combustion modifying agents are disclosed in many prior art patents and publications and are known to those of ordinary skill in the art.

The carbonaceous fuel elements used in practicing the invention are substantially free of volatile organic material. By that, it is meant that the fuel element is not impregnated or mixed with substantial amounts of volatile organic materials, such as volatile aerosol forming or flavoring agents, which could degrade at the combustion temperatures of the fuel. However, small amounts of water, which are naturally absorbed by the fuel, may be present in the fuel. Similarly, small

amounts of aerosol forming substances may migrate from the aerosol generator and thus also may be present in the fuel.

A preferred carbonaceous fuel element is a pressed carbon plug prepared from porous carbon and a binder, by conventional pressure forming techniques. A preferred activated carbon for pressure forming is PCB-G, and a preferred non-activated carbon is PXC, both available from Calgon Carbon Corporation, Pittsburgh, PA. Other preferred nonactivated carbons for pressure forming are prepared from pyrolyzed cotton linters or pyrolized papers, such as Grande Prairie Canadian Kraft available from Buckeye Cellulose Corp., Memphis, TN.

The binders which may be used in preparing such a fuel element are well known in the art. A preferred binder is sodium carboxymethylcellulose (SCMC), which may be used alone, which is preferred, or in conjunction with materials such as sodium chloride, vermiculite, bentonite, calcium carbonate, and the like. Other useful binders include gums, such as guar gum, and other cellulose derivatives, such as methylcellulose and carboxymethylcellulose (CMC).

A wide range of binder concentrations can be utilized. Preferably, the amount of binder is limited to minimize contribution of the binder to undesirable combustion products. On the other hand, sufficient binder must be included to hold the fuel element together during manufacture and use. The amount used will thus depend on the cohesiveness of the carbon in the fuel.

In general, the fuel is prepared by admixing from about 50 to 99 weight percent, preferably about 80 to 95 weight percent, of the carbonaceous material, with from 1 to 50 weight percent, preferably about 5 to 20 weight percent of the binder, with sufficient water to make a paste. The paste is homogenized by mixing and then dried to reduce the moisture content to about 5 to 10 weight percent. The dried paste is then ground to a particle size of about −20 to +100 mesh size. This ground material is treated with water to raise the moisture level to about 30 weight percent, and the moist solid is fed to forming means, such as a conventional pill press, wherein a die punch pressure of from 1,000 pounds (455 kg) to 10,000 pounds (4550 kg), preferably about 5,000 pounds (2273 kg), of load is applied to create a pressed pellet having the desired dimensions. The pressed pellet is then dried at from about 55° to about 100° C. to reduce the moisture content to between 5 to 10 weight percent. The longitudinal passage or passages 16, if desired, may be drilled using conventional techniques, or they may be formed at the time of pressing.

Alternatively, the forming means used may be a standard extruder. In that case, the amount of water used is just sufficient to obtain a stiff dough consistency. The dough is then extrude into the desired shape followed by drying, e.g., at 80° C. overnight.

If desired, the aforesaid pressed carbon fuel element may be pyrolyzed after formation, for example, to about 650° C. for two hours, to convert the binder to carbon and thereby form a virtually 100% carbon fuel plug. Alternatively, a virtually pure carbon plug can be formed by using sufficient pressure.

The pressed carbon fuel elements also may contain one or more additives to improve burning, such as up to about 5 weight percent sodium chloride to improve smoldering characteristics and as a glow retardant. Also, up to about 5 weight percent of potassium carbonate may be included to improve lightability. Additives to improve physical characteristics, such as clays like kaolins, serpentines, attapulgites, and the like also may be used.

Another preferred carbonaceous fuel element is a carbon fiber fuel, which may be prepared by carbonizing a fibrous precursor, such as cotton, rayon, paper, polyacrylonitile, and the like. Generally, pyrolysis at about 650° C. to 1000° C., preferably at about 950° C., for about 30 minutes, in an inert atmosphere or vacuum, is sufficient to produce a suitable carbon fiber with good burning characteristics. Combustion modifying additives also may be added to these preferred fuels.

The aerosol generating means used in practicing the invention is physically separate from the fuel element. By physically separate it is meant that the substrate or body which contains the aerosol forming materials is not mixed with, or a part of, the fuel. As noted previously, this arrangement helps reduce or eliminate thermal degradation of the aerosol forming substance and the presence of sidestream smoke. While not a part of the fuel, the aerosol generator preferably is in a conductive heat exchange relationship with the fuel element. As used herein, a conductive heat exchange relationship is defined as a physical arrangement of the substrate and the fuel element whereby conductive heat transfer from the burning fuel element takes place throughout the burning period of the fuel element. Preferably, the heat exchange relationship is achieved by providing heat conductive means which efficiently conducts or transfers heat from the burning fuel element to the aerosol generating means. In most preferred embodiments, the aerosol generator abuts or is adjacent to the fuel element so that the fuel and the aerosol generator are in a heat exchange relationship throughout the burning of the fuel element.

Preferably, the aerosol generating means includes one or more thermally stable materials which carry one or more aerosol forming substances. As used herein, a thermally stable material is one capable of withstanding the high temperature, e.g., 400°–600° C., which exist near the fuel without decomposition or burning. The use of such material is believed to help maintain the simple "smoke" chemistry of the aerosol, as evidenced by the lack of Ames test activity which is described in greater detail hereinafter. While not preferred, other aerosol generating means, such as heat rupturable microcapsules, or solid aerosol forming substances, are within the scope of the invention, provided they are capable of releasing sufficient aerosol forming vapors to satisfactorily resemble tobacco smoke.

The thermally stable materials which may be used as the carrier or substrate for the aerosol forming substance are well known to those skilled in the art. Useful carriers should be porous or in particulate form, and must be capable of retaining an aerosol forming compound and releasing a potential aerosol forming vapor upon heating by the fuel. Useful thermally stable materials include thermally stable adsorbent carbons, such as electrode grade carbons, graphite, activate,, or non-activated carbons, and the like. Other suitable materials include inorganic solids such as ceramics, alumina, vermiculite, clays such as bentonite, glass beads, and the like. The currently preferred substrate materials are carbon felts, fibers, and mats, activated carbons, and porous carbons such as PC-25 and PG-60 available from Union Carbide.

The aerosol generating means used in the invention is usually no more than about 30 mm, preferably no more

than 20 mm from the lighting end **11** of the article. The aerosol generator is usually less than about 20 mm in length. The preferred length is between about 5 to 15 mm. If a non-particulate substrate is used, it may be provided with one or more holes, such as hole **32** in FIG. **2**, to increase the surface area of the substrate and to increase air flow and heat transfer into passageway **26**.

The aerosol forming substance or substances used in the invention must be capable of forming an aerosol at the temperatures present in the aerosol generating means. Such substances preferably will be composed of carbon, hydrogen and oxygen, but they may include other materials. The boiling point of the substance and/or the mixture of substances can range up to about 500° C. Substances having these characteristics include polyhydric alcohols, such as glycerin and propylene glycol, as well as aliphatic esters of mono-, di-, or poly-carboxylic acids, such as methyl stearate dimethyl dodecandioate, dimethyl tetradecandioate, and others.

Preferably, the aerosol forming substances will include a mixture of a high boiling, low vapor pressure substance and a low boiling, high vapor pressure substance. It is believed, on early puffs, the low boiling substance will provide most of the initial aerosol, while, when the temperature in the aerosol generator increases, the high boiling substance will provide most of the aerosol.

The preferred aerosol forming substances are polyhydric alcohols, or mixtures of polyhydric alcohols. A more preferred aerosol former is a mixture of glycerin and propylene glycol, which most preferably contains about 50 weight percent of each.

The aerosol forming substance may be dispersed on or within the carrier or substrate material, in a concentration sufficient to permeate or coat the material, by any known technique. For example, the aerosol forming substance may be applied full strength or in a dilute solution by dipping, spraying, vapor deposition, or similar techniques. Solid aerosol forming components may be admixed with the substrate material and distributed evenly throughout prior to formation of the final substrate.

While the loading of the aerosol forming substance will vary from carrier to carrier and from aerosol forming substance to aerosol forming substance, the amount of liquid aerosol forming substances may generally vary from about 20 mg to about 120 mg, preferably from about 35 mg to about 85 mg, and most preferably from about 45 mg to about 65 mg. As much as possible of the aerosol former carried on the substrate should be delivered to the user as WTPM. Preferably, above about 2 weight percent, more preferably above about 15 weight percent, and most preferably above about 20 weight percent of the aerosol former carried on the substrate is delivered to the user as WTPM.

The aerosol generating means also may include one or more volatile flavoring agents, such as menthol, vanillin, artificial coffee, tobacco extracts, nicotine, caffeine, liquors, and other agents which impart flavor to the aerosol. It also may include any other desirable volatile solid or liquid materials. Alternatively, these optional agents may be placed between the aerosol generator and the mouthend, such as in a separate substrate or chamber in passage **26** which connects the aerosol generator to the mouthend, or in the optional tobacco charge. If desired, these volatile agents may be used in lieu of part or all of the aerosol forming substance, so that the article delivers a nonaerosol flavor or other material to the user.

Articles of the type disclosed herein may be used or may be modified for use as drug delivery articles, for delivery of volatile pharmacologically or physiologically active materials such as ephedrine, metaproterenol, terbutaline or the like.

In most embodiments of the invention, the fuel and aerosol generator will be attached to a mouthend piece, such as foil lined tube **14**, although a mouthend piece may be provided separately, e.g., in the form of a cigarette holder. This element of the article provides the enclosure which channels the vaporized aerosol forming substance into the mouth of the user. Due to its length, preferably about 50 to 60 mm or more, it also keeps the hot fire cone away from the mouth and fingers of the user.

Suitable mouthpieces should be inert with respect to the aerosol forming substances, should have a water or liquid proof inner layer, should offer minimum aerosol loss by condensation or filtration, and should be capable of withstanding the temperature at the interface with the other elements of the article. Preferred mouthpieces include the foil lined tube of FIGS. **1-3** and the cellulose-acetate tube employed in the embodiment of FIG. **4**, as described hereinafter. Other suitable mouthpieces will be apparent to those of ordinary skill in the art.

The mouthend pieces of the invention may include an optional "filter" tip, which is used to give the article the appearance of the conventional filtered cigarette. Such filters include low density cellulose acetate filters and hollow or baffled plastic filters, such as those made of polypropylene. In addition, the entire length of article or any portion thereof may be overwrapped with cigarette paper.

The aerosol produced by the preferred articles of the present invention is chemically simple, consisting essentially of air, oxides of carbon, the aerosol which carries any desired flavorants or other desired volatile materials, water, and trace amounts of other materials. The wet total particulate matter (WTPM) produced by the preferred articles of this invention has no mutagenic activity as measured by the Ames test, i.e., there is no significant dose response relationship between the WTPM of the present invention and the number of revertants occurring in standard test microorganisms exposed to such products. According to the proponents of the Ames test, a significant dose dependent response indicates the presence of mutagenic materials in the products tested. See Ames et al., *Mut. Res.*, 31:347-364 (1975); Nagao et al., *Mut Res.*, 42:335 (1977).

A further benefit from the preferred embodiments of the present invention is the relative lack of ash produced during use in comparison to ash from a conventional cigarette. As the preferred carbon fuel source is burned, it is essentially converted to oxides of carbon, with relatively little ash generation, and thus there is no need to dispose of ashes while using the article.

The following embodiments include the current best modes of carrying out the invention as of the filing of this application, many of which are the result of efforts by our co-workers. However, these embodiments are described herein in order to disclose the best known modes for carrying out our invention.

The embodiment illustrated in FIG. **4** includes a fibrous carbon fuel element **10**, such as carbonized cotton or rayon. The fuel element includes a single axial hole

16. The substrate 38 of the aerosol generator is a granular, thermally stable carbon. A mass of tobacco 28 is located immediately behind the substrate. This article is provided with a cellulose acetate tube 40, in place of the foil lined tube. This tube 40 includes an annular section 42 of cellulose acetate tow surrounding an optional plastic, e.g., polypropylene tube 44. The mouthend 15 of this element includes a low efficiency cellulose acetate filter plug 45. The entire length of the article is wrapped in cigarette-type paper 46. A cork or white ink coating 48 may be used on the mouthend to simulate tipping. A foil strip 50 is located o the inside of the paper, toward the fuel end of the article. This strip preferably extends from the rear portion of the fuel element to the mouthend of the tobacco charge 28. It may be integral with the paper or it may be a separate piece applied before the paper overwrap.

The embodiment of FIG. 5 is similar to that of FIG. 4. In this embodiment, the aerosol generating means 12 is formed by an aluminum macrocapsule 52 which is filled with a granular substrate or, as shown in the drawing, a mixture of a granular substrate 54, and tobacco 56. The macrocapsule 52 is crimped in at its ends 58, 60 to enclose the material inside and to inhibit migration of the aerosol former. The crimped end 58, at the fuel end, preferably abuts the rear end of the fuel element to provide for conductive heat transfer. A void space 62 formed by end 58 also helps to inhibit migration of the aerosol former to the fuel. Holes 59 and 61 are provided to permit the passage o air and the aerosol forming substance. Macrocapsule 52 and fuel element 10 may be united by a conventional cigarette paper 47, as illustrated in the drawing, by a perforated ceramic paper, or a foil strip. If cigarette paper is used, a strip 64 near the rear end of the fuel should be printed or treated with sodium silicate or other known materials which cause the paper to extinguish. The entire length of the article is overwrapped with conventional cigarette paper 46.

FIG. 6 illustrates another embodiment having a pressed carbon fuel plug 10. In this embodiment, the fuel element has a tapered lighting end 11 for easier lighting and a tapered rear end 9 for easy fitting into a tubular foil wrapper 66. Abutting the rear end of the fuel element is an aluminum disc 68 with a center hole 70. A second, optional aluminum disc 72 with hole 74 is located at the mouthend of the aerosol generator 12. In between is a zone 76 of a particulate substrate and a zone 78 of tobacco. The foil wrapper 66 in which the fuel element is mounted extends back beyond the second aluminum disc 72. This embodiment also includes a hollow cellulose acetate rod 42 with an internal polypropylene tube 44, and a cellulose acetate filter plug 45. The entire length of the article is preferably wrapped with cigarette paper 46.

The embodiment shown in FIG. 7 illustrates the use of a substrate 80 embedded within a large cavity 82 in fuel element 10. In this embodiment, the fuel element preferably is formed from an extruded carbon, and the substrate 80 usually is a relatively rigid, porous material. The entire length of the article is wrapped with conventional cigarette paper 46. This embodiment may also include a foil strip 84 to couple fuel element 10 to the cellulose acetate tube 40 and to help extinguish the fuel.

The embodiments shown in FIGS. 8 and 9 include a nonburning fiber jacket 86 around fuel element 10 to insulate and concentrate the heat in the fuel element. These embodiments also help to reduce any fire causing potential of the burning fire cone.

In the embodiment shown in FIG. 8, both fuel element 10 and substrate 30 are located within an annular jacket or tube 86 of ceramic fibers, such as fiberglass.

Nonburning carbon or graphite fibers may be used in place of ceramic fibers. Fuel element 10 is preferably an extruded carbon plug having a hole 16. In the illustrated embodiment, the lighting end 11 extends slightly beyond the edge of jacket 86 for ease of lighting. Substrate 30 is a solid porous carbon material, although other types of substrates may be used. The substrate and the rear portion of the fuel element are surrounded by a piece of aluminum foil 87. As illustrated, this jacketed fuel/substrate unit is coupled to a mouthend piece, such as the elongated cellulose acetate tube 40 shown in the drawing, with an overwrap of conventional cigarette paper 46. The jacket 86 extends to the mouth end of substrate 30, but may replace cellulose acetate rod 42.

In the embodiment shown in FIG. 9, an aluminum macrocapsule 52 of the type shown in FIG. 5 is used to enclose a granular substrate 54 and tobacco 56. This macrocapsule is preferably positioned entirely within the ceramic fiber jacket 86. In addition, the lighting end 11 of fuel element 10 does not protrude beyond the forward end of fiber jacket 86. Preferably, the macrocapsule and the rear portion of the fuel element are surrounded by a piece of aluminum foil in a manner similar to that shown in FIG. 8.

Alternatively, the aluminum foil 52 which surrounds the substrate is not crimped at either end. In this embodiment, the rear end of the fuel element is inserted into one end of the foil and a polypropylene tube is inserted into the other end. The entire assembly is overwrapped with fiberglass to a diameter of a conventional cigarette.

The smoking article of the present invention will be further illustrated with reference to the following examples which aid in the understanding of the present invention, but which are not to be construed as limitations thereof. All percentages reported herein, unless otherwise specified, are percent by weight. All temperatures are expressed in degrees Celsius and are uncorrected. In all instances, the articles have a diameter of about 7 to 8 mm, the diameter of a conventional cigarette.

EXAMPLE 1

A smoking article was constructed in accordance with the embodiment of FIG. 1. The fuel element was a 25 mm long piece of blow pipe charcoal, with five 0.040 in. (1.02 mm) longitudinally extending holes made with a number 60 drill bit. The charcoal weighed 0.375 g. The fuel element was wrapped with conventional treated cigarette paper. The substrate was 500 mg of glass beads (0.64 in. [1.63 mm] average diameter) having two drops, approximately 50 mg, of glycerol coated on their surface. When packed into the tube, this substrate was about 6.5 mm long. The foil lined tube consisted of a 0.35 mil (0.0089 mm) layer of aluminum foil inside a 4.25 mil (0.108 mm) layer of white spirally wound paper. This tube surrounded the rear 5 mm of the fuel element. A short (8 mm) piece of cellulose acetate with four grooves around the periphery was used to hold the glass beads against the fuel source. An additional grooved cellulose acetate filter piece of 8 mm length was inserted into the mouthend of the tube to give the appearance of a conventional cigarette. The overall length of the article was about 70 mm.

Models of this type delivered considerable aerosol on the lighting puff, reduced amounts of aerosol on puffs 2

and 3, and good delivery of aerosol on puffs 4 through 9. Models of this type generally yielded about 5-7 mg of wet total particulate matter (WTPM), when machine smoked under standard FTC smoking conditions of a 35 ml puff volume, a two second puff duration, and a 60 second puff frequency.

EXAMPLE 2

A. Four smoking articles were constructed with 10 mm long pressed carbon fuel elements and glass bead substrates. The fuel elements were formed from 90% PCB-G and 10% SCMC, at about 5000 pounds (2273 kg) of applied load with the tapered lighting end illustrated in FIG. 2A. A single 0.040 in (1.02 mm) hole was formed down the center of each element. Three of the four fuel sources were wrapped with 8 mm wide strips of conventional cigarette paper. The fuel elements were inserted about 2 mm into 70 mm long sections of the foil lined tube described in Example 1. Glass beads, coated with the amount of glycerol indicated in the following table, were inserted into the open end of the foil lined tube and were held against the fuel element by 5 mm long foamed polypropylene filters having a series of longitudinally extending peripheral grooves. A 5 mm long low efficiency cellulose acetate filter piece was inserted into the mouthend of each article. These articles were machine smoked under standard FTC smoking conditions and the wet total particulate matter (WTPM) was collected on a series of Cambridge pads. The results of these experiments are reported in Table I.

TABLE I

	Glass Beads (wt)	Aerosol Former (wt)	WTPM (mg)/Puffs 1-3	4-6	7-9	10-12	Total
A	400.4 mg	40.5 mg	8.1	4.5	0.9	0	13.5
B*	405.6 mg	59.4 mg	10.2	1.9	0.7	0	12.8
C	404.0 mg	60.6 mg	7.6	6.9	0.4	0	14.9
D	803.8 mg	81.0 mg	5.9	2.5	3.7	0.9	13.0

*The fuel rod in this model was not wrapped with cigarette paper.

B. Three smoking articles similar to those described in Example 2A were constructed with 20 mm long blowpipe charcoal fuel elements of the type described in Example 1. These articles were machine smoked under standard FTC smoking conditions, and the WPPM was collected on a series of Cambridge pads. The results of these tests are reported in Table II.

TABLE II

	Glass Beads (wt)	Aerosol Former (wt)	WTPM (mg)/Puffs 1-3	4-6	7-9	10-12	Total
E	402.4 mg	60.6 mg	0.1	5.4	6.2	0.6	12.3
F*	404.7 mg	63.1 mg	0.5	0.9	2.2	3.1	7.0
G	500.0 mg	50.0 mg	0.3	2.9	3.0	0	6.2

*The fuel rod in this model was not wrapped with cigarette paper.

EXAMPLE 3

A. Four smoking articles were constructed as shown in FIG. 2 with a 10 mm pressed carbon fuel element having the tapered lighting end illustrated in FIG. 2A. The fuel element was made from 90% PCB-G carbon and 10% SCMC, at about 5000 pounds (2273 kg)of applied load. A 0.040 in. (1.02 mm) hole was drilled down the center of the element. The substrate for the aerosol former was cut and machined to shape from PC-25, a porous carbon sold by Union Carbide Corporation, Danbury, CT. The substrate in each article was about 2.5 mm long, and about 8 mm in diameter. It was loaded with an average of about 27 mg of a 1:1 propylene glycol-glycerol mixture. The foil lined tube mouthend piece, of the same type as used in Example 1, enclosed the rear 2 mm of the fuel element and the substrate. A plug of burley tobacco, about 100 mg was placed against the mouthend of the substrate. A short, about 5-9 mm, baffled polypropylene filter piece was placed in the mouthend of the foil lined tube. A 32 mm length of a cellulose acetate filter with a hollow polypropylene tube in the core was placed between the tobacco and the filter piece. The overall length of each article was about 78 mm.

B. Six additional articles were constructed substantially as in Example 3A, but the substrate length was increased to 5 mm, and a 0.040 in (1.02 mm) hole was drilled through the substrate. In addition, these articles did not have a cellulose acetate/polypropylene tube. About 42 mg of the propylene glycol-glycerol mixture was applied to the substrate. In addition, two plugs of burley tobacco, about 100-150 mg each, were used. The first was placed against the mouthend of the substrate, and the second one was placed against the filter piece.

C. Four additional articles were constructed substantially as in Example 3A, except that an approximately 100 mg plug of flue-cured tobacco containing about six percent by weight of diammonium monohydrogen phosphate was used in lieu of the plug of burley tobacco.

D. The smoking articles from Examples 3A-C were tested using the standard Ames Test. See Ames, et al., *Mut. Res.*, 31:347-364 (1975), as modified by Nagao et al., *Mut. Res.*, 42:335 (1977), and 113:173-215 (1983). The samples 3A and C were "smoked" on a conventional cigarette smoking machine using the conditions of a 35 ml puff volume, a two second puff duration, and a 30 second puff frequency, for ten puffs. The smoking articles of Example 3B were smoked in the same manner except that a 60 second puff frequency was used. Only one filter pad was used for each group of articles. This afforded the following wet total particulate matter (WTPM) for the indicated groups of articles:

	WTPM
Example 3A	63.4 mg
Example 3B	50.6 mg
Example 3C	69.2 mg

The filter pad for each of the above examples containing the collected WTPM was shaken for 30 minutes in DMSO to dissolve the WTPM. Each sample was then diluted to a concentration of 1 mg/ml and used "as is" in the Ames assay. Using the procedure of Nagao et al., *Mut. Res.*, 42:335-342 (1977), 1 mg/ml concentrations of WTPM were admixed with the S-9 activating system, plus the standard Ames bacterial cells, and incubated at 37° C. for twenty minutes. The bacterial strain used in this Ames assay was *Salmonella typhimurium*, TA 98. See Purchase et al., *Nature*, 264:624-627 (1976). Agar was then added to the mixture, and plates were prepared. The agar plates were incubated for two days at 37° C., and the resulting cultures were counted. Four plates were run for each dilution and the standard deviations of the colonies were compared against a pure DMSO control culture. As shown in Table III, there

was no mutagenic activity caused by the WTPM obtained from any of the smoking articles tested. This can be ascertained by comparison of the mean number of revertants per plate with the mean number of revertants obtained from the control (0 μg WTPM/Plate). For mutagenic samples, the mean number of revertants per plate will increase with increasing doses.

TABLE III

Dose (μg WTPM/Plate)	Mean Revertants/Plate	S.D.*
Example 3A		
Control 0	49.3	3.4
33	51.3	9.1
66	50.5	7.0
99	50.8	5.2
132	51.5	5.3
165	53.8	10.1
198	48.3	4.6
Example 3B		
Control 0	56	10.5
31.5	40	7.8
63	48.3	6.3
94.5	54.0	8.4
126	39	4.7
157.5	42.5	9.3
189	43	9.1
Example 3C		
Control 0	48.3	5.7
36	50.3	9.9
72	49.0	3.9
108	55.3	4.5
144	43.0	6.4
180	42.3	8.8
216	44.3	7.8

*Standard Deviation

EXAMPLE 4

Five smoking articles were constructed as shown in FIG. 2. Each article had a 10 mm pressed carbon fuel source as described in Example 3A. This fuel element was inserted 3 mm into one end of a 70 mm long aluminum foil lined tube of the type describe in Example 1. A 5 mm long carbon felt substrate, cut from rayon carbon felt sold by Fiber Materials, Inc., was butted against the fuel source. This substrate was loaded with an average of about 97 mg of a 1:1 mixture of glycerin and propylene glycol, about 3 mg of nicotine, and about 0.1 mg of a mixture of flavorants. A 5 mm long section of blended tobacco was butted against the mouthend of the substrate. A 5 mm long cellulose acetate filter piece was placed in the mouthend of the foil lined tube.

These articles were machine smoked under the standard FTC conditions. The aerosol from these articles was collected on a single Cambridge pad (133.3 mg WTPM), diluted in DMSO to a final concentration of 1 mg WTPM per ml and tested for Ames activity as described in Example 3D using each of the following strains: *Salmonella typhimurium* TA 1535, 1537, 1538, 98, and 100. As shown in Table IV there was no mutagenic activity caused by the WTPM collected from the articles tested.

TABLE IV

Dose*	Mean Revertants	Dose*	Mean Revertants
TA 1535		TA 1537	
Control 0	16	Control 0	14
25	13	25	13
50	14	50	14
75	17	75	11
100	14	100	13
125	13	125	13
150	12	150	14
TA 1538		TA 98	
Control 0	15	Control 0	61
25	13	25	62
50	22	50	47
75	16	75	42
100	20	100	44
125	19	125	39
150	19	150	40
TA 100			
Control 0	110		
25	109		
50	105		
75	99		
100	107		
125	108		
150	109		

*μg WTPM/Plate

EXAMPLE 5

A smoking article was built as shown in FIG. 2 with a 10 mm pressed carbon fuel plug having the configuration shown in FIG. 2A, but with no tobacco. The fuel element was made from a mixture of 90% PCB-G activated carbon and 10% SCMC as a binder at about 5000 pounds (2273 kg) of applied load. The fuel element was provided with a 0.040 in (1.02 mm) axial hole. The substrate was a 10 mm long porous carbon plug made from Union Carbide's PC-25. It was provided with a 0.029 in. (0.74 mm) drilled axial hole, and was loaded with 40 mg of a (1:1) mixture of propylene glycol and glycerol. The foil lined tube, as in Example 1, encircled the rear 2 mm of the fuel element and formed the mouthend piece. The article did not have a filter tip, but was overwrapped with conventional cigarette paper. The total length of the article was 80 mm.

The average peak temperatures for this article are shown for both "puff" and "smolder" in FIG. 10. As shown, the temperature declines steadily between the rear end of the fuel element and mouthend. This assures the user of no unpleasant burning sensation when using a product of this invention.

EXAMPLE 6

A smoking article was constructed in accordance with the embodiment of FIG. 3. The fuel element was a 19 mm long piece of blowpipe charcoal, with no holes. Embedded 15 mm into the fuel element was a $\frac{1}{8}$ in. (3.2 mm) diameter aluminum rod, 28 mm in length. Four 9 mm×0.025 in. (0.64 mm) peripheral grooves, spaced 90° apart were cut into the portion of the aluminum rod which pierced the substrate. The substrate was Union Carbide PC-25 carbon 8 mm in length. The grooves in the aluminum rod extended about 0.5 mm beyond the end of the substrate toward the fuel. The substrate was loaded with 150 mg of glycerol. The foil lined tube, which was the same as in Example 1, enclosed a portion of the rear of the fuel element. A gap was left between the non-burning end of the fuel element and the substrate. A series of holes were cut through the foil lined tube in this gap region to allow for air flow. A similar smoking article was constructed with a pressed carbon fuel plug.

EXAMPLE 7

A smoking article was constructed as shown in FIG. 4 with a fuel source of carbonized cotton fiber. Four slivers of cotton were tightly braided together with cotton string to form a rope with a diameter of about 0.4 in. (10.2 mm). This material was placed in a nitrogen atmosphere furnace which was heated to 950° C. It took about 1½ hours to reach that temperature, which was then held for ½ hour. A 16 mm piece was cut from this pyrolyzed material to be used as the fuel element. A 2 mm axial hole 16 was made through the element with a probe. The fuel element was inserted 2 mm into a 20 mm long foil lined tube of the type described in Example 1. 100 mg of Union Carbide PC-25, in granular form, containing 6 mg of a 1:1 propylene glycol-glycerol mixture, was inserted into the foil lined tube. A 5 mm long plug of tobacco, about 60 mg, was located immediately behind the granular substrate in the foil lined tube. A 48 mm long annular cellulose acetate tube with an internal 4.5 mm I.D. polypropylene tube was inserted about 3 mm into the foil lined tube. A second foil lined tube, 50 mm in length, has inserted over the cellulose acetate tube until it abutted against the 20 mm foil lined tube. A 5 mm long cellulose acetate filter plug was inserted into the end of this second foil lined tube. The overall length was 84 mm. When lit, this article produced substantial amounts of aerosol throughout the first six puffs with a tobacco flavor.

EXAMPLE 8

A smoking article was constructed as shown in FIG. 5 with a 15 mm long fibrous fuel element substantially as described in Example 7. The macrocapsule **52** was formed from a 15 mm long piece of 4 mil (0.10 mm) thick aluminum foil, which was crimped to form a 12 mm long capsule. This macrocapsule was loosely filled with 100 mg of granulated PG-60 carbon obtained from Union Carbide, and 50 mg of blended tobacco. The granular carbon was impregnated with 60 mg of a 1:1 mixture of propylene glycol and glycerol. The macrocapsule, the fuel element, and the mouthend piece were united by an 85 mm long piece of conventional cigarette paper.

EXAMPLE 9

A smoking article was constructed in accordance with the embodiment of FIG. 6 with a 7 mm long pressed carbon fuel element containing 90% PXC carbon and 10% SCMC. The center hole was 0.040 in. (1.02 mm) in diameter. This fuel plug was inserted into a 17 mm long aluminum foil lined tube so that 3 mm of the fuel element was inside the tube. An 8 mm diameter disc of 3.5 mil (0.089 mm) aluminum foil, with a 0.049 in. (1.24 mm) diameter center hole, was inserted into the other end of the tube and butted against the end of the fuel source.

Union Carbide PG-60 carbon was granulated and sieved to a particle size of −6 to +10 mesh. 80 mg of this material was used as the substrate, and 80 mg of a 1:1 mixture of glycerin and propylene glycol was loaded on this substrate. The impregnated granules were inserted into the foil tube and rested against the foil disk on the end of the fuel source. 50 mg of blended tobacco was loosely placed against the substrate granules. An additional foil disk with a 0.049 in. (1.24 mm) central hole was inserted into the foil tube on the mouthend of the tobacco. A long hollow cellulose acetate rod with a hollow polypropylene tube as described in Example 7 was inserted 3 mm into the foil lined tube. A second foil lined tube was inserted over the cellulose acetate rod against the end of the 17 mm foil lined tube.

This model delivered 11.0 mg of aerosol in the first three puffs when "smoked" under standard FTC smoking conditions. Total aerosol delivery for nine puffs was 24.9 mg.

EXAMPLE 10

A smoking article having the fuel element and substrate configuration of FIG. 7 was made using a 15 mm long annular pressed carbon fuel element with an inner diameter of about 4 mm and an outer diameter of about 8 mm. The fuel was made from 90% PCB-G activated carbon and 10% SCMC. The substrate was a 10 mm long piece formed of Union Carbide PC-25 carbon with an external diameter of about 4 mm. The substrate, loaded with 55 mg of a 1:1 glycerin/propylene glycol mixture, was inserted within the end of the fuel closer to the mouthend of the article. This fuel/substrate combination was inserted 7 mm into a 70 mm foil lined tube which had a short cellulose acetate filter at the mouthend. The length of the article was about 77 mm.

The article delivered substantial amounts of aerosol on the first three puffs, and over the useful life of the fuel element.

EXAMPLE 11

A modified version of the smoking article of FIG. 9 was made as follows: A 9.5 mm long carbon fuel source with a 4.5 mm diameter and a 1 mm diameter central hole was extruded from a mixture of 10% SCMC, 5% potassium carbonate, and 85% carbonized paper mixed with 10% water. The mixture had a dough-like consistency and was fed into an extruder. The extruded material was cut to length after drying at 80° C. overnight. The macrocapsule was made from a 22 mm long piece of 0.0089 mm thick aluminum formed into a cylinder of 4.5 mm I.D. The macrocapsule was filled with (a) 70 mg of vermiculite containing 50 mg of a 1:1 mixture of propylene glycol and glycerin, add (b) 30 mg of burley tobacco to which 6% glycerin and 6% propylene glycol had been added. The fuel source and macrocapsule were joined by inserting the fuel source about 2 mm into the end of the macrocapsule. A 35 mm long polypropylene tube of 4.5 mm I.D. was inserted in the other end of the macrocapsule. The fuel source, macrocapsule and polypropylene tube were thus joined to form a 65 mm long, 4.5 mm diameter segment. This segment was wrapped with several layers of Manniglas 1000 from Manning Paper Company until a circumference of 24.7 mm was reached. The unit was then combined with a 5 mm long cellulose acetate filter and wrapped with cigarette paper. When smoked under standard FTC smoking conditions, the article delivered 8 mg of WTPM over the initial three puffs; 7 mg WTPM over puffs 4–6; and 5 mg WTPM over puffs 7–9. Total aerosol delivery over the 9 puffs was 20 mg. When placed horizontally on a piece of tissue paper, the article did not ignite or eve scorch the tissue paper.

What is claimed is:

1. A cigarette-type smoking article comprising:

(a) a carbonaceous fuel element;

(b) a physically separate aerosol generating means including a volatile substance, the aerosol generating means being longitudinally adjacent to the fuel element; and

(c) a mouthend piece;
the fuel element and the aerosol generating means being arranged in a conductive heat exchange relationship by contact between the aerosol generating means and a part of the fuel element such that the aerosol generating means receives conductive heat transfer substantially throughout the time of burning of the fuel element.

2. A smoking article comprising:
(a) a carbonaceous fuel element;
(b) a physically separate aerosol generating means including a volatile substance; and
(c) a heat conducting member which contacts both the fuel element and the aerosol generating means;
the fuel element and the aerosol generating means being arranged in a conductive heat exchange relationship such that the aerosol generating means receives conductive heat transfer substantially throughout the time of burning of the fuel element.

3. A smoking article comprising:
(a) a carbonaceous fuel element;
(b) a physically separate aerosol generating means including a volatile substance; and
(c) heat conducting member which encompasses at least a portion of the fuel element;
the fuel element and the aerosol generating means being arranged in a conductive heat exchange relationship such that the aerosol generating means receives conductive heat transfer substantially throughout the time of burning of the fuel element.

4. The article of claim 2, wherein the heat conducting member encompasses at least a portion of the aerosol generating means.

5. A smoking article comprising:
(a) a carbonaceous fuel element;
(b) a physically separate aerosol generating means including a volatile substance; and
(c) a heat conducting member at least partially within the fuel element;
the fuel element and the aerosol generating means being arranged in a conductive heat exchange relationship such that the aerosol generating means receives conductive heat transfer substantially throughout the time of burning of the fuel element.

6. The article of claim 1 or 2, wherein the aerosol generating means comprises a heat stable substrate bearing a volatile substance.

7. The article of claim 7, wherein the heat conducting member comprises a conductive rod embedded within at least a portion of both the fuel element and the aerosol generating means.

8. A cigarette type article of claim 1, 2, 3, 5 or 7 wherein the fuel element is less than about 30 mm in length.

9. A cigarette type article of claim 1, 2, 3, 5 or 7 wherein the fuel element is less than about 15 mm in length.

10. The article of claim 6, wherein the substrate is loaded with from about 35 mg to 85 mg of volatile substance.

11. The article of claim 1 or 2, wherein above about 15 weight percent of the volatile substance carried by the substrate is delivered as wet total particulate matter under smoking conditions of 35 ml puffs of 2 seconds duration separated by 58 seconds of smolder.

12. The article of claim 1, 2, 3, 4, 5 or 7 charge of tobacco located between the mouth end of the fuel element and the mouth end of the article.

13. The article of claim 1 or 2, wherein the volatile substance includes at least one substance selected from the group of aerosol producing substances, flavor producing substances, pharmacologically active substances, and physiologically active substances.

14. The article of claim 1 or 2, wherein the smoke produced consists essentially of the oxides of carbon, air, water, the volatile substance, other desired volatiles and trace amounts of other materials.

15. The article of claim 2, 3, 4, 5, or 7 wherein the fuel element is substantially free of volatile organic material.

16. A cigarette-type smoking article comprising:
(a) a carbonaceous fuel element less than about 30 mm in length prior to smoking;
(b) a physically separate aerosol generating means including a volatile substance; and
(c) means for delivering the volatile substance to the user.

17. The article of claim 16, further comprising a heat conducting member for conducting heat from the fuel element to the aerosol generating means.

18. The article of claim 17, wherein the heat conducting member encompasses at least a portion of the fuel element.

19. The article of claim 17, wherein the heat conducting member encompasses at least a portion of both the fuel element and the aerosol generating means.

20. The article of claim 17 wherein the heat conducting member is at least partially embedded within the fuel element.

21. The article of claim 16 or 17, wherein the volatile substance includes at least one substance selected from the group of aerosol producing substances, flavor producing substances, pharmacologically active substances and physiologically active substances.

22. The article of claim 16, 17, or 18 wherein the portion of the volatile substance closest to the fuel element is less than about 30 mm from the lighting end of the fuel element.

23. The article of claim 16, 17, 18 or 20 wherein the fuel element is less than 20 mm in length.

24. The article of claim 16, 17, 18 19 or 20 wherein the fuel element is less than 15 mm in length.

25. A cigarette-type article comprising:
(a) a carbonaceous fuel element less than 30 mm in length;
(b) a mouthend piece;
(c) a carrier between the non-lighting end of the fuel element and the mouthend piece bearing an aerosol forming substance;
(d) a heat conducting member for conducting heat from the fuel element to the carrier; and
(e) a passageway for delivering the aerosol forming substance to the mouthend piece.

26. The article of claim 25, wherein the heat conducting member encompasses at least a portion of the fuel element.

27. The article of claim 25, wherein the heat conducting member encompasses at least a portion of both the fuel element and the carrier.

28. The article of claim 25, 26, 27, wherein the fuel element is less than 15 mm in length.

29. The article of claim 25, 26, 27, wherein the portion of the carrier closest to the fuel element is less than 20 mm from the lighting end of the fuel element.

30. A disposable cartridge smoking article for use with a separate mouthpiece comprising:

(a) a carbonaceouos fuel element less than about 30 mm in length prior to smoking;

(b) a physically separate carrier adjacent to the fuel element including at least one substance selected from the group consisting of aerosol producing substances, flavor producing substances, pharmacologically active substances, and physiologically active substances; and

(c) means for coupling the carrier to the fuel element.

31. The article of claim **30** further comprising a heat conducting member which contacts the fuel element and the carrier.

32. The article of claim **30**, further comprising a heat conducting member which comprises a metallic member which circumscribes a portion of the external longitudinal periphery of the fuel element and at least a portion of the external longitudinal peripheral of the carrier.

33. The article of claim **30**, further comprising a heat conducting member at least partially within the fuel element.

34. The article of claim **31**, further comprising a mass of tobacco.

35. The article of claim **30, 32** or **34** wherein the fuel element is less than about 15 mm in length.

36. The article of claim **1, 2, 17, 25, 26, 27, 30** or **31**, wherein the volatile substance is an aerosol forming substance and the article delivers at least about 0.6 mg of wet total particulate matter in the first three puffs under smoking conditions of 35 ml puff of 2 seconds duration separated by 58 seconds of smolder.

37. The article of claim **1, 2, 16, 17, 25, 26, 27, 30** or **31**, wherein the volatile substance is an aerosol forming substance and the article delivers at lest about 1.5 mg of wet total particulate matter in the first three puffs under smoking conditions of 35 ml puffs of 2 seconds duration separated by 58 seconds of smolder.

38. The article of claim **1, 2, 16, 17, 25, 26, 27, 30** or **31**, where in the volatile substance is an aerosol forming substance and the article delivers an average of at least about 0.8 mg per puff of wet total particulate matter under smoking conditions of 35 ml puffs of 2 seconds duration separated by 58 seconds of smolder.

39. The article of claim **1, 2, 16, 17, 25, 26, 27, 30** or **31**, having no mutagenic activity in the wet total particulate matter, a measured by the Ames Test.

40. The article of claim **1, 2, 16, 17 25, 26, 27, 30, 31, 32** or **33**, wherein the fuel element produces substantially no visible sidestream smoke during smolder.

41. The smoking article of claim **1, 2, 3, 4, 5, 7, 16, 17, 18, 25, 26, 27, 31, 32** or **33**, wherein the fuel element is about 10 mm or less in length.

42. The smoking article of claim **16, 17, 18, 25, 26, 30, 31** or **32**, wherein the fuel element is substantially free to volatile organic material.

43. A smoking article comprising:

(a) a carbonaceous fuel element;

(b) a physically separate aerosol generating means spaced from the lighting end of the fuel element, which means includes a volatile substance; and

(c) a heat conducting member spaced from the lighting end of the fuel element which conducts heat from the fuel element to the aerosol generating means.

44. A smoking article comprising:

(a) a carbonaeous fuel element less than about 30 mm in length; generating means

(b) a physically separate aerosol spaced from the lighting end of the fuel element which means includes a volatile substance;

(c) a heat conducting member for conducting heat from the fuel element to the aerosol generating means, the member being spaced from the lighting end of the fuel element; and

(d) means for delivering the volatile substance to the user.

45. The article of claim **44**, wherein the fuel element is less than 15 mm in length and the heat conducting member encompasses a portion of the fuel element and at least a portion of the aerosol generating means.

46. The article of claim **44** or **45** wherein the fuel element is substantially free of volatile organic material.

47. The article of claim **44** or **45**, wherein the portion of the volatile material closest to the fuel element is less than about 20 mm form the lighting end of the fuel element.

48. A smoking article comprising:

(a) a carbonaceous fuel element less than 30 mm in length;

(b) a mouthend pieces;

(c) a carrier between the non-lightning end of the fuel element and the mouthend piece bearing an aerosol forming substance;

(d) a heat conducting member spaced from the lighting end of the fuel element for conducting heat from the fuel element to the carrier; and

(e) a passageway for delivering the aerosol forming substance to the mouthend piece.

49. The article of claim **48**, wherein the fuel element is less than 15 mm in length and the heat conducting member encompasses a portion of the fuel element and at least a portion of the carrier.

50. The article of claim **48** or **49**, wherein the heat conducting member is metallic.

51. The article of claim **48** or **49**, wherein the portion of the carrier closes to the fuel element is less than 20 mm from the lighting end of the fuel element.

52. The article of claim **48** or **49** further comprising a mass of tobacco between the non-lighting end of the fuel element and the mouth end of the article.

53. The article of claim **52**, wherein the fuel element is substantially free of volatile organic material.

54. A disposable cartridge smoking article for use with a separate mouthend piece comprising:

(a) a carbonaceous fuel element less than about 30 mm in length;

(b) a physically separate carrier adjacent to the fuel element, including at least one substance selected from the group consisting of aerosol producing substances, flavor producing substances, pharmacologically active substances, and physiologically active substances; and

(c) a heat conducting member which couples the carrier to the fuel element, said member being spaced from the lighting end of the fuel element.

55. The smoking article of claim **34**, wherein the article delivers an average of at least about 0.8 mg per puff of wet total particulate matter for at least 7 puffs.

56. The article of claim **30, 31, 32, 54**, wherein the article has a diameter of about 8 mm or less.

57. The article of claim **43**, wherein the heat conductive member contacts both the fuel element and the aerosol generating means.

58. The article of claim **1, 2, 3, 4** or **5**, which has the size and shape of a cigarette.

59. The article of claim **58**, wherein the heat conductive member is a metallic member.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 4,793,365

DATED : 12/27/88

INVENTOR(S) : Andrew J. Sensabaugh, Jr., et al.

It is certified that error appears in the above—identified patent and that said Letters Patent is hereby corrected as shown below:

At number [56] on the cover sheet, under U.S. Patent Documents, insert the following:

235,885	12/1880	Lindsley	3,586,005	6/1971	Lippman
346,025	7/1886	Cook	3,608,560	9/1971	Briskin
492,676	2/1883	Harris	3,614,956	10/1971	Thornton
1,437,956	12/1922	Blair	3,667,478	6/1972	Waterbury
1,605,059	11/1926	Oakes	3,738,374	6/1973	Bennett
1,952,352	3/1934	Banks	3,831,609	8/1974	Briskin
2,108,860	2/1938	Kaufman	3,834,398	9/1974	Briskin
2,178,820	11/1938	Todoroff	3,861,401	1/1975	Briskin
2,349,551	5/1944	Helm	3,861,402	1/1975	Briskin
2,907,686	10/1959	Siegel	3,880,172	4/1975	Anderson
2,976,190	3/1961	Meyers	3,885,574	5/1975	Borthwick
3,081,777	3/1963	Sipos	3,894,543	7/1975	Anderson
3,106,210	10/1963	Reynolds	3,916,914	11/1975	Brooks
3,144,024	8/1964	Eichwald	3,931,824	1/1976	Miano
3,200,819	8/1965	Gilbert	3,943,941	3/1976	Boyd
3,236,244	2/1966	Irby	3,943,942	3/1976	Anderson
3,258,015	6/1966	Ellis	3,972,335	8/1976	Tigglebeck
3,280,823	10/1966	Bauley	4,008,723	2/1977	Borthwick
3,288,146	11/1966	Bauley	4,014,349	3/1977	Mormon
3,297,476	10/1966	Noznick	4,019,520	4/1977	Strubel
3,339,558	9/1967	Waterbury	4,019,521	3/1977	Briskin
3,356,094	12/1967	Ellis	4,044,777	8/1977	Boyd
3,424,171	1/1969	Rooker	4,055,191	10/1977	Norman
3,498,299	3/1970	White	4,079,742	3/1978	Rainer
3,516,417	6/1970	Moses	4,123,592	10/1978	Rainer
3,525,582	8/1970	Waterbury	4,133,317	1/1979	Briskin
3,529,602	9/1970	Hind	4,186,756	1/1980	Takemoto
3,545,448	12/1970	Mormon	4,195,645	4/1980	Bradley
3,584,630	6/1971	Inskeep	4,216,784	8/1980	Norman

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 4,793,365

DATED : 12/27/88

INVENTOR(S) : Andrew J. Sensabaugh, Jr., et al.

It is certified that error appears in the above—identified patent and that said Letters Patent is hereby corrected as shown below:

4,219,031	8/1980	Rainer
4,219,032	8/1980	Tabatznik et al.
4,284,089	8/1981	Ray
4,286,604	9/1981	Ehretsman
4,289,149	9/1981	Kyriakou
4,326,544	4/1982	Hardwick
4,340,072	7/1982	Bolt
4,347,855	9/1982	Lanzillotti
4,391,285	7/1983	Burnett
4,596,258	5/1984	Steiner

Reference "0,117,355 9/1984 Hearn" should be DELETED.

At number [56] on the cover sheet, under Foreign Patent Documents, insert the following:

276,250	2/1968	Australia	ADD -- 0,117,355 9/1984 EPO --
074,201	3/1983	EPO	
117,355	9/1984	EPO	
370,962	2/1907	France	
998,556	9/1951	France	
1,264,962	8/1960	France	
2,033,749	11/1970	France	
1,692,936	1/1972	Germany	
2,704,218	2/1977	Germany	
582,489	10/1976	Switzerland	
1,185,887	3/1970	United Kingdom	
1,431,045	4/1973	United Kingdom	
1,597,105	9/1981	United Kingdom	
1,597,106	9/1981	United Kingdom	

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 4,793,365

DATED : 12/27/88

INVENTOR(S) : Andrew J. Sensabaugh, Jr., et al.

It is certified that error appears in the above—identified patent and that said Letters Patent is hereby corrected as shown below:

At number [56], on the cover sheet, under Other Publications, insert the following:

Ames et al., Mutation Research, 31:347 - 364 (1975)

Gilbert, Herbert A., "Smokeless Cigarette" - Materials submitted to the Senate Committee on Commerce

Guiness Book of World Records, Pgs. 242 - 243 (1985 edition)

Guiness Book of World Records, Pg. 194 (1966 edition)

Kiefer et al., "Factors that Affect Elution of Plasticizer from Cigarette Filters," Eastman Kodak Pub. No. FTR-65.

Lyerly, "Direct Vapor Chromatographic Determination of *** Triacetin in Cigarette Smoke," Tob. Sci. 50:26 (1967)

Miller, K. "Now A 'Smokeless Cigaret ," Beaver County Times, July 1967

Nagao et al., Mutation Research, 42:335 - 342 (1977)

Maron et al., Mutation Research, 113:173 (1983)

Reynolds, M.L., "Influence of Filter Additives on Smoke Composition," Rec. Adv. Tob. Sci., 4:47 (1978)

Sittig, Tobacco Substitutes, Noyes Data Corporation - 1976, Chemical Technology Review No. 67

Hagg,C., General Inorganic Chemistry, pg. 592 (John Wiley & Sons 1969)

Purchase et al., Nature, 264:624-627 (1976)

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 4,793,365

DATED : 12/27/88

INVENTOR(S) : Andrew J. Sensabaugh, Jr., et al.

It is certified that error appears in the above—identified patent and that said Letters Patent is hereby corrected as shown below:

At Abstract, line 26, change "relationshp" to --relationship--.

At Column 1, line 61, change "end" to --tend--.

At Column 2, line 50, change "Tee" to --The--.

At Column 6, line 19, change "ma" to --may--.

At Column 7, line 9, change "fill" to --foil--.

At Column 10, line 59 change "activate,," to --activated,--.

At Column 13, line 12, change "o" to --on--.

At Column 13, line 30, change "o" to --of--.

At Column 15, line 12, insert --carbon-- after PCB-G.

At Column 18, Table IV, TA 98 move column of numbers --62,47,42,44,39,40-- to the right under the heading Mean Revertants column.

At Column 21, line 47, change "7" to --5--.

At Column 21, line 51, insert --4-- after 3,.

At Column 21, line 53, insert --prior to smoking-- after length.

At Column 21, line 54, insert --4-- after 3,.

At Column 21, line 56, insert --prior to smoking -- after length.

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 4,793,365

DATED : 12/27/88

INVENTOR(S) : Andrew J. Sensabaugh, Jr., et al.

It is certified that error appears in the above—identified patent and that said Letters Patent is hereby corrected as shown below:

At Column 21, line 65, insert -- further comprising a-- after 7,.

At Column 22, line 14, insert --located at the lighting end of the article-- after smoking.

At Column 22, line 40, insert --19-- after 18.

At Column 22, line 46, insert --prior to smoking-- after length.

At Column 23, line 2, insert --located at the lighting end of the article-- after smoking.

At Column 23, line 17, change "peripheral" to --periphery--.

At Column 23, line 26, delete "or".

At Column 23, line 26, insert --16-- after 2,.

At Column 23, line 26, insert --43,44,48 or 54-- after 31,.

At Column 23, line 32, delete "or".

At Column 23, line 33, insert --43,44,48 or 54-- after 31,.

At Column 23, line 34, change "lest" to --least--.

At Column 23, line 38, delete "or".

At Column 23, line 39, insert --43,44,48 or 54-- after 31,.

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 4,793,365

DATED : 12/27/88

INVENTOR(S) : Andrew J. Sensabaugh, Jr., et al.

It is certified that error appears in the above—identified patent and that said Letters Patent is hereby corrected as shown below:

At Column 23, line 44, delete "or".

At Column 23, line 45, insert --43,44,48 or 54-- after 31,.

At Column 23, line 46, change "a" to --as--.

At Column 23, line 48, delete "or".

At Column 23, line 48, insert --43,44,48 or 54-- after 31,.

At Column 23, line 67, change "lengthy generating means" to --length--.

At Column 23, line 67, insert --prior to smoking-- after length.

At Column 24, line 1, insert --generating means-- after aerosol.

At Column 24, line 18, change "form" to --from--.

At Column 24, line 22, insert --prior to smoking-- after length.

At Column 24, line 39, change "closes" to --closest--.

At Column 24, line 49, insert --prior to smoking-- after length.

At Column 24, line 59, change "34" to --38--.

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 4,793,365

DATED : 12/27/88

INVENTOR(S) : Andrew J. Sensabaugh, Jr., et al

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

At column 18, Table IV, TA 98 move column of numbers --25,50,75,100,125, 150-- to the right, below the numeral "0".

Signed and Sealed this

Sixth Day of April, 1993

Attest:

STEPHEN G. KUNIN

Attesting Officer

Acting Commissioner of Patents and Trademarks

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/IE2006/000006

International filing date: 02 February 2006 (02.02.2006)

Document type: Certified copy of priority document

Document details: Country/Office: IE
Number: S2005/0051
Filing date: 02 February 2005 (02.02.2005)

Date of receipt at the International Bureau: 22 February 2006 (22.02.2006)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse

Patents Office
Government Buildings
Hebron Road
Kilkenny

I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

Application No.	S2005/0051
Date of Filing	2 February 2005
Applicant	OGLESBY & BUTLER RESEARCH & DEVELOPMENT LIMITED, an Irish company of Industrial Estate, Dublin Road, Carlow, Ireland.

Dated this 9 day of February 2006.

An officer authorised by the
Controller of Patents, Designs and Trademarks.

S050051

FORM NO. 1

REQUEST FOR THE GRANT OF A PATENT

PATENTS ACT, 1992

The Applicant(s) named herein hereby request(s)

☐ the grant of a patent under Part II of the Act

☒ the grant of a short-term patent under Part III of the Act

on the basis of the information furnished hereunder.

1. Applicant(s)

Name

OGLESBY & BUTLER RESEARCH
& DEVELOPMENT LIMITED

Address

Industrial Estate, Dublin Road, Carlow, Ireland.

Description/Nationality

An Irish company.

2. Title of Invention

"Apparatus for vaporising vaporisable matter"

3. Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)

Previous filing date	Country in or for which filed	Filing No.

4. Identification of Inventor(s)

Name(s) of person(s) believed
by Applicant(s) to be the inventor(s)
ALFRED PETER OGLESBY and JOHN PAUL OGLESBY

Address
A British subject of Castle Hill, Carlingford, County Louth, Ireland; and
A British subject of Anneville, Shrule, Carlow, Ireland.

5. **Statement of right to be granted a patent (Section 17 (2) (b))**
The applicant has derived the right to be granted a Patent from the inventors by virtue of a Deed of Assignment dated February 1, 2005.

6. **Items accompanying this request – tick as appropriate**

(i) [X] Prescribed filing fee (€60.00)

(ii) [ ] Specification containing a description and claims

[X] Specification containing a description only

[X] Drawings referred to in description or claims

(iii) [ ] An abstract

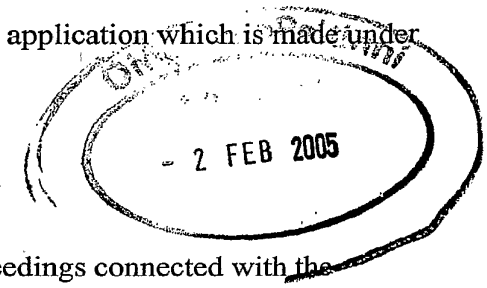
(iv) [ ] Copy of previous application(s) whose priority is claimed

(v) [ ] Translation of previous application whose priority is claimed

(vi) [ ] Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant(s))

7. **Divisional Application(s)**
The following information is applicable to the present application which is made under Section 24 –

Earlier Application No: .....
Filing Date: .....



8. **Agent**
The following is authorised to act as agent in all proceedings connected with the obtaining of a patent to which this request relates and in relation to any patent granted –

Name	Address
F.F. GORMAN & CO.	15 Clanwilliam Square, Dublin 2, Ireland.

9. **Address for Service (if different from that at 8)**
F.F. GORMAN & CO., at its address as recorded for the time being in the Register of Patent Agents.

Signed F.F. GORMAN & CO., Authorised Patent Agents

BY: _____ EXECUTIVE

Date February 2, 2005

S050051

TRUE COPY
AS
LODGED

"Apparatus for vaporising vaporisable matter"

The present invention relates to apparatus for vaporising vaporisable matter for facilitating inhaling of the vaporised matter. For example, the apparatus is suitable for vaporising vaporisable matter which comprises one or more of flavour components, medicinal components and psychoactive components, such as tobacco, mullein, passion flower, cloves, yohimbe, mint, tea, eucalyptus, camomile, cannabis and other such herbs and plant matter. The invention also relates to a device for providing a hot gaseous fluid for delivering to the vaporisable material for vaporising thereof.

Herbs, for example, tobacco, cannabis and the like are smoked by burning, in order to release psychoactive compounds, which are then inhaled. The psychoactive compounds are released into the fumes of combustion, which are then inhaled. However, burning of such herbs as well as producing psychoactive compounds also produces toxins, which largely result from the actual combustion process. Such toxins are known to be carcinogenic, and also can result in lung and heart disease. Thus, the smoking of such herbs and other such plant matter is hazardous and undesirable. An alternative to releasing flavour, medicinal and psychoactive compounds from such herbs and plant matter by smoking is to raise the temperature of the herb to an appropriate temperature for causing the vaporisable constituent or constituents to be vaporised, and then inhale the vaporised constituent or constituents. However, the temperature range at which such compounds can be vaporised in herbs and plant matter ranges from approximately 130°C to 250°C. If

the temperature is below 150°C, in general, vaporisation does not occur. However, if the temperature to which the herb or plant matter is heated exceeds 300°C, combustion of the herb or plant matter may commence. Thus, in order to satisfactorily vaporise flavour, medicinal and psychoactive constituents in herbs and plant matter, the temperature at which the herb or plant matter is maintained for producing the vaporised compounds must be controlled within reasonably tight tolerances.

It is known to provide apparatus for vaporising desirable constituents from herbs by electrically heating the herb. However, due to the energy requirements of such apparatus, a mains electricity supply is required to power the apparatus, and thereby the apparatus is not portable when in use. This thus renders a person immobile when using such apparatus. An alternative device for vaporising vaporisable constituents in herbs and plant matter is disclosed in U.S. published Patent Application Specification No. 2004/0031495 of Steinberg. Steinberg discloses a pipe which is substantially similar to a smoking pipe in which the herb, typically, tobacco to be vaporised is located in a bowl portion of the pipe. A heat resistant and porous flame filter is located in the bowl above the herb, and a flame from a match or cigarette lighter is used to heat the porous filter while air is being drawn through the pipe. Thus, a mixture of air and the products of combustion from the flame are mixed in the porous filter and drawn through the herb in the bowl for heating the herb for in turn vaporising desirable constituents in the herb. The mixture of air, the products of combustion and the vaporised constituent are then drawn through a mouthpiece of the pipe and inhaled. However, due to the fact that the flame is

played on the heat resistant porous flame filter, there is a danger of the flame being drawn through the filter and thus causing combustion of the herb in the bowl of the pipe. However, even where the herb does not combust, the products of combustion of the flame are inhaled along with the vaporised constituent. This is undesirable.

There is therefore a need for apparatus for vaporising vaporisable matter which overcomes this problem, and there is also a need for a device for providing a hot gaseous fluid for use in the vaporisation of vaporisable matter.

The present invention is directed towards providing such an apparatus and device.

According to the invention there is provided a device for providing a hot gaseous fluid for delivery to a vaporisation chamber containing vaporisable matter for vaporising thereof, the device comprising a combustion chamber within which fuel gas is converted to heat, a heat exchanger co-operating with the combustion chamber for transferring heat from the combustion chamber to a gaseous fluid for heating thereof, a fuel gas supply means for supplying fuel gas to the combustion chamber for conversion to heat therein, and a coupling means for coupling the heat exchanger to the vaporisation chamber for delivering the hot gaseous fluid thereto for vaporising the vaporisable matter.

In one embodiment of the invention a gaseous fluid accommodating means is provided for accommodating the gaseous fluid through the heat exchanger for heating thereof.

In another embodiment of the invention the gaseous fluid accommodating means comprises a gaseous fluid passageway extending through the heat exchanger, the gaseous fluid passageway extending between an upstream fluid inlet for receiving gaseous fluid into the gaseous fluid passageway, and a downstream fluid outlet through which the hot gaseous fluid is delivered.

In another embodiment of the invention the coupling means comprises an engagement means for engaging the vaporisation chamber, and preferably, the engagement means extends from the heat exchanger.

In one embodiment of the invention the gaseous fluid outlet is located in the engagement means for delivering the gaseous fluid directly into the vaporisation chamber.

In another embodiment of the invention an exhaust gas port is provided from the combustion chamber for exhausting exhaust gases therefrom.

Preferably, an exhaust gas passageway extends through the heat exchanger from the exhaust gas port, and terminates in an exhaust gas outlet from which exhaust gases are discharged, the exhaust gas passageway being separated from the gaseous fluid for preventing mixing of the exhaust gas with the gaseous fluid.

Advantageously, the exhaust gas passageway and the gaseous fluid passageway

are located adjacent each other, and preferably, are located for facilitating contra-flow between the exhaust gas in the exhaust gas passageway and the gaseous fluid in the gaseous fluid passageway.

Preferably, a gas catalytic combustion element is located in the combustion chamber for converting fuel gas to heat by catalytic reaction.

In one embodiment of the invention a flame ignition chamber is located adjacent the combustion chamber for facilitating initial flame ignition of the fuel gas for in turn raising the temperature of the gas catalytic combustion element to its ignition temperature, and ideally, the flame ignition chamber is located adjacent the combustion chamber so that as the gas catalytic combustion element is raised to its ignition temperature by the flame ignition, the flame is starved of fuel gas and is extinguished.

Ideally, an ignition means is provided for igniting the fuel gas to initially burn with a flame, and preferably, the ignition means comprises at least one electrode for generating a spark for igniting the fuel gas to burn with a flame in the flame ignition chamber.

Preferably, the exhaust gas port extends from the flame ignition chamber.

In one embodiment of the invention the combustion chamber is located within the heat exchanger, and preferably, the flame ignition chamber is located within the heat

exchanger.

In one embodiment of the invention an inspection port is provided through the heat exchanger to the flame ignition chamber for facilitating inspection of the flame ignition chamber, and advantageously, the inspection port extends through the heat exchanger to the combustion chamber for facilitating inspection of the gas catalytic combustion element.

In another embodiment of the invention a thermal mass is located in the combustion chamber associated with the catalytic combustion element for temporarily maintaining at least a portion of the gas catalytic combustion element at or above its ignition temperature during temporary disruptions of fuel gas to the combustion chamber.

In another embodiment of the invention a thermostatically responsive valve is provided for controlling the flow of fuel gas to the combustion chamber, and preferably, the thermostatically responsive valve is in direct or indirect heat conducting engagement with the heat exchanger. Advantageously, the thermostatically responsive valve defines a valving chamber, and a bi-metal disc located in the valving chamber, the bi-metal disc co-operating with one of a valve inlet and a valve outlet to the valving chamber for controlling the flow of fuel gas through the valving chamber in response to temperature. Ideally, the bi-metal disc is of the type which transitions from one state to another state, which are mirror images of each other, as the temperature of the disc exceeds a predetermined transition

temperature, and the disc is constrained within the valving chamber to prevent transitioning of the disc from one of said states to the other.

In one embodiment of the invention the thermostatically responsive valve is suitable for controlling the temperature of the heat exchanger so that the temperature of the gaseous fluid being delivered from the device is at a temperature which lies in the range of 100°C to 500°C.

In another embodiment of the invention the thermostatically responsive valve is suitable for controlling the temperature of the heat exchanger so that the temperature of the gaseous fluid being delivered from the device is at a temperature which lies in the range of 125°C to 400°C.

In a further embodiment of the invention the thermostatically responsive valve is suitable for controlling the temperature of the heat exchanger so that the temperature of the gaseous fluid being delivered from the device is at a temperature which lies in the range of 130°C to 300°C.

In a still further embodiment of the invention the thermostatically responsive valve is suitable for controlling the temperature of the heat exchanger so that the temperature of the gaseous fluid being delivered from the device is at a temperature which lies in the range of 150°C to 250°C.

In another embodiment of the invention a temperature responsive fuel gas cut-out

means is provided for isolating the combustion chamber from a fuel gas supply in the event of the temperature of the heat exchanger exceeding a predetermined safe maximum temperature. Preferably, the fuel gas cut-out means comprises a temperature sensitive member located in a fuel gas passageway through which fuel gas is delivered to the combustion chamber, the temperature sensitive member having a melt temperature which is a function of the predetermined safe maximum temperature, so that when the temperature of the heat exchanger reaches the predetermined safe temperature, the temperature sensitive member melts, thus blocking the fuel gas passageway. Ideally, the temperature sensitive member is located adjacent a porous filter so that on melting of the temperature sensitive member the melting material of the temperature sensitive member blocks the porous filter.

In one embodiment of the invention the heat exchanger comprises an inner body member within which the combustion chamber is formed. An intermediate body member extending around the inner body member, and an outer body member extending around the intermediate body member, so that the intermediate body member is sandwiched between the inner and outer body members.

Preferably, one of the gaseous fluid and exhaust gas passageways is formed between the inner body member and the intermediate body member, and the other of the gaseous fluid and exhaust gas passageways is formed between the intermediate body member and the outer body member.

Preferably, the body member formed between the inner body member and the intermediate body member extend around the inner body member, and advantageously, the passageway formed between the outer body member and the intermediate body member extends around the intermediate body member.

In one embodiment of the invention each passageway is of helical shape. Alternatively, each passageway is formed by a plurality of annular chambers extending around the heat exchanger, with adjacent annular chambers communicating through at least one communicating groove extending from one annular chamber to its next adjacent annular chamber, and preferably, the communicating grooves communicating adjacent annular chambers are staggered from annular chamber to annular chamber.

In one embodiment of the invention one or more heat exchange fins extends from the inner body member and sealably engage the intermediate body member for forming the annular chambers between the inner body member and the intermediate body member.

In another embodiment of the invention one or more heat exchange finds extends from the intermediate body member and sealably engages the outer body member for forming the passageway formed between the outer body member and the intermediate body member.

Ideally, the exhaust gas passageway is formed between the outer body member and

the intermediate body member, and the gaseous fluid passageway is formed between the inner body member and the intermediate body member.

Ideally, the inner body member, the intermediate body member and the outer body member are of cylindrical construction, and each defines a central geometrical axis, and preferably, the central geometrical axes of the respective inner, intermediate and outer body members coincide. Ideally, the combustion chamber defines a central geometrical axis which coincides with the central geometrical axis defined by the inner, intermediate and outer body members.

Ideally, the intermediate body member terminates in the engagement means for engaging the vaporisation chamber.

In one embodiment of the invention a fuel gas reservoir is provided for supplying fuel gas to the fuel gas supply means, and preferably, the fuel gas reservoir is coupled to the housing.

Ideally, the fuel gas supply means comprises a control means for controlling the supply of fuel gas from the fuel gas reservoir to the combustion chamber, and preferably, the fuel gas supply means comprises a mixing means for mixing the fuel gas with air for delivery to the combustion chamber.

Ideally, the device is adapted for heating the gaseous fluid when the gaseous fluid is air.

The invention also provides apparatus for vaporising vaporisable matter, the apparatus comprising a holder having a vaporisation chamber therein, for holding the vaporisable material, and the device according to the invention for providing a hot gaseous fluid to the vaporisation chamber, the holder comprising a receiving means for receiving the coupling means of the device for coupling the device to the holder for providing the hot gaseous fluid to the vaporisation chamber, so that the hot gaseous fluid is delivered to the vaporisation chamber for heating the vaporisable material therein to a temperature for vaporising thereof.

In one embodiment of the invention a vapour outlet is provided from the vaporisation chamber for accommodating the vapour of the vaporisable matter therefrom.

Preferably, the holder forms a mouthpiece communicating with the vaporisation chamber for facilitating drawing of the vapour of the vaporisable material from the vaporisation chamber.

Advantageously, the vaporisation chamber defines a central geometrical axis, which coincides with the longitudinal axis of the device for providing the hot gaseous fluid.

In one embodiment of the invention the mouthpiece defines a longitudinally extending geometrical axis, and the mouthpiece is located relative to the vaporisation chamber so that the longitudinal axis defined by the vaporisation chamber coincides with the longitudinal axis of the mouthpiece.

Alternatively, the mouthpiece is disposed relative to the vaporisation chamber with the longitudinal axis of the mouthpiece located at an angle of approximately 90° to the longitudinal axis defined by the vaporisation chamber.

The invention will be more clearly understood from the following description of and embodiment thereof, which is given by way of example only, with reference to the accompanying drawings, in which:

Fig. 1 is a side elevational view of apparatus according to the invention for vaporising vaporisable matter,

Fig. 2 is a transverse cross-sectional side elevational view of a device also according to the invention for providing a hot gaseous fluid for vaporising the vaporisable matter for use in the apparatus of Fig. 1,

Fig. 3 is a transverse cross-sectional side elevational view of a portion of the apparatus of Fig. 1,

Fig. 4 is a transverse cross-sectional side elevational view of a detail of the device of Fig. 2, and

Fig. 5 is a transverse cross-sectional side elevational view of a portion of a device according to another embodiment of the invention for providing a hot

gaseous fluid for vaporising vaporisable matter for use in the apparatus of Fig. 1.

Referring to the drawings and initially to Figs. 1 to 4, there is illustrated apparatus according to the invention, indicated generally by the reference numeral 1, for vaporising vaporisable matter 2, typically from tobacco, cannabis, and other herbs or oils for providing vaporised flavour compounds, medicinal compounds and/or vaporised psychoactive compounds, suitable for inhaling by an individual. The apparatus 1 comprises a holder 5 for holding the vaporisable matter, in this case tobacco 2, and a device also according to the invention and indicated generally by the reference numeral 8 for delivering a hot gaseous fluid, namely, hot air to the holder 5 for vaporising the tobacco 2 therein for inhaling. The holder 5 is of cylindrical construction, and is symmetrical about a longitudinally extending central axis 9, and forms a vaporisation chamber 10 within which the tobacco 2 is vaporised. A mouthpiece 11 extends axially from the vaporisation chamber 10, and a bore 12 extends through the mouthpiece 11 from the vaporisation chamber 10 for accommodating vaporised compounds vaporised from the tobacco 2 for inhaling. A gauze screen 14 in the vaporisation chamber 10 prevents particles of the tobacco 2 being drawn into the bore 12 when the vaporised compounds are being inhaled. The holder 5 is not much bigger than a conventional cigarette holder.

The device 8 is also of cylindrical construction and is symmetrical about a geometric central axis 17, and when the device 8 is coupled to the holder 5 as will be described below, the central axis 17 of the device 8 coincides with the central axis 9 of the

holder 5 so that the device 8 and the holder 5 are in alignment with each other. The device 8 comprises a housing 19 of heat conducting material, typically, aluminium, which forms a heat exchanger 20 within which the hot air to be delivered to the vaporisation chamber 10 of the holder 5 is heated by a gas burner 18 which is located within the heat exchanger 20. The housing 19 comprises an inner body member 21 which is located within an intermediate body member 22, which in turn is located within an outer body member 23. The inner body member 21, the intermediate body member 22 and the outer body member 23 are of cylindrical construction, with the intermediate body member 22 extending around the inner body member 21 and the outer body member extending around the intermediate body member 22.

The burner 18 comprises a combustion chamber 25 which is formed in the inner body member 21, and a gas catalytic combustion element 26 of metal and of hollow cylindrical construction is located in the combustion chamber 25 for converting a mixture of fuel gas and air to heat. The fuel gas/air mixture is supplied to the combustion chamber 25 by a fuel gas supply means which comprises a fuel gas supply control system 27 which is described in more detail below. A flame ignition chamber 29 is located adjacent and communicates with the combustion chamber 25 for initially combusting the fuel gas/air mixture in a flame to raise the temperature of the gas catalytic combustion element 26 to its ignition temperature. An end plug 28 closes the flame ignition chamber 29. The initial ignition of the fuel gas/air mixture will be described in more detail below.

An exhaust port 30 extending from the flame ignition chamber 29 accommodates exhaust gases from the flame ignition chamber 29 and the combustion chamber 25, which are delivered into a tortuous exhaust gas passageway 32 formed between the outer body member 23 and the intermediate body member 22. The exhaust gas passageway 32 is formed by a plurality of annular chambers 33 defined by a plurality of corresponding circumferential heat exchange fins 34 extending from the intermediate body member 22 and sealably engaging the outer body member 23. Longitudinally extending communicating grooves 35 extend through the fins 34 for communicating adjacent annular chambers 33. The grooves 35 through the fins 34 are staggered relative to the bores of the adjacent fins 34 for forming the tortuous exhaust gas passageway 32 in conjunction with the annular chambers 33. The exhaust gas passageway 32 terminates in a downstream exhaust gas outlet 37 through which exhaust gases are exhausted to atmosphere. A gauze panel 38 extends across the exhaust port 30 to act as a flame trap in order to prevent the flame in the flame ignition chamber 29 extending into the exhaust gas passageway 32.

A gaseous fluid accommodating means comprising a tortuous gaseous fluid passageway, namely, an air passageway 40 accommodates air through the heat exchanger 20 for heating thereof for supply to the vaporisation chamber 10. The air passageway 40 is located between the inner body member 21 and the intermediate body member 22, and is formed by a plurality of annular chambers 41 which are formed by a plurality of corresponding circumferential heat exchange fins 42 which extend from the inner body member 21 and sealably engage the intermediate body

member 22. A plurality of longitudinally extending communicating grooves 43 extend through the heat exchange fins 42 for communicating adjacent annular chambers 41 to form the air passageway 40. The communicating grooves 43 of adjacent fins 42 are staggered for forming the air passageway 40 as a tortuous air passageway. The air passageway 40 terminates in an upstream air inlet 45 and a downstream air outlet 46 through which hot air is delivered into the vaporisation chamber 10 for vaporising the tobacco 2 therein.

Accordingly, the air passageway 40 and the exhaust gas passageway 32 are located adjacent each other, and are arranged so that the exhaust gases in the exhaust gas passageway 32 and the air in the air passageway 40 are separated from each other and flow in the respective passageways 32 and 40 in contra-flow relative to each other. Arranging the respective passageways 32 and 40 in contra-flow relative to each other maximises the efficiency with which heat can be recovered from the exhaust gases.

The intermediate body member 22 terminates in an engagement means, namely, an engagement plug 48 for engaging in an upstream receiving portion 49 of the vaporisation chamber 10 of the holder 5. An O-ring seal 50 located in an annular groove 51 extending around the plug 48 sealably engages the receiving portion 49 of the vaporisation chamber 10. The downstream outlet 46 from the air passageway 40 terminates in a central bore 52 of the intermediate body member 22 so that hot air from the downstream air outlet 46 is accommodated into the vaporisation chamber 10 through the central bore 52. A gauze screen 53 is located across the

central bore 52 for preventing particles of the tobacco 2 entering the air passageway 40.

The inner body member 21 terminates at its end opposite to the engagement plug 48 in a mounting means, namely, a mounting plug 55 for receiving a reservoir 56 for storing fuel gas in liquid form for supply to the fuel gas supply control system 27. Fuel gas from the reservoir 56 is delivered to a fuel gas supply pipe 60 of the fuel gas supply control system 27. The fuel gas is delivered from the fuel gas supply pipe 60 into a temperature responsive fuel gas cut-out valve 61. Fuel gas from the cut-out valve 61 is supplied through a thermostatically responsive valve 62 to a nozzle outlet 63. The temperature responsive cut-out valve 61 and the thermostatically responsive valve 62 are described in more detail below. A venturi mixer 65 formed in the inner body member 21 receives fuel gas from the nozzle outlet 63 and mixes the fuel gas with air. An air inlet 66 accommodates air to the venturi mixer 65. The fuel gas/air mixture from the venturi mixer 65 is delivered through an elongated central bore 67 extending from the venturi mixer 65 into the combustion chamber 25.

An electrode 70 extends into the flame ignition chamber 29 and is powered by a piezo-electric igniter (not shown) for igniting the fuel gas/air mixture initially to burn in a flame in the flame ignition chamber 29. The electrode 70 terminates in a tip (not shown) which is spaced apart from the end plug 28 to define a spark gap, across which a spark jumps on activation of the piezo-electric igniter (not shown) for igniting the fuel gas/air mixture to burn in a flame. The flame ignition chamber 29 is located

relative to the combustion chamber 25 so that the root of the flame sits adjacent the catalytic combustion element 26 for raising the temperature of the catalytic combustion element 26 to its ignition temperature. Thus, when the catalytic combustion element 26 is raised to its ignition temperature and commences to convert fuel gas to heat, the flame is starved of fuel gas and is automatically extinguished.

An inspection port 71 extends through the inner, intermediate and outer body members 21, 22 and 23 into the flame ignition chamber 29 and the combustion chamber 25 for facilitating inspection of the flame and the gas catalytic combustion element.

A thermal mass 72 is attached to the catalytic combustion element 26 for retaining the catalytic combustion element 26 adjacent the thermal mass 72 at its ignition temperature for temporary periods during temporary interruption of fuel gas/air mixture to the combustion chamber 25, resulting from control of the supply of fuel gas to the combustion chamber 25 by the thermostatically responsive valve 62 for controlling the temperature of the heat exchanger 20. The thermal mass 72 may be provided by any suitable mass which has a relatively high capacity to store and conduct heat. For example, the thermal mass may comprise a relatively small block of metal secured to the catalytic combustion element 26, and a particularly suitable thermal mass would be a screw with a relatively large head secured to the catalytic combustion element 26 by a nut such that the head, nut and screw would act as the thermal mass.

Returning now to the temperature responsive cut-out valve 61 and the thermostatically responsive valve 62, both valves 61 and 62 are substantially similar to a safety cut-out valve and a thermostatically responsive valve which are described in detail in PCT Published Patent Application Specification No. WO 02/48591 A1. Briefly, referring now to Fig. 4, the temperature responsive cut-out valve 61 comprises a housing 75 through which a fuel gas accommodating bore 76 extends from the pipe 60. A porous filter member 77 is located in the bore 76 for filtering fuel gas passing therethrough. A temperature sensitive member 78 is also located in the bore 76. The temperature sensitive member 78 is of plastics material impregnated with glass fibre particles. The plastics material of the member 78 has a melt temperature which is a function of the maximum temperature over which the heat exchanger 20 should not exceed, so that should the temperature of the heat exchanger 20 exceed the maximum temperature, the plastics material of the temperature sensitive member 78 melts, and the melting plastics material with the glass fibre particles block the filter member 77, thus isolating the fuel gas supply control system 27 from the fuel gas supply from the reservoir 56.

The thermostatically responsive valve 61 comprises a housing 79 from which the housing 75 extends, and the housing 79 defines a valving chamber 80 within which a bi-metal circular temperature responsive disc 81 is located. The fuel gas accommodating bore 76 through the housing 75 terminates in a fuel gas inlet 82 to the valving chamber 80 for accommodating fuel gas into the fuel gas chamber 80. The disc 81 carries a valving member 84, which co-operates with the inlet 82 for

varying the flow rate of fuel gas through the inlet 82 in response to the temperature of the heat exchanger 20. The bi-metal disc 81 is of the type described in PCT Published Application Specification No. WO 02/48591 A1, which when unconstrained transitions between two states which are mirror images of each other at a respective upper transition temperature and a lower transition temperature. However, the bi-metal disc 81 is constrained within the valve chamber 80 to prevent such transitioning, so that the bi-metal disc 81 operates the valving member 84 for controlling the flow of fuel gas through the valve inlet 82 with an analogue type action. This is described in detail in PCT Published Application Specification No. WO 02/48591.

The bi-metal disc 81 of the thermostatically responsive valve 62 is selected to control the supply of fuel gas to the combustion chamber 26, so that the heat exchanger 20 is maintained at an appropriate temperature for heating the air being delivered to the vaporisation chamber within a temperature range which is suitable for vaporising the vaporisable components of the tobacco to be vaporised. In this embodiment of the invention the air temperature is maintained at a temperature in the range of 130°C to 250°C. However, it is important that the temperature of the air delivered to the vaporisation chamber 10 should be sufficient to vaporise the compounds to be vaporised, but should be such as to avoid releasing carcinogens from the tobacco.

The housings 75 and 79 are of heat conductive material, and are in heat conducting relationship with each other. The housing 79 of the thermostatically responsive valve 62 is in direct heat conducting engagement with the inner body member 21 so

that the housings 79 and 75 are maintained at a temperature substantially similar to the temperature of the inner body member 21. A circlip 85 is located in an annular internal groove 86 formed in a central bore 87 of the inner body member 21, and a spring 88 acting between the circlip 85 and the housing 79 of the thermostatically responsive valve 62 urges the housing 79 of the valve 62 into tight heat conducting engagement with the heat exchanger 20. If there is a temperature drop between the housings 75 and 79 and the inner body member 21, this is taken account of by appropriately selecting the melt temperature of the plastics material of the temperature sensitive member 78 of the temperature responsive cut-out valve 61 and appropriately selecting the bi-metal disc 81 of the thermostatically responsive valve 62.

Additional fuel gas control mechanisms, for example, an on/off switch and a fuel gas flow control switch, as well as a fuel gas pressure regulator may also be provided, and these, typically, will be located between the fuel gas reservoir 56 and the device 8.

A groove 89 is formed in the outer body member 23 adjacent the engagement plug 48 for engaging corresponding toggle clasps (not shown) extending from the holder 5 for securing the device 8 to the holder 5. A groove 90 is provided in the inner body member 21 adjacent the mounting plug 55 for engaging corresponding toggle clamps (also not shown) extending from the fuel gas reservoir 56 for securing the fuel gas reservoir 56 to the device 8.

An outer cylindrical casing 92 is provided around the outer body member 23 in order to avoid any danger of a user coming in contact with the heat exchanger 20.

In use, the tobacco 2 in flake form to be vaporised is placed in the vaporisation chamber 10 in the holder 5, and the device 8 is then secured to the holder 5 with the engagement plug 48 engaged in the upstream portion 49 of the vaporisation chamber 10, and the device 8 is then secured by the toggle clamps (not shown) to the holder 5. Initially the fuel gas supply from the fuel gas reservoir 56 is switched on, and by operating the piezo-electric igniter (not shown) a spark which arcs between the electrode 70 and the end plug 28 ignites the fuel gas/air mixture from the venturi mixer 65 to burn in the flame ignition chamber 29 with a flame. The flame rapidly raises the catalytic combustion element 26 to its ignition temperature, which in turn commences to convert the fuel gas/air mixture to heat by catalytic reaction, thus starving the flame of fuel gas which is extinguished. Thereafter the heat exchanger 20 is heated by catalytic conversion of the fuel gas/air mixture to heat by the catalytic combustion element 26.

In order to inhale vaporised compounds from the tobacco 2, a user draws on the mouthpiece, which in turn draws air through the air passageway 40, which is heated by the heat exchanger 20, and in turn is drawn into the vaporisation chamber 10. The hot air is drawn through the tobacco 2, thereby vaporising the components therein to be vaporised. The air with the vaporised components entrained therein is drawn through the mouth piece 11 and inhaled by the individual. Each time the individual draws on the mouthpiece 11, hot air with the vaporised components

entrained therein is drawn and can thus be inhaled.

The advantages of the apparatus according to the invention are many. The main advantage of the invention is that only air and vaporised components from the tobacco are drawn by the individual. There is no danger of any products of combustion being drawn through the mouthpiece, since the air passageway 40 is separated from the exhaust gas passageway 37. Thus, a person using the device according to the invention to vaporise vaporisable matter placed in the vaporisation chamber is not subjected to any products of combustion, and in particular, is not subjected to carcinogenic products of combustion.

Referring now to Fig. 5, there is illustrated an engagement plug indicated by the reference numeral 95 for use with a device (not shown) according to another embodiment of the invention for providing a hot gaseous fluid, namely, air, for vaporising the vaporisable matter in the vaporisation chamber 10 of apparatus (also not shown) according to this embodiment of the invention. The device and the apparatus according to this embodiment of the invention are substantially similar to the device 8 and the apparatus 1 described with reference to Figs. 1 to 4, with the exception of the engagement plug 95. The engagement plug 95 is used in place of the engagement plug 48 for closing the flame ignition chamber 29 of the device 8 of Fig. 2. However, additionally, as well as acting to close the flame ignition chamber 29, the engagement plug 95 also acts to distribute the hot air from the air passageway 40 to the central bore 52. The engagement plug 95 comprises a pair of spaced apart discs, namely, an inner disc 96 and an outer disc 97 which are joined

by a central core 98, and when located in the inner body member 21, the discs 96 and 97 define with the inner body member 21 and the central core 98 an annular air chamber 99. Bores 100 extending through the inner disc 96 align with the downstream outlet 46 from the air passageway 40 for accommodating hot air from the downstream outlet 46 into the annular air chamber 99. A plurality of circumferentially and radially spaced apart outlet bores 101 through the outer disc 97 accommodate hot air from the annular air chamber 99 for distributing the hot air into the central bore 52 for in turn distributing the hot air evenly throughout the vaporisation chamber 10.

An earthed electrode 104 extends centrally from the inner disc 96 into the flame ignition chamber 29 and defines with the tip (not shown) of the electrode 70 a spark gap across which a spark arcs on activation of the piezo-electric igniter for in turn igniting the fuel gas to burn with a flame in the flame ignition chamber 29.

Otherwise, the engagement plug 95 acts to close off the flame ignition chamber 29, and the bores 100 are appropriately located in the inner disc 96 to avoid any danger of the products of combustion in the flame ignition chamber 29 mixing with the hot air being delivered from the downstream air outlet 46 into the bores 100 in the inner disc 96.

The remainder of the device and the apparatus according to this embodiment of the invention is similar to the device 8 and apparatus 1 described with reference to Figs. 1 to 4, and its use is also similar.

While the exhaust gas passageway and the air passageway have been described as being formed by a plurality of respective adjacent communicating annular chambers, it is envisaged that any suitably shaped passageways may be provided, for example, in certain cases, it is envisaged that the exhaust gas and air passageways may be of helical construction.

Additionally, it will be appreciated that while the apparatus according to the invention has been described with the holder and the device for producing the hot air being arranged in axial alignment with each other, so that the construction of the apparatus according to the invention is substantially similar to that of a cigarette holder, it is envisaged in certain cases that the apparatus according to the invention may be constructed to be of shape substantially similar to a tobacco smoking pipe, and in which case, it is envisaged that the vaporisation chamber would extend substantially perpendicularly from the mouthpiece, and the device for providing the hot air to the vaporisation chamber would be aligned in substantially straight or axial alignment with the vaporisation chamber. Needless to say, many other constructions, shapes and configurations of the device are envisaged, which will be readily apparent to those skilled in the art.

While the apparatus according to the invention has been described for vaporising vaporisable components in tobacco, it will be readily apparent to those skilled in the art that the apparatus may be used for vaporising vaporisable components in any herb, plant matter, essential oils, or, indeed, any other matter which is vaporisable,

or comprises components which may be vaporised. Where the apparatus is to be used for vaporising essential oils, or other liquid matter, the vaporisation chamber will be appropriately shaped and arranged for retaining the liquid matter so that the hot air passes over the liquid surface of the liquid matter.

While the means for igniting the fuel gas/air mixture to burn with a flame in the flame ignition chamber has been described as a piezo-electric igniter which delivers a charge to an electrode for causing a spark to arc in the flame ignition chamber, any other suitable ignition means may be used. Indeed, in certain cases, an electrically powered hot wire element may be used, and indeed, in certain cases, a flint ignition mechanism may be used. It is also envisaged that the catalytic combustion element may be raised to its ignition temperature by means other than a flame, for example, by an electrically powered heating element, or by any other suitable means. Needless to say, it will be appreciated that the ignition means may be dispensed with, and ignition of the fuel gas/air mixture to initially burn in a flame for raising the temperature of the catalytic combustion element to its ignition temperature may be initiated manually by a match, a flint spark, or by other suitable means.

While the heat exchange fins extending from the inner body member have been described as being in sealable engagement with the intermediate body member, and the heat exchange fins extending from the intermediate body member have been described as being in sealable engagement with the outer body member, it is envisaged in certain cases, that the heat exchange fins need not be in sealable engagement with the corresponding intermediate and outer body member. In certain

cases, it is envisaged that a small clearance may be provided between the heat exchange fins and the corresponding intermediate or outer body member.

Needless to say, while the combustion chamber has been described as being coaxial with the housing which forms the heat exchanger, the combustion chamber may be located in any orientation relative to the heat exchanger, and indeed, in certain cases, the combustion chamber may be formed externally of the heat exchanger but in heat conductive engagement with the heat exchanger. For example, in certain cases, it is envisaged that the combustion chamber may be located adjacent the heat exchanger, and the combustion chamber may define a central axis which would extend substantially parallel to the central axis of the heat exchanger.

While the gaseous fluid accommodating means for accommodating the gaseous fluid through the heat exchanger for heating thereof has been described as comprising a tortuous gaseous fluid passageway, it is envisaged that the gaseous fluid accommodating means may be provided as a porous filter, which would be located in the heat exchanger through which the air or other gaseous fluid to be heated would be drawn. Preferably, the porous filter would be of a heat conductive material for enhancing heat transfer to the air being drawn through the filter, and advantageously, it is envisaged that the filter may be a sintered filter. Where a porous filter is provided for accommodating the gaseous fluid therethrough, it is envisaged that the porous filter may be in the form of an annular filter, which would extend around the inner body member and would be located between the inner body

member and the intermediate body member in heat conducting engagement with both the inner and the intermediate body members. Alternatively, the porous filter may be located in a bore extending through the heat exchanger. Needless to say, other suitable arrangement, construction and location of a porous filter in the heat exchanger may be used without departing from the scope of the invention.

While the exhaust gases from the combustion chamber have been described as being directed through an exhaust gas passageway for facilitating recovery of heat from the exhaust gases, while this is advantageous, it is not essential, and in certain cases, it is envisaged that the exhaust gases may be directly outputted to atmosphere from the combustion chamber.

It is also envisaged that a control valve may be provided for controlling the rate at which air can be drawn through the air passageway.

While an O-ring has been described for sealing between the engagement plug extending from the intermediate body member, and the vaporisation chamber, in certain cases, it is envisaged that the O-ring may be omitted.

While the thermostatically responsive valve for controlling the flow of fuel gas to the venturi mixer has been described, any other suitable thermostatically responsive valves may be used. For example, in certain cases, it is envisaged that a battery in an electrically powered self-latching relay may be used, which may be powered, for example, by a relatively small battery. Needless to say, any other suitable

thermostatically responsive valves may be used.

Additionally, it is envisaged that an on/off switch provided for switching the fuel gas on and off to the device from the reservoir may be coupled to the ignition means for igniting the fuel gas to burn with a flame in the flame ignition chamber. For example, it is envisaged that the fuel gas on/off switch may be coupled to the piezo-electric igniter for activating the piezo-electric igniter to deliver a burst of electrical energy to the electrode in the flame ignition chamber each time the on/off switch is switched on.

It is also envisaged that an evaporator may be provided in an outlet from the reservoir for evaporating fuel gas as it exits the reservoir outlet, and in certain cases, it is envisaged that the evaporator may be provided by a sintered filter, which may, for example, be of the type which would permit a flow rate of the order of 9gms to 30gms per hour from the reservoir.

The invention is not limited to the embodiment hereinbefore described, which may be varied in construction and detail.

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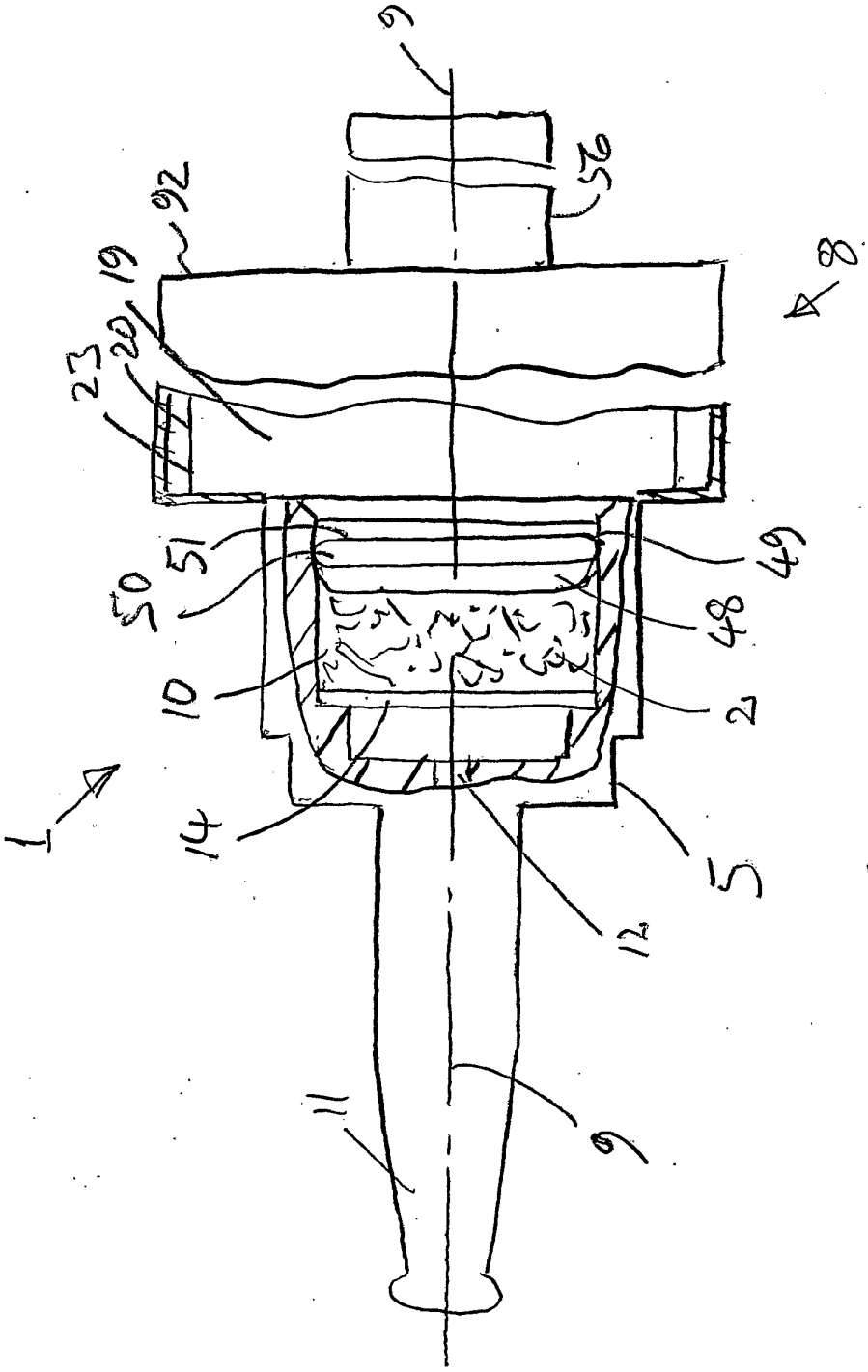

FIG 1

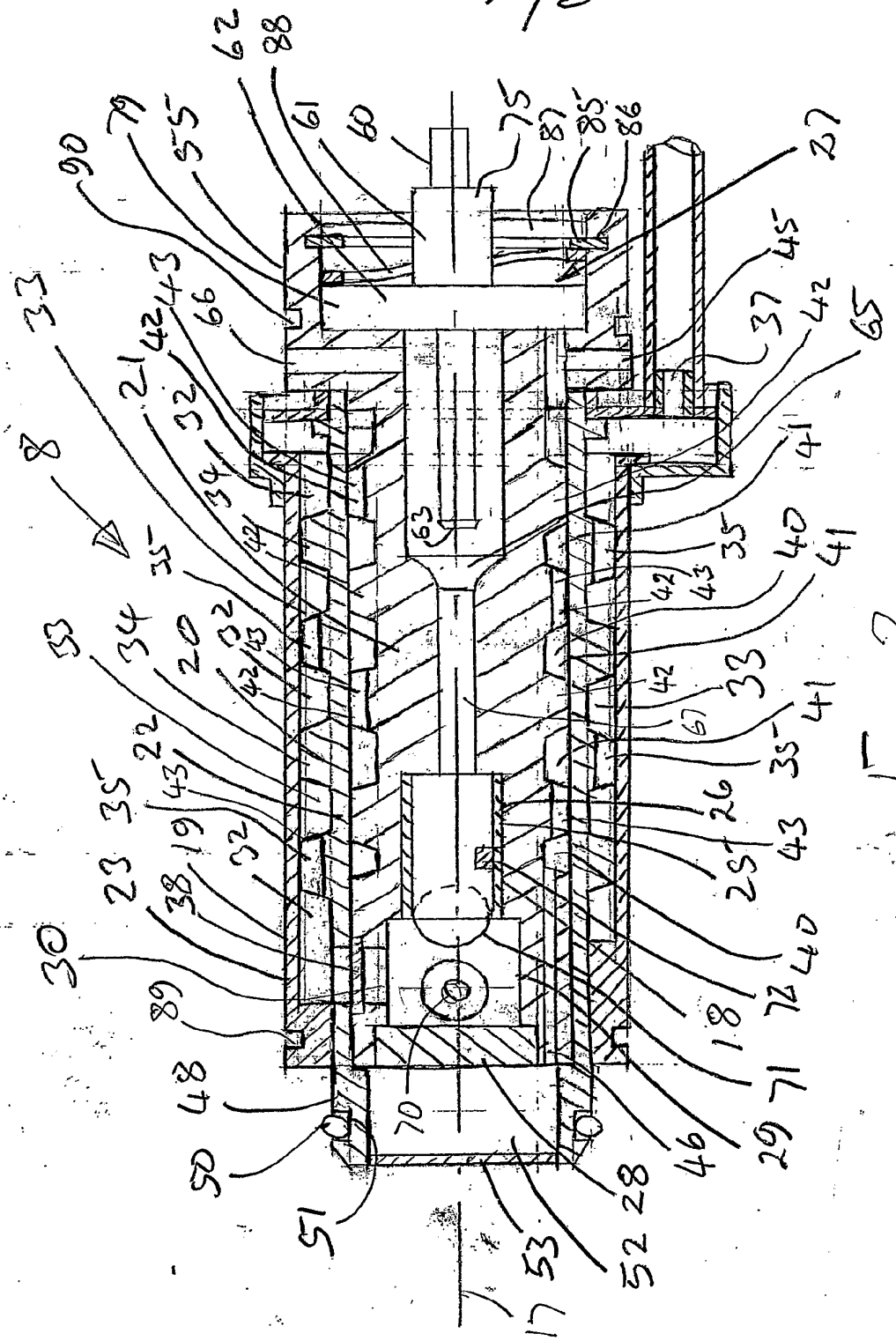
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FIG 2

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FIG 3

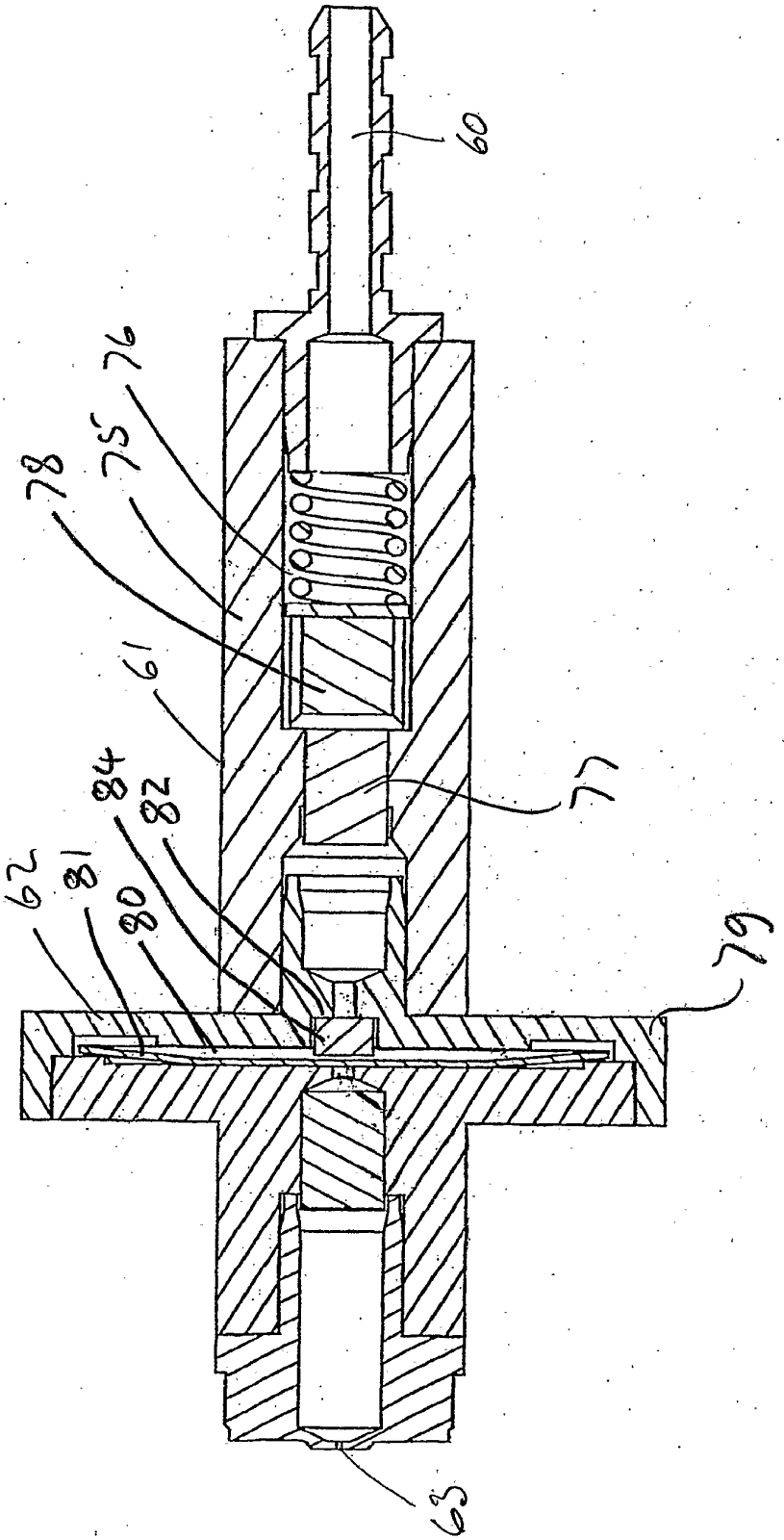

FIG 4

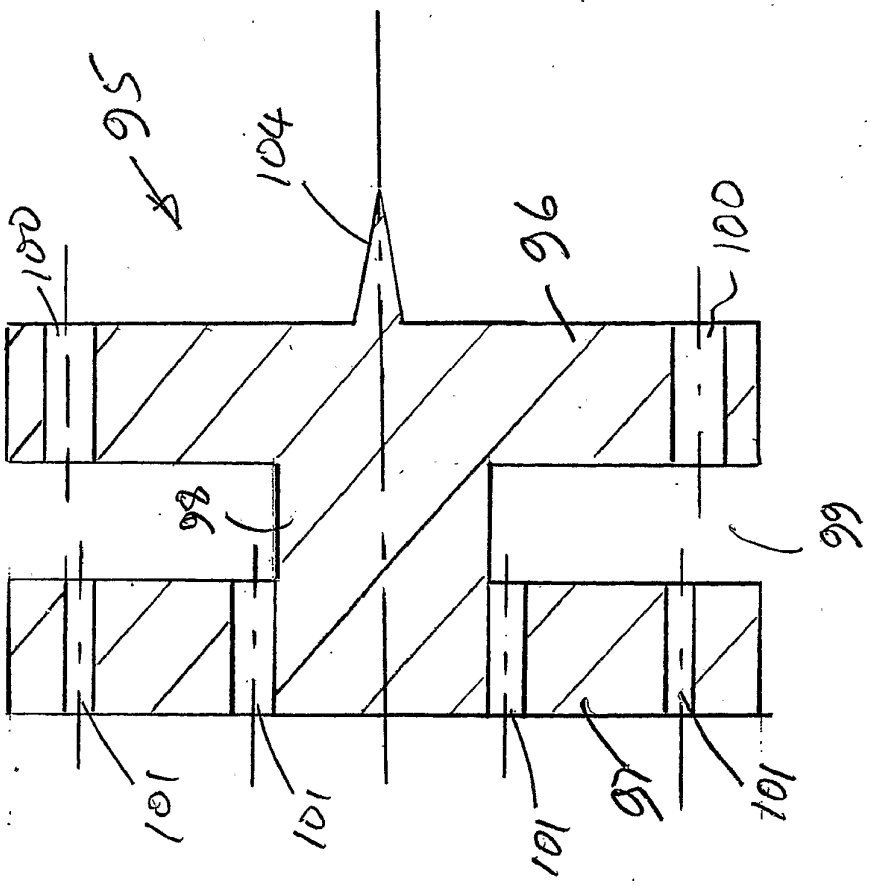

FIG 5

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/IE2006/000006

International filing date: 02 February 2006 (02.02.2006)

Document type: Certified copy of priority document

Document details: Country/Office: IE
Number: S2005/0563
Filing date: 24 August 2005 (24.08.2005)

Date of receipt at the International Bureau: 22 February 2006 (22.02.2006)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

World Intellectual Property Organization (WIPO) - Geneva, Switzerland
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Patents Office
Government Buildings
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Kilkenny

I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

Application No.	S2005/0563
Date of Filing	24 August 2005
Applicant	OGLESBY & BUTLER RESEARCH & DEVELOPMENT, an Irish company of Industrial Estate, Dublin Road, Carlow, Ireland.

Dated this 9 day of February 2006.

An officer authorised by the
Controller of Patents, Designs and Trademarks.

FORM NO. 1

REQUEST FOR THE GRANT OF A PATENT

PATENTS ACT, 1992

The Applicant(s) named herein hereby request(s)

☐ the grant of a patent under Part II of the Act

☒ the grant of a short-term patent under Part III of the Act

on the basis of the information furnished hereunder.

1. Applicant(s)

Name

OGLESBY & BUTLER RESEARCH
& DEVELOPMENT LIMITED

Address

Industrial Estate, Dublin Road, Carlow, Ireland.

Description/Nationality

An Irish company.

2. Title of Invention

"A device for vaporising vaporisable matter"

3. Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)

Previous filing date	Country in or for which filed	Filing No.

4. Identification of Inventor(s)

Name(s) of person(s) believed
by Applicant(s) to be the inventor(s)
ALFRED PETER OGLESBY and JOHN PAUL OGLESBY

Address
A British subject of Castle Hill, Carlingford, County Louth, Ireland; and
A British subject of Anneville, Shrule, Carlow, Ireland.

5. **Statement of right to be granted a patent (Section 17 (2) (b))**
The applicant has derived the right to be granted a Patent from the inventors by virtue of a Deed of Assignment dated August 23. 2005.

6. **Items accompanying this request – tick as appropriate**

(i) [X] Prescribed filing fee (€60.00)

(ii) [ ] Specification containing a description and claims

[X] Specification containing a description only

[X] Drawings referred to in description or claims

(iii) [ ] An abstract

(iv) [ ] Copy of previous application(s) whose priority is claimed

(v) [ ] Translation of previous application whose priority is claimed

(vi) [ ] Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant(s))

7. **Divisional Application(s)**
The following information is applicable to the present application which is made under Section 24 –

Earlier Application No: .....
Filing Date: .....

24 AUG 2005

8. **Agent**
The following is authorised to act as agent in all proceedings connected with the obtaining of a patent to which this request relates and in relation to any patent granted –

Name	Address
F.F. GORMAN & CO.	15 Clanwilliam Square, Dublin 2, Ireland.

9. **Address for Service (if different from that at 8)**
F.F. GORMAN & CO., at its address as recorded for the time being in the Register of Patent Agents.

Signed F.F. GORMAN & CO., Authorised Patent Agents

BY: _____ EXECUTIVE

Date August 24. 2005

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"A device for vaporising vaporisable matter"

The present invention relates to a device for vaporising vaporisable matter for facilitating inhaling of the vaporised matter. For example, the device is suitable for vaporising vaporisable matter which comprises one or more of flavour components, medicinal components and psychoactive components, such as tobacco, mullein, passion flower, cloves, yohimbe, mint, tea, eucalyptus, camomile and other such herbs and plant matter.

Herbs, for example, tobacco and the like are smoked by burning, in order to release psychoactive compounds, which are then inhaled. The psychoactive compounds are released into the fumes of combustion, which are then inhaled. However, burning of such herbs as well as producing psychoactive compounds also produces toxins, which largely result from the actual combustion process. Such toxins are known to be carcinogenic, and also can result in lung and heart disease. Thus, the smoking of such herbs and other such plant matter is hazardous and undesirable. An alternative to releasing flavour, medicinal and psychoactive compounds from such herbs and plant matter by smoking is to raise the temperature of the herb to an appropriate temperature for causing the vaporisable constituent or constituents to be vaporised, and then inhale the vaporised constituent or constituents. However, the temperature range at which such compounds can be vaporised in herbs and plant matter ranges from approximately 130°C to 250°C. If the temperature is below 130°C, in general, vaporisation does not occur. However, if the temperature to which the herb or plant matter is heated exceeds 300°C, combustion of the herb or

plant matter may commence. Thus, in order to satisfactorily vaporise flavour, medicinal and psychoactive constituents in herbs and plant matter, the temperature at which the herb or plant matter is maintained for producing the vaporised compounds must be controlled within reasonably tight tolerances.

It is known to provide apparatus for vaporising desirable constituents from herbs by electrically heating the herb. However, due to the energy requirements of such apparatus, a mains electricity supply is required to power the apparatus, and thereby the apparatus is not portable when in use. This thus renders a person immobile when using such apparatus. An alternative device for vaporising vaporisable constituents in herbs and plant matter is disclosed in U.S. published Patent Application Specification No. 2004/0031495 of Steinberg. Steinberg discloses a pipe which is substantially similar to a smoking pipe in which the herb, typically, tobacco to be vaporised is located in a bowl portion of the pipe. A heat resistant and porous flame filter is located in the bowl above the herb, and a flame from a match or cigarette lighter is used to heat the porous filter while air is being drawn through the pipe. Thus, a mixture of air and the products of combustion from the flame are mixed in the porous filter and drawn through the herb in the bowl for heating the herb for in turn vaporising desirable constituents in the herb. The mixture of air, the products of combustion and the vaporised constituent are then drawn through a mouthpiece of the pipe and inhaled. However, due to the fact that the flame is played on the heat resistant porous flame filter, there is a danger of the flame being drawn through the filter and thus causing combustion of the herb in the bowl of the pipe. However, even where the herb does not combust, the products of combustion

of the flame are inhaled along with the vaporised constituent. This is undesirable.

There is therefore a need for a device for vaporising vaporisable matter which overcomes this problem.

The present invention is directed towards providing such a device.

According to the invention there is provided a device for vaporising vaporisable matter, the device comprising a vaporising chamber for the vaporisable matter, a combustion chamber within which fuel gas is converted to heat, a heat transfer means for transferring heat from the combustion chamber to the vaporising chamber for vaporising the vaporisable matter therein.

In one embodiment of the invention the device comprises a body member of heat conducting material, and the combustion chamber is formed in the body member, the vaporising chamber being coupled to the body member and being in heat conducting engagement therewith so that the body member acts as the heat transfer means.

Preferably, the vaporising chamber is releasably coupleable to the body member.

In another embodiment of the invention at least one heat transfer member extends into the vaporising chamber for engaging the vaporisable matter for heating thereof. Advantageously, a plurality of spaced apart heat transfer members extend into the

vaporising chamber, and ideally, each heat transfer member is an elongated heat transfer member.

In one embodiment of the invention an outlet is provided from the vaporising chamber for drawing vapour from the vaporisable matter from the vaporising chamber, and preferably, the outlet terminates in a mouthpiece for facilitating drawing the vaporisable matter into the mouth.

In another embodiment of the invention an air inlet is provided to the vaporising chamber for facilitating air being drawn into the vaporising chamber as the vapour from the vaporisable matter is being drawn through the outlet therefrom.

Additionally or alternatively, a heat exchange means is provided for co-operating with the combustion chamber for transferring heat from the combustion chamber to a heat transfer gaseous fluid for heating thereof and the heat transfer gaseous fluid acts as the heat transfer means for transferring heat from the combustion chamber to the vaporising chamber.

Preferably, the heat exchange means communicates with the vaporising chamber for delivering the heated gaseous fluid into the vaporising chamber for heating the vaporisable matter therein.

Preferably, a portion of the vaporisable chamber is perforated for accommodating the heated gaseous fluid from the heat exchange means to the vaporising chamber.

In one embodiment of the invention the heat exchange means is located in the body member.

Preferably, an exhaust gas chamber is formed in the body member, and an exhaust port from the combustion chamber communicates exhaust gases from the combustion chamber to the exhaust gas chamber. Ideally, a heat exchange chamber is located in the body member, and the heat exchange means comprises a heat exchanger, which is located in the heat exchange chamber. In one embodiment of the invention an air inlet is provided to the heat exchange chamber for accommodating air thereto, and an air outlet is provided from the heat exchange chamber for delivering heated air from the heat exchanger chamber to the vaporising chamber.

In one embodiment of the invention the body member terminates at one end in a coupling member for coupling the vaporising chamber to the body member.

Preferably, a gas catalytic combustion element is located in the combustion chamber for converting fuel gas to heat by catalytic reaction.

In one embodiment of the invention a flame ignition chamber is located adjacent the combustion chamber for facilitating initial flame ignition of the fuel gas for in turn raising the temperature of the gas catalytic combustion element to its ignition temperature, and ideally, the flame ignition chamber is located adjacent the

combustion chamber so that as the gas catalytic combustion element is raised to its ignition temperature by the flame ignition, the flame is starved of fuel gas and is extinguished.

Ideally, an ignition means is provided for igniting the fuel gas to initially burn with a flame, and preferably, the ignition means comprises at least one electrode for generating a spark for igniting the fuel gas to burn with a flame in the flame ignition chamber.

In another embodiment of the invention a thermostatically responsive valve is provided for controlling the flow of fuel gas to the combustion chamber, and preferably, the thermostatically responsive valve is in direct or indirect heat conducting engagement with the body member. Advantageously, the thermostatically responsive valve defines a valving chamber, and a bi-metal disc located in the valving chamber, the bi-metal disc co-operating with one of a valve inlet and a valve outlet to the valving chamber for controlling the flow of fuel gas through the valving chamber in response to temperature. Ideally, the bi-metal disc is of the type which transitions from one state to another state, which are mirror images of each other, as the temperature of the disc exceeds a predetermined transition temperature, and the disc is constrained within the valving chamber to prevent transitioning of the disc from one of said states to the other.

In one embodiment of the invention the thermostatically responsive valve is suitable for controlling the temperature of the heat exchanger so that the temperature of the

vaporisable matter in the vaporising chamber lies in the range of 100°C to 500°C.

In another embodiment of the invention the thermostatically responsive valve is suitable for controlling the temperature of the heat exchanger so that the temperature of the vaporisable matter in the vaporising chamber lies in the range of 125°C to 400°C.

In a further embodiment of the invention the thermostatically responsive valve is suitable for controlling the temperature of the heat exchanger so that the temperature of the vaporisable matter in the vaporising chamber lies in the range of 130°C to 300°C.

In a still further embodiment of the invention the thermostatically responsive valve is suitable for controlling the temperature of the heat exchanger so that the temperature of the vaporisable matter in the vaporising chamber lies in the range of 150°C to 250°C.

In another embodiment of the invention a temperature responsive fuel gas cut-out means is provided for isolating the combustion chamber from a fuel gas supply in the event of the temperature of the heat exchanger exceeding a predetermined safe maximum temperature. Preferably, the fuel gas cut-out means comprises a temperature sensitive member located in a fuel gas passageway through which fuel gas is delivered to the combustion chamber, the temperature sensitive member having a melt temperature which is a function of the predetermined safe maximum

temperature, so that when the temperature of the body member reaches the predetermined safe temperature, the temperature sensitive member melts, thus blocking the fuel gas passageway. Ideally, the temperature sensitive member is located adjacent a porous filter so that on melting of the temperature sensitive member the melting material of the temperature sensitive member blocks the porous filter.

In one embodiment of the invention a fuel gas supply means is provided in the body member for supplying fuel gas to the combustion chamber.

In another embodiment of the invention a fuel gas reservoir is provided for supplying fuel gas to the fuel gas supply means, and preferably, the fuel gas reservoir is coupled to the housing.

Ideally, the fuel gas supply means comprises a mixing means for mixing the fuel gas with air for delivery to the combustion chamber.

The invention will be more clearly understood from the following description of some embodiments thereof, which are given by way of example only, with reference to the accompanying drawings, in which:

Fig. 1 is a perspective view of a device according to the invention for vaporising vaporisable matter,

Fig. 2 is a cutaway perspective view of the device of Fig. 1,

Fig. 3 is a side elevational view of the device of Fig. 1,

Fig. 4 is an end view in the direction of the arrow A of the device of Fig. 3,

Fig. 5 is a transverse cross-sectional side elevational view of the device of Fig. 1 on the line V-V of Fig. 3,

Fig. 6 is a transverse cross-sectional side elevational view of the device of Fig. 1 on the line VI-VI of Fig. 3,

Fig. 7 is a transverse cross-sectional end elevational view of the device of Fig. 1 on the line VII-VII of Fig. 3,

Fig. 8 is a transverse cross-sectional side elevational view of the device of Fig. 1 on the line VIII-VIII of Fig. 3,

Fig. 9 is a perspective view of a portion of the device of Fig. 1,

Fig. 10 is a side elevational view of the portion of Fig. 9 of the device of Fig. 1,

Fig. 11 is an end elevational view of the portion of Fig. 9 of the device of Fig.

1,

Fig. 12 is a top plan view of the portion of Fig. 9 of the device of Fig. 1,

Fig. 13 is a transverse cross-sectional side elevational view of the portion of Fig. 9 on the line XIII-XIII of Fig. 10 of the device of Fig. 1,

Fig. 14 is a plan view of a device according to another embodiment of the invention for vaporising vaporisable matter, and

Fig. 15 is a transverse cross-sectional side elevational view of a portion of the apparatus of Fig. 14 on the line XV-XV of Fig. 14.

Referring to the drawings, and initially to Figs. 1 to 13, there is illustrated a device according to the invention, indicated generally by the reference numeral 1, for vaporising vaporisable matter, typically, tobacco and other herbs or oils for providing vaporised flavour compounds, medicinal compounds and/or vaporised psychoactive compounds, suitable for inhaling by an individual. The device 1 comprises a body member 2 of heat conductive material, in this embodiment of the invention brass, within which a combustion chamber 3 is formed. A gas catalytic combustion element 5 of cylindrical construction is located within the combustion chamber 3 for converting a mixture of fuel gas and air to heat. An exhaust gas chamber 7 is also formed in the body member 2, and an exhaust port 8 communicates the combustion chamber 3 with the exhaust gas chamber 7 for delivering exhaust gases from the

combustion chamber 3 to the exhaust gas chamber 7. A heat exchange chamber 10 also formed in the body member 3 accommodates a heat exchange means, namely, a heat exchanger 12 for heating a heat transfer gaseous fluid, namely, air. The conversion of the fuel gas/air mixture to heat in the combustion chamber 3 and the exhaust gas from the combustion chamber 3 in the exhaust gas chamber 7 act to heat the body member 2, and in turn the heat exchanger 12 for heating air as it passes therethrough.

A vaporising chamber 15 of heat conductive material, namely, brass, is releasably coupled to the body member 2, as will be described below, for the vaporisable matter which is to be vaporised. The vaporising chamber 15 comprises a cylindrical side wall 16 and a perforated end wall 17 which is perforated with holes 18 for accommodating heated air from the heat exchanger 12, as will be described below, for heating the vaporisable matter in the vaporising chamber 15. The body member 2 terminates in a coupling member 19 for releasably coupling the vaporising chamber 15 to the body member, and a receiving chamber 20 formed in the coupling member 19 for receiving the vaporising chamber 15 therein communicates directly with an air outlet 21 from the heat exchanger 12 for accommodating heated air from the heat exchanger 12 into the vaporising chamber 15 through the holes 18 in the perforated end wall 17. The coupling member 19 is of heat conducting material, namely, brass, and is in heat conducting engagement with the body member 2 and the vaporising chamber 15 for conducting heat from the body member 2 to the vaporising chamber 15. The vaporising chamber 15 is releasably coupled to the coupling member 19 by a bayonet coupling mechanism 23, although any other

suitable releasable coupling may be used, for example, a magnetic coupling. Indeed, in certain cases the vaporising chamber 15 may be coupled to the body member by a non-releasable coupling. A plurality of spaced apart elongated heat transfer members 25 extend from the end wall 17 of the vaporising chamber 15 into the vaporising chamber 15 for engaging the vaporisable matter for transferring heat thereto for heating thereof.

The device 1 is portable, and is supplied with fuel gas from a fuel gas reservoir (not shown) which is coupled to the body member 2 by a coupling spigot 27 extending from the body member 2. A bore 28 extending through the spigot 27 delivers fuel gas from the reservoir (not shown) in series through a safety cut-out valve 29 and a temperature responsive valve 30 and in turn through a fuel gas supply means, comprising a venturi mixer 31 for mixing the fuel gas with air. The fuel gas/air mixture is delivered from the venturi mixer 31 into the combustion chamber 3 through a nozzle 32, where it is converted to heat by catalytic conversion by the catalytic combustion element 5.

A flame combustion chamber 33 is located in the body member 2 downstream of the combustion chamber 3 for initially igniting the fuel gas/air mixture to burn in a flame for raising the temperature of the gas catalytic combustion element 5 to its ignition temperature. The flame combustion chamber 33 and the combustion chamber 3 as well as the catalytic combustion element 5 are located relative to each other so that when the combustion element 5 is raised to its ignition temperature by the flame, the flame is rapidly starved of fuel gas/air mixture and extinguished, so that conversion

of the fuel gas/air mixture to heat is carried out exclusively by the catalytic reaction in the gas catalytic combustion element 5. An electrode (not shown) which is powered by a piezo-electric ignition device (also not shown) generates a spark in the flame combustion chamber 33 for igniting the fuel gas to initially burn in a flame.

Returning now to the safety cut-out valve 29 and the temperature responsive valve 30, both the cut-out valve 29 and the temperature responsive valve 30 are in heat conducting engagement with the body member and are similar to the safety cut-out valve and the thermostatically responsive valve which are both described in detail in PCT published Patent Application Specification No. WO 02/48591 A1, and further description should not be required here.

The heat exchanger 12 comprises an elongated heat exchanging member 35 which is located in the heat exchange chamber 10. A plurality of axially spaced apart circumferentially extending flanges 37 extend circumferentially around the heat exchanging member 35, which substantially sealably engage an inner surface 38 of the heat exchange chamber 10. When engaged in the heat exchange chamber 10 the heat exchanging member 35 defines a plurality of axially spaced apart annular chambers 39. An axially extending groove 40 extends axially through each groove 37 for communicating adjacent pairs of annular chambers 39. The axial grooves 40 are angularly staggered around the heat exchanging member 37 from flange 37 to flange 37 for defining with the annular chambers 39 a tortuous passageway for the air through the heat exchange chamber 10 for heating thereof.

An air inlet 41 through the body member 2 accommodates air into the heat exchange chamber 10, which in turn is directed through the tortuous passageway defined by the axial grooves 40 and the annular chambers 39, and in turn through an air port 42 communicating one of the annular chambers 39 with an axially extending bore 43, which extends through the heat exchanger 12. Heated air is accommodated through an air outlet 44 defined by an end 45 of the bore 43, and is delivered through a connecting member 47 from the outlet 44 of the heat exchanger 12 to the receiving chamber 20 of the coupling member 19, for in turn delivery into the vaporising chamber 15 through the perforated end wall 17.

An outlet 49 from the vaporising chamber 15 terminates in a mouthpiece (not shown) for facilitating drawing of the vapour from the vaporisable matter in the vaporising chamber 15 into the mouth. A typical mouthpiece is described below with reference to the embodiment of the invention described with reference to Figs. 14 and 15. An air inlet 51 to the vaporising chamber 15 accommodates ambient air into the vaporising chamber 15. An annular sleeve (not shown) extending around the vaporising chamber 15 is axially slideable for varying the size of the inlet 51 for controlling the rate at which ambient air is drawn into the vaporising chamber 15 as the vapour from the vaporisable matter is being drawn through the mouthpiece 50.

In use, vaporisable matter to be vaporised is placed in the vaporising chamber 15 with the heat transfer members 25 extending through the vaporisable matter for transferring heat from the body member 2 to the vaporisable matter. Fuel gas from the fuel gas reservoir (not shown) is supplied through the safety cut-out valve 29, the

temperature responsive valve 30 and a venturi mixer 31 where air is mixed with the fuel gas. The fuel gas/air mixture is delivered into the combustion chamber 3 through the nozzle 32. The piezo-electric igniter (not shown) is operated for igniting the fuel gas/air mixture to burn with a flame in the flame combustion chamber 33 for raising the temperature of the gas catalytic combustion element 5 to its ignition temperature. On the gas catalytic combustion element 5 reaching its combustion temperature, the fuel gas/air mixture is converted to heat by catalytic reaction in the catalytic combustion element 5, and the flame is starved of the fuel gas/air mixture, and thus extinguished. Heat from the combustion chamber 3 and exhaust in the exhaust gas chamber 7 rapidly heat the body member 2, which in turn heats the air in the heat exchange chamber 10 for in turn heating the vaporisable matter in the vaporising chamber 15. Additionally, heat is transferred from the body member 2 through the coupling member 19 and in turn through the heat transfer members 25 to the vaporisable matter. As the vaporisable matter commences to heat as a result of heat transfer from the heat transfer members 25, vapours are released therefrom. By drawing on the mouthpiece (not shown), vapour released from the vaporisable matter is drawn from the vaporising chamber 15. The drawing on the mouthpiece (not shown) draws heated air from the heat exchanger 12 into the vaporising chamber 15 for further heating the vaporisable matter. As the vaporisable matter is heated, the temperature of the vaporisable matter can be controlled by controlling the amount of ambient air being drawn through the inlet 51 by appropriately adjusting the position of the sleeve (not shown) around the vaporising chamber 15.

The temperature responsive valve 30 is set in order to control the temperature of the

body member 2 such that the temperature of the vaporisable matter in the vaporising chamber 15 is kept within a temperature range of approximately 140°C to 190°C, which is a suitable temperature range for vaporising tobacco. However, needless to say, the temperature at which the vaporisable matter is to be maintained will be determined by the actual vaporisable matter, and it is envisaged that devices according to the invention will be provided to operate within different predetermined ranges of temperatures to suit different vaporisable matter. This would be achieved by appropriately selecting the temperature responsive valve for controlling the temperature within the desired temperature range. In general, each temperature range would have a 50°C range between the maximum and minimum temperatures of the temperature range. Typical temperature ranges would be from 130°C to 180°C, to 180°C to 230°C.

Referring now to Figs. 14 and 15, there is illustrated a device according to another embodiment of the invention, indicated generally by the reference numeral 55 for vaporising vaporisable matter. The device 55 comprises a body member 56 of circular transverse cross-section, within which a combustion chamber 58, also of circular transverse cross-section is located for housing a catalytic combustion element 59 for converting fuel gas to heat, for heating the body member 56. A vaporising chamber 60 for the vaporisable matter, and within which the vaporisable matter is vaporised is releasably engageable with a receiving socket 62 formed in the body member 56, and is in heat conducting engagement with the body member 56 for transferring heat from the combustion chamber 58 to the vaporising chamber 60, as will be described below. A mouthpiece 64 extending from the vaporising

chamber 60 is provided for facilitating drawing vapour vaporised from the vaporisable matter from the vaporising chamber 60.

A fuel gas reservoir 65 for storing fuel gas in liquid form is coupled to a safety cut-out valve 66 by a coupling tube 67 for delivering fuel gas in gaseous form to the cut-out valve 66. The cut-out valve 66 is similar to the safety cut-out valve 29 of the device 1 described with reference to Figs. 1 to 13. An isolating valve 68 at an outlet end 69 of the reservoir 65 selectively controls the supply of fuel gas to the cut-out valve 66. A pressure reduction valve (not shown) is also located at the outlet end 69 of the reservoir 65 for vaporising the fuel gas as it exits from the reservoir to the isolating valve 68.

Fuel gas from the isolating valve 68 is delivered to a temperature responsive valve 70, which is similar to the temperature responsive valve 30 of the device 1 described with reference to Figs. 1 to 13. The temperature responsive valve controls the supply of fuel gas to the combustion chamber 58 in order to control the temperature of the body member 56, so that the temperature of the body member 56 produces a temperature in the vaporising chamber 60 within the desirable temperature range. A venturi mixer 71 receives fuel gas from the temperature responsive valve 70, where the fuel gas is mixed with air drawn into the venturi mixer 71 through air inlet ports 72. The venturi mixer 71 is formed in the body member 56, and the body member 56 also forms part of the housing of the temperature responsive valve 70. Fuel gas/air mixture from the venturi mixer 71 is delivered into the combustion chamber 58 through a nozzle 74 and a diffuser 75 which diffuses the fuel gas/air mixture from

the nozzle 74 into the combustion chamber 58.

In this embodiment of the invention the gas catalytic combustion element 59 is of hollow cylindrical shape of wire mesh coated with a suitable precious metal, and converts the fuel gas/air mixture by a catalytic reaction. A thermal mass 77 provided by a small brass block or steel block is secured to the gas catalytic combustion element 59 for retaining heat for in turn maintaining the temperature of at least a portion of the gas catalytic combustion element adjacent the thermal mass 77 at or above its ignition temperature during periods while the fuel gas may be interrupted by the temperature responsive valve 70 as a result of the controlling action of the temperature responsive valve 70 in controlling the temperature of the body member 56, for in turn controlling the temperature in the vaporising chamber 60. In this embodiment of the invention the thermal mass 77 comprises a steel screw which is secured to the catalytic combustion element 59 by a steel nut (not shown), such that the catalytic combustion element 59 is tightly clamped between the head of the screw and the nut.

The combustion chamber 58 terminates at its downstream end in a flame combustion chamber 78 within which the fuel gas/air mixture is initially ignited to burn in a flame for raising the temperature of the catalytic combustion element 59 to its ignition temperature. An electrical insulator comprising a ceramic plug 79 extends through a bore 80 in the body member 56 for accommodating an electrode (not shown) through a bore 81 in the ceramic plug 79 into the flame combustion chamber 78 for igniting the fuel gas/air mixture to initially burn in a flame. A piezo-electric

igniter 82 which is secured to the reservoir 65 is provided for applying a high voltage EMF to the electrode (not shown) for causing an arc between the electrode (not shown) and an inner surface of the body member 56 defining the flame combustion chamber 78 for igniting the fuel gas/air mixture to burn in a flame. An actuating plunger 85 extends into the piezo-electric igniter 82 for operating the piezo-electric igniter 82 for applying the high volt EMF to the electrode (not shown). The flame combustion chamber 78 and the combustion chamber 58 as well as the gas catalytic combustion element 59 are located and arranged so that the flame raises the temperature of the gas catalytic combustion element 59 to its ignition temperature relatively rapidly, and on reaching its ignition temperature, the gas catalytic combustion element 59 commences to convert the fuel gas/air mixture to heat by the catalytic reaction, thereby starving the flame of fuel gas/air mixture and thus extinguishing the flame.

Inspection ports 73 and 76 which are closed by glass lenses are provided for facilitating inspection of the flame combustion chamber 78 and the combustion chamber 58, respectively in order to facilitate visual monitoring of the operation of the device 55.

An exhaust gas chamber 83 is located downstream of the flame combustion chamber 78 and exhaust gases from the combustion chamber 58 and the flame combustion chamber 78 are delivered into the exhaust gas chamber 83 through a flame retention mesh 84. The flame retention mesh 84 is such as to retain the flame in the flame combustion chamber 78, and to avoid the flame extending into the

exhaust gas chamber 83. Exhaust gases from the exhaust gas chamber 83 are delivered therefrom through exhaust ports 86 in the body member 56. A transversely extending end wall 87 closes the exhaust gas chamber 83.

A heat transfer means, namely, a heat transfer member 88, is secured in and extends through a bore 89 in the end wall 87 into the exhaust gas chamber 83 for transferring heat from the exhaust gases in the exhaust gas chamber 83 and from the body member 56 through the end wall 87 by heat conduction into the vaporising chamber 60. The heat transfer member 88 extends through a perforated disc 90 into the receiving socket 82, and in turn into the vaporising chamber 60. The perforated disc 90 defines with the end wall 87 a heating chamber 92 for heating air prior to the air being drawn into the vaporising chamber 60 as vapour from the vaporising chamber 60 is drawn through the mouthpiece 64. An air inlet 93 accommodates air into the heating chamber 92. Bores 94 through the perforated disc 90 accommodate air from the heating chamber 92 through a metal mesh disc 95 into the receiving socket 62, and in turn into the vaporising chamber 60.

The vaporising chamber 60 comprises a cylindrical side wall 96 which extends from an end wall 97 and is shaped at 98 to form a relatively tight sliding fit into the receiving socket 62 for facilitating ease of removal and insertion of the vaporising chamber 60 into the receiving socket 62. A bore 99 through the end wall 97 accommodates vapours drawn from the vaporising chamber into an outlet tube 100 which terminates in the mouthpiece 64. A metal mesh disc 91 in the vaporising chamber 60 adjacent the end wall 97 prevents the vaporisable matter being drawn

through the bore 99 as the vapours are being drawn therethrough. Annular heat exchange fins 101 extend around the vaporising chamber 60 for assisting in controlling the temperature of the vaporising chamber 60.

A heat sink means, in this embodiment of the invention a heat sink element 103 of brass is located in a bore 104 of the outlet tube 100 for cooling the vapours being drawn from the vaporising chamber 60. The heat sink element 103 comprises a central solid core 105 having a plurality of spaced apart annular flanges 106 extending circumferentially around the core 105 for defining with the outlet tube 100 a plurality of annular chambers 107 which are interconnected by axially extending grooves formed in the respective annular flanges 106. The grooves 108 are staggered from flange 106 to flange 106 in order to present the vapours being drawn from the vaporising chamber 60 with a tortuous path to maximise heat transfer from the vapours to the heat sink element 103. Additionally, it has been found that tar and other undesirable compounds entrained in the vapours being drawn from the vaporising chamber 60 condense on the heat sink element 103, and can be periodically removed by removing the heat sink element 103 at appropriate intervals for cleaning thereof.

In use, with the vaporising chamber 60 removed from the receiving socket 62, the vaporising matter to be vaporised is placed in the vaporising chamber 60, and the vaporising chamber 60 is re-engaged with the receiving socket 62. The vaporising matter may be any suitable matter, for example, tobacco, and may be in loose form, or may be in a pre-packaged form, for example, in a sachet of paper or mesh.

Where in a sachet of paper or mesh, it is envisaged that the sachet or paper would be punctured by the heat transfer member 88 as the vaporising chamber 60 is being inserted in the receiving socket 62. In this embodiment of the invention the heat transfer member 88 terminates in a point at its distal end, which would function to puncture such a sachet. Puncturing the sachet would allow the vapours from the vaporisable matter to be released into the vaporising chamber 60 when heated.

With the vaporisable matter in the vaporising chamber 60, and the vaporising chamber 60 located in the receiving chamber 62, the isolating valve 68 is operated for delivering fuel gas from the reservoir 65 to the safety cut-out valve 66, which in turn is mixed with air in the venturi mixer 71 and delivered into the combustion chamber 58. The actuating plunger 85 of the piezo-electric igniter 82 is operated for generating a spark in the flame combustion chamber 78 for igniting the fuel gas/air mixture to burn in a flame. As the flame raises the temperature of the gas catalytic combustion element 59 to its ignition temperature, the fuel gas/air mixture is converted to heat by the catalytic reaction in the gas catalytic combustion element 59, thus extinguishing the flame in the flame combustion chamber 78. Heat from the combustion chamber 58 is conducted through the body member 56, and in turn the receiving socket 62 into the vaporising chamber 60. Heat is also conducted from the body member 56 and the exhaust gases in the exhaust gas chamber 83 through the heat transfer member 88 into the vaporising chamber 60. As the vaporisable matter in the vaporising chamber 60 commences to heat, vapours are released therefrom, and can thus be drawn from the vaporising chamber 60 through the mouthpiece 64.

As the vapours are drawn from the vaporising chamber 60 through the mouthpiece 64, air to replace the vapours is drawn into the vaporising chamber 60 through the air inlet 93 and in turn through the heating chamber 92 to the vaporising chamber 60. The air being drawn through the heating chamber 92 is heated by heat conduction, radiation and convection from the body member, and thus, further assists in maintaining the temperature in the vaporising chamber 60 at the desired vaporising temperature.

The vapours being drawn from the vaporising chamber 60 are cooled in the heat sink element 103, and any tar or other undesirable compounds in the vapours drawn from the vaporising chamber 60 are condensed on the heat sink element 103 to be removed periodically by removing and cleaning the heat sink element 103 at appropriate intervals.

The main difference between the device 55 and the device 1 is that the majority of heat transferred from the body member 56 to the vaporising chamber 60 is by heat conduction, rather than by heat convection by heated air.

While the device 55 has been described as comprising a single heat transfer member 88, it is envisaged in certain cases that more than one heat transfer member 88 may be provided extending into the receiving socket 62 for transferring heat into the vaporising chamber 60.

A particularly important advantage of the invention is that the heat transfer to the

vaporisable matter through the heat transfer members 25 and 88 initially heats the vaporisable matter for initiating vaporising thereof. Further and additional heating of the vaporisable matter is achieved by the heated air from the heat exchanging chamber 10 of the device 1 as the heated air is drawn into the vaporising chamber 15 as the mouthpiece (not shown) is drawn on, however, in the device 55 a greater proportion of the heat is transferred into the vaporising chamber 60 by heat conduction through the heat transfer member 88 and the direct contact between the vaporising chamber 60 and the receiving socket 62. A particularly important advantage of the invention is that the vaporisable matter is heated gradually in the vaporising chamber 15 so that the vaporisable components in the vaporisable matter are gradually released over a period of time, rather than all being released substantially simultaneously.

While the devices according to the invention have been described as comprising heat transfer to the vaporisable matter by both temperature conduction through the body member, the coupling member and the heat transfer members and also by heat transfer through the heated air, in certain cases, it is envisaged that the device according to the invention may be provided with only one form of heat transfer for transferring heat to the vaporisable matter. In which case, heat transfer would either be through direct heat conduction through the body member, the coupling member and vaporising chamber, or through heat transfer by air from the heat exchange chamber to the vaporising chamber. In which case, where heat transfer is by heat conduction only, the heat exchange chamber of the device 1 and the heating chamber 92 of the device 55 would be omitted, and where heat transfer is to be

mainly through air heat transfer, the heat transfer members would be omitted from the vaporising chamber.

The invention is not limited to the embodiments hereinbefore described, which may be varied in construction and detail.

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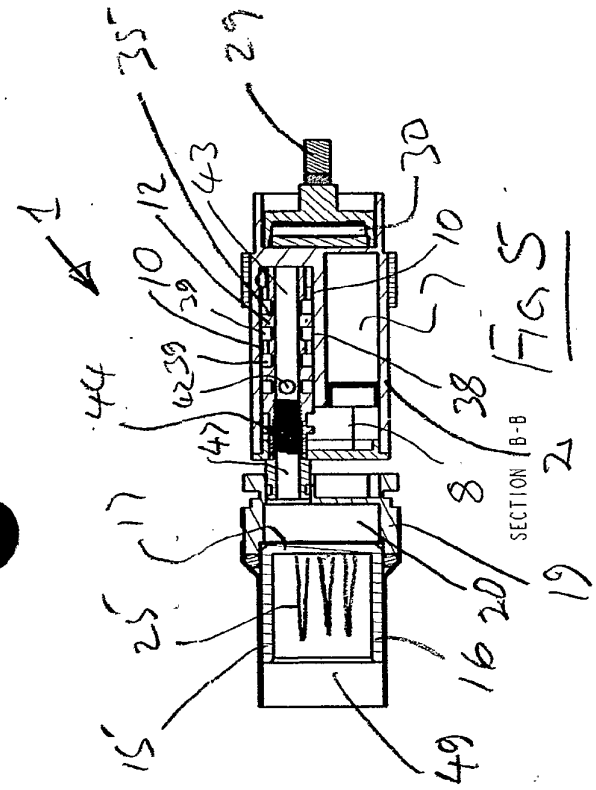


FIG 5

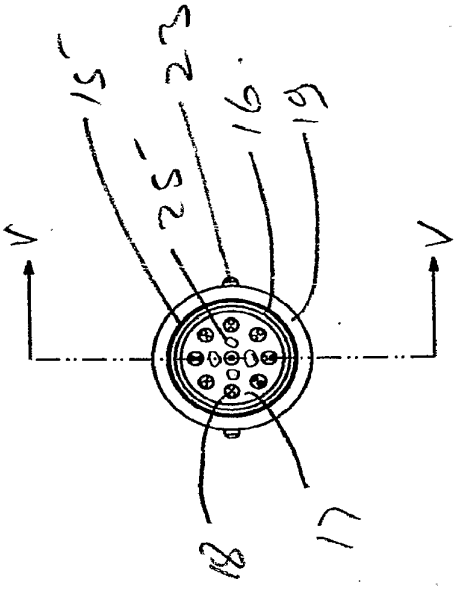


FIG 4

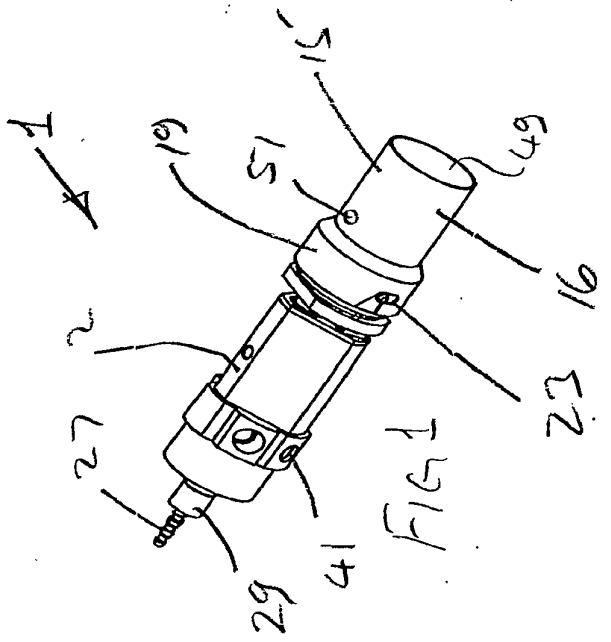
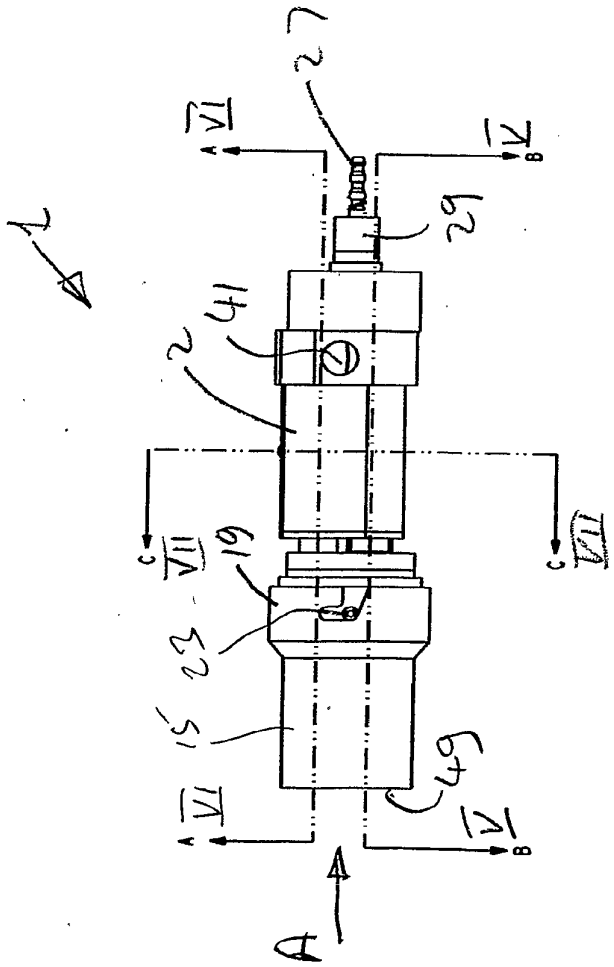


FIG 1



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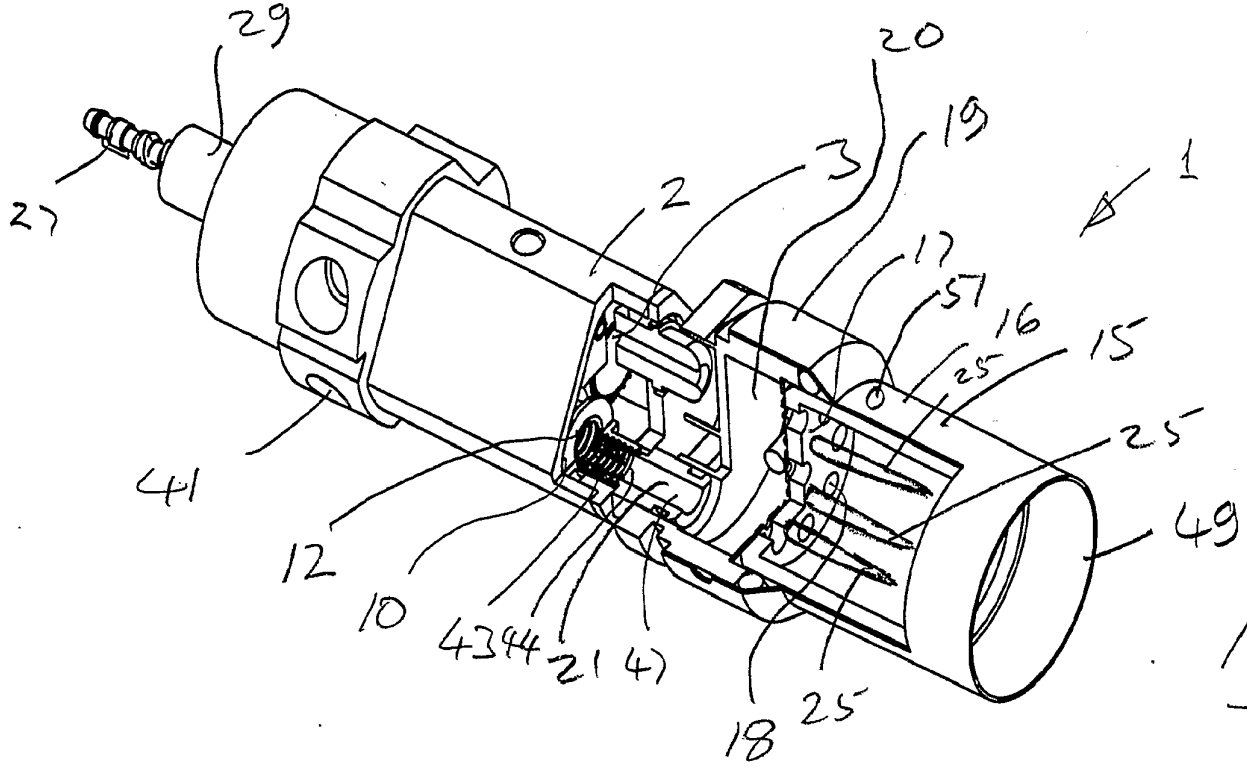

FIG 2

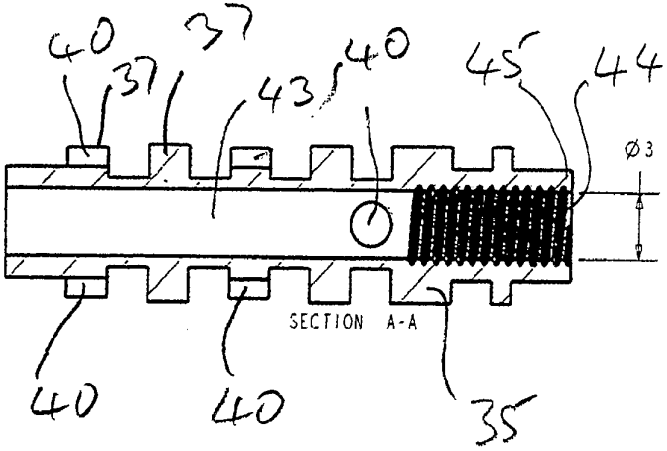

FIG 13

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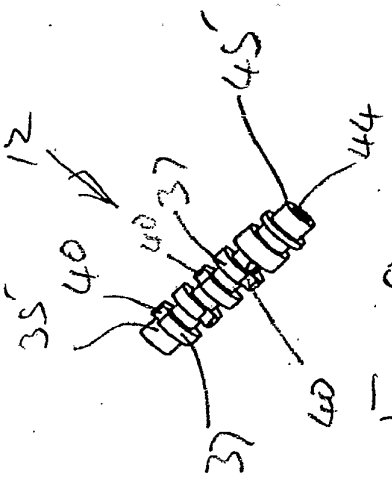


FIG 10

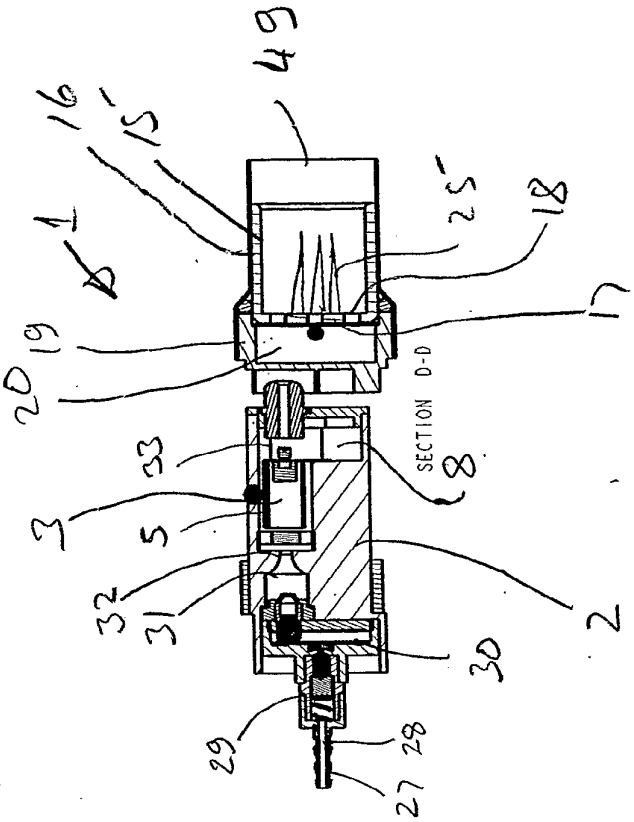


FIG 8

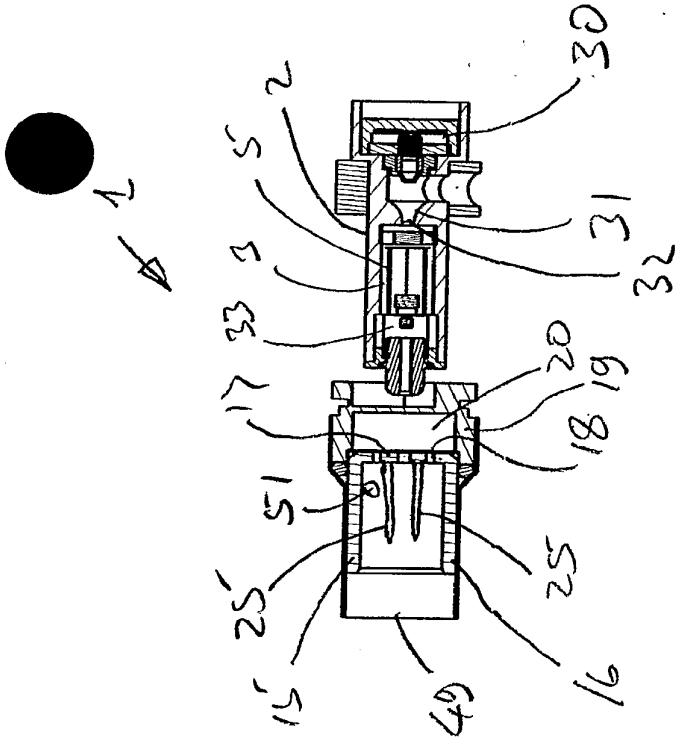
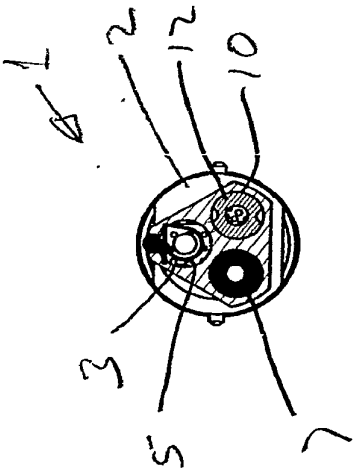


FIG 6



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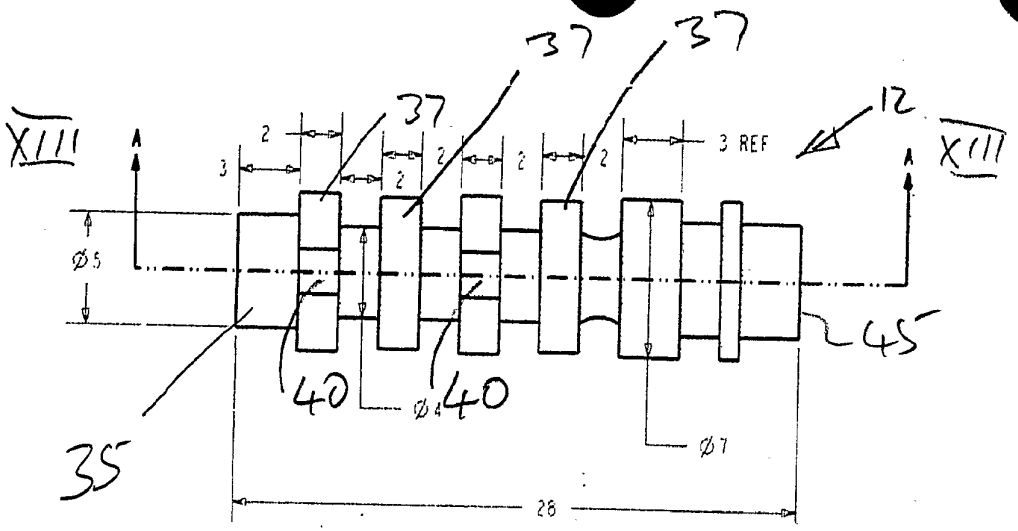

FIG 10

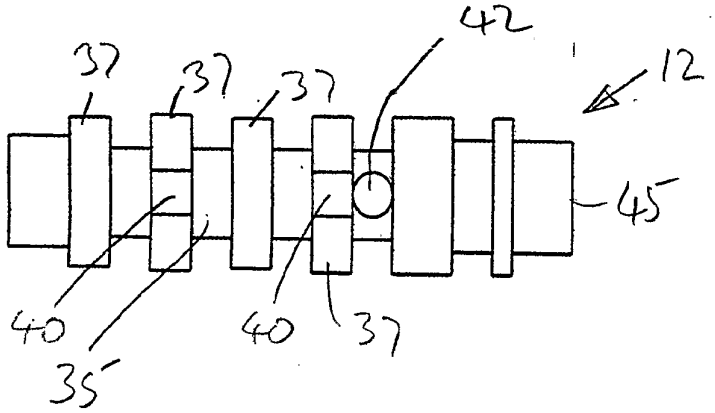

FIG 12

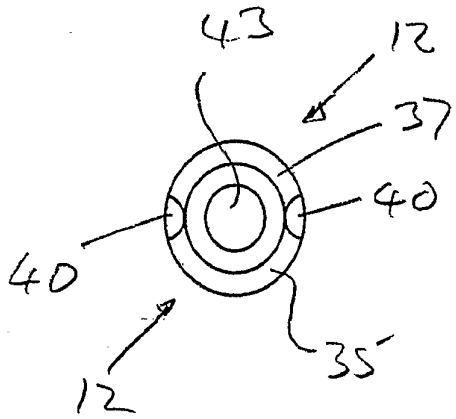

FIG 11

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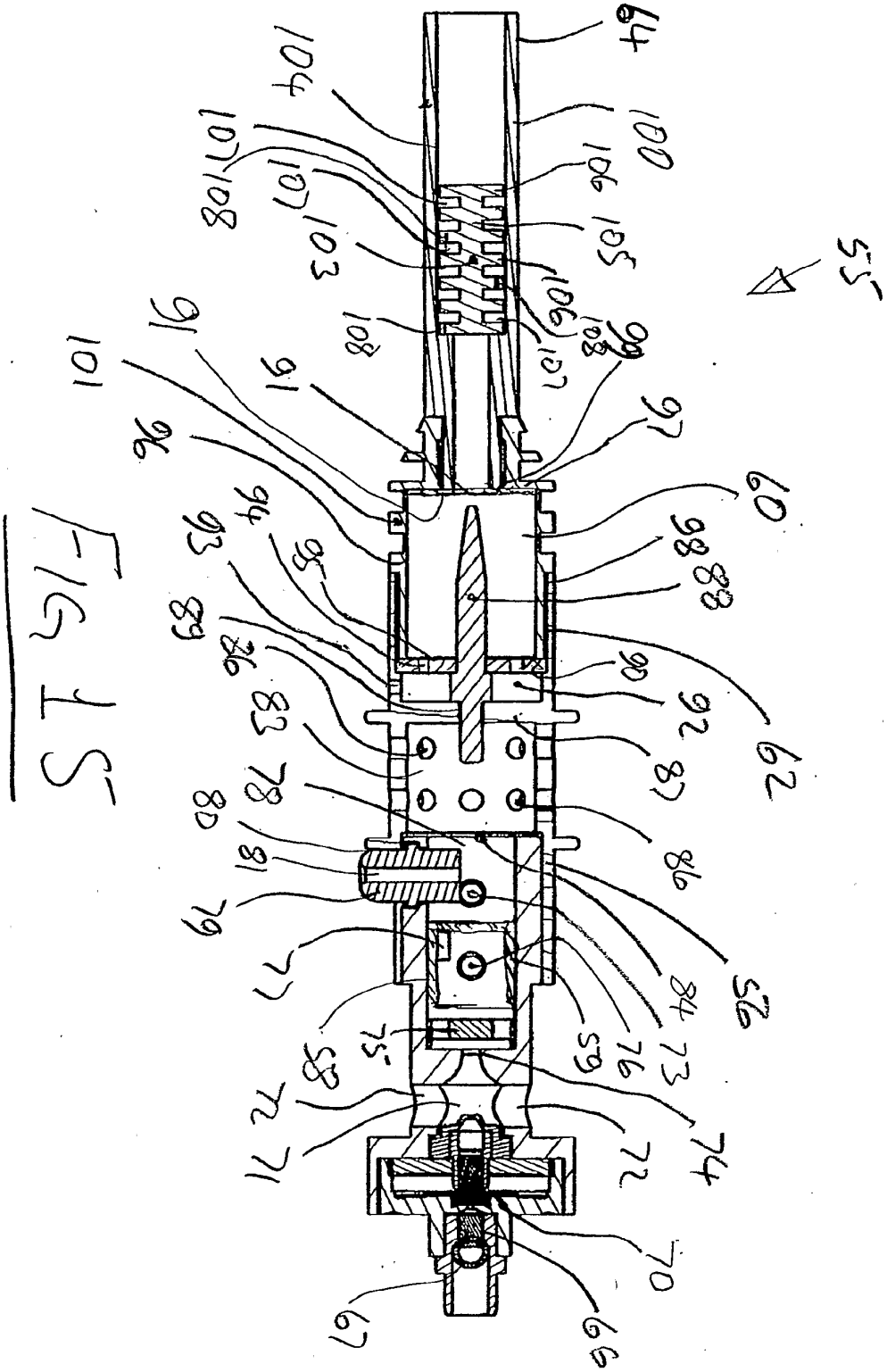
FIG 15
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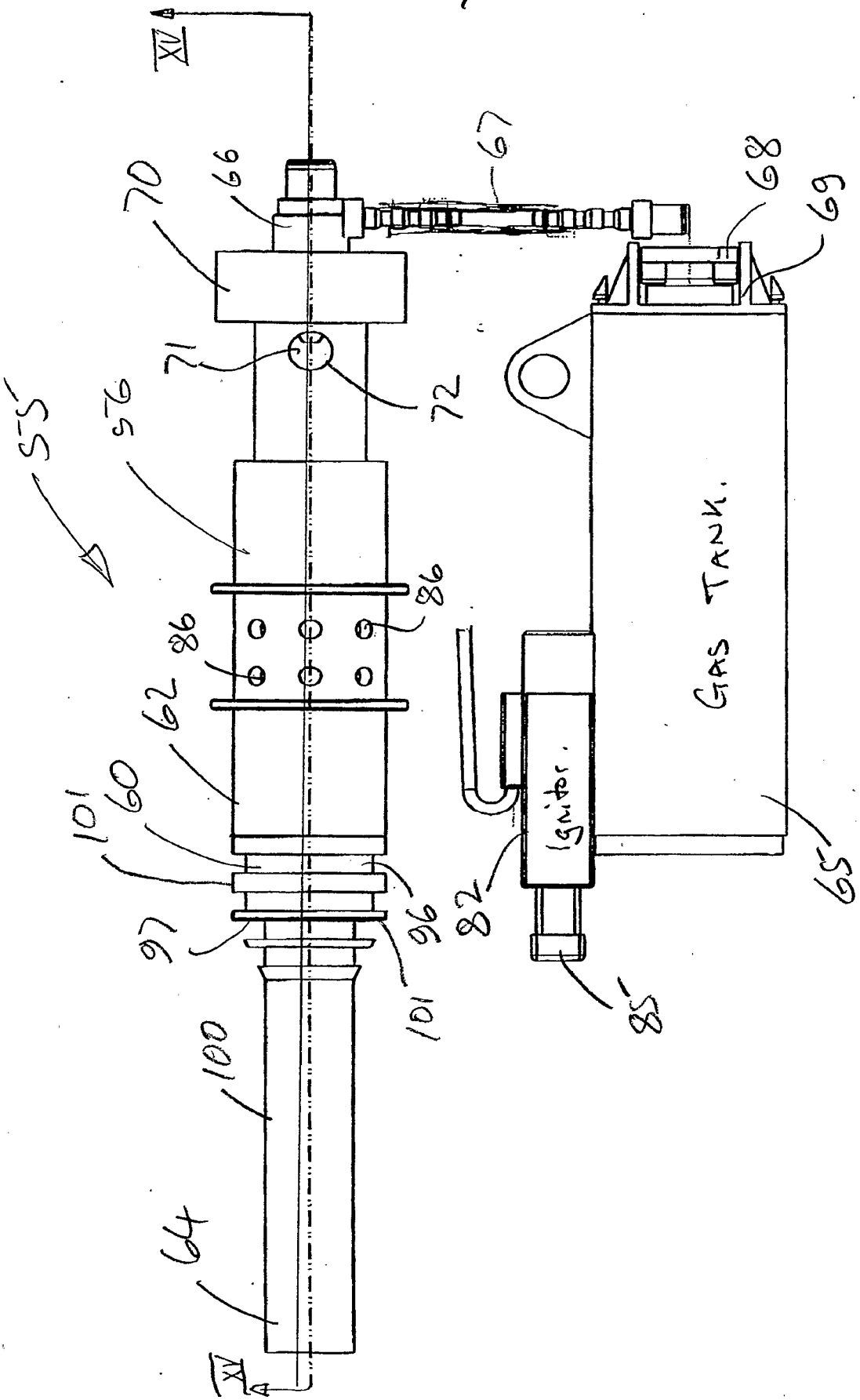
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69
70
71
72
S-S'
S6
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62
60
101
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101
100
64
XV
GAS TANK.
Igniter.
82
85'
65'

FIG 14

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/IE2006/000006

International filing date: 02 February 2006 (02.02.2006)

Document type: Certified copy of priority document

Document details: Country/Office: IE
Number: S2005/0615
Filing date: 19 September 2005 (19.09.2005)

Date of receipt at the International Bureau: 22 February 2006 (22.02.2006)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse

Patents Office
Government Buildings
Hebron Road
Kilkenny

I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

Application No.	S2005/0615
Date of Filing	19 September 2005
Applicant	OGLESBY & BUTLER RESEARCH & DEVELOPMENT, an Irish company of Industrial Estate, Dublin Road, Carlow, Ireland.

Dated this 9 day of February 2006.

An officer authorised by the
Controller of Patents, Designs and Trademarks.

S050615

FORM NO. 1

REQUEST FOR THE GRANT OF A PATENT

PATENTS ACT, 1992

The Applicant(s) named herein hereby request(s)

☐ the grant of a patent under Part II of the Act

☒ the grant of a short-term patent under Part III of the Act

on the basis of the information furnished hereunder.

1. Applicant(s)

Name

OGLESBY & BUTLER RESEARCH
& DEVELOPMENT LIMITED

Address

Industrial Estate, Dublin Road, Carlow, Ireland.

Description/Nationality

An Irish company.

2. Title of Invention

"A device for vaporising vaporisable matter"

3. Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)

Previous filing date	Country in or for which filed	Filing No.

4. Identification of Inventor(s)

Name(s) of person(s) believed
by Applicant(s) to be the inventor(s)
ALFRED PETER OGLESBY and JOHN PAUL OGLESBY

Address
A British subject of Castle Hill, Carlingford, County Louth, Ireland; and
A British subject of Anneville, Shrule, Carlow, Ireland.

5. **Statement of right to be granted a patent (Section 17 (2) (b))**
The applicant has derived the right to be granted a Patent from the inventors by virtue of a Deed of Assignment dated September 16. 2005.

6. **Items accompanying this request – tick as appropriate**

(i) [X] Prescribed filing fee (€60-00)

(ii) [ ] Specification containing a description and claims

[X] Specification containing a description only

[X] Drawings referred to in description or claims

(iii) [ ] An abstract

(iv) [ ] Copy of previous application(s) whose priority is claimed

(v) [ ] Translation of previous application whose priority is claimed

(vi) [ ] Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant(s))

7. **Divisional Application(s)**
The following information is applicable to the present application which is made under Section 24 –

Earlier Application No: .....
Filing Date: .....

19 SEP 2005

8. **Agent**
The following is authorised to act as agent in all proceedings connected with the obtaining of a patent to which this request relates and in relation to any patent granted –

Name	Address
F.F. GORMAN & CO.	15 Clanwilliam Square, Dublin 2, Ireland.

9. **Address for Service (if different from that at 8)**
F.F. GORMAN & CO., at its address as recorded for the time being in the Register of Patent Agents.

Signed F.F. GORMAN & CO., Authorised Patent Agents

BY: _____ EXECUTIVE

Date September 19. 2005

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"A device for vaporising vaporisable matter"

The present invention relates to a device for vaporising vaporisable matter for facilitating inhaling of the vaporised matter. For example, the device is suitable for vaporising vaporisable matter which comprises one or more of flavour components, medicinal components and psychoactive components, such as tobacco, mullein, passion flower, cloves, yohimbe, mint, tea, eucalyptus, camomile and other such herbs and plant matter.

Herbs, for example, tobacco and the like are smoked by burning, in order to release psychoactive compounds, which are then inhaled. The psychoactive compounds are released into the fumes of combustion, which are then inhaled. However, burning of such herbs as well as producing psychoactive compounds also produces toxins, which largely result from the actual combustion process. Such toxins are known to be carcinogenic, and also can result in lung and heart disease. Thus, the smoking of such herbs and other such plant matter is hazardous and undesirable. An alternative to releasing flavour, medicinal and psychoactive compounds from such herbs and plant matter by smoking is to raise the temperature of the herb to an appropriate temperature for causing the vaporisable constituent or constituents to be vaporised, and then inhale the vaporised constituent or constituents. However, the temperature range at which such compounds can be vaporised in herbs and plant matter ranges from approximately 130°C to 250°C. If the temperature is below 130°C, in general, vaporisation does not occur. However, if the temperature to which the herb or plant matter is heated exceeds 300°C, combustion of the herb or

plant matter may commence. Thus, in order to satisfactorily vaporise flavour, medicinal and psychoactive constituents in herbs and plant matter, the temperature at which the herb or plant matter is maintained for producing the vaporised compounds must be controlled within reasonably tight tolerances.

It is known to provide apparatus for vaporising desirable constituents from herbs by electrically heating the herb. However, due to the energy requirements of such apparatus, a mains electricity supply is required to power the apparatus, and thereby the apparatus is not portable when in use. This thus renders a person immobile when using such apparatus. An alternative device for vaporising vaporisable constituents in herbs and plant matter is disclosed in U.S. published Patent Application Specification No. 2004/0031495 of Steinberg. Steinberg discloses a pipe which is substantially similar to a smoking pipe in which the herb, typically, tobacco to be vaporised is located in a bowl portion of the pipe. A heat resistant and porous flame filter is located in the bowl above the herb, and a flame from a match or cigarette lighter is used to heat the porous filter while air is being drawn through the pipe. Thus, a mixture of air and the products of combustion from the flame are mixed in the porous filter and drawn through the herb in the bowl for heating the herb for in turn vaporising desirable constituents in the herb. The mixture of air, the products of combustion and the vaporised constituent are then drawn through a mouthpiece of the pipe and inhaled. However, due to the fact that the flame is played on the heat resistant porous flame filter, there is a danger of the flame being drawn through the filter and thus causing combustion of the herb in the bowl of the pipe. However, even where the herb does not combust, the products of combustion

of the flame are inhaled along with the vaporised constituent. This is undesirable.

There is therefore a need for a device for vaporising vaporisable matter, which preferably is portable, and overcomes the problems of prior art devices.

The present invention is directed towards providing a device for vaporising vaporisable matter, which addresses at least some of the problems of prior art devices.

According to the invention there is provided a device for vaporising vaporisable matter, the device comprising a vaporising chamber for the vaporisable matter, a heating means for heating the vaporisable matter for vaporising thereof, an outlet from the vaporising chamber through which vapour from the vaporisable matter is drawn, and an air inlet to the vaporising chamber for accommodating air into the vaporising chamber to replace air and vapour drawn therefrom.

In one embodiment of the invention the heating means is an electrically powered heating means.

In another embodiment of the invention the heating means comprises a positive temperature control resistive heating element.

In another embodiment of the invention the heating means comprises an electrical resistive heating element, and in a further embodiment of the invention the heating

means comprises an electrical induction heating means.

Preferably, the heating means extends into the vaporising chamber, and advantageously, comprises an elongated member. Preferably, the elongated member terminates in a pointed distal end, and ideally, a plurality of spaced apart elongated members forming the heating means are provided in the vaporising chamber.

Alternatively, the heating means comprises a heating means located externally of the vaporising chamber, and a heat transfer means transfers heat from the heating means to the vaporising chamber, preferably, the heat transfer means extends into the vaporising chamber from the heating means. In one embodiment of the invention the heat transfer means comprises an elongated member extending into the vaporising chamber, and ideally, the elongated member forming the heat transfer means terminates in a pointed distal end. Advantageously, a plurality of spaced apart elongated members each forming heat transfer means extend into the vaporising chamber.

Preferably, the vaporising chamber is formed by a main base wall and a main side wall extending from and around the main base wall, and defining with the main base wall a main hollow interior region which forms the vaporising chamber.

In another embodiment of the invention the main side wall defines an open mouth to the main hollow interior region, and advantageously, a closure means is provided for

closing the open mouth.

In one embodiment of the invention the outlet is located in the closure means, and preferably, a mouthpiece through which the vapour from the vaporising chamber is drawn is coupled to the outlet, and ideally, is coupled to the outlet through a tubular member. Ideally, a cooling means is located in the tubular member for cooling the vapour, and preferably, the cooling means comprises a heat sink member, and advantageously, the heat sink member defines a tortuous passageway for accommodating the vapour from the outlet to the mouthpiece for collecting condensable undesirable compounds entrained in the vapour.

In one embodiment of the invention the closure member comprises a secondary base wall, and a secondary side wall extending from and around the secondary base wall and defining with the secondary base wall a secondary hollow interior region, the secondary side wall being engageable in the main hollow interior region in a plug/socket manner so that the main and secondary hollow interior regions together form the vaporising chamber.

Preferably, the main and secondary side walls are of cylindrical construction.

Ideally, the device is portable, and where the heating means is an electrically powered heating means, the device is battery powered.

Alternatively, the heating means may be gas powered, and in which case, the

heating means would be supplied with a fuel gas supply from a reservoir adapted for storing the fuel gas in liquid form.

The invention will be more clearly understood from the following description of some embodiments thereof, which are given by way of example only, with reference to the accompanying drawings, in which:

Fig. 1 is a side elevational view of a device according to the invention for vaporising vaporisable matter,

Fig. 2 is a transverse cross-sectional side elevational view of a portion of the device of Fig. 1 on the line II-II of Fig. 1,

Fig. 3 is an exploded perspective view of the device of Fig. 1,

Fig. 4 is an enlarged perspective view of a detail of the device of Fig. 1,

Fig. 5 is an exploded perspective view of a portion of a device according to another embodiment of the invention for vaporising vaporisable matter, and

Fig. 6 is an enlarged perspective view of a detail of the device of Fig. 5.

Referring to the drawings and initially to Figs. 1 to 4, there is illustrated a device according to the invention, indicated generally by the reference numeral 1, for

vaporising vaporisable matter, which may be any type of vaporisable matter, but typically, would be tobacco. The device 1 comprises a vaporising chamber 3 within which the vaporisable matter is vaporised. The vaporising chamber 3 is formed by a main base wall 4 and a main cylindrical side wall 5 which defines with the main base wall 4 a main hollow interior region 6. The main side wall 5 defines a main open mouth 7 to the main hollow interior region 6, which is closed by a closure means which comprises a closure member 8.

The closure member 8 comprises a secondary base wall 10 and a secondary cylindrical side wall 11 extending from the secondary base wall 10, which defines with the secondary base wall 10 a secondary hollow interior region 12. The secondary side wall 11 defines a secondary open mouth 14 to the secondary hollow interior region 12, and the secondary side wall 11 is sized relative to the main side wall 5 for engaging the main side wall 5 in the main hollow interior region 6 in a plug/socket manner so that the main and secondary hollow interior regions 6 and 12 form the vaporising chamber 3. In this embodiment of the invention the secondary side wall 11 and the main side wall 5 are sized so that the secondary side wall 11 engages the main side wall 5 with a relatively tight sliding fit for facilitating removal thereof to provide access to the vaporising chamber 3 for placing the vaporisable matter therein, while at the same time preventing inadvertent disengagement of the closure member 8 from the main hollow interior region 6.

An outlet 15 in the secondary base wall 10 accommodates vapour from the vaporisable matter being drawn from the vaporising chamber 3. A tubular member

16 extending from the outlet 15 terminates in a mouthpiece 17 through which the vapour from the vaporising chamber 3 is drawn. An air inlet 19 in the main side wall 5 accommodates air into the vaporising chamber 3 to replace air and vapour drawn therefrom through the mouthpiece 17. A gauze partition 20 extending transversely across the main hollow interior region 6 retains the vaporisable matter in the combustion chamber 3 from the air inlet 19, while at the same time accommodating air from the air inlet 19 through the combustion chamber 3.

A heating means, in this embodiment of the invention comprising an electrically powered positive temperature control resistive heating element 23 extends into the vaporising chamber 3 through a bore 24 in the main base wall 4. The heating element 23 is encased in an elongated tubular member 26 which extends into the vaporising chamber 3 through the bore 24 in the main base member 4 and engages the bore 24 with a relatively tight interference fit. The tubular member 26 terminates in a tapered distal portion 27 which terminates in a point 28 for puncturing a sachet in the event of the vaporisable matter being placed in the vaporising chamber 3 in a sachet, such as a tea-bag type sachet. A housing 29 extending from the main base wall 4 accommodates a battery (not shown) and suitable electrical and electronic control circuitry (also not shown) for powering the heating element 23.

A cooling means comprising a heat sink member 30 is located in the tubular member 16 between the outlet 15 and the mouthpiece 17 for cooling vapour as it is being drawn through the tubular member 16 in order to avoid the vapours burning the mouth. The heat sink member 30 is of brass and comprises a central core 31 and a

plurality of spaced apart circumferential flanges 32 extending from the central core 31. The flanges 32 define with the central core 31 respective spaced apart annular chambers 34 which communicate with each other through longitudinally extending grooves 35 formed in the flanges 32. The grooves 35 in the flanges 32 are staggered from flange to flange in order to form with the annular chambers 34 a tortuous passageway for the vapour through the heat sink member 30 for facilitating cooling of the vapour. Additionally, it has been found that as the vapours are cooled, undesirable compounds entrained in the vapour, for example, tar and the like, condense on the heat sink member 30. The heat sink member 30 is located in the tubular member 16 for facilitating removal for cleaning thereof for the removal of the condensed compounds therefrom at appropriate periodic intervals.

In use, with the closure member 8 disengaged from the main hollow interior region 6, and vaporisable matter to be vaporised is placed in the secondary hollow interior region 12 defined by the closure member 8. The vaporisable matter may be placed in the secondary hollow interior region 12 in loose form or in sachet form. With the vaporisable matter in the secondary hollow interior region 12, the closure member 8 is engaged in the main hollow interior region 6, thereby forming the vaporising chamber 3. As the closure member 8 is being engaged in the main hollow interior region 6, the tubular member 26 punctures the sachet in which the vaporisable matter is contained, if the vaporisable matter is placed in the secondary hollow interior region 12 in such a sachet. A power switch (not shown) on the housing 29 is operated for coupling the battery to the heating element 23 through the electrical and electronic control circuitry (not shown) for powering the heating element 23. Heat is

transferred through the tubular member 26 from the heating element 23 therein to the vaporisable matter, and on the vaporisable matter being brought to the appropriate temperature, vapour begins to be released therefrom. The vapour is then drawn from the vaporising chamber 3 through the outlet 15 and the mouthpiece 17, and as the vapour is being drawn through the tubular member 16, the heat sink member 30 acts to cool the vapour to a desirable temperature, and condensable compounds, such as tar entrained in the vapour are condensed on the heat sink member 30. Periodically the heat sink member 30 is removed for cleaning for removing the condensed compounds therefrom.

Referring now to Figs. 5 and 6, there is illustrated a device according to another embodiment of the invention, indicated generally by the reference numeral 40, also for vaporising vaporisable matter. The device 40 is substantially similar to the device 1 and similar components are identified by the same reference numerals. The main difference between the device 40 and the device 1 is that the device 40 is provided with four tubular members 26 extending into the vaporising chamber 3, each of which contains a heating element 23. Otherwise, the device 40 and its use is similar to that of the device 1.

While the heating means has been described as being provided by a positive temperature control resistive heating element, any other suitable heating means may be provided. For example, where the heating means is being provided by an electrically powered heating means, the heating means may comprise a conventional resistive heating element, an induction heating element or any other

suitable heating means. It is also envisaged that the heating means may be provided by a gas powered heating means, which would be located in the housing 29, and the elongated member 26 would be provided as a solid heat transfer member of, for example, brass or copper for transferring heat from the heat source into the vaporising chamber. It is also envisaged that where the heating means is provided by an electrically powered heating means, the heating means may be located externally of the vaporising chamber, for example in the housing 29, and in which case, the elongated member 26 would act as a heat transfer member and would be provided as a solid member for transferring heat from the external electrical heat source into the vaporising chamber.

While the cooling means has been described as a heat sink member, any other cooling means may be used, for example, in certain cases the cooling means may be provided as a fibrous filter of the type commonly used in cigarettes.

It is also envisaged that the temperature of the vaporising chamber may be controlled by an electronic thermostat using a self latching valve in the event of the vaporising device being gas powered, and in which case the self latching valve would control the supply of fuel gas to the device.

The invention is not limited to the embodiments hereinbefore described, which may be varied in construction and detail.

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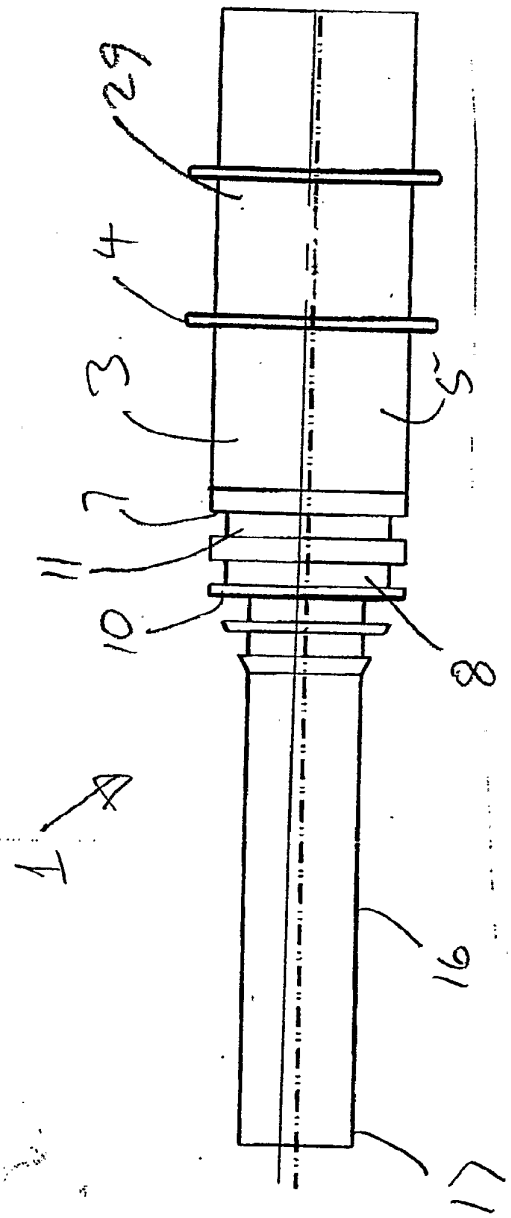
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FIG 1

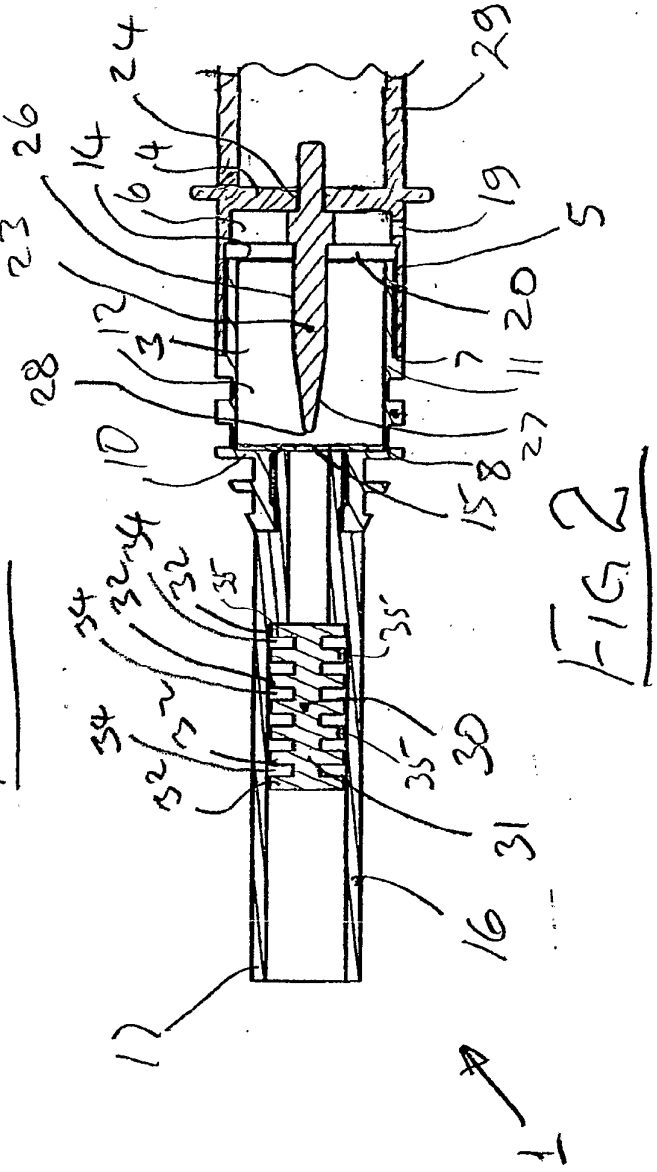
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FIG 2

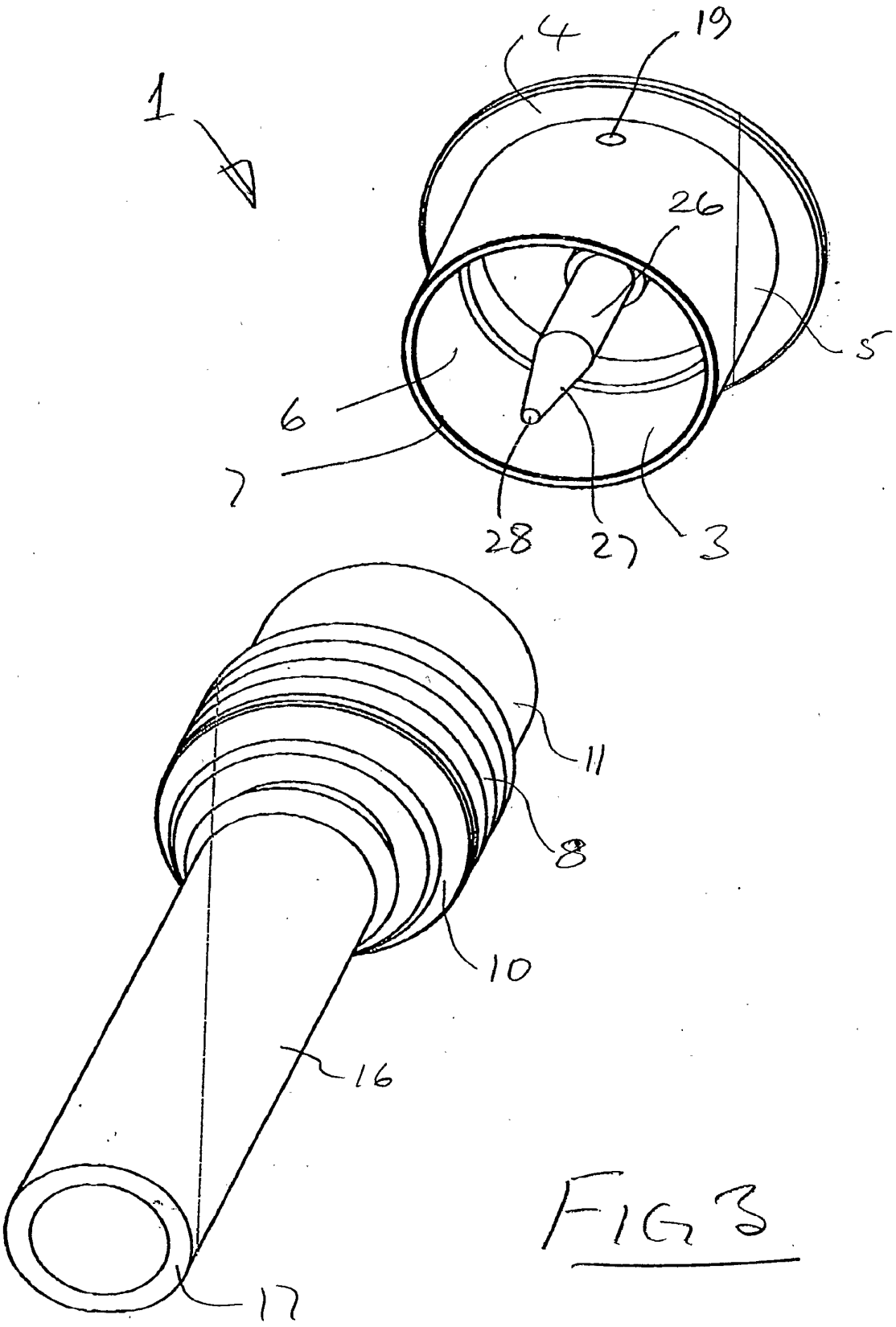


FIG 3

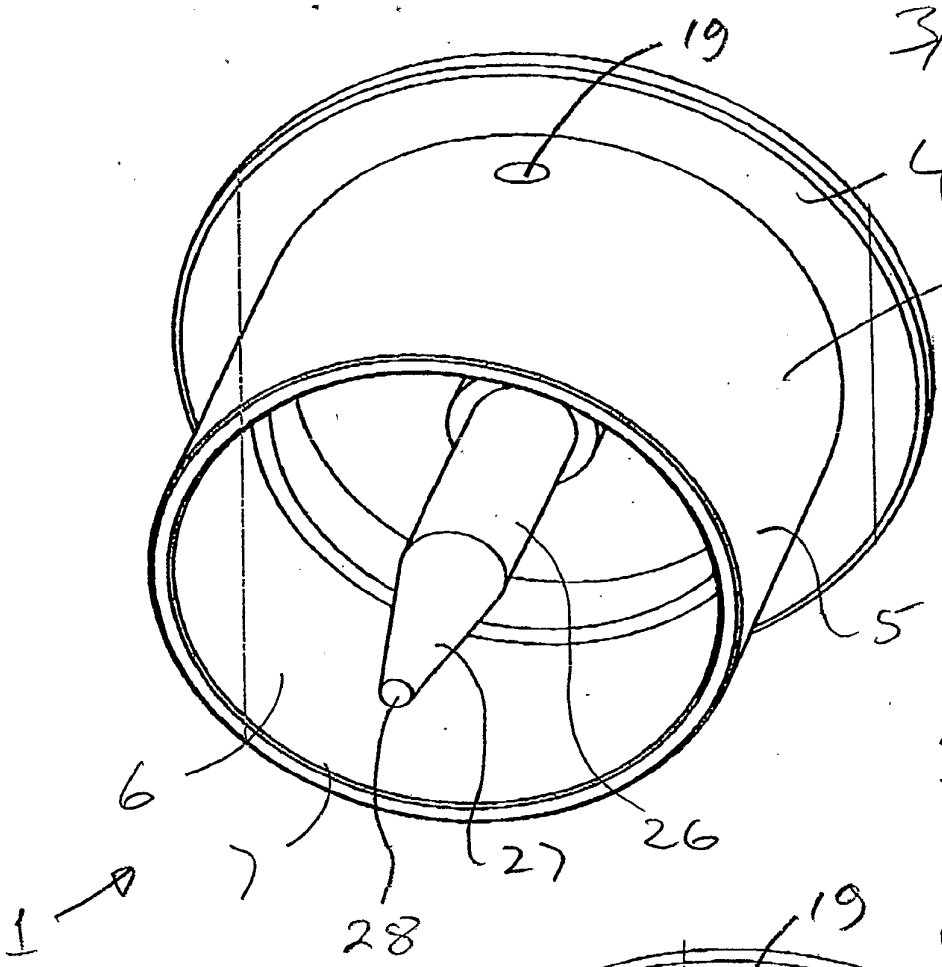


FIG 4

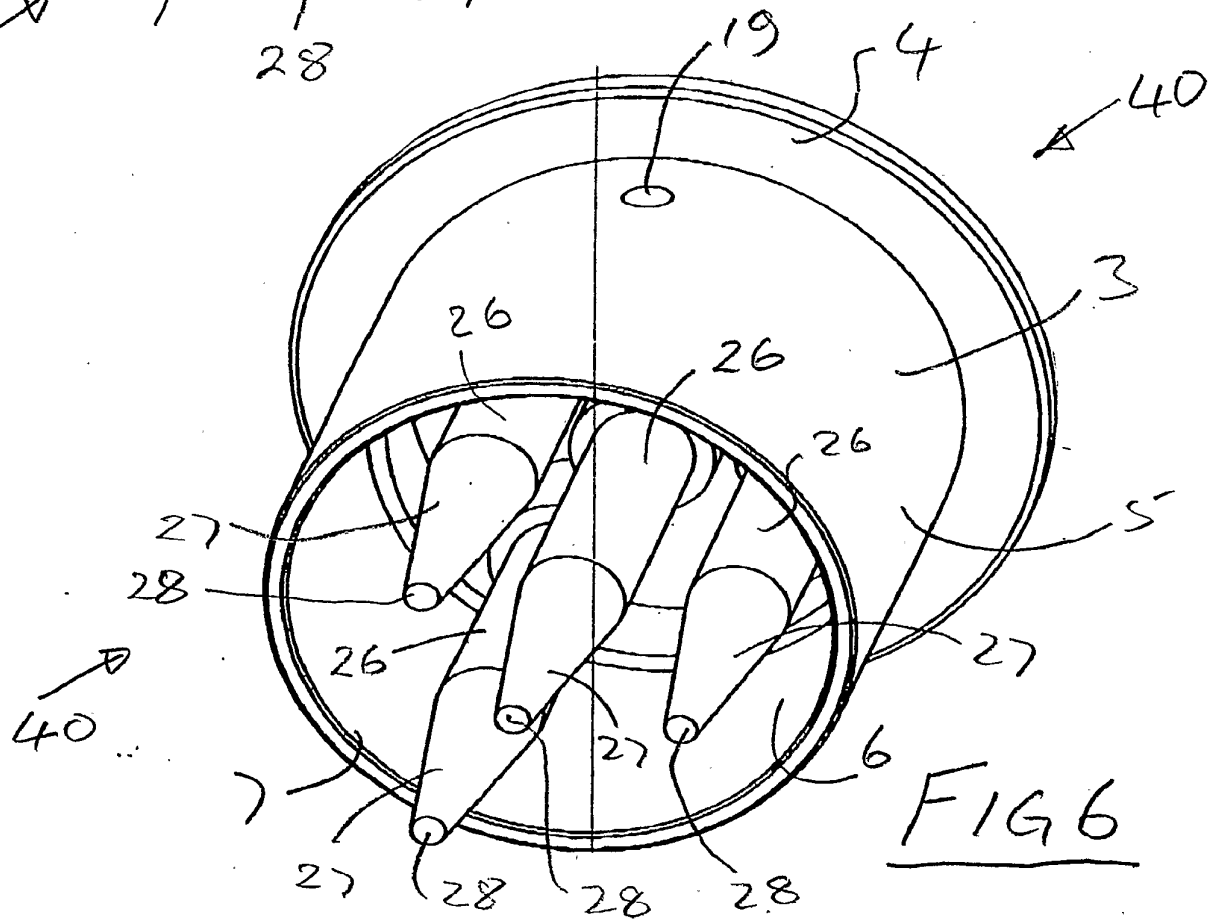
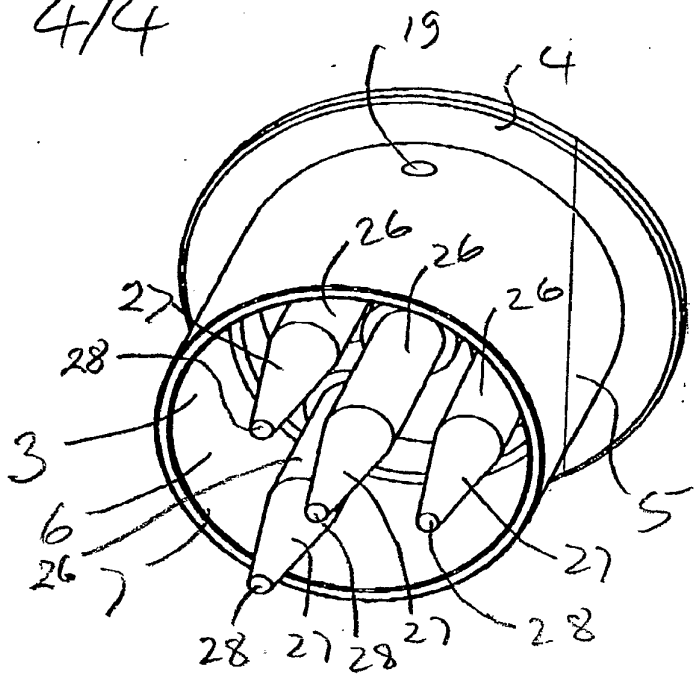


FIG 6



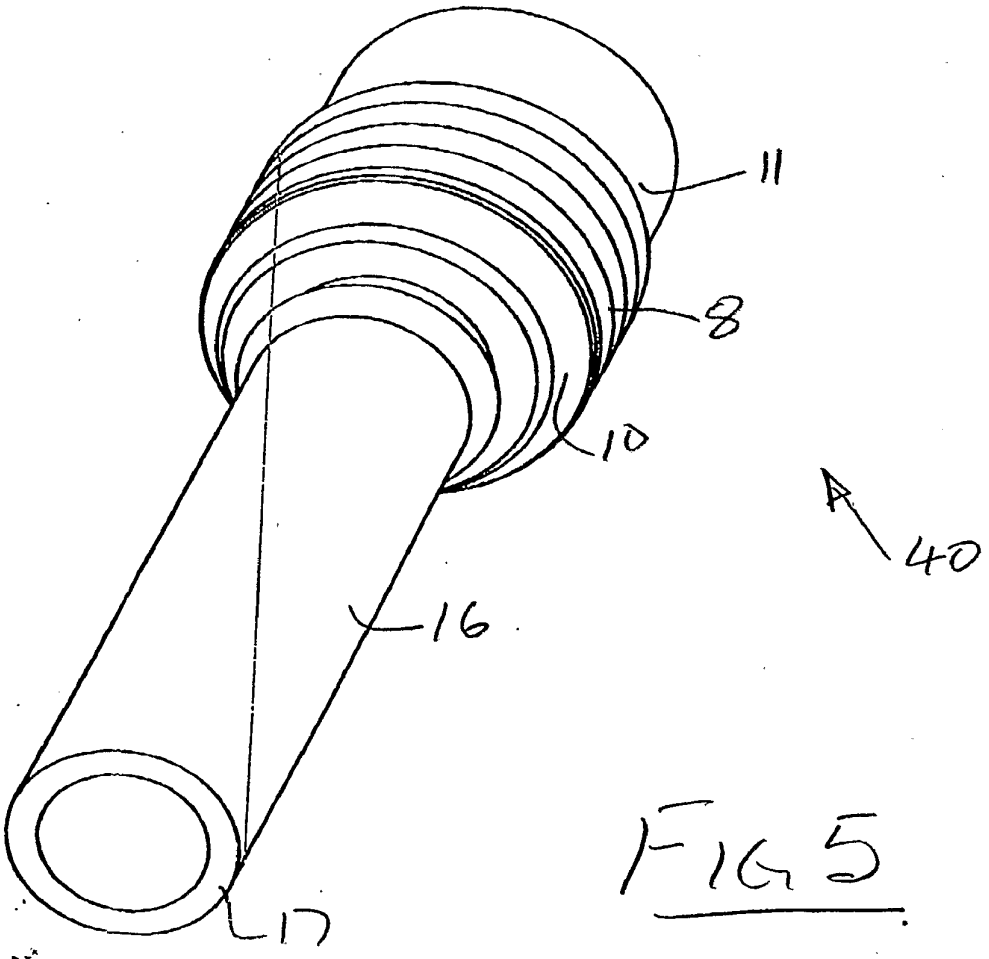


FIG 5

United States Patent [19]

Cohen et al.

[11] **Patent Number: 4,896,683**

[45] **Date of Patent: Jan. 30, 1990**

[54] **SELECTIVE DELIVERY AND RETENTION OF NICOTINE BY-PRODUCT FROM CIGARETTE SMOKE**

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[73] Assignee: **Hercules Incorporated**, Wilmington, Del.

[21] Appl. No.: **258,366**

[22] Filed: **Oct. 17, 1988**

[51] **Int. Cl.**[4] **A24D 3/06**; A24D 3/08; A24D 3/16

[52] **U.S. Cl.** **131/342**; 131/343; 131/345; 131/331

[58] **Field of Search** 131/334, 342, 343, 345, 131/331

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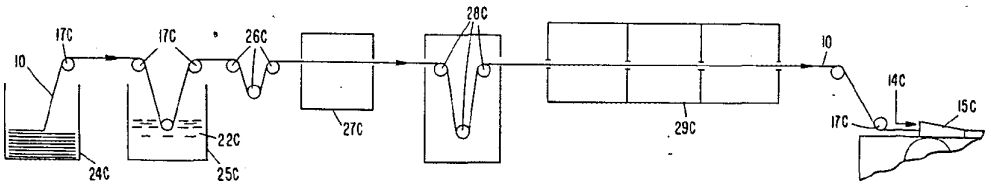
Primary Examiner—V. Millin

Attorney, Agent, or Firm—John E. Crowe

[57] **ABSTRACT**

A method for controlling nicotine delivery through a cigarette filter relative to total particulate pass-through concentration, and the corresponding filter utilizing, as a filter modifier component, at least one water-soluble metal salt of a weak acid, the choice and amount of salt within the filter favoring an alkaline pH exceeding about pH 8, the amount of alkalinity being correlated to the desired amount of nicotine pass-through while corresponding nicotine filter retention properties are keyed to the presence and concentration of a water soluble salt of a strong acid within the filter.

22 Claims, 2 Drawing Sheets



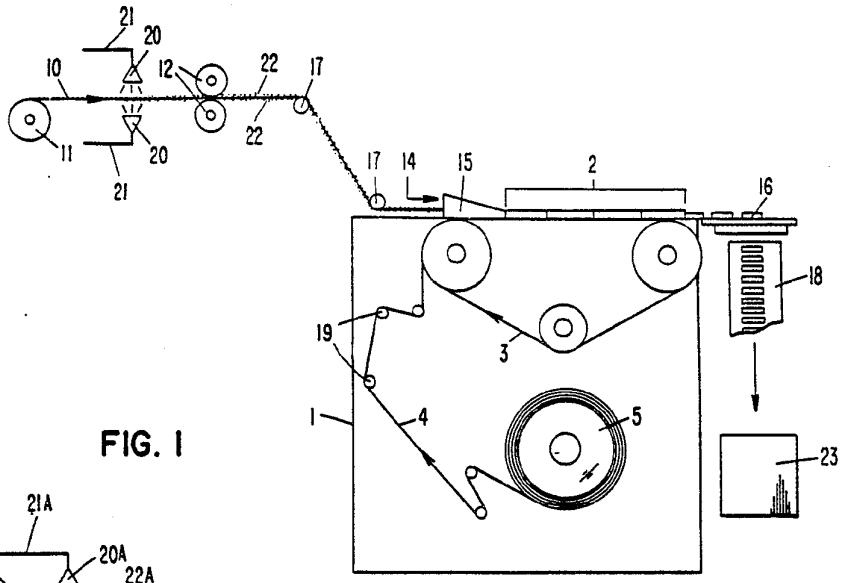


FIG. 1

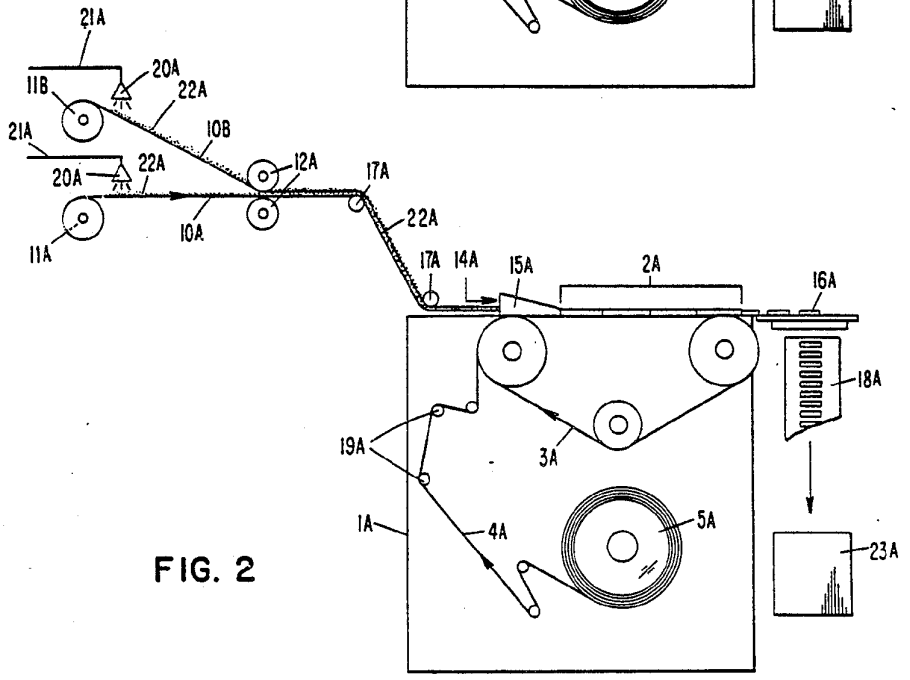


FIG. 2

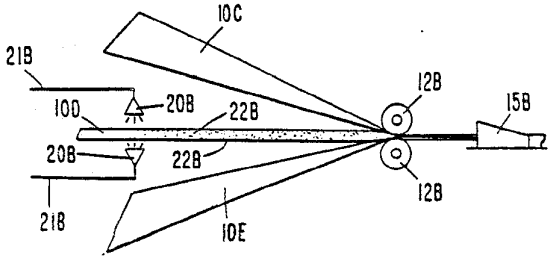


FIG. 3

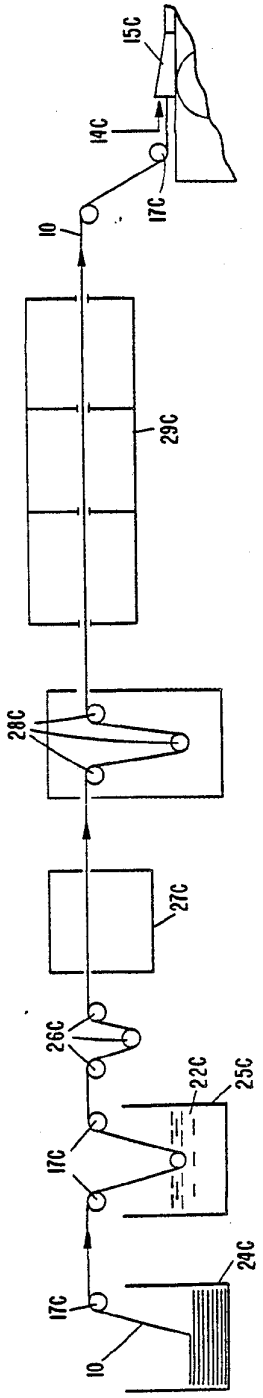


FIG. 4

SELECTIVE DELIVERY AND RETENTION OF NICOTINE BY-PRODUCT FROM CIGARETTE SMOKE

The present invention relates to an improved cigarette filter and method for selectively controlling nicotine delivery relative to delivered particulate matter from cigarette smoke by using a cigarette filter element containing at least one active water soluble modifier component.

BACKGROUND

Although fiber-based cigarette filter elements are well known and have been used for a number of years, the choice of components for this class of filters has remained quite limited over the years due to cost factors and lack of general suitability of many natural fibers for high speed filter production using state of the art filter rod-making apparatus. In addition, the demands on present day commercial cigarette filter elements tend to conflict, particularly with respect to general filtration efficiency and increased demand for selective filtration of cigarette smoke components.

While various fibers and fiber mixtures have been tried and evaluated, a substantial number of cigarette filter elements continue to favor old technology because of certain cost and handling advantages. For example, cellulose acetate tow can be readily processed into cuttable filter rods using an essentially unmodified state-of-the art filter rod-making apparatus without serious jamming problems. This advantage is enjoyed despite increased need for substantial amounts of additives, including organic plasticizers such as triacetin, diacetin, citric acid, as well as lubricants, flavors, medicines, selective filtering agents and the like. Generally, such additives are applied as aqueous solutions onto opened fiber tow by art-recognized dipping, spraying, or printing techniques.

The advantages of cellulose acetate fiber as filter substrate, however, are countered by certain disadvantages. For example, such fiber tends to be relatively weak compared with thermoplastic synthetics such as polyolefin fiber or filament. This characteristic seriously limits the amount of tension and crimp that a cellulose acetate fiber tow of low dpf will tolerate prior to introduction into a conventional filter rod-making apparatus.

Synthetics such as polyolefin fiber, however, also have some disadvantages. These arise from the fact that polyolefin substrates are generally hydrophobic and tend to be chemically inert, while a majority of known cigarette filter additives are hydrophilic. For this reason it is sometimes very difficult to apply and retain such additives in proper amount and functional condition within filter elements using hydrophobic synthetic fiber as a major substrate component.

Another problem, unique to the cigarette filter art, concerns the difficulty in optimizing fiber denier and general filter efficiency of synthetic fiber filters without corresponding sacrifice in dimensional stability, hardness, and pressure drop or draw across the filter element.

It is an object of the present invention to obtain cigarette filters of superior efficiency and draw which can be tailored to a wide variety of tobacco mixtures while retaining known advantages of various filter substrates or combinations thereof.

It is a further object of the present invention to control selectively both filter delivery and filter retention of nicotine by-product in cigarette smoke, compared with pass through concentrations of total particulate matter.

THE INVENTION

The above objects are obtained in accordance with the instant method for controlling nicotine filter retention and pass through characteristics of a cigarette filter element, comprising one or a combination of cellulose acetate- or thermoplastic synthetic- fiber substrate. These can include one or more substrates singly or in combination in the form of an (a) opened fiber tow, (b) ribbon of a nonwoven material, (c) sliver or (d) fibrillated film, which are activated by

(A) treating one or more substrate of said filter element or plug component thereof with an aqueous solution or suspension containing an effective amount of a non-toxic water soluble salt of a weak acid as an active modifier; or

(B) treating one or more substrate of said filter element or plug component thereof with an aqueous solution or suspension containing an effective amount of a non-toxic water soluble inorganic salt of a strong acid as an active modifier; and

(C) completing fabrication of the desired cigarette, inclusive of drying the filter element; whereby (1) treatment of the substrate or plug component of the filter element with the salt of a weak acid increases filter pass through of nicotine smoke component relative to total particulate pass through concentration, and (2) treatment of the substrate or plug component of the filter element with the salt of a strong acid decreases filter pass through of nicotine smoke component relative to total particulate pass through concentration.

General filter efficiency, particularly solid particulate removal, depends substantially upon fiber denier, filter length and density, but selective filtration properties, particularly control over gassified flavor components, such as nicotine retention and pass through characteristics, are less easily predicted, and remain a continuing problem in the filter art.

The present invention relates to a way of more easily tailoring cigarette filters for specific tobacco mixtures and to satisfy taste and health demands in a rapidly changing market.

In particular, it is found that increased nicotine delivery or pass through is obtained by applying and utilizing one or more salt of a weak acid selected from carbonic, phosphoric, acetic, citric and fumaric acids, in the form of non-toxic water soluble metal salts of group 1(a), 2(a) and Transition Elements, preferably acetate, carbonate, or phosphate salts exemplified by $Mn(OAc)_2$, $Mg(OAc)_2$, $KHCO_3$, K_2CO_3, Na_2CO_3, $NaHCO_3$, K_3PO_4, $KHPO_4$ and KH_2PO_4. For such purposes, it is found particularly advantageous to apply the above salt solutions or suspensions onto one or more filter substrate in sufficient concentration to obtain a pH range of about pH 8 to about pH 12, and preferably about pH 8.0 to about pH 10.5.

Where the tobacco mixture requires increased filter retention to obtain a proper flavor balance, it is found that such retention can be selectively promoted, relative to total particulate pass through, without substantially changing fiber denier or filter density, by merely adding to one or more filter substrate an active amount of a non-toxic water-soluble metal salt of a strong mineral

acid. Salts of hydrochloric, or hydrobromic acid are found useful for such purpose.

Active salts of the latter type include, for example, selected metal salts of group 1(a), 2(a) and Transition Elements, inclusive of calcium, potassium, zinc, lithium, and magnesium. Such salts specifically include, for instance, $ZnCl_2$, LiBr, KBr, $CaBr_2$, $MnCl_2$, and $MgCl_2$.

Salts of the above-defined types are individually applied, as needed, onto one or more appropriate fiber- or fibrillated film substrate(s) in a manner and in effective amounts as indicated hereafter.

Cigarette filter rods or elements within the scope of the present invention usefully comprise, in combination,

(a) a filter plug of compacted substrate comprising one or more of cellulose acetate- or synthetic thermoplastic-fiber continuing substrate such as a fiber- or film forming polyolefin, polyester or polyamide;

(b) a plurality of active filter loci distributed within the compacted substrate, wherein the loci consist essentially of solid and/or solid/liquid phases of the desired water soluble salt of a strong or a weak acid and a nontoxic metal. While the loci may vary somewhat with storage, the preferred initial configuration consists of crystals or noncrystalline solids in conjunction with a small surrounding liquid phase in the form of a saturated or concentrated aqueous salt solution; and

(c) a plug wrap such as paper or film securing the compacted substrate to form the rod and, ultimately, a filter element of desired nicotine retention or pass-through properties as above described.

If desired, one or more active modifier salt component(s) can be applied onto separate filter substrate surfaces (ref. FIGS. 2-3), which are then introduced singly or in register as garniture feed into a filter rod-making apparatus. In such instance, application of active modifier salt component can be conveniently effected by spraying the garniture feed component, or a solution of the active modifier salt can be vacuum drawn through the resulting formed filter rod. In each case filter rod or element is oven dried under controlled heat and humidity before storage or direct combination with a tobacco plug to complete fabrication of the filter element.

An "effective amount of active modifier component", for purposes of the present invention, is an amount of the salt totaling about 2% by weight or more, and preferably about 3–10%, based on total weight of dry filter plug substrate. As above noted, the salt is best distributed in the form of a plurality of filter loci evenly distributed onto a filter substrate and dried to form solid or solid/liquid phases within the filter element.

Also included within the scope of the present invention are filter elements additionally containing surfactant material in a concentration of about 0.1%–10% and preferably 0.5%–10% by weight of one or more of a class described as (1) a polyoxyalkylene derivative of a sorbitan fatty acid ester, (2) a fatty acid monoester of a polyhydroxy-alcohol, or (3) a fatty acid diester of a polyhydroxy alcohol.

Suitable surfactants can include, for instance, ethoxylates, carboxylic acid esters, glycerol esters, polyoxyethylene esters, anhydrosorbitol esters, ethoxylated anhydrosorbitol esters, ethoxylated natural fats, oils and waxes, glycol esters of fatty acids, polyoxyethylene fatty acid amides, polyalkylene oxide block copolymers, poly(oxyethylene-co-oxypropylene) and the like.

The term "substrate", as above defined, denotes a tow, sliver or web of fiber or fibrillated film usable as garniture feed for a filter rod- making apparatus, including one or more of an opened fiber tow of cellulose acetate fiber or thermoplastic synthetic fiber of mono-, bi- or tri-component fibers inclusive of side-by-side and sheath/core varieties having a sheath of lower melting point than the core. Webs of such feed, as above noted, are conveniently introduced into a garniture of a filter rod-making apparatus alone or in complete or partial register (see FIGS. 2 and 3).

Such garniture feed can conveniently include up to about four or more webs of substrate component(s) of a homogeneous or mixed variety, the desired active components being applied onto one or both faces of selected substrates, the manner and number of faces treated depending upon desired filter selectivity and efficiency, plus feel, hardness, and draw characteristics.

For purposes of the present invention, it is immaterial whether the garniture feed is fabricated, in situ, (i.e. immediately upstream of the garniture) or earlier produced and stored before use.

It is also found suitable to use one or more nonwoven fabrics of the same or different fiber composition and denier as garniture feed, particularly when not all of the substrate in the filter element is to be used as a carrier surface for active modifier component(s).

When a ribbon of a nonwoven fabric or a fiber tow is used as garniture feed component in accordance with the present invention, such can again usefully comprise up to about 100% by weight of cellulose acetate- or synthetic thermoplastic substrate and preferably 10%–100% by weight of polyolefin (mono , bi-, or tri-component) fiber of the side-by-side and sheath/core types, identified here as staple fiber, or may consist of webs or tows having filaments of homogeneous or mixed denier, or combination of fibers such as (a) polypropylene/polyethylene, polypropylene/polyvinylidene chloride, polypropylene/cellulose acetate, polypropylene/rayon, polypropylene/nylon, cellulose acetate/polyethylene, plasticized cellulose acetate, polypropylene/paper; or (b) polypropylene/polystyrene/polyethylene, and the like, in preferred ratios of about (a) 10%–90% 90% –10% or (b) 10%–90%/4-5%–5%/45%–5% based on fiber weight, and as described, for instance, in U.S. Pat. No. 3,393,685.

Fibrillated film can be employed as a substrate component for use alone or in combination with other substrate components as garniture feed within the present invention. Such can be obtained, for instance, in accordance with components disclosed in U.S. Pat. No. 4,310,594 (Yamazaki) and U.S. Pat. No. 3,576,931 (Chopra).

For present purposes, and as part of the step of completing fabrication of the desired filter element is the use of a conventional filter rod-making apparatus. Such device generally contains a tow trumpet, garniture, shaping means, wrapping means, and cutting means in accordance with components and processes described, for instance, in U.S. Pat. Nos. 3,144,023 and 2,794,480. If desired, however, modifications can be made to permit in-situ or prior spraying, dipping, printing, vacuum draw, or other traditional application methods for introducing one or more salt components of the present invention prior to or after the formation of a filter plug.

By way of further background, baled sliver or other garniture feed can, if desired, be continuously dip coated or feedably contacted using one or more printing roll(s) fed from reservoir(s) containing desired active components(s), and the fabrication step completed, as

above noted, by conventional drying, using nip rolls, heated drying rolls, ovens, and the like. Suitable drying can occur at temperatures within the range of about 70° C.–125° C.

When desired, nonwoven material suitable for use as garniture feed is obtained from fiber of homogeneous or mixed denier, using art-recognized techniques. Preferably such nonwovens fall within a weight range of about 10–50 grams per m^2, and a ribbon width of about 4"–12" will generally assure successful passage through the garniture of a conventional filter rod-making apparatus operating at production speeds.

As above-noted, a suitable garniture feed may include about 1–4 or even more substrate webs of identical or different weight, dimensions, bonding properties, absorption properties, fiber composition, and denier. A plurality of such webs can be introduced wholly or partly in register and in machine, cross, or diagonal directions as desired. For best results, however, one relatively lightly thermally bonded fabric, tow, sliver or fibrillated film in register with one nonwoven fabric, or between two nonwoven fabrics (ref. FIG. 2) is found to offer good salt retention, filter draw, and hardness.

The inclusion of an additional low melting fiber such as polyethylene, combined with other polyolefin fiber as garniture feed is also found useful for obtaining tow plugs of widely varying bonding and adsorption properties.

Cost-wise, opened fiber tow and nonwoven ribbons are found to be an especially useful combination since they permit the use of relatively cheap polyolefin webs of mixed denier, and simplify the task of precise distribution of modifier salt components without the need for abandoning art-recognized techniques and equipment such as printing rolls and spray heads for substrate coating.

Supplemental components, in addition to the abovedefined active modifier salt components, can also be employed such as, for instance, aqueous solutions, emulsions, suspensions, or dispersions of one or more humectants, exemplified by polyhydric alcohols such as glycerols, glycols, etc.; flavors and perfumes such as ketoses and polysaccharides, including wintergreen, spearmint, peppermint, chocolate, licorice, cinnamon, fruit flavors, citrus etc.; medicines, such as menthol and decongestants, and other art-recognized additives as found in U.S. Pat. Nos. 4,485,828 and 4,715,390.

In order to maintain precise control over application of additives, it is found useful if the receiving substrate is carefully controlled and consistent with respect to moisture content before conversion into a filter element. In addition, a filter element and its applied additive components is usefully further isolated or shielded from direct contact with the lips by applying the active component onto a tow, sliver or nonwoven fabric which is, in turn, sandwiched between two or more untreated nonwoven fabrics of lesser permeability (Ref. FIG. 3). If desired, the resulting filter element can also be externally coated with cork or similar inert heat-insulating material (not shown). The amount and effectiveness of modifier(s) applied to filter elements in the above way is determined substantially by the substrate width and number of substrates which are fed simultaneously into a garniture, as well as the amount of treated surface exposed to cigarette smoke in the filter element.

For purposes of the present invention both treated and combinations of treated and untreated fabric ribbon, tow, and the like can be usefully wrapped using conventional plug wrap such as paper having a weight within a range of about 25–90 g/m^2 or higher, as desired.

The instant invention is further illustrated in FIGS. **1–4**, in which FIG. **1** diagrammatically represents a conventional cigarette filter rod-making apparatus capable of converting treated substrate in accordance with the instant invention, into cigarette filter elements; FIGS. **2–4** diagrammatically represent further modifications and improvements within the instant invention, whereby one or more tows, slivers, ribbons of nonwovens, and fibrillated film are treated with one or more active modifier components by spraying, dipping, or by vacuum draw of wrapped filter plug, the use of multiple substrates in this manner favoring increased filter element bulk and improved crush resistance, or hardness.

Referring to FIG. **1** in further detail, a single continuous substrate such as opened fiber tow, sliver, fibrillated film or ribbon of nonwoven fabric (**10**) is fed from feed reel (**11**) or a bale (not shown) and across one or more opposed spray heads (**20**) feedably connected to feed lines (**21**) from outside sources (not shown) to apply one or more active modifier component (**22**). The resulting treated substrate is then dried by air drying means (not shown) and by passing through drying rolls (**12**), to obtain the desired degree of dryness, and then led by guide rolls (**17**) into a garniture trumpet (**15**) and garniture (**14**) of a cigarette filter rod manufacturing apparatus (**1**), comprised of a garniture section (**2**) including (but not showing) means for shaping and retaining the substrate feed, wrapping means, and cutting means for converting the wrapped plug or rod into filter element (**16**); the wrapping means is conveniently supplied with tow wrap from wrap feed reel (**5**) supported by support rolls (**19**) and moved onto a continuous garniture belt (**3**) for introduction into the rod-making apparatus.

The apparatus, as described, comprises conventional means for sealing a tow wrap around a filter plug (not shown), the wrapped plug then being cut by cutting means into generally cylindrical filter elements (**16**) of desired length (normally 90 mm or more), which are removed through filter chute (**18**) (shown in fragment) for packing in container (**23**).

FIG. **2** diagrammatically demonstrates a further arrangement for separately applying one or more filter modifier salt component(s) or other additives onto substrates (**10A**) and (**10B**), whereby differently arranged spray heads (**20A**) fed by feed lines (**21A**), separately apply active modifier components (identical or otherwise) (**22A**) onto separate substrates (**10A**, **10B**), which are then at least partially dried using air and heated rolls (**12A**), before being fed through garniture (**14A**) of rod-making apparatus (**1A**), to form filter elements (**16A**) as before. Substrates (**10A** and **10B**), are fed from feed rolls (**11A**) and (**11B**) or bales (not shown) and conveniently brought into register at heated nip rolls (**12A**), then guided by guide rolls (**17A**) into garniture (**14A**), the garniture feed or substrate components shown being similarly defined by arabic numbers in each of FIGS. **1–3**.

FIG. **3** diagrammatically demonstrates a further modification of the equipment and process of FIGS. **1** and **2**, whereby several substrates of the same or different types (**10C**, **10D**, and **10E**) as described above from reels or boxes (not shown) are fed through a nip created by heated rolls (**12B**), the middle substrate (**10D**) preferably being of different width and having higher absorption or adsorption properties for retaining active com-

ponents (22B) than the two external untreated substrates (10C and 10E). As shown, substrate (10D) is sprayed on both sides to selectively expose it to one or more active modifier components (22B) applied by spray heads (20B) fed from feedlines (21B), one substrate (10E) preferably being arranged so as to catch surplus drip or misdirected active components not retained or captured by ribbon (10D), all three substrates are then at least partially air dried by passing in register through heated nip rolls (12B), as before, and directed by guide rolls (not shown) into the garniture of a filter rod apparatus in the manner of FIGS. 1 and 2.

FIG. 4 is a diagrammatic representation of a further modification in which one or more substrates, as above defined, (shown as 10C) are separately fed from a bale or box (24C), passed over guide rolls (17C), and dipped into a reservoir (25C) containing one or more active modifier component(s) (22C) in solution, suspension, or emulsion, and then passed through nip rolls (26C), through a heating oven (27C), drawer rolls (28C), a three step drying oven (29C), then to garniture (14C) of a cigarette rod manufacturing apparatus in the manner of FIGS. 1–3, supra, or boxed and stored for future use.

Where a continuous fiber tow is used as a substrate component, preparation of the tow is conveniently carried out in the usual way by drawing the fiber from one or more creels through a fluid bulking or texturing jet (not shown in figures) and then handled as noted above.

Substrates which are employed in the above manner can usefully comprise a variety of synthetic filaments as noted above. Thus, it is possible to use polyesters, polyamides, acrylics, as well as polypropylene and the like. Due to its relatively low density, compared to other synthetic fiber-forming material and excellent spin properties, combinations of filament-forming copolymers of propylene with ethylene or other lower olefins monomers are particularly preferred as tow, nonwoven ribbon and fibrillated film material.

The bulk denier of a tow for carrying out the present invention can conveniently fall between about 2,000 and 10,000, and this substrate can be supplied as a crimped fiber from a single creel or bale, or a composite of several creels or bales combined and passed through a fluid jet simultaneously. For best performance of fiber tow as cigarette filters, however, it is preferred that at least some tow be substantially untwisted and untexturized prior to entering a fluid jet.

The invention is further illustrated by the following Examples.

EXAMPLE I

(A) Baled 4.5 dpf "y" cross section polypropylene fiber obtained from melt spun isotactic polypropylene having a melt flow rate (MFR) of 16, is broken, opened, carded, crimped and pulled to form a thin tow of about 12—inches in width. This ribbon is drawn, without further treatment, through the garniture of a conventional filter rod-forming apparatus identified as model PM-2 obtained from Molins Ltd. of Great Britain; and the garniture feed is compressed to form filter plugs which are wrapped with BXT-100 polypropylene film to obtain 108 mm filter rods. The rods are then cut and sorted into 27 mm lengths of substantially equal weight, and draw*[1], and taped onto R. J. Reynolds' Camel Light tobacco plugs, stored for 48 hours in a humidity cabinet at 55%–65% relative humidity at 22° C.*[2], and then used as control samples group-wise identified as C-1 and C-2 and identically smoked down to 35 mm lengths in two second puffs per minute on a Borgwaldt smoking machine*[3]. The particulate matter in the resulting smoke is trapped in a preweighed Cambridge filter pad, and the pad reweighed to determine total and average particulate matter (TPM) passed through the cigarette filter. The Cambridge pad is then soaked overnight in anhydrous isopropyl alcohol, and the resulting extract conventionally tested for nicotine and water content using a GC (gas chromatograph) autosampler*[4].

*[1]All tested filter elements have a resistance to draw (RID) within the range of 111–136 mm Wg (water gauge).
*[2]According to CORESTA Standard Method #10
*[3]Models RM 20/CS 20 and RM 1/G
*[4]Hewitt Packard Model HP5890

(B) Fiber tow from the same bale is identically processed to obtain ten test filter elements in the manner of Example 1A except that the cut filter elements are then treated with 1%, 2% and 5% solutions of $KHCO_3$, $K_2CO_3/KHCO_3$ mixed salts, $Mg(OAc)_2$, $Mn(OAc)_2$ and $MgCl_2$, respectively, using a suction bulb to draw up and impregnate each filter element with an amount of solution sufficient to treat in a uniform manner with about 20 mg. of modifier salt. The test filter elements are then air and oven dried, stored in a humidity cabinet for 48 hours, and then taped to an R. J. Reynolds' Camel Light tobacco plug as before. Conventional tests for nicotine, total particulate matter (TPM) and filter efficiency, are carried out as before, averaged on a per/-cigarette basis, and reported in Table I as S-1 through S-19.

TABLE I

Sample	Solution	Conc (%)	pH	Nic/TPM (%)
S-1	$KHCO_3$	2	8.20	6.86
S-2	$KHCO_3$	1	8.20	7.72
S-3	$KHCO_3$	2	8.31	6.65
S-4	$KHCO_3$	5	8.47	9.41
S-5	$KHCO_3$	1	8.53	9.33
S-6	$KHCO_3$	5	8.74	6.36
S-7	$K_2CO_3/KHCO_3(1/4)$*[5]	5	9.00	6.90
S-8	$K_2CO_3/KHCO_3(1/1)$	5	9.50	6.99
S-9	$K_2CO_3/KHCO_3(1/1)$	5	9.58	6.66
S-10	$K_2CO_3/KHCO_3(4/1)$	5	10.10	8.45
S-11	$K_2CO_3/KHCO_3(4/1)$	5	10.40	8.90
S-12	K_2CO_3	2	11.50	8.20
S-13	K_2CO_3	5	11.80	8.10
S-14	$Mg(OAc)_2$	2	8.21	8.73
S-15	$Mg(OAc)_2$	5	8.13	7.02
S-16	$Mg(OAc)_2$	2	7.65	8.66
S-17	$Mg(OAc)_2$	5	7.68	6.84
S-18	$MgCl_2$*[6]	2	9.38	3.19
S-19	$MgCl_2$	5	9.09	4.87
C-1		—	7.00	5.14

*[5]in parts by weight.
*[6]2 a strong acid salt.

EXAMPLE II

Fiber tow from the same bale as Example I is identically processed to obtain filter elements, except that the cut elements (identified as S-20 through S-24) are impregnated with K_3PO_4 and K_2HPO_4 solutions to obtain effective concentrations of active salt equal to about 20 mg/filter element. The resulting treated and dried filter elements are taped to R. J. Reynolds' Light tobacco plugs, as before, air dried, and stored in a humidity cabinet for 48 hours, before smoking in an identical manner. The samples are collected and tests run as before, average results being reported in Table II below.

TABLE II

Sample	Solution	Conc (%)	pH	Nic/TPM	TDR
S-20	K_3PO_4	5	11.7	7.7	30.4
S-21	K_3PO_4/K_2HPO_4 (1/1)	5	11.0	7.2	36.3 —
S-22	K_3PO_4/K_2HPO_4 (1/8)	5	10.1	8.2	29.8
S-23	K_2HPO_4	5	9.0	7.0	35.5
S-24	KH_2PO_4	5	4.4	5.8	36.4
C-2	—	—	—	5.5	35.9

What is claimed:

1. A method for controlling nicotine filter retention and pass through characteristics of a cigarette filter element comprising one or a combination of cellulose acetate- or thermoplastic synthetic- substrate, comprising,

A. treating one or more fiber of film substrate forming said filter element or plug component, thereof with an aqueous solution or suspension having a pH within a range of about pH 8 to about pH 12 and containing an effective amount of a non-toxic water soluble salt of a weak acid as an active modifier; or

B. treating one or more fiber or film substrate forming said filter element or plug component thereof with an aqueous solution or suspension containing an effective amount of a non-toxic water soluble inorganic salt of a strong acid as an active modifier; and

C. completing fabrication of the desired filter element;

whereby (1) treatment of said substrate or plug component of the filter element with the salt of a weak acid increases filter pass through of nicotine smoke component relative to total particulate pass through concentration, and (2) treatment of said substrate or plug component of the filter element with the salt of a strong acid decreases filter pass through of nicotine smoke component relative to total particulate pass through concentration.

2. The method of claim 1 wherein the non-toxic water soluble metal salt of acid is applied to one or more substrate of said filter element or plug thereof as a buffered solution or suspension having a pH within a range of about pH 8 to about pH 12.

3. The method of claim 2 wherein the pH range of said buffered solution or suspension is from about pH 8.0 to about pH 10.5.

4. The method of claim 2, wherein said substrate comprises thermoplastic synthetic fiber, and said aqueous solution or suspension comprises at least one non-toxic metal salt of an acid selected from the group consisting of carbonic, phosphoric, acetic, citric, and fumaric acid.

5. The method of claim 4, wherein the non-toxic metal salt is a member selected from the group consisting of at least one of $Mg(OAc)_2$, $Mn(OAc)_2$, $KHCO_3$, $K_2CO_3/KHCO_3$, $NaHCO_3$, $KHPO_4$, and KH_2PO_4.

6. The method of claim 1, wherein said aqueous solution or suspension contains at least one non-toxic metal salt of an acid selected for the group consisting of hydrochloric and hydrobromic acid.

7. The method of claim 6 wherein the non-toxic metal salt is at least one member selected from the group consisting of $ZnCl_2$, LiBr, KBr, $CaBr_2$ and $MgCl_2$.

8. The method of claim 1, wherein the cigarette filter element comprises up to 100% by weight of cellulose acetate.

9. The method of claim 1, wherein the substrate of the cigarette filter comprises up to 100% by weight of synthetic thermoplastic substrate.

10. The method of claim 9 wherein the cigarette filter comprises up to 100% by weight of a polyolefin.

11. A cigarette filter rod or element comprising, in combination,

(a) a filter plug of compacted substrate comprising one or more of cellulose acetate- or synthetic thermoplastic-fiber containing substrate;

(b) a plurality of active filter loci distributed within said compacted substrate; said loci consisting essentially of solid and/or solid/liquid phases of the desired water soluble salt of a strong or a weak acid and a nontoxic metal; and

(c) a plug wrap securing said compacted substrate; whereby the presence of filter loci comprising the nontoxic water soluble salt of a weak acid favor filter pass through of nicotine relative to total particulate filter pass through concentration, and the presence of filter loci comprising the nontoxic water soluble salt of a strong acid favor filter retention of nicotine, relative to total particulate filter pass through concentration.

12. A cigarette filter rod or element of claim 11 wherein said active filter loci consist essentially of solid/liquid phases of a nontoxic water soluble salt of a weak acid, said liquid phase having a pH within a range of about pH 8 to about pH 12.

13. A cigarette filter of claim 11 wherein the water soluble salt is a non-toxic metal salt of an acid selected from the group consisting of acetic, carbonic, phosphoric, citric and fumaric acid.

14. A cigarette filter element of claim 13 wherein the water soluble salt is at least one of $Mg(OAc)_2$, $Mn(OAc)_2$, $KHCO_3$, K_2CO_3 and $NaHCO_3$.

15. A cigarette filter element of claim 11 wherein the water soluble salt is at least one of $MgCl_2$, LiBr, $CaCl_2$ and $CaBr_2$.

16. A cigarette utilizing as filter element the element defined in claim 11.

17. A cigarette utilizing as filter element the element defined in claim 12.

18. A cigarette utilizing as filter element the element defined in claim 13.

19. A cigarette utilizing as filter element the element defined in claim 14.

20. A cigarette utilizing as filter element the element defined in claim 15.

21. A method for controlling nicotine filter retention and pass through characteristics of a cigarette filter element comprising one or a combination of cellulose acetate- and thermoplastic synthetic-substrate, comprising,

treating one or more substrate consisting of an open fiber tow, a ribbon of a nonwoven material, a sliver, and a fibrillated film with a buffered aqueous solution or suspension having a pH within a range of about pH 8 to about pH 12, said solution or suspension containing an effective amount of a non-toxic water soluble salt of a weak acid as active modifier; and

completing fabrication of the desired filter element; whereby treatment of said substrate or plug component of the filter element with the salt of a weak acid increase filter pass through of nicotine smoke component relative to total particulate pass through concentration.

22. A cigarette filter rod or element comprising, in combination,

(a) a filter plug of compacted substrate comprising one or more of cellulose acetate- or synthetic thermoplastic-substrate in the form of at least one of an opened fiber tow, a ribbon of nonwoven material, a sliver, and a fibrillated film;

(b) a plurality of active filter loci distributed within said compacted substrate, said loci consisting essentially of solid and/or solid/liquid phases of desired nontoxic water water soluble salt of a strong or a weak acid; and

(c) a plug wrap securing said compacted substrate; whereby the presence of filter loci, comprising said nontoxic water soluble salt of a weak acid, favors filter pass through of nicotine relative to total particulate filter pass through concentration, and the presence of filter loci comprising the nontoxic water soluble salt of a strong acid favors filter retention of nicotine relative to total particulate filter pass through concentration.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 4,896,683

DATED : JANUARY 30, 1990

INVENTOR(S) : COHEN & GIBBONI

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 1, Line 31

"state-of-the art" should read --state-of-the-art--

Column 4, Line 31

"(mono , bi-, or..." should read --(mono-, bi-, or...--

Column 4, Line 42

"(b) 10%-90%/4-" should read --(b) 10%-90%/--

Column 4, Line 43

"5%-5%/45%-5%" should read --45%-5%/45%-5%--

Signed and Sealed this

Sixteenth Day of April, 1991

Attest:

Attesting Officer

HARRY F. MANBECK, JR.

Commissioner of Patents and Trademarks

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 4,896,683

DATED : JANUARY 30, 1990

INVENTOR(S) : COHEN & GIBBONI

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 5, Lines 37-38

"abo-vedefined" should read --above-defined--

Column 7, Line 56

"12--inches" should read --12-14 inches--

Column 8, Line 54

"*^{6}2 a strong acid salt." should read

--*^{6} a strong acid salt.--

Column 9, Line 18

"fiber of film" should read --fiber or film--.

US005105836A

United States Patent [19]

Gentry et al.

[11] Patent Number: 5,105,836

[45] Date of Patent: Apr. 21, 1992

[54] CIGARETTE AND SMOKABLE FILLER MATERIAL THEREFOR

[75] Inventors: **Jeffery S. Gentry**, Pfafftown; **Gary R. Shelar**, Greensboro; **Richard L. Lehman**, Belle Mead; **James L. Resce**, Yadkinville; **Olivia D. Furin**, Winston-Salem; **Stephen W. Jakob**, Winston-Salem; **William C. Squires**, Winston-Salem, all of N.C.

[73] Assignee: **R. J. Reynolds Tobacco Company**, Winston-Salem, N.C.

[21] Appl. No.: **567,520**

[22] Filed: **Aug. 15, 1990**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 414,833, Sep. 29, 1989.

[51] **Int. Cl.**[5] **A24B 15/14**; A24D 1/18

[52] **U.S. Cl.** **131/359**; 131/355; 131/369

[58] **Field of Search** 131/359, 369, 355

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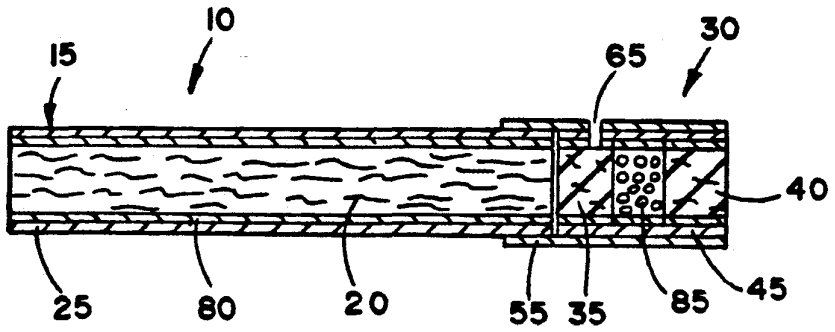
Primary Examiner—V. Millin

Attorney, Agent, or Firm—August J. Borschke

[57] **ABSTRACT**

A combustible smokable filler material includes an agglomerated matrix filler having an inorganic component (e.g., particles of calcium carbonate) and a carbonaceous component (e.g., calcined molasses). The smokable filler material includes a binding agent and an aerosol forming material. Tobacco extracts and/or pieces of tobacco laminae can be incorporated into the smokable filler material, and/or the smokable filler material can be blended with tobacco cut filler. Cigarettes are provided by wrapping the smokable filler material in a paper wrapping material. A typical paper wrapping material has a porosity of less than about 5 CORESTA units.

42 Claims, 1 Drawing Sheet



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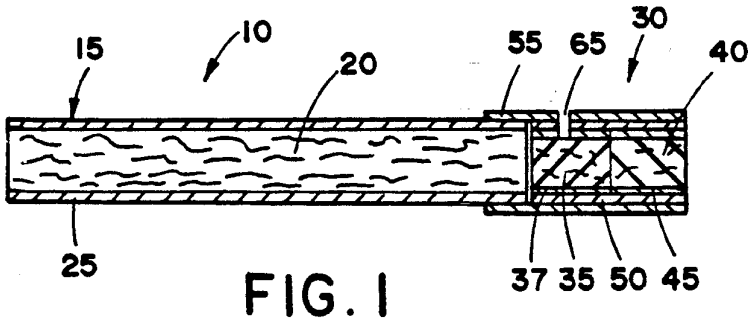

FIG. 1

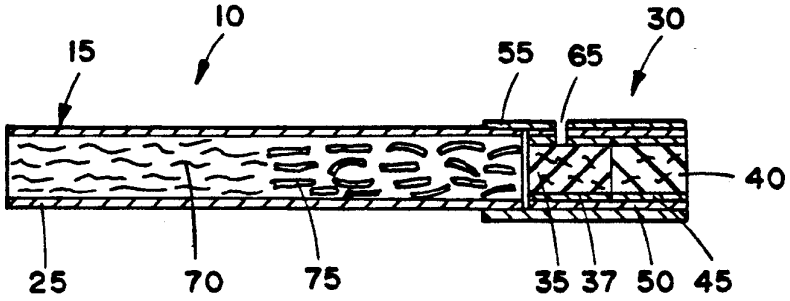

FIG. 2

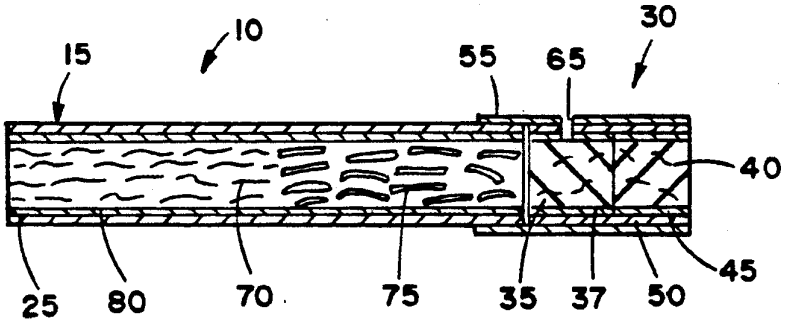

FIG. 3

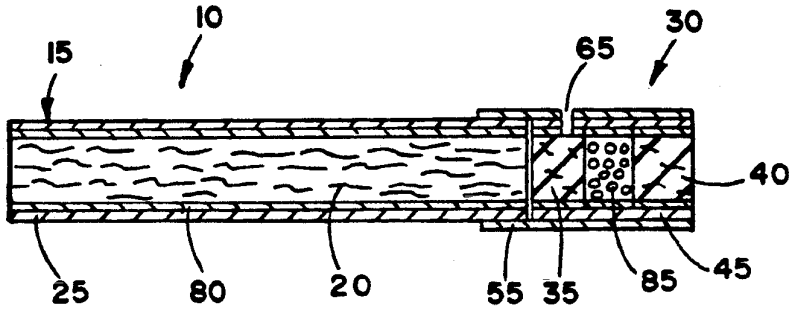

FIG. 4

CIGARETTE AND SMOKABLE FILLER MATERIAL THEREFOR

CROSS-REFERENCE TO RELATED APPLICATION

This is a continuation-in-part of U.S. Patent application Ser. No. 414,833, filed Sep. 29, 1989, the disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

The present invention relates to cigarettes and other smoking articles, and in particular to cigarettes, which when smoked, yield relatively low levels of incomplete combustion products, generate low amounts of sidestream "tar" and odor, and sustain smolder during FTC smoking conditions.

Popular smoking articles, such as cigarettes, have a substantially cylindrical rod shaped structure and include a roll or charge of smokable material, such as shredded tobacco material (e.g., in cut filler form), wrapped in a paper wrapper, thereby forming a so-called "smokable rod". Normally, a cigarette has a cylindrical filter element aligned in an end-to-end relationship with the smokable rod. Typically, a filter element includes cellulose acetate tow circumscribed by plug wrap, and is attached to the smokable rod using a circumscribing tipping material.

Typically, cigarettes are employed by the smoker by lighting one end thereof and burning the smokable rod. As such, smoke normally is provided by burning smokable material, which typically is tobacco cut filler. The smoker then receives mainstream smoke (e.g., mainstream tobacco smoke) into his/her mouth by drawing on the opposite end (e.g., the filter end) of the cigarette. As such, the smoker is provided with the pleasures of smoking (e.g., smoking taste, feel, satisfaction, and the like).

During the time that the cigarette is burning, sidestream smoke is generated. Sidestream smoke is smoke which directly enters the atmosphere from the lit end of the cigarette. Sidestream smoke diffuses into the atmosphere, and the characteristic visible nature and odor thereof may be perceived negatively by some individuals. The relative amount of visible sidestream smoke generated by a burning cigarette is related to the amount of sidestream "tar" generated by that burning cigarette. Typical commercially available cigarettes which burn tobacco cut filler, and have lengths of about 84 mm (e.g., having a smokable rod length of about 57 mm and a filter element length of about 27 mm), often yield about 25 to about 35 mg of sidestream "tar" per cigarette. See, Proctor et al, Analyst, Vol. 113, p. 1509 (1988), for an apparatus and technique for determining the sidestream "tar" of a cigarette.

Numerous cigarettes which reportedly yield relatively low levels of visible sidestream smoke have been proposed. See, for example, U.S. Pat. Nos. 4,637,410 to Luke; 4,624,268 to Baker et al; 4,407,308 to Baker; 4,231,377 to Cline et al; 4,420,002 to Cline; 4,450,847 to Owens; 4,108,151 to Martin; 4,225,636 to Cline; 4,433,697 to Cline; 4,461,311 to Mathews et al; and 4,561,454 to Guess.

Through the years, there have been proposed various methods for altering the composition of mainstream tobacco smoke. For example, many tobacco substitute materials have been proposed, and a substantial listing of such materials can be found in U.S. Pat. No. 4,079,742 to Rainer et al. In addition, tobacco substitute smoking materials having the tradenames Cytrel and NSM were introduced in Europe during the 1970's.

Numerous references have proposed articles which generate flavored vapor and/or visible aerosol. Most of such articles have employed a combustible fuel source to provide an aerosol and/or to heat an aerosol forming material. See, for example, the background art cited in U.S. Pat. No. 4,714,082 to Banerjee et al.

Smoking articles which are capable of providing the pleasures associated with cigarette smoking, by heating but not necessarily burning tobacco, and without delivering considerable quantities of incomplete combustion products, are described in U.S. Pat. Nos. 4,714,082 to Banerjee et al; 4,756,318 to Clearman et al; and 4,793,365 to Sensabaugh, Jr. et al. Such smoking articles employ a combustible fuel element for heat generation; and aerosol forming substances positioned physically separate from, and in a heat exchange relationship with, the fuel element. During use, heat generated by the fuel element acts to volatilize the aerosol forming substances, thereby providing an aerosol which resembles tobacco smoke. Such smoking articles yield extremely low levels of visible sidestream smoke as well as low levels of FTC "tar".

It would be desirable to provide a good tasting cigarette which provides good smoking satisfaction, provides relatively low mainstream gas phase yields, provides relatively low levels of incomplete combustion products, sustains smolder during FTC smoking conditions, yields an ash having desirable physical characteristics, and generates low levels of sidestream "tar" and hence the low levels of visible sidestream smoke.

SUMMARY OF THE INVENTION

The present invention relates to smoking articles incorporating tobacco in cut filler form and/or in a processed form. Preferred smoking articles have the form of a cigarette having two essential components: (i) a roll or charge of smokable material, and (ii) an outer wrapping material (e.g., a paper wrapper) circumscribing the roll of smokable material. Cigarettes of the present invention incorporate a smokable filler material (described in greater detail hereinafter) as at least a portion of the smokable material thereof.

The preferred wrapping material, which surrounds the roll of smokable material to thereby form a "smokable rod", is a low air permeability cigarette paper wrapper. Highly preferred wrappers having a low air permeability or low porosity exhibit a porosity below about 5 CORESTA units. A CORESTA unit is a measure of the linear air velocity which passes through a 1 cm^2 area of wrapper at a constant pressure of 1 centibar. See CORESTA Publication ISO/TC 126/SC I N159E (1986).

One form of smokable material is a tobacco-containing smokable filler material. Such a smokable material of the present invention comprises an intimate mixture of (i) tobacco (e.g., shredded tobacco laminae milled tobacco laminae, pieces of tobacco stems, tobacco fines, tobacco dust, or a tobacco extract or other form of processed tobacco), and (ii) an agglomerated matrix filler. The agglomerated matrix filler has, in intimate contact, a carbonaceous component and an inorganic component. Preferably, the agglomerated matrix filler is provided in particulate form. The smokable filler material includes a binding agent in intimate contact

with the agglomerated matrix filler and tobacco. As such, the binding agent acts to maintain particles of the tobacco and agglomerated matrix filler together to form the smokable filler material. Such a tobacco-containing smokable filler material also can include certain flavoring agents (e.g., cocoa, licorice, organic acids, menthol, and the like) and/or aerosol forming material (e.g., glycerin, propylene glycol, and the like) in intimate contact therewith. The tobacco-containing smokable filler material can be cast as a sheet from an aqueous slurry, provided as a sheet using a paper-making process, or provided in extruded form. Such a tobacco-containing smokable filler material can be employed individually as the sole smokable material of the cigarette, or that tobacco-containing smokable filler material can be physically mixed with (i.e., blended) or otherwise employed with other smokable materials, such as tobacco cut filler.

Another form of smokable filler material of the present invention comprises an agglomerated matrix filler. The agglomerated matrix filler has, in intimate contact, a carbonaceous component and an inorganic component. Preferably, the agglomerated matrix filler is provided in particulate form. The smokable filler material includes a binding agent in intimate contact with the agglomerated matrix filler. As such, the binding agent acts to maintain particles of agglomerated matrix filler together to form the smokable filler material. Such a smokable filler material also can include certain flavoring agents and/or aerosol forming materials in intimate contact therewith. The smokable filler material can be cast as a sheet from an aqueous slurry, provided as a sheet using a paper-making process, or provided in extruded form. Such a smokable filler material can be physically mixed with or otherwise employed with tobacco-containing smokable materials and/or tobacco cut filler.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1** through **4** are longitudinal sectional views of smoking articles of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A preferred embodiment of a cigarette and smokable filler material of the present invention is shown in FIG. **1**. The cigarette **10** includes a generally cylindrical rod **15**. The rod includes a roll of smokable material **20** wrapped in at least one layer of circumscribing outer wrapping material **25** (e.g., paper). The rod **15** is hereinafter referred to as a "smokable rod". The ends of the smokable rod **15** are open to expose the smokable material which is to be burned. The smokable rod is used by lighting one end thereof, and aerosol (e.g., smoke) is provided as a result of the combustion of the burning smokable material. As such, the smokable rod burns from the lit end thereof towards the opposite end thereof.

The cigarette **10** also includes a filter element **30** positioned adjacent one end of the smokable rod **15** such that the filter element and smokable rod are axially aligned in an end-to-end relationship, preferably abutting one another. Filter element **30** has a generally cylindrical shape, and the diameter thereof is essentially equal to the diameter of the smokable rod. The ends of the filter element are open to permit the passage of air and smoke therethrough. The preferred filter element has at least two filter segments. As shown in FIG. **1**, a first filter segment is positioned adjacent the smokable rod, and preferably includes a carbonaceous filter material **35** circumscribed by a wrapping material **37**; while a second filter segment is positioned at the extreme mouthend of the cigarette, and preferably includes a filter material **40**, such as a gathered non-woven polypropylene web or cellulose acetate tow, circumscribed by a wrapping material **45**. The filter material **40** of the segment preferably is a material which provides an aesthetically pleasing, white appearance. Each of the filter segments is manufactured using known filter rod making machinery. The two segments are combined using known plug tube combining techniques, and are held together using circumscribing wrap **50** so as to form the filter element.

The filter element **30** normally is attached to the smokable rod **15** by tipping material **55**, which circumscribes both the entire length of the filter element and an adjacent region of the smokable rod. The inner surface of the tipping material **55** is fixedly secured to the outer surface of the plug wrap **50** and the outer surface of the wrapping material **25** of the smokable rod, using a suitable adhesive. The cigarette **10** can be manufactured using known cigarette making techniques and equipment. Optionally, a ventilated or air diluted cigarette is provided with an air dilution means such as a series of perforations **65** which extend through the tipping material **55**, plug wrap **50** and wrapping material **37**. Such ventilation can be provided to the cigarette using known techniques, such as laser perforation techniques.

Another preferred embodiment of a cigarette and smokable filler material of the present invention is shown in FIG. **2**. The cigarette **10** is generally similar to the cigarette described with reference to FIG. **1**, except that the smokable material has the form of a blend which is provided in a segmented fashion. At one end of the smokable rod **15** (i.e., at the end of the cigarette to be lit) is located a first segment **70** of smokable material. At the other end of the smokable rod **15** (i.e., at the end of the smokable rod adjacent the filter element) is located a second segment **75** of smokable material. Each segment is defined or identified in terms of its composition (i.e., the composition of each segment is different). The segments are aligned in an abutting end-to-end relationship; however, there can be a certain amount of intermixing of smokable materials in the region where the two segments meet. The length which each segment of smokable material extends along the smokable rod can vary. However, the relative longitudinal length of the first segment relative to the second segment normally ranges from about 1:2 to about 2:1, with about 1:1 being preferred. Such smokable rods can be manufactured using apparatus described in U.S. Pat. Nos. 4,009,722 to Wahle et al and 4,516,585 to Pinkham.

For preferred cigarettes of the type shown in FIG. **2**, the first segment **70** normally includes tobacco in some type of smokable form. Such a form of tobacco includes tobacco cut filler (e.g., tobacco laminae, processed tobacco materials, volume expanded tobacco filler, reconstituted tobacco filler materials, and the like, and blends thereof), and blends thereof with other smokable materials. Examples of processed tobacco materials are deproteinated reconstituted tobacco materials described in U.S. Pat. Nos. 4,887,618 to Bernasek et al and 4,941,484 to Clapp et al, which are incorporated herein by reference. Another example of a processed tobacco material is a tobacco material processed according to the methods set forth in U.S. Patent application Ser. No. 484,587,

now U.S. Pat. No. 5,065,775 to Fagg filed Feb. 23, 1990, which is incorporated herein by reference. Preferred cigarettes also have a second segment **75** which includes a smokable material or blend of smokable materials different in overall composition from the overall composition of the smokable material(s) of the first segment **70**. The first segment **70** and/or the second segment **75** include at least one smokable filler material of the present invention.

Another preferred embodiment of a cigarette of the present invention is shown in FIG. **3**. The cigarette **10** is generally similar to the cigarette described with reference to FIGS. **1** and **2**, except that the smokable material **20**, which incorporates smokable filler material of the present invention, is wrapped or contained in a processed tobacco sheet **80**, or other inner wrapper material. The processed tobacco sheet **80** normally is a reconstituted tobacco sheet which is manufactured using a paper-making process, and a single layer of the sheet circumscribes the smokable material. The smokable material wrapped in the processed tobacco sheet **80** is in turn wrapped in a single layer of circumscribing outer wrapping material **25** (e.g., cigarette paper).

Another preferred embodiment of a cigarette of the present invention is shown in FIG. **4**. The cigarette **10** is generally similar to the cigarette described with reference to FIGS. **1**, **2** and **3**, except that the filter element includes three segments. Segment **85**, positioned between first filter material **35** and filter material **40**, preferably is composed of a particulate matter such as activated carbon granules, magnesium silicate granules, silica gel particles, or the like.

The smokable material employed in the manufacture of the smokable rod can vary, and most preferably has the form of cut filler. As used herein, the term "cut filler" in referring to smokable materials is meant to include smokable materials which have a form suitable for use in the manufacture of smokable rods for cigarettes. As such, cut filler can include smokable materials which are blended and are in a form ready for cigarette manufacture. Smokable materials normally are employed in the form of strands or shreds as is common in cigarette manufacture. For example, cut filler can be employed in the form of strands or shreds cut from sheet-like or "strip" materials. Such strip materials are cut into widths ranging from about 1/5 inch to about 1/60 inch, preferably from about 1/25 inch to about 1/35 inch. Generally, the resulting strands or shreds have lengths which range from about 0.25 inch to about 3 inches. Cut filler also can have an extruded form (e.g., extruded strands), or other physically processed form.

The smokable rods of cigarettes of the present invention include smokable filler material of the present invention. The smokable filler material can be employed in a cut filler form.

One preferred type of smokable filler material of the present invention comprises an agglomerated matrix filler including an agglomerated matrix of a carbonaceous component and an inorganic component in intimate contact. The agglomerated matrix filler is in turn intimately mixed with a binding agent to provide the smokable filler material. Such a smokable filler material most preferably includes as part of the ultimate mixture, at least one aerosol forming material and/or at least one flavoring agent. If desired, other agents, which have the ability to alter the composition of the aerosol generated by the smokable filler material, can be incorporated into that smokable filler material. The agglomerated matrix filler normally includes about 80 to about 97, preferably about 90 to about 97 weight percent inorganic component, and about 3 to about 20, preferably about 3 to about 10 weight percent carbon provided by the carbonaceous component. Such a smokable filler material normally includes about 60 to about 95, preferably about 65 to about 90 weight percent agglomerated matrix filler; up to about 20, preferably about 2 to about 10 weight percent binding agent; up to about 20, preferably about 3 to about 10 weight percent aerosol forming material; and sufficient amounts of flavoring agent to provide the desired flavor characteristics. If desired, a further carbonaceous material (e.g., pyrolyzed alpha cellulose) can be incorporated into the smokable filler material, usually in amounts of up to about 10, and sometimes up to about 30 weight percent, based on the total dry weight of the smokable filler material. However, such further carbonaceous material is not a necessary component of the smokable filler material, and the smokable filler material can be absent of such carbonaceous material. The smokable filler material is combustible, and is normally employed with (e.g., blended with) another smokable material (e.g., tobacco cut filler) in order to provide a cigarette of the present invention.

One preferred type of tobacco-containing smokable filler material of the present invention comprises an agglomerated matrix filler including an agglomerated matrix of a carbonaceous component and an inorganic component in intimate contact. The agglomerated matrix filler is in turn intimately mixed with some form of tobacco and binding agent to provide the smokable filler material. Such a tobacco-containing smokable filler material preferably includes as part of the ultimate mixture, at least one aerosol forming material and/or at least one flavoring agent. If desired, other agents, which have the ability to alter the composition of the aerosol generated by the smokable filler material, can be incorporated into that smokable filler material. The agglomerated matrix filler normally includes about 80 to about 97, preferably about 90 to about 97 weight percent inorganic component, and about 3 to about 20, preferably about 3 to about 10 weight percent carbon provided by the carbonaceous component. Such a tobacco-containing smokable filler material normally includes up to about 50, typically up to about 20 weight percent of some form of tobacco; about 45 to about 90, preferably about 50 to about 85 weight percent agglomerated matrix filler; up to about 20, preferably about 2 to about 10 weight percent binding agent; up to about 20, preferably about 3 to about 15 weight percent aerosol forming material; and sufficient amounts of flavoring agent to provide desired flavor characteristics. If desired, a further carbonaceous material (e.g., pyrolyzed alpha cellulose) can be incorporated into the smokable filler material, usually in amounts of up to about 10, and sometimes up to about 30 weight percent, based on the total dry weight of the smokable filler material. However, such further carbonaceous material is not a necessary component of the smokable filler material, and the smokable filler material can be absent of such carbonaceous material. The smokable filler material is combustible and can be employed individually as the sole smokable material of a cigarette of the present invention.

Another preferred type of smokable filler material of the present invention comprises agglomerated matrix filler including an agglomerated matrix of a carbonaceous component and an inorganic component. The

agglomerate matrix filler is intimately mixed with a binding agent and at least one aerosol forming material to provide a smokable filler material. Such a smokable filler material most preferably includes as part of the ultimate mixture, at least one flavoring agent and some form of tobacco. The agglomerated matrix filler normally includes about 80 to about 97, preferably about 90 to about 97 weight percent inorganic component and about 3 to about 20, preferably about 3 to about 10 weight percent carbon provided by the carbonaceous component. Such a smokable filler material normally includes up to about 20, preferably about 3 to about 15 weight percent binding agent; greater than about 20, preferably about 25 to about 80, more preferably about 30 to about 50 weight percent aerosol forming material; and less than about 80, preferably about 30 to about 70 weight percent filler component including the previously described agglomerated matrix filler. In particular, the filler component can include (i) all of the previously described agglomerated matrix filler, or (ii) a blend of the previously described agglomerated matrix filler with an inorganic filler material (e.g., precipitated calcium carbonate) and/or an organic filler material (e.g., tobacco). Amounts of flavoring agent sufficient to provide the desired flavor characteristics to the smokable filler material can be incorporated into that material. If desired, a further carbonaceous material (e.g., pyrolyzed alpha cellulose) can be incorporated into the smokable filler material, usually in amounts of up to about 10, and sometimes up to about 30 weight percent, based on the total dry weight of the smokable filler material. However, such further carbonaceous material is not a necessary component of the smokable filler material, and the filler smokable material can be absent of such carbonaceous material. The smokable filler material is combustible and can be blended with other smokable materials.

The tobacco-containing smokable filler materials of the present invention have some form of tobacco incorporated therein during manufacture. The tobacco which is employed to provide such a tobacco-containing smokable filler material can have a variety of forms, including tobacco extracts, milled tobacco laminae, tobacco fines or dust, shredded or comminuted tobacco laminae, tobacco stems, volume expanded tobacco filler and other forms of processed tobacco, and the like, and combinations thereof. Tobacco extracts are processed forms of tobacco and are provided by extracting a tobacco material using a solvent such as water, carbon dioxide, a hydrocarbon, or a halocarbon, as well as various other organic and inorganic solvents. Tobacco extracts can include spray dried extracts; freeze dried extracts; heat treated extracts, such as those extracts described in U.S Patent application Ser. Nos. 511,158, filed Apr. 19, 1990 and 452,175, now U.S. Pat. No. 5,060,699 to White, et al., filed Dec. 18, 1989; tobacco essences, such as those essences described in European Patent Application No. 326,370; and aroma oils and extracts described in U.S. Pat. No. 4,506,682 to Mueller and U.S. Patent application Ser. No. 310,413, filed Feb. 13, 1989.

The smokable filler materials of the present invention incorporate a binding agent. Examples of suitable binding agents include hydroxypropylcellulose such as Klucel H from Aqualon Co.; hydroxypropylmethylcellulose such as Methocel K4MS from The Dow Chemical Co.; hydroxyethylcellulose such as Natrosol 250 MRCS from Aqualon Co.; microcrystalline cellulose such as Avicel from FMC; methylcellulose such as Methocel A4M from The Dow Chemical Co.; and sodium carboxymethylcellulose such as CMC 7HF and CMC 7H4F from Hercules Inc. Especially preferred binding agents include the alginates, such as ammonium alginate, sodium alginate, propylene glycol alginate and potassium alginate. The alginates, and particularly the high viscosity alginates, can be employed in conjunction with controlled levels of free calcium ions. Other binding agents include starches (e.g., corn starch), guar gum, locust bean gum, pectins and xanthan gum. Combinations or blends of binding agents (e.g., a mixture of guar gum and locust bean gum) can be employed.

The smokable filler materials of the present invention can have at least one aerosol forming material and/or at least one flavoring agent incorporated therein. The preferred aerosol forming materials include polyhydric alcohols (e.g., glycerin, propylene glycol or triethylene glycol), any other materials which yield a visible aerosol, or mixtures thereof. The aerosol forming material can be provided as a portion of the binding agent (e.g., when the binding agent is propylene glycol alginate). Combinations of aerosol forming materials can be employed. The flavoring agents can vary, and include menthol, vanillin, citric acid, malic acid, cocoa, licorice, and the like, as well as combinations thereof. See, Leffingwell et al, *Tobacco Flavoring for Smoking Products* (1972).

It is sometimes desirable to incorporate a caramelizing material into the smokable filler materials of the present invention. Caramelizing materials can act to improve (i) the integrity of the ash and fire cone of the cigarette, (ii) the appearance of the smokable filler material, and (iii) the flavor characteristics of the mainstream smoke of the cigarette. The caramelizing material can be incorporated into the smokable filler material during the preparation of that material and/or applied to the surface of that material (e.g., as a powder) after the manufacture thereof. Normally, the amount of caramelizing material which is employed to treat a particular smokable filler material is such that the resulting material which incorporates the caramelizing material includes up to about 20 weight parts, typically up to about 5 weight parts, of caramelizing material and greater than about 80 weight parts of the smokable material which is treated. Examples of suitable caramelizing materials include sugars, such as glucose, fructose and sucrose; and compositions such as Carob Powder Code 1739 from M. F. Neal, Inc.

The smokable filler materials of the present invention can be surface treated with certain substances. For example, the smokable filler materials can have powdered substances applied to the surface thereof. Exemplary substances include cocoa powder, licorice powder, powdered inorganic materials (e.g., potassium carbonate or iron oxide), tobacco dust, finely divided tobacco laminae, or the like, or blends thereof. The surface treatment of the smokable filler materials can provide to those materials improved color and appearance, improved ash characteristics, and improved flavor characteristics.

The previously described agglomerated matrix filler has the form of an agglomerated matrix of an inorganic component and a carbonaceous component. The inorganic component can include particles of calcium carbonate, calcium sulfate, magnesium oxide, and the like. A particularly preferred agglomerated matrix filler is agglomerated calcium carbonate, and most preferably,

agglomerated precipitated calcium carbonate. Such an agglomerated matrix filler can be prepared by providing an aqueous slurry of calcium carbonate particles and a binding material, and drying the slurry to form an agglomerated matrix of calcium carbonate (i.e., a matrix of a plurality of calcium carbonate particles spaced within a continuous or semi-continuous phase of binding material). If desired, the slurry can be volume expanded by incorporating a foaming agent therein. Examples of suitable foaming agents include linear sodium benzene sulfonates, linear alkyl sulfonates and linear alkyl ethoxy sulfates. Calcium carbonate particles which are employed to provide the agglomerated matrix typically exhibit a surface area of less than about 20 m^2/g, frequently less than about 10 m^2/g, and sometimes less than about 1 m^2/g, as determined using the Brunauer, Emmett and Teller (BET) method described in *J. Am. Chem. Soc,*. Vol. 60, p. 309 (1938). Typical binding materials are organic materials, such as cellulosic derivatives (e.g., sodium carboxymethylcellulose), and preferably are sugar containing materials, such as molasses, high fructose corn syrup, or Carob Powder Code 1739 from M. F. Neal, Inc. Other organic materials, such as pectins and alginates, also can be employed.

Preferably, a high solids content aqueous slurry (e.g., about 40 to about 55 weight percent solids content slurry) of calcium carbonate and binding material is spray dried to provide agglomerated particles (e.g., normally spherical particles) of calcium carbonate particles and binding material. Alternatively, the slurry can be dried by the application of heat to provide a solid mass of agglomerated calcium carbonate and binding material, and the solid mass can be ground to yield particles of the desired size. Preferably, the amount of calcium carbonate relative to binding material ranges from about 20:1 to about 2:1, more preferably about 15:1 to about 4:1, on a dry weight basis. Normally, the inorganic particles agglomerated using saccharide and polysaccharide materials tend to lose their agglomerated character when contacted with water under ambient conditions, as a result of the propensity of the saccharide and polysaccharide materials to be soluble in water.

The agglomerated matrix of inorganic component and organic binding material is subjected to heat treatment. As such, volatile components from the organic binding material are expelled, and the organic binding material is calcined to form an essentially water insoluble, clean burning carbonaceous component. Normally, the heat treatment of the agglomerated matrix filler is provided under controlled atmosphere, in order to minimize or prevent oxidation of the binding material. Preferably, the heat treatment provides a binding material which is in the form of a carbonaceous material, and in turn, provides a means for agglomerating the particles of inorganic component into a matrix form. In particular, the particles of agglomerated calcium carbonate and binding material can be heat-treated (e.g., to a temperature of up to about 625° C., and usually up to about 600° C.) using an oven, batch furnace, a fluidized bed, rotary calciner, belt calciner, or the like. For example, particles of spray dried calcium carbonate particles agglomerated using molasses can be heated in a fluidized bed having gaseous nitrogen flowing therethrough, heated at temperatures sufficient to heat the particles from about 300° C. to about 625° C., and collected. The agglomerated matrix of inorganic component and organic binding material can be subjected to heat treatment sufficient to calcine the organic binding material by subjecting the agglomerated matrix to very high temperatures (e.g., up to about 900° C.) for a short time period and under conditions sufficient to avoid decomposition of the inorganic component (e.g., when the inorganic component is calcium carbonate). However, if the inorganic component is calcium carbonate, and the calcium carbonate undergoes some decomposition during the calcining step, the agglomerated material can be re-carbonated by (i) exposing that material to carbon dioxide atmosphere, or (ii) dispersing that material in water and bubbling carbon dioxide into the dispersion.

After the calcining process, the agglomerated calcium carbonate particles normally have a calcium carbonate content of greater than about 80, frequently greater than about 90 weight percent and a carbon content provided by the carbonaceous component of greater than about 3 weight percent. Normally, the resulting agglomerated particles are screened to sizes of about −50/+325 US Mesh, and often about −80/+200 US Mesh. Preferred agglomerated calcium carbonate particles which have been calcined are essentially insoluble in water, are spherical in shape, are free flowing, and exhibit a bulk density of about 0.1 g/cm^3 to about 1.1 g/cm^3, frequently about 0.3 g/cm^3 to about 1 g/cm^3, using mercury intrusion techniques. As such, calcined agglomerated calcium carbonate particles provide an inorganic material having a bulk density less than about 2 g/cm^3, and preferably less than about 1 g/cm^3, which includes an inorganic component having a bulk density greater than about 2.5 g/cm^3. Normally, such calcined agglomerated calcium carbonate particles exhibit a surface area of less than about 30 m^2/g, and often about 10 m^2/g to about 25 m^2/g, as determined using the BET method.

If desired, the bulk density of the calcined agglomerated inorganic filler can be lowered by digesting away part of the inorganic component with an acidulant. For example, calcined agglomerated can be dispersed in water, and an aqueous hydrochloric acid solution can be added to the resulting slurry which is agitated. The acid reacts with the calcium carbonate, and essentially does not react with the carbonaceous component. Thus, the carbonaceous component acts to hold together the remaining calcium carbonate, while a portion of the calcium carbonate reacts to produce carbon dioxide gas and water soluble calcium chloride.

Other inorganic materials can be incorporated as fillers in the smokable filler materials of the present invention. Such inorganic materials often have a fibrous, flake, crystalline, hollow, amorphous or particulate form. Examples of inorganic materials include calcium carbonate, calcium sulfate particles, magnesium oxide, magnesium hydroxide, perlite, synthetic mica, vermiculite, clays, thermally stable carbon fibers, zinc oxide, dawsonite, low density hollow spheres of calcium carbonate, glass spheres, glass bubbles, sodium silicate, thermally stable carbon microspheres, calcium sulfate fibers, hollow ceramic microspheres, alumina, calcium carbonate agglomerated using an organic material, low density processed calcium carbonate, and the like. If desired, organic materials (e.g., grains) can be incorporated as fillers into smokable filler materials of the present invention. Such inorganic and organic fillers are employed to occupy space in the smokable filler materials of the present invention.

Calcium carbonate agglomerated using ammonium alginate is an example of an agglomerated matrix filler having an inorganic component in an organic compo-

nent. Other inorganic components include calcium sulfate, magnesium oxide and magnesium carbonate. Such an agglomerated matrix filler is provided by preparing an aqueous slurry of calcium carbonate particles and hydrated alginate, and drying the slurry to form an agglomerated matrix of calcium carbonate (i.e., a matrix of a plurality of calcium carbonate particles spaced within a continuous or semi-continuous phase of alginate). If desired, the slurry can be volume expanded by incorporating a foaming agent therein. Examples of suitable foaming agents include linear sodium benzene sulfonates, linear alkyl sulfonates and linear alkyl ethoxy sulfates. Preferably, a high solids content aqueous slurry of calcium carbonate and alginate is spray dried to provide agglomerated particles (e.g., normally spherical particles) of calcium carbonate particles and alginate. Alternatively, the slurry can be dried by the application of heat to provide a solid mass of agglomerated calcium carbonate and alginate, and the solid mass can be ground to yield particles of the desired size. Preferably, the amount of calcium carbonate relative to alginate ranges from about 99:1 to about 10:1, on a dry weight basis. Typically, the particles of calcium carbonate agglomerated using alginate are essentially insoluble in water under ambient conditions. In particular, the essentially water insoluble character of the alginate in the agglomerated matrix filler tends to limit to a great degree any propensity of the agglomerated matrix filler to lose its agglomerated character when contacted with water under ambient conditions. The agglomerated matrix filler is rendered insoluble due to the interaction of the alginate with calcium ions of the calcium carbonate. If desired, the agglomerated matrix filler can be treated with a dilute solution of acid to decompose a portion of the calcium carbonate and liberate calcium ions and the resulting calcium ions can act to render insoluble the alginate component of the agglomerated matrix filler.

The agglomerated matrix filler having an inorganic component and an organic component can incorporate a variety of other organic components. For example, the organic component can be pectin, which has a tendency to become essentially water insoluble upon interaction with calcium. Alternatively, agglomerated matrix filler having a polysaccharide organic component can be treated with divalent ions (e.g., calcium, barium, cobalt, iron or manganese ions) or trivalent ions (e.g., iron or aluminum ions) to render the polysaccharide essentially water insoluble. As yet another example, a slurry of polysaccharide material (e.g., ethylcellulose) and inorganic component particles can be provided in a non-aqueous solvent (e.g., alcohol) and dried, resulting in the formation of an agglomerated matrix filler which is essentially water insoluble.

Another type of inorganic material which can be incorporated into smokable filler materials of the present invention is a low density inorganic filler. Such a filler is provided by providing particles of a calcium salt, decomposing the anion of the salt and contacting the particles with carbon dioxide. Examples of suitable salts include calcium propionate, succinate, tartrate, stearate, salicylate, palmitate, oleate, lactate, gluconate, citrate, ascorbate, acetylsalicylate and benzoate. Other suitable salts include calcium salts of saccharides and polysaccharides. Such salts are subjected to conditions sufficient to decompose the anion thereof, which usually involves subjecting the salt to heat treatment under carbon dioxide atmosphere.

One method for providing a low density inorganic filler involves heating calcium lactate particles screened to −80/+170 US Mesh at about 600° C. for about 8 hours under a steady 228 ml/min. flow of carbon dioxide gas, so as to provide a material which has undergone about a 65 percent weight loss. About 20 weight parts of the material is charged into about 80 weight parts water, and the resulting slurry is contacted with sufficient hydrochloric acid solution to lower the pH thereof to about 6.8. The material then is removed from the water, washed with water, dried, and screened to a particle size of −80/+170 US Mesh. Such material is greater than about 95 weight percent calcium carbonate, and exhibits a bulk density of about 0.4 g/cm^3, as determined using mercury intrusion techniques.

Typically, the smokable filler materials of the present invention are provided by forming an aqueous slurry of binding agent and the other components of that smokable filler material, casting the slurry as a sheet, and drying the cast material to form a relatively dry, workable sheet. Techniques and equipment for casting a slurry as a sheet will be apparent to the skilled artisan. Other materials, such as calcium acetate, potassium carbonate, pH control agents, urea, amino acids, potassium chloride and/or calcium hydroxide, can be incorporated into the slurry. Sequestering agents (e.g., diammonium hydrogen orthophosphate, potassium hexametaphosphate, sodium citrate or tetrasodium pyrophosphate) can be incorporated into the slurry in amounts sufficient to control the free calcium ion concentration in the slurry. The cast material can be dried at ambient temperatures or at elevated temperatures. Further, an aqueous solution of calcium salts can be applied to the cast slurry. The resulting dried sheet can be cut or broken into "strip" form, and later can be cut or shredded into cut filler form.

The smokable filler materials of the present invention can be provided using a paper-making process. In particular, an aqueous slurry of a cellulosic material (e.g., softwood pulp, hardwood pulp, flax fibers and/or shredded tobacco stems) and the previously described filler can be cast as a mat on a fibrous belt or wire screen, and dried to the desired moisture level. Normally, a slurry, dispersion or solution of flavoring agents, tobacco extracts, tobacco parts, aerosol forming materials, and the like, can be applied to the mat (e.g., as a spray), and the resulting mat can be dried further to form a sheet. The resulting dried sheet can be cut or broken in "strip" form, and later can be cut or shredded into cut filler form. Techniques and equipment for making a paper-type sheet will be apparent to the skilled artisan.

The smokable filler materials of the present invention can be extruded into the desired shape using suitable extrusion techniques. See, for example, the types of processes described in U.S. Pat. No. 4,880,018 to Graves, Jr. et al, which is incorporated herein by reference. Alternatively, an aqueous slurry of the components of the smokable material and an alginate binding agent can be extruded into an aqueous solution of calcium ions (e.g., an aqueous solution of calcium chloride), collected and dried. If desired, extruded smokable filler materials can be physically processed (e.g., subjected to treatment using rollers, etc.) and formed into the desired shape.

The smokable rods of cigarettes of the present invention often include a physical mixture or blend of smokable materials. The blend can include two or more

smokable filler materials of the present invention, or a physical mixture of at least one smokable filler material of the present invention with at least one other smokable material. Certain preferred cigarettes include within such a blend, a sufficient amount of at least one of the smokable filler materials of the present invention such that the smokable material within each cigarette comprises at least about 1 percent of the carbonaceous material, based on the total weight of the blend. In particular, cigarettes having such types of smokable filler materials and having low porosity paper outer wrappers (e.g., having outer wrappers having less than about 5 CORESTA units) have the propensity to sustain smolder (e.g., not self-extinguish), when smoked under FTC smoking conditions. FTC smoking conditions consist of 35 ml puffs of 2 second duration, taken every 60 seconds.

The smokable filler materials of the present invention can be blended with tobacco cut filler. The type of tobacco can vary, and can include flue-cured, Burley, Maryland and Oriental tobaccos, as well as the rare and specialty tobaccos, and blends thereof. Such tobacco cut filler can be provided in the form of tobacco laminae; volume expanded or puffed tobacco laminae; processed tobacco stems such as cut-rolled or cut-puffed stems; reconstituted tobacco materials, such as (i) deproteinated tobacco materials described in U.S. Pat. Nos. 4,887,618 to Bernasek et al and 4,941,484 to Clapp et al, (ii) a phosphate-containing reconstituted tobacco material described in U.S. Pat. Nos. 3,353,541 and 3,420,241 to Hind et al, and 3,386,449 to Hind, as well as U.S. Patent application Ser. Nos. 406,637, filed Sep. 13, 1989 now U.S. Pat. No. 4,987,906 to Young, et al., and 461,216, filed Jan. 5, 1990, (iii) a reconstituted tobacco material described in U.S. Patent application Ser. No. 272,156, now U.S. Pat. No. 4,962,774 to Thomasson, et al., filed Nov. 16, 1988 and *Tobacco Encyclopedia.* edit. by Voges, p. 389, TJI (1984), (iv) the reconstituted tobacco materials described in U.S. Patent application Ser. Nos. 416,332, filed Sep. 29, 1989 and 414,833, filed Sep. 29, 1989; or blends thereof.

Smokable materials can be cased and top dressed as is conventional during various stages of cigarette manufacture. For example, flavoring agents can be applied to the smokable material as is commonly performed when cigarette cut filler is processed. Suitable flavoring agents include vanillin, cocoa, licorice, menthol, and the like. Flavor modifying agents can be applied to the smokable material. A flavor modifying agent in the form of levulinic acid can be applied to the smokable material (e.g., in amounts ranging from about 0.01 to about 2 percent, normally from about 0.1 to about 1 percent, preferably about 0.2 to about 0.6 percent, based on the dry weight of the smokable material). Another flavor modifying agent in the form of potassium carbonate can be applied to the smokable material (e.g., in amounts of less than about 5 percent, normally about 1 to about 3 percent, based on the dry weight of the smokable material). Aerosol forming materials and humectants, such as glycerin and propylene glycol, can be applied to the smokable material. Such components conveniently are applied to the smokable material as casing and top dressing components.

The preferred wrapping material which provides the smokable rod is a cigarette wrapping material having a low air permeability value. Such a wrapping material normally has an air permeability of less than about 5 CORESTA units, often less than about 3 CORESTA units, and frequently less than about 1 CORESTA unit. Typical wrapping materials are cigarette paper wrappers. Suitable wrapping materials are cigarette paper wrappers available as DD-71-1, DD-71-6, MTR-1021, P-2831-60-2, P-2831-60-3, P-2831-60-4, P-2831-60-5, P-2674-110, P-2831-60-1 and DD-100-2 from Kimberly-Clark Corp. Suitable low porosity cigarette paper wrappers are commercially available, and can have various levels of burn chemicals, fluxing agents, etc., incorporated therein. Particularly preferred are cigarette paper wrappers which include an amount of a polymeric film forming agent sufficient to provide a paper having the desirably low air permeability value. For example, a sufficient amount of a solution of a polymeric (e.g., carboxymethyl cellulose or ethylcellulose) film forming agent can be applied to a paper wrapper. The selection of the polymeric film forming agent will be apparent to the skilled artisan.

The optional polymeric film forming agent can be applied to the paper wrapper during the manufacture of the paper, or applied as a print or paint after manufacture of the paper is complete. Typically, the film forming agent is applied to the paper as a dilute solution (e.g., at a concentration of about 0.2 to about 5 weight percent relative to the solvent) for ease of processing. The amount of film forming agent applied to the paper wrapper depends upon factors such as the permeability of the paper and the film forming capabilities of the film forming agent. Typically, the amount of film forming agents employed ranges from about 1 to about 10 percent, based on the dry weight of the paper. For example, a 5 weight percent solution of ethylcellulose in ethanol or sodium carboxymethylcellulose in water can be applied to cigarette paper using a size press, and the paper can be dried to provide a non-wetting, moisture resistant paper wrapper having a porosity of less than about 1 CORESTA unit, preferably less than about 0.5 CORESTA unit.

The smokable rods and the resulting cigarettes can be manufactured in any known configuration using known cigarette making techniques and equipment. Smokable rods often include smokable material wrapped in a single layer of wrapping material, although a double layer of two types of wrapping materials can be employed. See, for example, U.S. Patent application Ser. No. 528,302, filed May 24, 1990, which is incorporated herein by reference.

Cigarettes having smokable rods which are double wrapped with two layers of wrapping material preferably include one of the previously described low porosity paper wrappers as the outer wrappers. The inner wrapper can vary, but typically is a tobacco-containing wrapping material. Exemplary inner wrappers are paper wrappers which include about 3 parts Java tobacco stem parts and about 1 part wood pulp, and are available from Kimberly-Clark Corp. as P-2249-115 and P-2831-23-3. Other suitable inner wrapping materials include tobacco parts and carbonaceous materials, and are available from Kimberly-Clark Corp. as P-2540-94-A, P-2540-94-C and P-2540-94-D. The inner wrapping materials (i) can include burn chemicals (e.g., potassium citrate, potassium acetate or potassium succinate), and/or (ii) act as a substrate for flavors (e.g., menthol or vanillin) or flavor precursors (e.g., vanillin glucoside or ethylvanillin glucoside).

Typically, the smokable rod has a length which ranges from about 30 mm to about 70 mm, preferably about 35 to about 60 mm; and a circumference of about

17 mm to about 27 mm, preferably about 22 mm to about 25 mm. Short smokable rods (i.e., having lengths from about 30 to about 50 mm) can be employed, particularly when smokable materials having a relatively high packing density are employed.

The packing density of the smokable material contained within the outer wrapping material can vary. Typical packing densities for smokable rods of cigarettes of the present invention range from about 150 to about 400 mg/cm^3. Normally, packing densities of such smokable rods range from about 200 to about 380 mg/cm^3, frequently about 250 to about 360 mg/cm^3, particularly when relatively short (i.e., less than 50 mm long) smokable rods are employed.

The cigarettes of the present invention preferably include a filter element, and most preferably a filter element having more than one segment. For example, a preferred filter element has two or more filter segments. Typically the segments of the preferred filter elements each have lengths which ranges from about 10 mm to about 30 mm; and circumferences of about 17 mm to about 27 mm, preferably about 22 mm to about 25 mm. The plug wrap which circumscribes the filter material of each filter segment typically is a conventional paper plug wrap, and can be either air permeable or essentially air impermeable.

Preferred filter materials of one of the filter segments include carbonaceous materials (e.g., activated carbon particles, charcoal particles, or carbon paper). An example of a particularly preferred filter material is provided by gathering a tobacco/carbon paper available as P-144-BAC from Kimberly-Clark Corp. Such filter materials reduce the levels of certain gas phase components from the mainstream smoke which passes to the mouth of the smoker. As such, preferred filter materials of that segment act to reduce the levels of any smoke components which may provide an off-taste or other undesirable characteristics to the mainstream smoke.

Preferred filter materials of another of the filter segments normally include fibrous materials. An example of a suitable filter material is a gathered nonwoven polypropylene web. A particularly preferred nonwoven polypropylene sheet-like web is available as PP-100-F from Kimberly-Clark Corp. Another example of a suitable filter material is a cellulose acetate tow. Particularly preferred cellulose acetate tow items include (i) 8 denier per filament/40,000 total denier, and (ii) 8 denier per filament/15,000 total denier, (iii) 8 denier per filament/25,000 total denier, and (iv) 8 denier per filament/30,000 total denier. Plasticizers, such as triacetin, propylene glycol or triethyl citrate, can be combined with the filler materials.

Another filter segment can have a filter material in the form of a gathered web of nonwoven thermoplastic (i.e., hydrophobic) fibers in intimate contact with a water soluble tobacco extract so as to provide an extract-containing filter material. A highly preferred web is a nonwoven web of polypropylene fibers available as PP 200 SD from Kimberly-Clark Corp. Exemplary filter segments and filter elements are described in U.S. Patent application Ser. Nos. 414,835, filed Sep. 29, 1989 and 518,597, filed May 3, 1990. Such segments can provide enhanced flavor characteristics to the mainstream smoke which passes therethrough.

Yet another filter segment can include a tobacco paper material as the filter material. For example, a filter material can have the form of a gathered web of tobacco paper available as P-144-B from Kimberly-Clark Corp.

The filter element segments suitable for use in this invention can be manufactured using known cigarette filter making techniques. Filter elements can be manufactured from cellulose acetate tow using known techniques. Filter elements can be manufactured from carbon paper, tobacco paper and a sheet-like nonwoven polypropylene web using filter making techniques described in U.S. Pat. No. 4,807,809 to Pryor et al, which is incorporated herein by reference. Alternatively, particles of charcoal or activated carbon can be incorporated into the filter element using a so-called "triple filter" configuration by positioning the particles between two segments of suitable filter materials.

The filter elements can have low, moderate or high filtration efficiencies. Preferred filter elements have minimal mainstream aerosol (i.e., smoke) removal efficiencies while maintaining the desirable draw characteristics of the cigarette. Such minimal smoke removal efficiencies are provided by "low efficiency" filter elements. Low efficiency filter elements have a minimal ability to remove mainstream smoke particulates. See, Keith in Schemeltz's *The Chemistry of Tobacco and Tobacco Smoke*, p. 157 (1972). Generally, low efficiency filter elements provide less than about 40 weight percent mainstream smoke particulate removal efficiency.

Tipping material circumscribes the filter element and an adjacent region of the smokable rod such that the tipping material extends about 3 mm to about 6 mm along the length of the smokable rod. Typically, the tipping material is a conventional paper tipping material. Tipping materials of varying porosities can be employed. For example, the tipping material can be essentially air impermeable, air permeable, or treated (e.g., by mechanical or laser perforation techniques) so as to have a region of perforations, openings or vents thereby providing a means for providing air dilution to the cigarette. The total surface area of the perforations and the positioning of the perforations along the periphery of the cigarette can be varied in order to control the performance characteristics of the cigarette.

For air diluted or ventilated cigarettes of the present invention, the amount of air dilution can vary. Typically, the amount of air dilution for an air-diluted cigarette is greater than about 25 percent, and frequently greater than about 40 percent. The upper limit for air dilution for a cigarette typically is less than about 75 percent, more frequently less than about 65 percent. As used herein, the term "air dilution" is the ratio (expressed as a percentage) of the volume of air drawn through the air dilution means to the total volume of air and aerosol (i.e., smoke) drawn through the cigarette and exiting the extreme mouthend portion of the cigarette. See, Selke et al, *Beitr. Zur Tabak. In.*, Vol. 4, p. 193 (1978).

Cigarettes of the present invention, when smoked, provide a flavorful mainstream aerosol. The mainstream aerosol of such cigarettes can yield low levels of incomplete combustion products as well as low levels of gas phase components. The cigarettes burn at an acceptable rate, and maintain static smolder, at least when smoked under FTC smoking conditions. The cigarettes, when smoked, have an ash and fire cone which is not overly cohesive, and hence, is not overly long. However, the cigarettes also provide an ash and fire cone which exhibit good integrity.

Cigarettes of the present invention, when smoked, generally yield less than about 20 mg, preferably less than about 10 mg of sidestream "tar" per cigarette, as determined using the apparatus and techniques described by Proctor et al, *Analyst.* Vol. 113, p. 1509 (1988). Such cigarettes normally provide more than about 5 puffs, preferably more than about 6 puffs per cigarette, when smoked under FTC conditions. Normally, cigarettes of the present invention provide less than about 20 puffs, and often less than about 15 puffs, when smoked under FTC conditions.

The following examples are provided in order to further illustrate the invention but should not be construed as limiting the scope thereof. Unless otherwise noted, all parts and percentages are by weight.

EXAMPLE 1

A. Preparation of a Tobacco-Containing Smokable Filler Material

An agglomerated matrix filler is provided as follows:

Into a low shear mixer are charged about 832 parts tap water at ambient temperature, about 757 parts precipitated particulate calcium carbonate available as Albacar 5970 from Pfizer Inc., and about 267 parts molasses. The calcium carbonate has a rosettic structure and an average particle size (i.e., diameter) of about 2 microns. The molasses is available as Refiner's Syrup from Savannah Sugar Co., and has a solids/water content of about 3.7:1. The resulting mixture is agitated for about 5 to about 10 minutes to provide a slurry having a solids content of about 52 percent and a viscosity of about 1,200 cps as measured by a Brookfield LVT viscometer with cylindrical LV spindle No. 4.

The slurry is spray dried by continuously pumping the slurry at about 6 lbs./min. at a feed pressure of about 475 to about 500 psig to a spray dryer. The spray dryer is a Bowen Type commercial unit equipped with an SD-046 nozzle, and operated in a commercial mode. The inlet temperature is about 470° F., and the outlet temperature is about 260° F. The resulting spray dried particles have a generally spherical shape, and a moisture content of below about 2 percent. The particles are screened to a particle size of −70/+200 US Mesh.

The spray dried particles are placed on a 12 inch by 36 inch steel tray to a thickness of about 0.5 inch. The tray then is passed into a continuous belt furnace at a rate of about 8 to about 12 inches/min., and is subjected to heating under nitrogen atmosphere at above about 600° C. for about 10 minutes, and at above about 400° C. for about 20 minutes. The oven is set at about 720° C., and the tray is subjected to a maximum air temperature of about 670° C. during that time. The heated particles are removed from the furnace into a cooling zone for about 1 hour under nitrogen atmosphere, and cooled to ambient temperature.

The calcined particles so collected are black, are spherical in shape, are free flowing, and resist wetting. The particles are about 93 percent calcium carbonate, and exhibit a bulk density of about 0.5 g/cm^3. The particles each are an agglomerated matrix of a plurality of precipitated calcium carbonate particles spaced within a carbonaceous material.

The tobacco-containing smokable filler material is provided as follows:

Into tap water at ambient temperature and maintained at high shear in a blender is charged about 2 parts sodium carboxymethylcellulose available as CMC 7HF from Hercules Inc. Then, about 4 parts glycerin is charged into the water. After a consistent slurry is provided, about 6 parts spray dried tobacco extract is charged into the slurry. Then, about 18 parts of the previously described calcined agglomerated matrix filler particles are folded into the slurry. The resulting slurry, which is an intimate mixture of the aforementioned components, has a solids content of about 25 percent, and exhibits a pH of about 7.

The slurry is cast to about a 0.02 inch thickness onto a high density polyethylene sheet and air dried. The resulting tobacco-containing smokable filler material is a very dark brown sheet having (i) a thickness of about 0.01 inch, (ii) a density of about 0.5 g/cm^3, (iii) a moisture content of about 2 to about 6 percent, and (iv) a flexible and pliable character. The sheet is provided in strip form, about 2 inches by about 3 inches in size. The strips are shredded at about 32 cuts per inch to provide a combustible tobacco-containing smokable cut filler.

B. Preparation of a Cigarette

Cigarettes substantially as shown in FIG. 1 are provided as follows:

The cigarettes each have a length of about 84 mm and a circumference of about 24.8 mm, and include a smokable rod having a length of about 57 mm, a first filter segment having a length of about 15 mm and a second filter segment having a length of about 12 mm. The first and second filter segments form a filter element. Each filter segment is attached to each smokable rod using nonporous tipping paper. For each cigarette, the tipping paper circumscribes the filter element and about a 4 mm length of the smokable rod in the region adjacent the filter element. The filter elements are not ventilated.

The smokable rod includes the previously described tobacco-containing smokable filler material in cut filler form.

The first filter segment is provided by gathering a 11.75 inch wide web of tobacco and carbon paper available as P-144-BAC from Kimberly-Clark Corp. using the filter rod forming apparatus described in Example 1 of U.S. Pat. No. 4,807,809 to Pryor et al. The plug wrap for the filter segment is available as Reference No. 5831 from Ecusta Corp. The first filter segment is positioned adjacent the smokable rod.

The second filter segment is provided by gathering a 11.75 inch wide web of non-woven polypropylene web available as PP-100-F from Kimberly-Clark Corp. using the filter rod forming apparatus described in Example 1 of U.S. Pat. No. 4,807,809 to Pryor et al. The plug wrap for the filter segment is available as Reference No. 5831 from Ecusta Corp. The second filter segment is positioned adjacent the first filter segment, at the extreme mouth end of the cigarette.

The cigarette paper wrapper exhibits an air permeability of about 1 CORESTA unit. The cigarette paper is available as MTR-1021 from Kimberly-Clark Corp.

Smokable cigarette rods are provided using known techniques. In particular, the smokable material is circumscribed by a single layer of paper wrap. The weight of the smokable filler material within each cigarette rod is about 0.92 g.

The cigarettes are employed by burning the smokable rod such that the smokable material within the paper wrapper burns to yield smoke. When employed, such cigarettes yield very low levels of visible sidestream smoke and essentially no sidestream odor. Cigarettes smoked and tested in this manner each yield 8.0 puffs,

18.7 mg wet total particulate matter (WTPM), 1.8 mg nicotine, 4.8 mg water and 4.8 mg glycerin, under FTC smoking conditions. The cigarettes do not self-extinguish during the smolder period experienced during FTC smoking conditions.

EXAMPLE 2

A. Preparation of a Smokable Filler Material

Into tap water at ambient temperature and maintained at high shear in a blender is charged about 3 parts sodium carboxymethylcellulose available as CMC 7HF from Hercules Inc. Then, about 6 parts glycerin is charged into the water. After a consistent slurry is provided, about 91 parts of the calcined agglomerated calcium carbonate described in Example 1 is folded into the slurry. The resulting slurry, which is an intimate mixture of the aforementioned components, has a solids content of about 25 percent, and exhibits a pH of about 7.

The slurry is cast to about a 0.02 inch thickness onto a flat high density polyethylene sheet and air dried. The resulting smokable filler material is a very dark brown sheet having (i) a thickness of about 0.01 inch, (ii) a density of about 0.5 g/cm^3, (iii) a moisture content of about 2.5 to about 6 percent, and (iv) a flexible and pliable character. The sheet is provided in strip form, about 2 inches by about 3 inches in size. The strips are shredded at about 32 cuts per inch to provide a smokable cut filler.

The smokable filler material has a powder mixture applied to the surface thereof. The powder mixture is about 9 parts cocoa powder and about 1 part iron oxide, and the powder mixture is applied such that the resulting smokable filler material includes about 3 percent of that powder mixture. The powder mixture provides a brown color to the combustible smokable cut filler.

B. Preparation of a Cigarette

Cigarettes substantially as shown in FIG. 3 are provided as follows:

The cigarettes each have a length of about 84 mm and a circumference of about 24.8 mm, and include a smokable rod having a length of about 57 mm, a first filter segment having a length of 15 mm and a second filter segment having a length of about 12 mm. The first and second segments form a filter element. Each filter segment is attached to each smokable rod using nonporous tipping paper. For each cigarette, the tipping paper circumscribes the filter element and about a 4 mm length of the smokable rod in the region adjacent the filter element. The filter elements are ventilated to about 60 percent air dilution by providing a ring of perforations through the tipping paper and plug wrap of the filter element circumscribing the cigarette about 12 mm from the extreme mouthend thereof.

The smokable rod includes two longitudinally positioned segments of smokable material within two layers of wrapper. The inner surface of the outer wrapper directly contacts the outer surface of the inner wrapper. The inner wrapper circumscribes the smokable material. The first segment of smokable material is positioned at the end of the smokable rod which is to be lit, and the second segment of smokable material is positioned at the end of the smokable rod which is adjacent the filter element. Each segment extends about 28.5 mm along the smokable rod.

The first segment of smokable material is about 0.6 g of a blend of about 65 parts of the previously described smokable filler material and 35 parts tobacco cut filler (strands of tobacco laminae cut at about 32 cuts per inch). The tobacco cut filler portion is a blend of about 30 parts volume expanded flue-cured tobacco, about 20 parts volume expanded Oriental tobacco, about 45 parts flue-cured tobacco, and about 5 parts of a spray dried aqueous Burley tobacco extract. The tobacco cut filler then is top dressed with a mixture of glycerin and potassium carbonate, such that the resulting cut filler includes about 91 percent tobacco, about 3 percent potassium carbonate and about 6 percent glycerin.

The second segment is composed entirely of about 0.6 g of the previously described smokable filler material.

The first filter segment is provided by gathering a 11.75 inch wide web of tobacco and carbon paper available as P-144-BAC from Kimberly-Clark Corp. using the filter rod forming apparatus described in Example 1 of U.S. Pat. No. 4,807,809 to Pryor et al. The plug wrap for the filter segment is available as Reference No. 5831 from Ecusta Corp. The first filter segment is positioned adjacent the smokable rod.

The second filter segment is cellulose acetate tow (8 denier per filament/40,000 total denier) which is plasticized with triacetin, and is circumscribed by nonporous paper plug wrap. The second filter segment is positioned adjacent the first filter segment, at the extreme mouth end of the cigarette.

The cigarette paper outer wrapper of the smokable rod exhibits an air permeability of about 0 CORESTA unit. The paper includes about 4.2 percent potassium citrate and about 1.1 percent sodium carboxymethylcellulose. The cigarette paper is available as P-2831-60-1 from Kimberly-Clark Corp.

The inner wrapper of the smokable rod is a tobacco-containing paper available as P-2831-23-3 from Kimberly-Clark Corp.

The cigarettes are employed by burning the smokable rod such that the smokable material within the paper wrapper burns to yield smoke. When employed, such cigarettes yield very low levels of visible sidestream smoke and essentially no sidestream odor. Cigarettes smoked and tested in this manner each yield 9.5 puffs, 5.2 mg wet total particulate matter (WTPM), 0.5 mg nicotine, 0.5 mg water and 1.5 mg glycerin, under FTC smoking conditions. The cigarettes do not self-extinguish during the smolder period experienced during FTC smoking conditions.

EXAMPLE 3

A smokable filler material is prepared as follows:

Into about 300 ml tap water at ambient temperature is dispersed about 5 g of a high viscosity ammonium alginate available as Amoloid HV from Kelco Division of Merck & Co., Inc. To this is charged about 6 g glycerin, and then about 89 g of the calcined agglomerated calcium carbonate described in Example 1. The resulting slurry is agitated for about 15 minutes using an egg beater type mixer, until the slurry exhibits a smooth texture. The slurry then is cast onto a high density polyethylene sheet at a thickness of about 0.02 inch and air dried. The resulting sheet exhibits good tensile strength, exhibits a flexible and pliable character, is water resistant, and does not undergo any significant amount of cracking during drying. The resulting sheet has a moisture content of about 20 percent, and a thickness of about 0.02 inch. The sheet is shredded at 32 cuts per inch to provide a combustible smokable cut filler.

EXAMPLE 4

A tobacco-containing smokable filler material is prepared as follows:

Into about 300 ml tap water at ambient temperature is dispersed about 5 g of the ammonium alginate described in Example 3. To this is charged about 6 g glycerin, then about 2 g diammonium phosphate, and then about 5 g of a spray dried aqueous extract of Burley tobacco. To this is charged about 82 g of the calcined agglomerated calcium carbonate described in Example 1. The resulting slurry is agitated gently using an egg beater type mixer until the slurry exhibits a smooth texture. The slurry then is cast onto a high density polyethylene sheet surface at a thickness of about 0.02 inch and air dried. The resulting sheet exhibits good tensile strength, exhibits a flexible and pliable character, is water resistant, and does not undergo any significant amount of cracking during drying. The resulting sheet has a moisture content of about 20 percent and a thickness of about 0.02 inch. The sheet is shredded at 32 cuts per inch to provide a combustible smokable cut filler.

EXAMPLE 5

A smokable filler material is prepared as follows:

Into about 300 ml tap water at ambient temperature is dispersed about 5 g of the ammonium alginate described in Example 3. To this is charged about 20 g glycerin, and then about 40 g of the calcined agglomerated calcium carbonate described in Example 1. The resulting slurry is mixed gently for about 15 minutes using an egg beater type mixer. The resulting slurry is extruded at ambient temperature using a 50 ml syringe through a die having a generally circular orifice having a diameter of about 1 mm. The extrudate exits the die into a solution of about 98 parts tap water and about 2 parts calcium chloride ambient temperature. Within about 30 seconds, extrudate is removed from the aqueous calcium chloride solution, and resembles a cylinder having a diameter of 1 mm. The extrudate is dried at ambient conditions. The extrudate is passed through the nip of two closely spaced, smooth surfaced metal rollers to produce ribbon about 2 mm wide and about 0.4 mm thick. The resulting material is suitable for use as a smokable filler material.

EXAMPLE 6

A tobacco-containing smokable filler material is provided as follows:

Into about 320 parts tap water at ambient temperature is dispersed about 4 parts of the ammonium alginate described in Example 3. To this is charged about 10 parts glycerin, then about 5 parts of powdered Java tobacco laminae, and then about 81 parts of the calcined agglomerated calcium carbonate described in Example 1. The resulting slurry is agitated until the slurry exhibits a smooth texture. The slurry is cast onto a flat high density polyethylene sheet at a thickness of about 0.02 inch, and air dried to a moisture content of about 12 percent and a thickness of about 0.012 inch. The resulting sheet is cut at about 32 cuts per inch to provide a combustible smokable cut filler.

EXAMPLE 7

A. Preparation of a Smokable Filler Material

A tobacco-containing smokable filler material is provided using a paper-making process as follows:

Into about 400 parts tap water at ambient temperature is dispersed about 2 parts hardwood pulp having a Canadian Standard Freeness of about 95. A slurry is provided by agitating the mixture in a high shear blender at high speed for about 4 minutes. Into the slurry is charged about 25 parts of the calcined agglomerated calcium carbonate described in Example 1. As such, the amount of cellulose pulp in the slurry is less than about 12 percent, based on the solids content of the slurry. The resulting slurry is agitated gently to provide a uniform, homogeneous slurry.

The homogeneous slurry is cast from a headbox as a mat onto a 100 mesh (U.S.) fabric. The slurry is metered from the headbox using a rotating drum having retractable metering veins which unload the slurry from the drum to the fabric. The rotating drum moves linearly relative to the surface of the fabric. The ratio of the speed of the perimeter of the rotating drum to the linear speed of the drum is about 1.6:1. A vacuum of about −25 inches water is pulled on the bottom of the fabric to provide a mat having a thickness of about 0.02 inch. A mixture of water, glycerin, spray dried aqueous tobacco extract is sprayed onto both sides of the mat. The aqueous spray dried tobacco extract is about 30 parts spray dried Burley tobacco and about 70 parts spray dried flue cured tobacco. Sufficient mixture is sprayed onto the mat so as to provide a sheet having about 20 parts tobacco extract, about 6 parts glycerin and about 74 parts mat, on a dry weight basis. The mat then is maintained overnight at a temperature of about 76° F. and at a relative humidity of about 60 percent to provide a paper-type material.

The mat then is cut into rectangular strips, about 2 inches by about 3 inches in size. The strip is shredded at 32 cuts per inch using a paper shredder available as Model 52 AM from Michael Business Machines Corp. The resulting strands of smokable cut filler then are dried at about 90° C. in an oven to a moisture level of about 3 percent.

B. Preparation of a Cigarette

Cigarettes substantially as shown in FIG. 3 are provided as follows:

The cigarettes each have a length of 84 mm and a circumference of 24.8 mm, and include a smokable rod having a length of 57 mm, a first filter segment having a length of 15 mm and a second filter segment having a length of 12 mm. The first and second segments form a filter element. Each filter element is attached to each smokable rod using nonporous tipping paper. For each cigarette, the tipping paper circumscribes the filter element and a 4 mm length of the smokable rod in the region adjacent the filter element. The filter elements are ventilated to about 63 percent air dilution by providing a ring of perforations through the tipping paper and plug wrap of the filter element circumscribing the cigarette about 12 mm from the extreme mouthend thereof.

The smokable rod includes the previously described smokable filler material wrapped within two layers of wrapper.

The first filter segment is provided by gathering a 11.75 inch wide web of tobacco and carbon paper available as P-144-BAC from Kimberly-Clark Corp. using the filter rod forming apparatus described in Example 1 of U.S. Pat. No. 4,807,809 to Pryor et al. The plug wrap for the filter segment is available as Reference No. 5831 from Ecusta Corp. The first filter segment is positioned adjacent the smokable rod.

The second filter segment is cellulose acetate tow (8 denier per filament/40,000 total denier) which is plasticized with triacetin, and is circumscribed by nonporous paper plug wrap. The second filter segment is positioned adjacent the first filter segment, at the extreme mouth end of the cigarette.

The cigarette paper outer wrapper of the smokable rod exhibits an air permeability of about 0 CORESTA unit. The paper includes about 4.2 percent potassium citrate and about 1.1 percent sodium carboxymethylcellulose. The cigarette paper is available as P-2831-60-1 from Kimberly-Clark Corp.

The inner wrapper of the smokable rod is a tobacco containing paper available as P-2831-22-2 from Kimberly-Clark Corp.

The weight of each cigarette is about 1.26 g.

The cigarettes are employed by burning the smokable rod such that the smokable material within the paper wrapper burns to yield smoke. When employed, such cigarettes yield very low levels of visible sidestream smoke and essentially no sidestream odor. Cigarettes smoked and tested in this manner each yield about 9 puffs, 7.3 mg wet total particulate matter (WTPM), 0.74 mg nicotine, 0.5 mg water and 1.2 mg glycerin, under FTC smoking conditions.

EXAMPLE 8

A smokable filler material is provided as follows:

Into about 240 parts tap water is charged about 4 parts of the ammonium alginate described in Example 3, followed by about 17.5 parts glycerin, then about 17.5 parts propylene glycol, and finally about 61 parts of the calcined agglomerated calcium carbonate described in Example 1. The resulting slurry is agitated using an egg beater type mixer, until the slurry exhibits a smooth texture. The slurry is cast onto a high density polyethylene sheet at a thickness of about 0.015 inch and air dried. The resulting dried sheet has a thickness of about 0.011 inch, an exhibits a density of about 0.745 g/cm^3.

Cigarettes are provided from the smokable filler material as follows:

The smokable material is circumscribed by a reconstituted tobacco paper-type wrapper containing Java tobacco stem parts and wood pulp. The inner wrapper is available as P-2831-23-3 from Kimberly-Clark Corp. The inner wrapper then is circumscribed by a paper wrapper available as P-2831-60-1 from Kimberly-Clark Corp. The cigarette includes the filter element and tipping material, substantially as described in Example 7.

EXAMPLE 9

A smokable filler material is provided as follows:

Into about 720 parts tap water is charged about 12 parts of the ammonium alginate described in Example 3, followed by about 48 parts glycerin, and finally about 40 parts of the calcined agglomerated calcium carbonate described in Example 1. The resulting slurry is agitated using an egg beater type mixer, until the slurry exhibits a smooth texture. The slurry is cast onto a high density polyethylene sheet at a thickness of about 0.015 inch and air dried. The resulting dried sheet has a thickness of about 0.007 inch, and exhibits a density of about 0.503 g/cm^3.

Cigarettes are provided from the smokable filler material as follows:

The smokable material is circumscribed by a reconstituted tobacco paper-type wrapper containing Java tobacco stem parts and wood pulp. The inner wrapper is available as P-2831-23-3 from Kimberly-Clark Corp. The inner wrapper then is circumscribed by a paper wrapper available as P-2831-60-1 from Kimberly-Clark Corp. The cigarette includes the filter element and tipping material, substantially as described in Example 7.

EXAMPLE 10

A smokable filler material is provided as follows:

Into about 720 parts tap water is charged about 12 parts of the ammonium alginate described in Example 3, followed by about 24 parts glycerin, then about 24 parts propylene glycol, and finally about 40 parts of the calcined agglomerated calcium carbonate described in Example 1. The resulting slurry is agitated using an egg beater type mixer, until the slurry exhibits a smooth texture. The slurry is cast onto a high density polyethylene sheet at a thickness of about 0.015 inch and air dried. The resulting dried sheet has a thickness of about 0.007 inch, and exhibits a density of about 0.47 g/cm^3.

Cigarettes are provided from the smokable filler material as follows:

The smokable material is circumscribed by a reconstituted tobacco paper-type wrapper containing Java tobacco stem parts and wood pulp. The inner wrapper is available as P-2831-23-3 from Kimberly-Clark Corp. The inner wrapper then is circumscribed by a paper wrapper available as P-2831-60-1 from Kimberly-Clark Corp. The cigarette includes the filter element and tipping material, substantially as described in Example 7.

EXAMPLE 11

A tobacco-containing smokable filler material is provided as follows:

Into about 400 ml tap water at ambient temperature is charged about 24.2 g glycerin and about 12.1 g propylene glycol, and the resulting mixture is agitated at a high rate using a high shear blender. To the resulting mixture is added about 7.2 g of the ammonium alginate described in Example 3, and the mixture which results is agitated at high speed using a blender for about 15 minutes in order to disperse the alginate in the liquid and hydrolyze the alginate. About 10 g precipitated calcium carbonate available as Code No. 2A from Pfizer Inc. is dispersed in about 100 ml of tap water; charged into the aqueous slurry of glycerin, propylene glycol and alginate; and the resulting mixture is agitated until a smooth slurry results. The resulting slurry is transferred to an egg beater type mixer, and about 10 g of the agglomerated calcium carbonate described in Example 1 is added to the slurry while the mixture is gently agitated. Into the slurry is added about 36.4 g of a mixture of volume expanded flue-cured and Burley tobacco laminae which has been ground to a particle size of −35/+80 US Mesh, and the mixture is gently agitated. About 3 g diammonium phosphate is dissolved in about 200 g water; charged into the slurry; and the resulting slurry is gently agitated for about 5 minutes.

The resulting slurry is cast to about a 0.03 inch thickness on a high density polyethylene sheet and air dried for about 80 minutes. Then, an aqueous solution of 1 percent calcium chloride is sprayed onto the top side of the cast slurry so as to apply about 1 percent calcium chloride to the cast slurry, on a dry weight basis. The slurry then is allowed to air dry to provide a relatively stiff sheet. The resulting sheet is shredded at about 32 cuts per inch to provide a smokable filler material.

EXAMPLE 12

Particles of calcium carbonate agglomerated with an alginate are provided as follows:

Into a blender is charged about 750 ml tap water, and then about 20 g glycerin. While the mixture is gently agitated, about 10 g of the ammonium alginate described in Example 3 is slowly added thereto, so as to disperse the alginate in the water. The resulting mixture is transferred into a 1 liter jar, sealed, and gently rolled overnight to hydrate the alginate.

A slurry of 250 g precipitated calcium carbonate available as Code No. 2A from Pfizer Inc. in 250 g tap water is provided. Then, the slurry is added to 200 g of the water/glycerin/alginate mixture. The resulting slurry is agitated gently so as to provide a slurry having a smooth texture.

The slurry is cast onto a high density polyethylene sheet at a thickness of about 0.04 inch, and air dried to provide pieces of dried sheet about 6 inches by about 6 inches in size. The resulting dried sheet is hand ground to a fine particle size and screened to −50 US Mesh.

A tobacco-containing smokable filler material is prepared as follows:

Into a high shear blender is charged about 225 ml tap water, and into the water is dispersed about 5 g of the ammonium alginate described in Example 3. The resulting mixture is gently agitated at ambient temperature for about 15 minutes, until the alginate is hydrated. Then, about 20 g glycerin is added to the mixture, followed by about 25 ml tap water. To the mixture is added about 16.7 g of an "American blend" of tobacco cut filler which has been ground to a powder. Then, about 25 ml tap water is added to the mixture. The resulting mixture is agitated until a smooth slurry results. To the slurry is added a mixture of about 13.8 g of the calcined agglomerated calcium carbonate described in Example 1 and about 13.8 g of particles of calcium carbonate agglomerated with ammonium alginate. The resulting slurry is agitated until the slurry exhibits a smooth texture. The resulting slurry is cast onto a high density polyethylene sheet at a thickness of about 0.025 inch and air dried.

EXAMPLE 13

A smokable filler material is provided as follows:

Into about 2,000 ml tap water is charged about 400 g of the calcined agglomerated calcium carbonate described in Example 1. The resulting slurry is agitated using a magnetic stirring bar, and into the slurry is added in a drop-wise manner about 500 ml of a 3 molar aqueous hydrochloric acid solution. The slurry then is filtered and washed with about 4,000 ml water. The resulting digested agglomerated matrix calcium carbonate exhibits a bulk density and weighs about 104 g.

Into a high shear mixer set at high speed containing about 430 g tap water is added about 5 g sodium carboxymethylcellulose available as CMC 7HF from Hercules Inc. Then, about 6 g glycerin is charged into the mixture. Agitation is ceased, and about 89 g of the previously described digested agglomerated matrix calcium carbonate is folded into the mixture. The resulting slurry is gently agitated until a smooth slurry results. The slurry is sieved through a 20 US Mesh screen to remove large clumps therefrom. The slurry is cast at about a 0.02 inch thickness and air dried. The resulting sheet has a thickness of about 0.015 inch, and exhibits a density of about 0.31 g/cm^3.

EXAMPLE 14

A tobacco-containing smokable filler material is provided as follows:

Into about 190 ml tap water at ambient temperature is mixed about 24.2 g of glycerin and 12.1 g of propylene glycol. The mixture is agitated using a high shear blender. To this is added about 3.6 g of the ammonium alginate described in Example 3. Agitation is continued for about 15 minutes until the ammonium alginate is completely dispersed and hydrated. Then about 10 g of precipitated calcium carbonate is added slowly and mixed until the material is evenly dispersed and the slurry becomes smooth. Then about 10 g of agglomerated calcium carbonate, as described in Example 1, is added and gently stirred until the mix is uniform. This mixture was cast at 0.02 inches onto a plastic surface. After drying for 1 hour, an aqueous solution of 1 percent calcium chloride is sprayed onto the top side as described in Example 6. This sheet is allowed to dry in air under ambient conditions. Next, into about 300 ml tap water at ambient temperature is added about 3.6 g of ammonium alginate and the mix is agitated until the alginate is dispersed and hydrated. Then about 14.6 g of Burley tobacco powder, about 2.9 g of milled Turkish tobacco, about 18.9 g of milled flue-cured tobacco; and about 13.5 g of propylene glycol is added and mixed until uniform. This mix was cast at about 0.07 inches over the sheet previously described in this Example. The resulting laminated sheet is shredded at 32 cuts per inch.

What is claimed is:

1. A cigarette comprising:

(a) a smokable filler material including an intimate mixture of (i) agglomerated matrix filler in particulate form having particles of inorganic filler spaced within a continuous or semi-continuous phase of a carbonaceous binding material, and (ii) tobacco; and

(b) wrapping material circumscribing the smokable filler material.

2. The cigarette of claim **1** wherein the smokable filler material includes a binding agent.

3. The cigarette of claim **1** wherein the wrapping material is a paper having a porosity of less than about 5 CORESTA units.

4. The cigarette of claim **1** or **3** wherein the agglomerated matrix filler comprises a calcium carbonate component and a carbonaceous component.

5. The cigarette of claim **4** further including tobacco cut filler.

6. The cigarette of claim **4** wherein the agglomerated matrix filler comprises greater than about 90 weight percent calcium carbonate component and greater than about 3 weight percent carbon provided by the carbonaceous component.

7. The cigarette of claim **1** or **3** wherein the agglomerated matrix filler comprises an inorganic component spaced within a continuous or semi-continuous phase of a carbonaceous binding component, and the agglomerated matrix filler is in particulate form exhibiting a particle size of −50/+325 U.S. Mesh.

8. The cigarette of claim **1** further including tobacco cut filler.

9. The cigarette of claim **1** wherein the smokable material includes up to about 50 weight percent tobacco, about 45 to about 90 percent agglomerated matrix filler; up to about 20 weight percent binding agent;

and up to about 20 weight percent aerosol forming material.

10. A cigarette comprising:

(a) smokable filler material including an intimate mixture of (i) agglomerated matrix filler, (ii) tobacco, and (iii) a binding agent which includes ammonium alginate; and

(b) wrapping material circumscribing the smokable filler material.

11. The cigarette of claim 1, 2 or 10 wherein the tobacco has the form of a tobacco extract.

12. The cigarette of claim 11 wherein the smokable filler material includes an aerosol forming material.

13. The cigarette of claim 11 further including tobacco cut filler.

14. A smokable filler material comprising an agglomerated matrix filler material in particulate form having particles of inorganic filler spaced within a continuous or semi-continuous phase of a carbonaceous binding material.

15. The smokable filler material of claim 14 including a binding agent.

16. The smokable filler material of claim 14 or 15 including an aerosol forming material.

17. The smokable filler material of claim 16 wherein the aerosol forming material includes a polyhydric alcohol.

18. The smokable filler material of claim 16 further comprising tobacco.

19. The smokable filler material of claim 14 wherein the agglomerated matrix filler comprises an inorganic component spaced within a continuous or semi-continuous phase of a carbonaceous binding component, and the agglomerated matrix filler is in particulate form exhibiting a particle size of −50/+325 U.S. Mesh.

20. The smokable filler material of claim 19 wherein the inorganic component includes particles of calcium carbonate.

21. The smokable filler material of claim 19 wherein the agglomerated matrix filler comprises greater than about 90 weight percent inorganic component and greater than about 3 weight percent carbon provided by the carbonaceous component.

22. The smokable filler material of claim 21 further comprising tobacco.

23. The smokable filler material of claim 19 including about 60 to about 95 weight percent agglomerated matrix filler, up to about 20 percent binding agent, and up to about 20 weight percent aerosol forming material.

24. The smokable filler material of claim 23 further comprising tobacco.

25. The smokable filler material of claim 19 consisting essentially of about 60 weight percent agglomerated matrix filler, up to about 20 weight percent binding agent, and up to about 20 weight percent aerosol forming material.

26. The smokable filler material of claim 25 further comprising tobacco.

27. The smokable filler material of claim 22, 24 or 26 wherein the tobacco has the form of a tobacco extract.

28. The smokable filler material of claim 22, 24 or 26 including up to about 50 weight percent tobacco, about 45 to about 90 weight percent agglomerated matrix filler, up to about 20 weight percent binding agent, and up to about 20 weight percent aerosol forming material.

29. The smokable filler material of claim 14 or 19 wherein the agglomerated matrix filler is (i) in particulate form, and (ii) exhibits a bulk density of less than about 1 g/cm^3.

30. The smokable filler material of claim 14, 15 or 19 further comprising tobacco.

31. The smokable filler material of claim 30 wherein the tobacco has the form of an extract.

32. A cigarette comprising:

(a) smokable filler material including agglomerated matrix filler in particulate form having particles of inorganic filler spaced within a continuous or semi-continuous phase of a carbonaceous binding material; and

(b) wrapping material circumscribing the smokable filler material.

33. The cigarette of claim 32 wherein the smokable filler material includes a binding agent.

34. The cigarette of claim 32 wherein the smokable material includes an aerosol forming material.

35. The cigarette of claim 32 wherein the wrapping material is a paper having a porosity of less than about 5 CORESTA units.

36. The cigarette of claim 32 or 35 wherein the agglomerated matrix filler comprises a calcium carbonate component and a carbonaceous component.

37. The cigarette of claim 36 wherein the smokable filler material comprises about 60 to about 95 weight percent agglomerated matrix filler, up to about 20 weight percent binding agent, and up to about 20 weight percent aerosol forming material.

38. The cigarette of claim 36 wherein the agglomerated matrix filler comprises greater than about 90 weight percent calcium carbonate component and greater than about 3 weight percent carbon provided by the carbonaceous component.

39. The cigarette of claim 32 or 35 wherein the agglomerated matrix filler comprises an inorganic component spaced within a continuous or semi-continuous phase of a carbonaceous binding component, and the agglomerated matrix filler is in particulate form exhibiting a particle size of −50/+325 U.S. Mesh.

40. The cigarette of claim 35 further including tobacco cut filler.

41. A cigarette comprising:

(a) smokable filler material including (i) agglomerated matrix filler, and (ii) a binding agent including ammonium alginate; and

(b) wrapping material circumscribing the smokable filler material.

42. The cigarette of claim 32, 33 or 41 further including tobacco cut filler.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,105,836

DATED : April 21, 1992

INVENTOR(S) : Jeffery S. Gentry, et al.

It is certified that error appears in the above—identified patent and that said Letters Patent is hereby corrected as shown below:

In the Title Page under [75] Inventors:

Line 3, after "Mead; insert --of New Jersey--.

Page 2 following U.S. PATENT DOCUMENTS, add:

--OTHER PUBLICATIONS, APV Anhydro Bulletin No. 165 and APV Anhydro Bulletin No. 701--.

Col. 24, line 62, "80" should be --30--.
Col. 27, line 55, after "60" insert --to about 90--.

Signed and Sealed this

Twenty-first Day of September, 1993

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

US 20050016550A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2005/0016550 A1

Katase (43) Pub. Date: Jan. 27, 2005

(54) ELECTRONIC CIGARETTE

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(21) Appl. No.: **10/886,508**

(22) Filed: **Jul. 7, 2004**

(30) **Foreign Application Priority Data**

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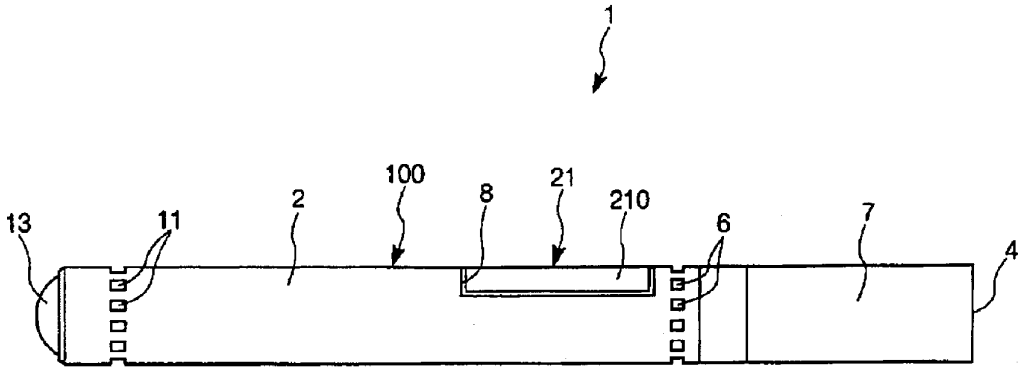
Publication Classification

(51) **Int. Cl.**[7] **A24F 1/22**

(52) **U.S. Cl.** **131/194**; 131/360

(57) **ABSTRACT**

An electronic cigarette is provided. The electronic cigarette includes a casing having an inhalation hole and a substantially cylindrical configuration, ejection means (first ejection means) provided in the casing and at least one ejection head. Pressure in a cavity filled with a liquid flavor generating medium is changed by driving an actuator to eject the flavor generating medium as droplets from a nozzle in communication with the cavity. Control means provided in the casing controls the driving of the ejection means.



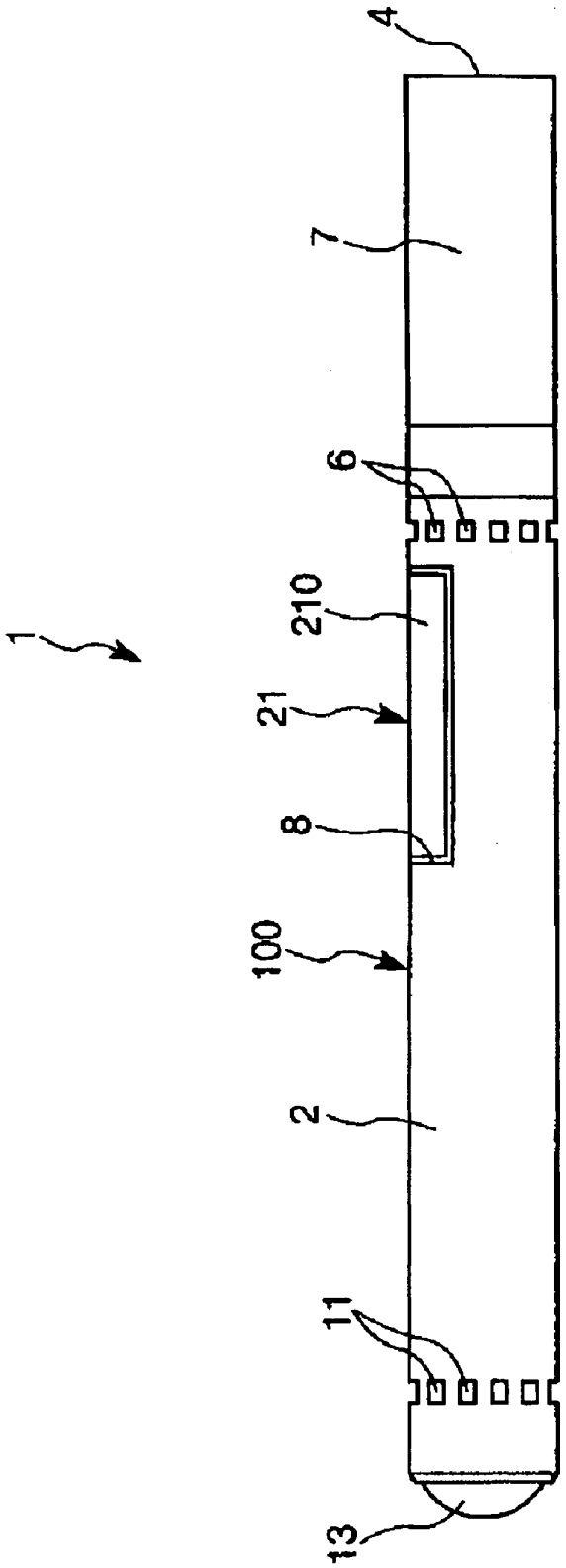


FIG. 1

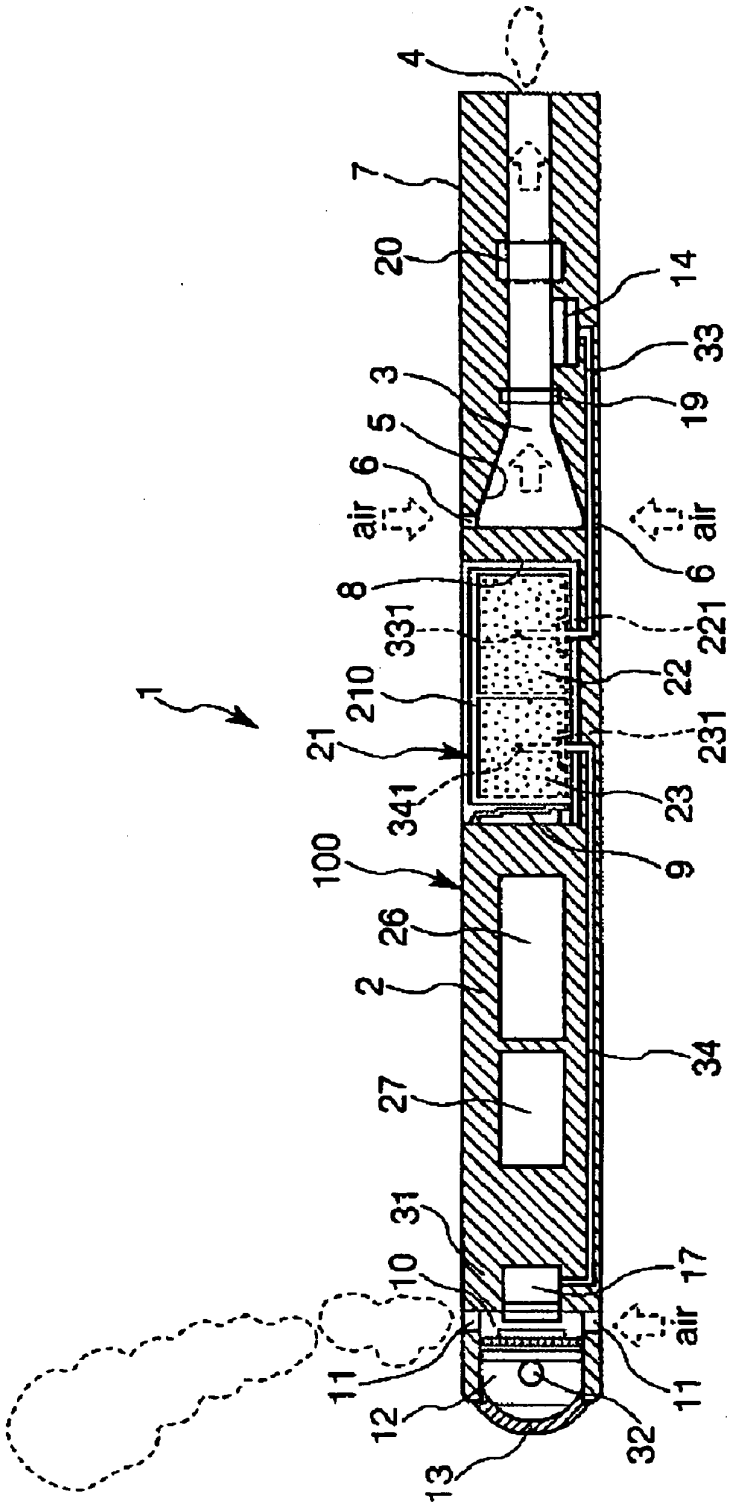

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FIG. 2

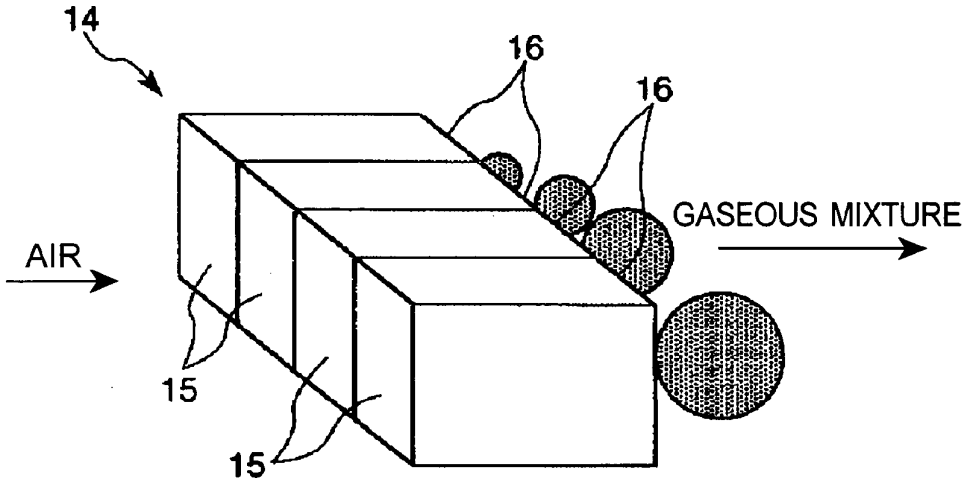

FIG. 3

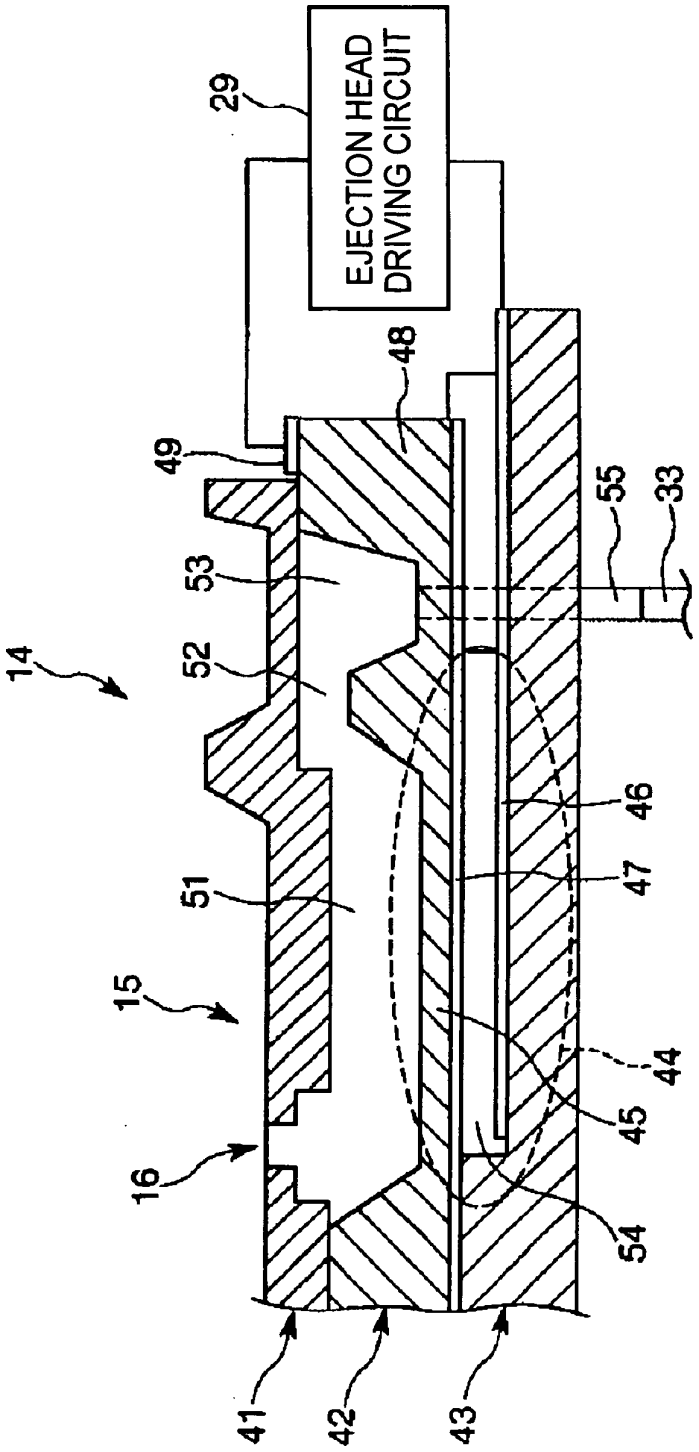
EJECTION HEAD DRIVING CIRCUIT
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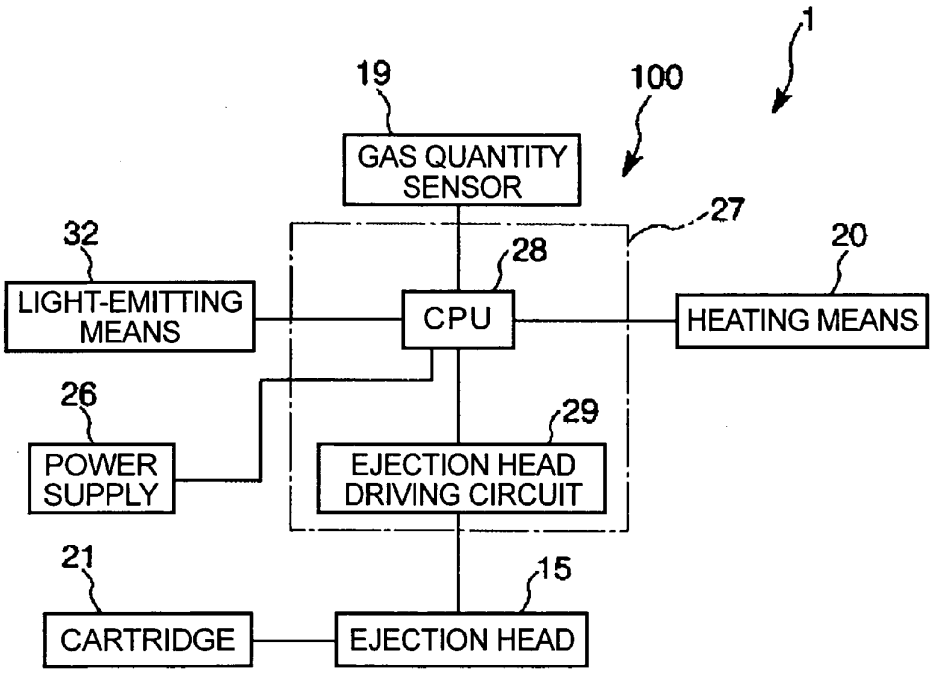
FIG. 4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CARTRIDGE
EJECTION HEAD

FIG. 5

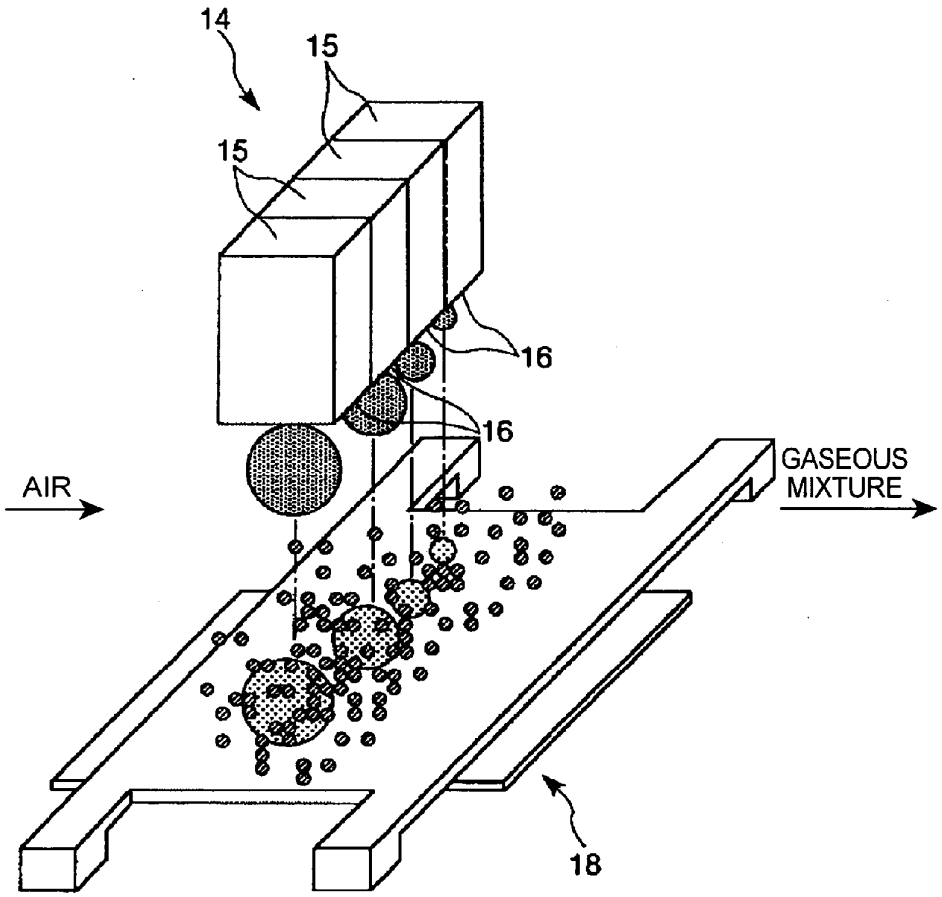
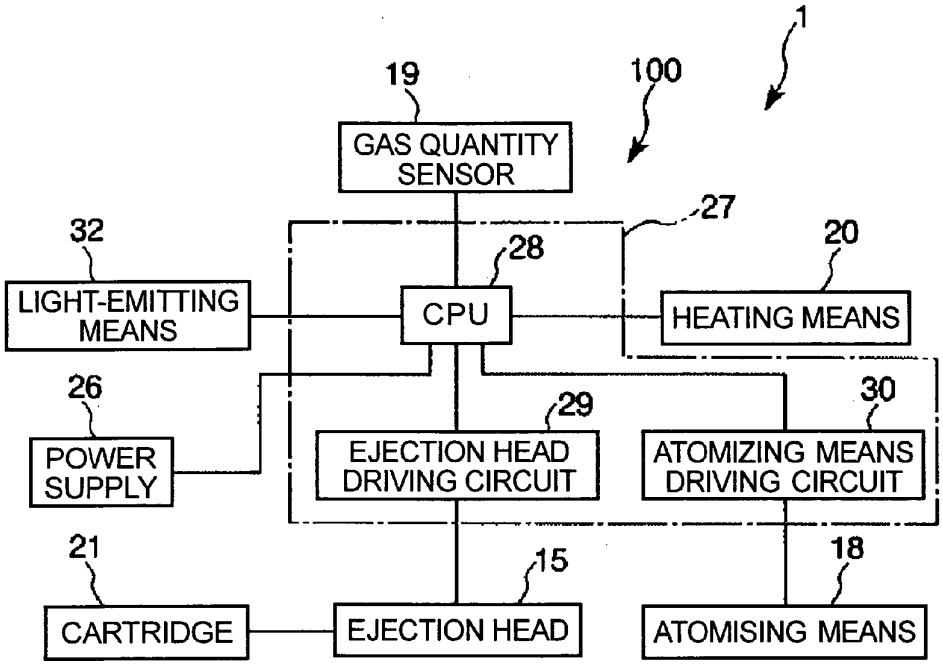


FIG. 6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ATOMIZING MEANS DRIVING CIRCUIT
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CARTRIDGE
EJECTION HEAD
ATOMISING MEANS

FIG. 7

ELECTRONIC CIGARETTE

RELATED APPLICATIONS

[0001] This application claims priority to Japanese Patent Application No. 2003-198701 filed Jul. 17, 2003 which is hereby expressly incorporated by reference herein in its entirety.

BACKGROUND

[0002] 1. Technical Field to which the Invention Belongs

[0003] The present invention relates to an electronic cigarette.

[0004] 2. Related Art

[0005] Recently, various types of smoking simulators for tasting a flavor resembling that of a cigarette without burning a cigarette have been proposed.

[0006] For example, smoking simulators have been proposed, in which a heating element and solid flavor generating medium are provided in a heat-insulating tube and in which the heat-insulating tube and a power supply of the heating element are wrapped in fine quality wrapping paper and formed like a cigarette (for example, see Japanese Patent Laid-Open No. JP-A-3-232481).

[0007] In a smoking simulator having such a configuration, electrical energy is supplied from the power supply to the heating element to heat the flavor generating medium which in turn generates flavor components. A flavor resembling that of a cigarette can be tasted by inhaling a gaseous mixture of the flavor components and air which has been taken into the smoking simulator.

[0008] In a smoking simulator having such a configuration, however, since it takes time to increase the temperature of the flavor generating medium, a long time is required for the flavor generating medium to generate a sufficient amount of flavor components. Thus, a sufficient amount of flavor components can not be obtained at the beginning of simulated smoking, and a feeling similar to that of a cigarette cannot be provided from the beginning of simulated smoking.

[0009] Since the amount of flavor components generated by the flavor generating medium cannot be controlled with high accuracy, the amount of flavor components cannot be adjusted according to the amount of inhalation. As a result, a feeling similar to that of a cigarette cannot be provided.

[0010] Further, since there is no function of generating smoke similar to that of a cigarette and no function of generating a fire similar to that of a cigarette, a feeling similar to that of a cigarette cannot be provided.

[0011] It is an object of the invention to provide an electronic cigarette which provides a sufficient amount of flavor components from the beginning of smoking when a smoker inhales to smoke on a simulated basis which allows the smoker to have feelings similar to those a cigarette provides.

SUMMARY

[0012] The above and other objects are achieved by the invention as described below.

[0013] An electronic cigarette according to the invention comprising: a casing having a inhalation hole and having a substantially bar-like configuration as a whole; ejection means which is provided in the casing and has at least one ejection head and which changes a pressure in a cavity filled with a liquid flavor generating medium by driving an actuator to eject the flavor generating medium as droplets from a nozzle in communication with the cavity; and control means which is provided in the casing and which controls the driving of the ejection means.

[0014] Thus, droplets of the flavor generating medium are ejected into the casing by driving the ejection means with the control means, and flavor components are supplied into the casing. When the smoker inhales with the inhalation hole side of the casing held in the mouth, a gaseous mixture of air which has flowed into the casing and the flavor components in the casing flows into the mouth, and the flavor components spread in the mouth to allow the smoker to taste a flavor resembling that of a cigarette.

[0015] In this case, since a sufficient amount of droplets of the flavor generating medium are ejected into the casing from the beginning of the driving of the ejection means, a sufficient amount of flavor components can be provided from the beginning of inhalation to obtain a feeling similar to that of a cigarette.

[0016] By using a flavor generating medium which has no harmful substance, no uncomfortable smell, taste, and the like, it is possible to prevent people around the smoker and the smoker him or herself from being damaged or made uncomfortable by smoking.

[0017] The electronic cigarette according to the invention preferably has atomizing means which is provided in the casing and which atomizes droplets of the flavor generating medium ejected from the ejection means.

[0018] Thus, droplets of the flavor generating medium ejected into the casing by driving the ejection means are atomized (refined) by the atomizing means. When the smoker inhales with the inhalation hole side of the casing held in the mouth, a gaseous mixture of air which has flowed into the casing and the atomized flavor components in the casing flows into the mouth, and the flavor components spread in the mouth to allow the smoker to taste a flavor resembling that of a cigarette.

[0019] In this case, the flavor components which have been atomized by the atomizing means can be inhaled into the mouth, the smoker can feel as if he or she was inhaling smoke of a cigarette.

[0020] In the electronic cigarette according to the invention, the atomizing means is preferably heating means which heats droplets of the flavor generating medium ejected from the ejection means to atomize them.

[0021] Thus, since particles of flavor components atomized by being heated with the heating means of the atomizing means can be inhaled into the mouth, the flavor components can be efficiently spread in the mouth, and the smoker can feel as if he or she was inhaling smoke of a cigarette.

[0022] In the electronic cigarette according to the invention, the atomizing means is preferably vibration means

which vibrates droplets of the flavor generating medium ejected from the ejection means to atomize them.

[0023] Thus, since flavor components atomized by being vibrated with the vibration means of the atomizing means can be inhaled into the mouth, the flavor components can be efficiently spread in the mouth, and the smoker can feel as if he or she was inhaling smoke of a cigarette.

[0024] In the electronic cigarette according to the invention, the atomizing means is preferably mountable and removable in and from the casing.

[0025] Thus, the atomizing means can be easily attached in the casing as occasion demands.

[0026] The electronic cigarette according to the invention preferably has a mounting portion in which a cartridge having a containing portion containing the liquid flavor generating medium is removably mounted.

[0027] Thus, the flavor generating medium is supplied from the containing portion to the ejection means by attaching the cartridge in the mounting portion of the casing, and the supply of the flavor generating medium from the containing portion to the ejection means is stopped by detaching the cartridge from the mounting portion of the casing.

[0028] In the electronic cigarette according to the invention, the ejection means is preferably provided at the cartridge.

[0029] Thus, the ejection means is mounted and removed to and from the casing integrally with the cartridge by mounting and removing the cartridge in and from the mounting portion of the casing.

[0030] The electronic cigarette according to the invention preferably has a power supply switch which turns a power supply on/off when the cartridge is mounted and removed in and from the mounting portion.

[0031] Thus, the power supply is turned on through the power supply switch by attaching the cartridge to the mounting portion of the casing, and the power supply is turned off through the power supply switch by detaching the cartridge from the mounting portion of the casing.

[0032] In the electronic cigarette according to the invention, the power supply is preferably provided in the casing.

[0033] The electronic cigarette according to the invention preferably has detection means which detects the quantity of a gas flowing through the casing.

[0034] Thus, the quantity of air or a gaseous mixture of air and flavor components flowing through the casing is detected by the detection means, and various types of control can be performed with control means based on the result of the detection with the detection means (according to a signal from the detection means).

[0035] The electronic cigarette according to the invention is preferably configured such that the driving of the ejection means is controlled by the control means based on the result of the detection with the detection means.

[0036] Thus, the quantity of air or a gaseous mixture of air and flavor components flowing through the casing is detected by the detection means, and the driving of the ejection means is controlled by the control means based on the result of the detection with the detection means (according to a signal from the detection means) to control turning on/off of the ejection means and the ejection amount of droplets of the flavor generating medium ejected from the ejection means.

[0037] Since smokers can therefore take flavor components into the mouth in an amount according to the inhalation capacity of the smoker, the smoker can feel as if he or she was inhaling smoke of a cigarette.

[0038] The electronic cigarette according to the invention preferably has light-emitting means provided at a tip end of the casing and has a configuration in which the driving of the light-emitting means is controlled by the control means based on the result of the detection with the detection means.

[0039] Thus, the quantity of air or a gaseous mixture of air and flavor components flowing through the casing is detected by the detection means, and the driving of the light-emitting means is controlled by the control means based on the result of the detection with the detection means (according to a signal from the detection means) to control the turning on/off of the light emitting means and the quantity of light of the same.

[0040] Since this makes it possible to increase or decrease the quantity of light of the light-emitting means according to the inhalation capacity of a smoker, the smoker can feel as if he or she was inhaling smoke of a cigarette.

[0041] The electronic cigarette according to the invention preferably has smoke generating means which generates simulated smoke from a tip end of the casing and has a configuration in which the driving of the smoke generating means is controlled by the control means based on the result of the detection with the detection means.

[0042] Thus, the quantity of air or a gaseous mixture of air and flavor components flowing through the casing is detected by the detection means, and the driving of the smoke generating means is controlled by the control means based on the result of the detection with the detection means (according to a signal from the detection means) to control the turning on/off of the smoke generating means and the amount of smoke.

[0043] Since this makes it possible to generate simulated smoke from the smoke generating means, to stop the generating of smoke, and to adjust the amount of smoke generated according to the inhalation capacity of a smoker, the smoker can feel as if he or she was inhaling smoke of a cigarette.

[0044] The electronic cigarette according to the invention preferably has heating means which heats air or a gaseous mixture including air and flavor components flowing through the casing.

[0045] Thus, since the air or the gaseous mixture of air and flavor components flowing through the casing is heated by the heating means, the smoker can feel as if he or she was inhaling smoke of a cigarette.

BRIEF DESCRIPTION OF THE DRAWINGS

[0046] **FIG. 1** is a plan view of a first embodiment of an electronic cigarette according to the invention.

[0047] **FIG. 2** is a sectional view of **FIG. 1**.

[0048] **FIG. 3** is an enlarged view of a part of **FIG. 2**

[0049] **FIG. 4** is a sectional view showing an example of a configuration of ejection means.

[0050] **FIG. 5** is a block diagram of the electronic cigarette according to the first embodiment.

[0051] **FIG. 6** is a partial enlarged view of an electronic cigarette according to a second embodiment.

[0052] **FIG. 7** is a block diagram of the electronic cigarette according to the second embodiment.

DETAILED DESCRIPTION

[0053] An electronic cigarette (smoking simulator) according to the invention will now be described in detail based on a preferred embodiment shown in the accompanying drawings.

[0054] FIGS. **1** to **5** show a first embodiment of an electronic cigarette according to the invention. **FIG. 1** is a plan view showing the electronic cigarette as a whole; **FIG. 2** is a sectional view of **FIG. 1**; **FIG. 3** is an enlarged view of a part of **FIG. 2**; **FIG. 4** is a sectional view showing an example of a configuration of ejection means; and **FIG. 5** is a block diagram of the electronic cigarette.

[0055] For convenience in description, the left side and the right side in **FIGS. 1 and 2** will be described as "tip end" and "base end", respectively.

[0056] As shown in **FIGS. 1 and 2**, an electronic cigarette **1** has a cigarette main body **100** having a round bar-like (bar-like) or cylindrical configuration as a whole and a cartridge **21** having a containing portion containing a liquid flavor generating medium.

[0057] The cigarette main body **100** has a casing **2**, first ejection means (ejection means) **14** which ejects droplets of the flavor generating medium into the casing **2** and second ejection means (smoke generating means) **17**, and control means **27** which controls the driving and the like of the first ejection means **14** and the second ejection means **17**.

[0058] The configuration as a whole of the casing **2** is in the form of a round bar (in the form of a bar) or substantially cylindrical. A mouthpiece portion **7** is provided at a base end of the casing **2** (one end in the longitudinal direction) which corresponds to a filter of a cigarette. A channel **3** with a predetermined length allowing air, a gaseous mixture including air and flavor components, or the like to flow through is provided along the longitudinal direction in the central part of the mouthpiece portion **7**.

[0059] The channel **3** has a circular cross section in the present embodiment. A base end of the same opens (is exposed) in the central part of an end face on the base end side of the mouthpiece portion **7**, and the opening is formed in a inhalation hole **4** for inhaling flavor components (a gaseous mixture including air and flavor components) into the mouth.

[0060] A tip end portion of the channel **3** is formed with a tapered surface **5** whose diameter gradually increases toward the tip end, and a plurality of intake holes (side holes) **6** penetrating through the casing **2** in the radial direction thereof are provided at the portion of the tapered surface **5** having the maximum diameter, the intake holes being provided at predetermined intervals in the circumferential direction. The channel **3** is exposed to the outer surface side of the casing **2** through the intake holes **6**. Referring to the shape of the intake holes **6**, for example, they may have a square sectional shape, a circular sectional shape, or the like (they have a square sectional shape in the present embodiment). When the smoker inhales with the mouth piece portion **7** held in the mouth, air is taken into the channel **3** through the intake holes **6**, and the air flows through the channel **3** toward the inhalation hole **4** and flows into the mouth through the inhalation hole **4**.

[0061] The first ejection means **14** which is ejection means is provided in a part of the casing **2** corresponding to a central part of the channel **3** in the longitudinal direction thereof such that it faces the channel **3**, and microscopic droplets of the flavor generating medium are ejected into the channel **3** by driving the first ejection means **14**. The droplets of the flavor generating medium ejected into the channel **3** by the first ejection means **14** are mixed with air flowing through the channel **3** and flow in the channel **3**, and a resultant gaseous mixture flows into the mouth through the inhalation hole **4**.

[0062] There is no particular limitation on the configuration material of the casing **2**, and various resins, various metals, various ceramics, wood, paper, and the like may be listed by way of example.

[0063] The flavor generating medium is a medium which can be ejected as droplets to generate a flavor instead of burning the same and is appropriately chosen depending on usage or the like. For example, the flavor generating medium includes substances extracted from various natural substances or predetermined ones among components constituting them. For example, as flavoring substances included in the flavor generating medium, menthol, caffeine, precursors such as glycosides which generate a flavor when thermally decomposed, components of tobacco such as components extracted from tobacco and components that are condensates of tobacco smoke, and the like may be used. In this case, it is preferable to make the flavor generating medium harmless and to eliminate harmful components.

[0064] For example, the flavor generating medium may include a substance which generates aerosol when heated in order to add smoke to the flavor. As the substance for generating aerosol, for example, glycerin, polyols such as propylene glycol, lower alcohols, sugars, mixtures of them, and the like may be used.

[0065] The first ejection means **14** employs a fluid jet method (e.g., an ink jet method). A fluid jet method is a method in which a pressure in a cavity (pressure chamber) filled with a fluid such as a liquid is changed by driving an actuator to eject the fluid as droplets from a nozzle that is in communication with the cavity. For example, such fluid jet methods include film boiling fluid jet methods such as the thermal jet method (bubble jet method ("bubble jet" is a registered trademark), piezoelectric methods, and electrostatic methods. The invention is not limited to those methods, and any method having the same function may be employed.

[0066] An ejection head according to a film boiling fluid jet method such as the thermal jet method (bubble jet method ("bubble jet" is a registered trademark")) is equipped with a

film boiling type actuator having a heating body (heater) which generates heat when energized. According to the film boiling fluid jet method, for example, the heating body is heated by energizing to generate bubbles, and droplets are ejected by the pressure of the bubbles (a change in a liquid pressure caused by the bubbles).

[0067] An ejection head according to a piezoelectric method has a piezoelectric element and a piezoelectric actuator which utilizes a piezoelectric effect of the piezoelectric element. According to the piezoelectric method, for example, a voltage is applied to the piezoelectric element to displace (deform) the piezoelectric element and to thereby change the volumetric capacity of the cavity (pressure chamber), and droplets are ejected by a resultant change in the pressure in the cavity **51**.

[0068] An ejection head according to an electrostatic method has an electrostatic actuator. According to the electrostatic method, for example, a voltage is applied between counter electrodes of the electrostatic actuator to generate a Coulomb force; a diaphragm is thereby displaced (deformed) to change the volumetric capacity of the cavity (pressure chamber); and droplets are ejected by a resultant change in the pressure in the cavity **51**.

[0069] In the present embodiment, as shown in **FIG. 3**, the first ejection means **14** has a plurality of (four in the illustrated example) ejection heads **15** according to a fluid jet method having a nozzle **16** for ejecting droplets of a flavor generating medium. That is, the first ejection means **14** has a head unit having a plurality of ejection heads **15** according to a fluid jet method. The number of the ejection heads **15** is not limited to four, and it may be one, two, three, or five or more.

[0070] The nozzle **16** of each ejection head **15** is formed with a different diameter, and the amount of the flavor generating medium ejected can be adjusted to a predetermined amount by turning on/off those ejection heads **15** in a certain combination, for example.

[0071] A typical example of a configuration of the ejection heads **15** when an electrostatic method is adapted will now be described based on **FIG. 4**. **FIG. 4** shows only one of the plurality of ejection heads **15**.

[0072] As shown in **FIG. 4**, the ejection head **15** has a three-layer structure in which a nozzle plate **41** made of silicon is stacked on top of a silicon substrate **42** and a glass substrate **43** is stacked on the underside of the same.

[0073] Between the silicon substrate **42** and the nozzle plate **41**, there is provided a cavity (pressure chamber) **51** filled with a flavor generating medium, a reservoir **53**, and an orifice (supply hole) **52** which communicates the reservoir **53** and the cavity **51** with each other. A nozzle (outlet) **16** which establishes communication between the inside and outside of the cavity **51** is provided in a part of the nozzle plate **41** associated with the cavity **51**. A part of the silicon substrate **42** that faces the cavity **51** is formed as a diaphragm (bottom wall) **45** which is smaller in thickness than other parts.

[0074] The diaphragm **45** is configured such that it can be elastically deformed (elastically displaced) in out-of-plane directions thereof (the direction of the thickness thereof) that is, upward and downward.

[0075] A major part of an electrostatic actuator (actuator) **44** is constituted by the diaphragm **45**, a segment electrode **46** provided on top of the glass substrate **43**, and an insulation layer **47** and a gap (recess) **54** between them.

[0076] An ejection head driving circuit (voltage application means) **29** including a driving circuit for applying a driving voltage between the segment electrode **46** and a common electrode **48** facing the segment electrode **46** (between counter electrodes) performs charging and discharging between the each counter electrodes according to signals (data for ejection) input from a CPU **28** which will be described later. One output terminal of the ejection head driving circuit **29** is connected to individual segment electrode **46** and another output terminal is connected to an input terminal **49** of the common electrode **48** formed on the silicon substrate **42**. An impurity is doped in the silicon substrate **42** which thus has conductivity in itself, a voltage can therefore be applied (supplied) from the input terminal **49** to the diaphragm **45** (the common electrode **48** as a whole).

[0077] When a driving voltage is applied between the counter electrodes from the ejection head driving circuit **29**, a Coulomb force is generated between the counter electrodes, and the diaphragm **45** deflects toward the segment electrode **46** from the initial state shown in **FIG. 4** to increase (expand) the volumetric capacity of the cavity **51**. When electrical charge between the counter electrodes is abruptly discharged in this state under control of the ejection head driving circuit **29**, the diaphragm **45** returns upward because of its elastic restoring force and moves upward beyond the position of the diaphragm **45** in the initial state shown in **FIG. 4**, which abruptly decreases (contracts) the volumetric capacity of the cavity **51**. As a result, the pressure in the cavity **51** increases, and the compression pressure generated in the cavity **51** ejects a part of the flavor generating medium filling the cavity **51** as microscopic droplets from the nozzle **16** that is in communication with the cavity **51**.

[0078] An intake hole **55** in communication with the reservoir **53** is provided in a part of the glass substrate **43** that is associated with the reservoir **53**. A base end side of a first supply pipe **33** to be described later is connected to the intake hole **55**, and the flavor generating medium is supplied into the reservoir **53** from a cartridge **21** to be described later through the first supply pipe **33** and the intake hole **55**.

[0079] As shown in **FIG. 2**, a gas quantity sensor **19** that is detection means is provided on the way of the channel **3** (at the base of the tapered surface **5** of the channel **3**) on the base end side (left side in the figure) of the first ejection means **14**, and the flow rate of a fluid (air or a gaseous mixture of air and flavor components) flowing through the channel **3** is detected by the gas quantity sensor **19**.

[0080] Heating means **20** is provided on the way of the channel **3** on the tip end side (right side in the figure) of the first ejection means **14**, and the fluid (air or a gaseous mixture including air and flavor components) flowing through the channel **3** is heated by driving the heating means **20**. Thus, the fluid heated to a predetermined temperature flows out from the inhalation hole **4**. There is no particular limitation on the heating means **20** as long as it has the function of allowing a fluid to be heated, and it may be a micro-heater or the like, for example. A micro-heater con-

verts electricity into thermal energy, and its configuration and type may be arbitrarily chosen. Normally, a heater thin film is formed, and a current is passed through such a resistor to generate heat.

[0081] The heating means **20** may be made mountable and removable to and from the mouthpiece portion **7** and may be attached to the mouthpiece portion **7** as occasion demands.

[0082] A configuration may be employed in which the heating means **20** is provided upstream of the first ejection means **14**, i.e., on the tip end side of the same (left side in **FIG. 2**) and in which the heating means **20** is driven to heat air which flows through the channel **3** and has not reached the first ejection means **14** yet (air which has not been mixed with droplets of the flavor generating medium yet).

[0083] In a central part of the casing **2** in the longitudinal direction thereof (a part of the same on the left side of the channel **3** in the figure), there is provided a cartridge chamber (mounting portion) **8** having a predetermined depth whose top side opens outwardly of the casing **2**, and a cartridge **21** containing (filled with) a liquid flavor generating medium is removably mounted in the cartridge chamber **8**. A cartridge detection/power supply switch **9** is provided on one end face of the cartridge chamber **8** in the axial direction thereof (left side in **FIG. 2**).

[0084] When the cartridge **21** is mounted in (attached to) the cartridge chamber **8**, the cartridge detection/power supply switch **9** is turned on. Thus, the state in which the cartridge **21** is mounted is detected, and a power supply **26** is turned on. When the cartridge **21** is removed (detached) from the cartridge chamber **8**, the cartridge detection/power supply switch **9** is turned off. Thus, the sate in which the cartridge **21** is not mounted is detected, and the power supply **26** is turned off.

[0085] The cartridge **21** has a cartridge main body (casing) **210** having a box-like configuration as a whole. The interior of the cartridge main body **210** is partitioned into two chambers, i.e., a first chamber **22** and a second chamber **23**, and a predetermined amount of a liquid flavor generating medium is contained (filled) in each of the first chamber **22** and the second chamber **23**. The flavor generating medium contained in the first chamber **22** and the flavor generating medium contained in the second chamber **23** may be identical to or different from each other.

[0086] There is no particular limitation on the configuration material of the cartridge main body (casing) **210**, and various resins or the like may be listed by way of example.

[0087] There may be only one chamber in the cartridge main body **210**. A configuration may be employed in which the above-described first ejection means **14** may be provided at the cartridge **21** (the cartridge **21** and the first ejection means **14** may be integrated) and are integrally removably mounted in the cartridge chamber (mounting portion) **8** of the casing **2** (cigarette main body **100**).

[0088] A lancable or stuck portion **221** is formed on the bottom side of the first chamber **22** of the cartridge main body **210**, the stuck portion being lanced or stuck by a sharp end **331** at a tip end side of a first supply pipe **33** to be described later. Similarly, a lancable or stuck portion **231** is formed on the bottom side of the second chamber **23**, the stuck portion being lanced or stuck by a sharp end **341** at a base end side of a second supply pipe **34** to be described later. When the cartridge **21** is mounted in the cartridge chamber **8**, the sharp end **331** of the first supply pipe **33** and the sharp end **341** of the second supply pipe **34** stick in and penetrate through the stuck portion **221** and the stuck portion **231** of the cartridge main body **210**, respectively. Thus, communication is established between the first chamber **22** and the first supply pipe **33**, and communication is established between the second chamber **23** and the second supply pipe **34**.

[0089] In an outer peripheral portion of the casing **2**, there is embedded the first supply pipe **33** which establishes mutual communication between a part of the cartridge chamber **8** associated with the first chamber **22** and the above-described first ejection means **14** in the axial direction and the second supply pipe **34** which establishes mutual communication between a part of the cartridge chamber **8** associated with the second chamber **23** and second ejection means **17** to be described later in the axial direction. The sharp end (sticking needle) **331** is formed at the tip end side of the first supply pipe **33**, and the sharp end (sticking needle) **341** is formed at the base end side of the second supply pipe **34**. The flavor generating media are supplied from the first chamber **22** of the cartridge **21** to the first ejection means **14** and from the second chamber **23** to the second ejection means **17** through the first supply pipe **33** and the second supply pipe **34**, respectively.

[0090] In a central part of the casing **2** in the longitudinal direction thereof (a part of the same on the left of the cartridge chamber **8**), the power supply (power supply portion) **26** and control means **27** are incorporated on the base end side and tip end side, respectively, the control means controlling the driving of the first ejection means **14**, the second ejection means **17**, the gas quantity sensor **19**, the heating means **20**, the power supply **26**, light-emitting means **32** to be described later, and the like. A configuration may be employed in which the power supply **26** can be removably mounted in the casing **2**.

[0091] For example, a battery such as a primary battery or a secondary battery may be used as the power supply **26**. In this case, compactness and a reduction of weight can be achieved by using a fuel battery which has a high energy density. The fuel battery may be provided in the form of a cartridge to facilitate replacement.

[0092] At the tip end of the casing **2** (the other end in the longitudinal direction thereof), a predetermined space **10** is provided, and a plurality of intake/discharge holes (side holes) **11** are provided at predetermined intervals in the circumferential direction of a part of the casing **2** facing the space **10**, the intake/discharge holes **11** penetrating through the casing **2** in the radial direction thereof. The space **10** is exposed to the outside of the casing **2** through the intake/discharge holes **11**. Referring to the shape of the intake/discharge holes **11**, for example, it may have a square sectional shape, a circular sectional shape, or the like (it has a square sectional shape in the present embodiment).

[0093] The second ejection means **17** which is smoke generating means is provided in a part of the casing **2** that is adjacent to the space **10** on the right side of the same in **FIG. 2** so as to face the space **10**, and microscopic droplets of the flavor generating media are ejected into the space **10** by driving the second ejection means **17**. In this case, for

example, simulated smoke (sidestream smoke) that resembles smoke (sidestream smoke) of a cigarette can be generated through selection, combination, or the like of the flavor generating media.

[0094] The configuration of the second ejection means **17** is not be illustrated and described because it is similar to that of the above-described first ejection means **14**.

[0095] Droplets of the flavor generating media are ejected into the space **10** by driving of the second ejection means **17**, and simulated smoke (sidestream smoke) resembling smoke (sidestream smoke) of a cigarette is thus generated in the space **10** and discharged from the intake/discharge holes **11**. In this case, the generated (discharged) simulated smoke is preferably harmless. The simulated smoke thus generated may be odorless, or it may have an odor. When simulated smoke with an odor is to be generated, for example, the odor is preferably a pleasant odor rather than an odor like that of sidestream smoke of a cigarette.

[0096] At the tip end of the casing **2** (the part adjacent to the space **10**), there is provided a recess **12** having a predetermined depth which opens at the tip end face of the casing **2**. The opening of the recess **12** is closed by a diffusing lens **13** having a curved shape.

[0097] Light-emitting means **32** is provided on the bottom surface side of the recess **12**, and the light-emitting means **32** can be driven for emission to generate a simulated safe fire that resembles the fire of a cigarette, which provides a visual effect that resembles the fire of a cigarette.

[0098] The amount of light emitted by the light-emitting means **32** is adjusted according to a signal from the gas quantity sensor **19** (based on the result of detection by the gas quantity sensor **19**). For example, the light-emitting means **32** may be a red LED (light-emitting diode), an organic EL (Electro Luminescence), or the like. However, the invention is not limited to them, and any device having a similar function may be used.

[0099] As shown in **FIG. 5**, the control means **27** has a CPU (Central Processing Unit) **28** for controlling the driving of the first ejection means **14**, the second ejection means **17**, the heating means **20**, the gas quantity sensor **19**, the light-emitting means **32**, the power supply **26**, and the like and the ejection head driving circuit **29** incorporating a circuit for driving the first ejection means **14** and the second ejection means **17**.

[0100] The provision of the control means **27** as described above allows the electronic cigarette **1** according to the present embodiment to perform various types of control.

[0101] For example, controlling of the turning on/off of the generation of simulated smoke resembling smoke (sidestream smoke) of a cigarette by controlling the turning on/off of the second ejection means **17**, controlling of the turning on/off of the emission of the light-emitting means **32** or the like may be possible. Therefore, the generation of simulated smoke can be turned off and the emission of the light-emitting means may be turned off in places where smoking is prohibited (e.g., public places, railway stations, restaurants, and so on).

[0102] The heating of air or a gaseous mixture including air and flavor components with the heating means **20** can be controlled such that it is turned off in summer and turned on in winter when a warm feel is desired.

[0103] In order to improve resemblance to a cigarette, control can be performed to reproduce states that resemble a week odor and a low temperature at the beginning of smoking attributable to the long channel through which the smoke of the cigarette flows and to reproduce states that resemble a strong odor and a high temperature at the end of smoking attributable to the short channel through which the smoke flows.

[0104] By branding electronic cigarettes **1** and switching simulated smoking programming data depending on the brands; such control can be varied for each of the brands. Further, customization can be made depending on the preference of individual. For example, a mild odor provided by a long filter can be reproduced, and the number of times of inhalation to smoke one virtual cigarette may be set.

[0105] Such programs for simulated smoking may be written in a ROM, and the ROM may be attached to the cartridge **21** or a separate cartridge (not shown) to allow the ROM to be removably mounted in the casing **2** (cigarette main body **100**) through the cartridge **21** or the separate cartridge. Another mode is possible, in which a RAM is provided in the cartridge **21** or a separate cartridge (not shown) that can be removably mounted in the casing **2** (cigarette main body **100**) and in which the program for simulated smoking is downloaded using, for example, a radio interface such as Bluetooth or transmitted on a infrared basis to the RAM.

[0106] Alternatively, a memory having predetermined programs for simulated smoking written therein may be incorporated in the casing **2** (cigarette main body **100**), and any of the patterns of preference may be selected using a dial or the like. In this case, for example, the storage of the programs for simulated smoking and the selection of the patterns of preference may be performed using a separate unit resembling a lighter to be paired.

[0107] For example, an RFID (radio tag) or the like may be attached to the casing **2** (cigarette main body **100**), the cartridge **21**, the separate cartridge (not shown), or the separate unit to allow the programs for simulated smoking to be switched or to allow parameters in the programs for simulated smoking to be changed.

[0108] When the smoker inhales with the mouthpiece portion **7** of the electronic cigarette **1** according to the present embodiment having the above-described configuration held in the mouth, air flows into the channel **3** through the intake holes **6**; the quantity of the gas flowing through the channel **3** is detected by the gas quantity sensor **19**; the first ejection means **14** is driven by the control means **27** according to a signal from the gas quantity sensor **19** (based on the result of detection by the gas quantity sensor **19**); a predetermined amount of droplets of the flavor generating media is ejected into the channel **3** from the nozzles **16** of the ejection heads **15**; the air and flavor components flowing through the channel **3** are mixed; and a gaseous mixture of them flows into the mouth through the inhalation hole **4**; and the flavor components spread in the mouth to allow a flavor resembling that of a cigarette to be tasted.

[0109] In this case, since a sufficient amount of droplets of the flavor generating media is ejected into the casing **2** from

the beginning of driving of the first ejection means **14**, a sufficient amount of flavor components can be obtained from the beginning of simulated smoking (the beginning of inhalation) to provide a feeling similar to that of a cigarette.

[**0110**] The second ejection means **17** is driven by the control means **27** according to a signal from the gas quantity sensor **19** (based on the result of detection by the gas quantity sensor **19**), and a predetermined amount of droplets of the flavor generating media is ejected from the nozzles of the ejection heads of the second ejection means **17** into the space **10**. As a result, simulated smoke resembling smoke (sidestream smoke) of a cigarette is generated in the space **10**; the smoke flows out the space **10** through the intake/discharge holes **11**; and the smoke resembling sidestream smoke of a cigarette spreads.

[**0111**] Further, the light-emitting means **32** emits light according to a signal from the gas quantity sensor **19** (based on the result of detection by the gas quantity sensor **19**), which provides a visual effect that seems similar to the fire of a cigarette.

[**0112**] A second embodiment will now be described.

[**0113**] **FIGS. 6 and 7** show a second embodiment of an electronic cigarette according to the invention. **FIG. 6** is an enlarged illustration of a part of the same, and **FIG. 7** is a block diagram of the electronic cigarette.

[**0114**] An electronic cigarette **1** according to the second embodiment will now be described, the description being focused on differences from the above-described first embodiment and omitting items that are identical between them.

[**0115**] As shown in **FIG. 6**, atomizing means **18** for atomizing (refining) droplets of a flavor generating medium ejected from the nozzle **16** of each ejection head **15** of the first ejection means **14** is provided facing the nozzles **16**. Although not shown, atomizing means **18** for atomizing (refining) droplets of a flavor generating medium ejected from the nozzle **16** of each ejection head **15** of the second ejection means **17** is similarly provided facing the nozzles **16**. As shown in **FIG. 7**, the control means **27** has an atomizing means driving circuit **30** incorporating a circuit for driving the atomizing means **18**. The configuration is otherwise similar to that shown in the first embodiment.

[**0116**] In this case, for example, the atomizing means **18** may be heating means which receives and heats droplets of the flavor generating medium ejected by the nozzles **16** of the ejection heads **15** to atomize them or vibration means which receives and vibrates droplets of the flavor generating medium to atomize them. For example, the heating means may be a micro-heater or the like, and the vibration means may be an ultrasonic vibration generator or the like.

[**0117**] Either of the atomizing means **18** of the first ejection means **14** and the atomizing means **18** of the second ejection means **17** may be omitted.

[**0118**] A configuration may be employed in which the atomizing means **18** are removably mounted in the casing **2** (cigarette main body **100**).

[**0119**] A configuration may be employed in which the atomizing means **18** is provided in the cartridge **21** (the cartridge **21** and the atomizing means **18** may be integrated) and in which they are integrally removably mounted in the cartridge chamber (mounting portion) **8** of the casing **2** (cigarette main body **100**).

[**0120**] In the present embodiment, droplets of the flavor generating medium ejected by the nozzles **16** of the first ejection means **14** and the second ejection means **17** are atomized by the respective atomizing means **18** associated therewith.

[**0121**] Specifically, droplets of the flavor generating medium ejected from the nozzles **16** of the first ejection means **14** are atomized by the atomizing means **18** associated therewith. Therefore, when the smoker inhales with a mouthpiece portion **7** of the casing **2** held in the mouth, a gaseous mixture of air which has entered the casing **2** through the intake holes **6** and atomized flavor components in the casing **2** flows into the mouth; the flavor components spread in the mouth to allow a flavor resembling that of a cigarette to be tasted. In this case, since the flavor components can be inhaled into the mouth after being atomized by the atomizing means **18**, the smoker can feel as if he or she was inhaling smoke of a cigarette.

[**0122**] When the atomizing means **18** is constituted by a micro-heater, particles of the flavor generating medium which have been atomized through heating flow into the mouth. Thus, flavor components can be efficiently spread in the mouth, and the smoker can feel as if he or she was inhaling smoke of a cigarette.

[**0123**] When the atomizing means **18** is constituted by an ultrasonic vibration generator, particles of the flavor generating medium which have been atomized by vibration flow into the mouth. Thus, flavor components can be efficiently spread in the mouth, and the smoker can feel as if he or she was inhaling smoke of a cigarette.

[**0124**] Similarly, when the smoker inhales with the mouthpiece portion **7** of the casing **2** held in the mouth, droplets of the flavor generating medium ejected from the nozzles **16** of the second ejection means **17** are atomized by the atomizing means **18** associated therewith. Thus, simulated smoke resembling smoke (sidestream smoke) of a cigarette is generated in the space **10**, and it flows outside through the intake/discharge holes **11**. The smoke resembling sidestream smoke of a cigarette then spreads. In this case, droplets of the flavor generating medium ejected by the second ejection means **17** is atomized by the atomizing means **18**, simulated smoke that is very similar to sidestream smoke of a cigarette can be generated.

[**0125**] The electronic cigarette **1** can provide advantages similar to those of the above-described first embodiment.

[**0126**] While the invention has been described based on the illustrated embodiments, the invention is not limited to them, and the configuration of each part may be replaced with any other configuration having the same function. The invention may also be configured with other constituents.

What is claimed is:

1. An electronic cigarette comprising:

a casing having an inhalation hole;

an ejector provided in the casing, the ejector having at least one ejection head and which changes a pressure in a cavity filled with a liquid flavor generating medium

by driving an actuator to eject the flavor generating medium as droplets from a nozzle in communication with the cavity; and

a controller provided in the casing, the controller controlling driving of the ejector.

2. The electronic cigarette according to claim 1, comprising an atomizer provided in the casing, the atomizer atomizing droplets of the flavor generating medium ejected from the ejector.

3. The electronic cigarette according to claim 2, wherein the atomizer comprises a heater, the heater heating droplets of the flavor generating medium ejected from the ejector to atomize them.

4. The electronic cigarette according to claim 2, wherein the atomizer comprises a vibrator, the vibrator vibrating droplets of the flavor generating medium ejected from the ejector to atomize them.

5. The electronic cigarette according to claim 2, wherein the atomizer is removably mounted to the casing.

6. The electronic cigarette according to claim 1, comprising a mounting portion to which a cartridge having a containing portion containing the liquid flavor generating medium is removably mounted.

7. The electronic cigarette according to claim 6, wherein the ejector is provided at the cartridge.

8. The electronic cigarette according to claim 7, comprising a power supply switch which turns a power supply on/off when the cartridge is mounted and removed in and from the mounting portion.

9. The electronic cigarette according to claim 1, wherein the power supply is provided in the casing.

10. The electronic cigarette according to claim 1, comprising detector which detects a quantity of a gas flowing through the casing.

11. The electronic cigarette according to claim 10, wherein the controller controls the driving of the ejector based on a result of the detection by the detector.

12. The electronic cigarette according to claim 10, wherein a light-emitter is provided at a tip end of the casing, the controller controlling the driving of the light-emitter based on a result of the detection by the detector.

13. The electronic cigarette according to claim 10, comprising a smoke generator, the smoke generator generating simulated smoke from a tip end of the casing, the controller controlling the driving of the smoke generator based on a result of the detection with the detector.

14. The electronic cigarette according to claim 1, comprising a heater which heats at least one of air and a gaseous mixture including air and flavor components flowing through the casing.

* * * * *

United States Patent [19]

Hensgen et al.

[11] **Patent Number: 4,870,748**

[45] **Date of Patent: Oct. 3, 1989**

[54] **APPARATUS FOR ASSEMBLING ELEMENTS OF A SMOKING ARTICLE**

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[73] Assignee: **R. J. Reynolds Tobacco Co.**, Winston-Salem, N.C.

[21] Appl. No.: **74,811**

[22] Filed: **Jul. 17, 1987**

[51] **Int. Cl.**[4] **A24C 5/18**; B23P 21/00

[52] **U.S. Cl.** **29/773**; 131/84.1; 131/94; 131/369

[58] **Field of Search** 29/776, 773; 53/151; 131/77, 84.1, 94, 108, 369, 273; 198/461

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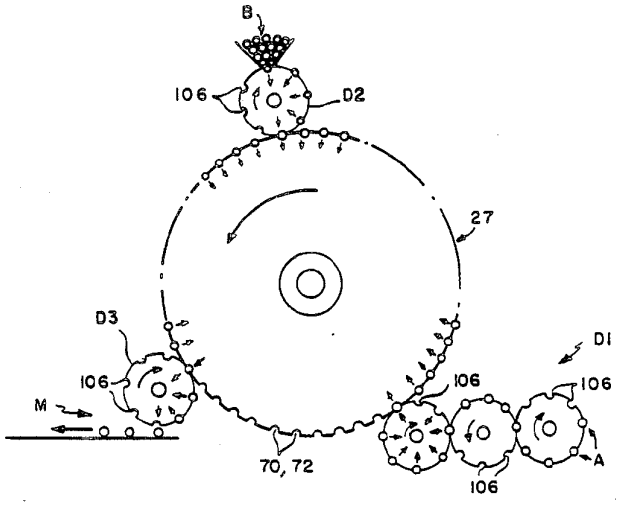
Primary Examiner—Timothy V. Eley

Attorney, Agent, or Firm—Grover M. Myers; David G. Conlin

[57] **ABSTRACT**

An apparatus for making smoking articles is described. The preferred apparatus comprises structure to form a passage axially through a jacketed rod of tobacco, at one end of which there is a tubular sleeve of non-combustible material, and to insert an aerosol generating cartridge containing an aerosol forming substance, at one end of which there is a fuel element, into the passage so that the aerosol forming substance is within the passage in the rod of tobacco and the fuel element is within the sleeve of non-combustible material.

74 Claims, 12 Drawing Sheets



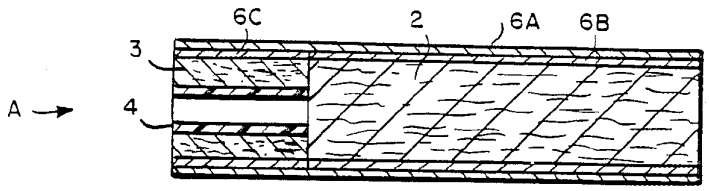


FIG. 1

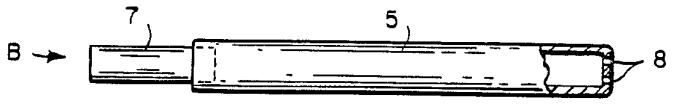


FIG. 2

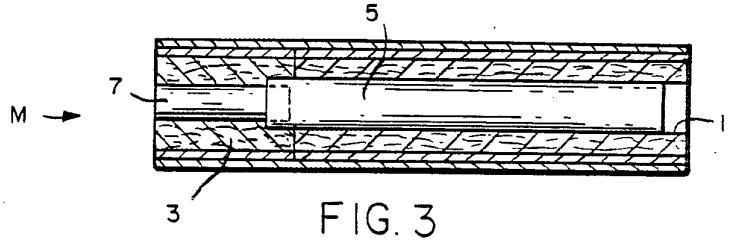


FIG. 3

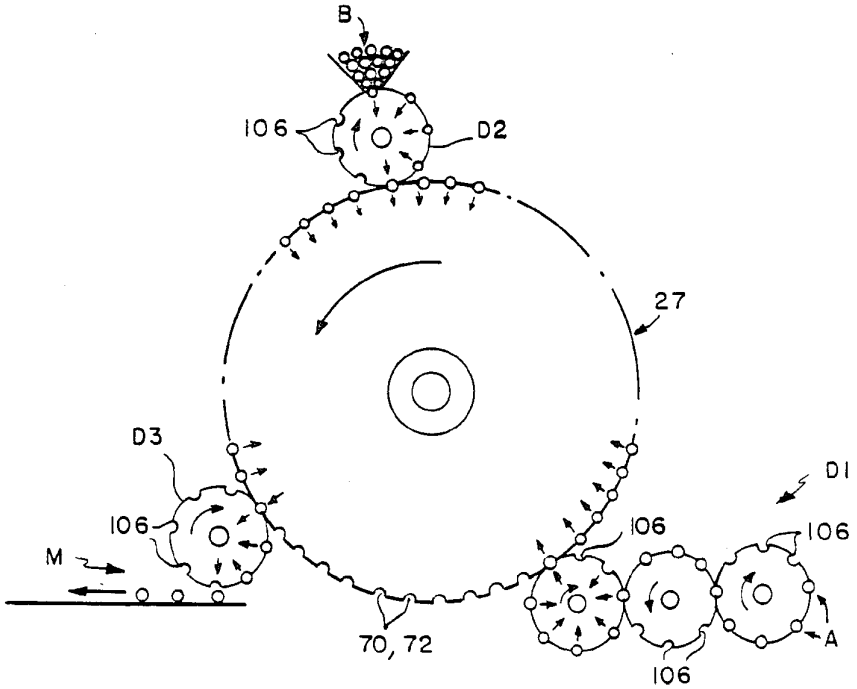


FIG. 4

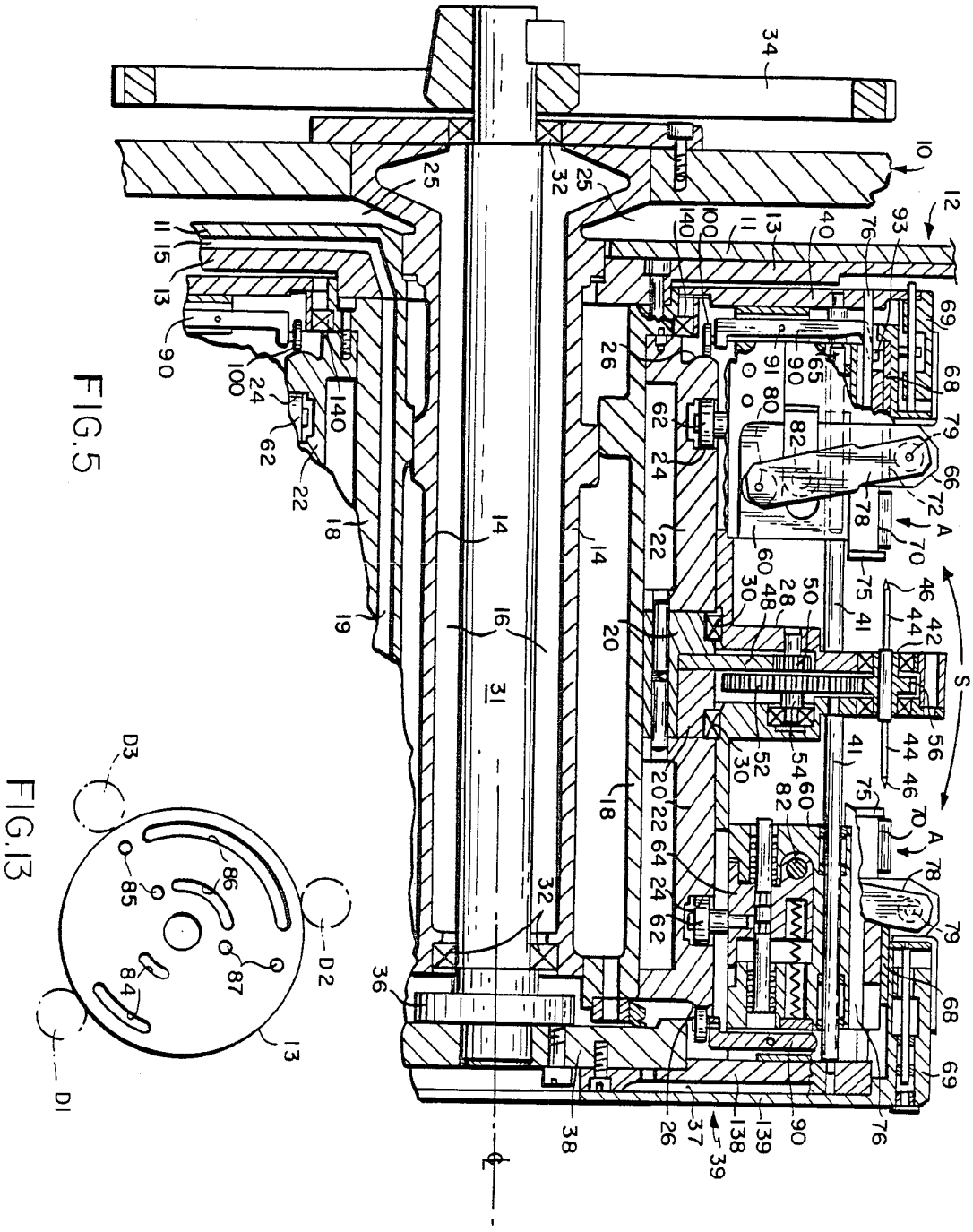


FIG. 5

FIG. 13

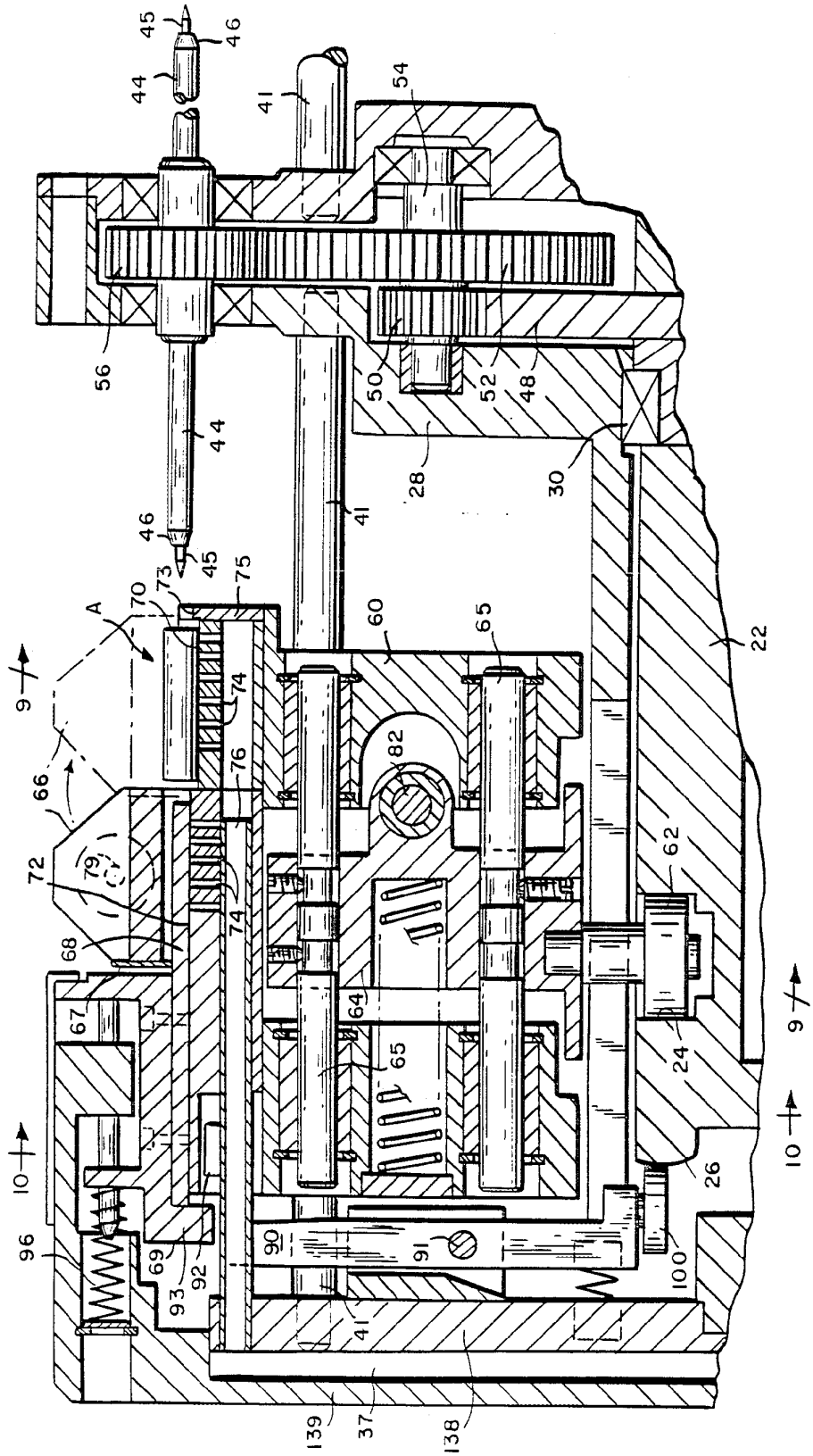

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FIG.6

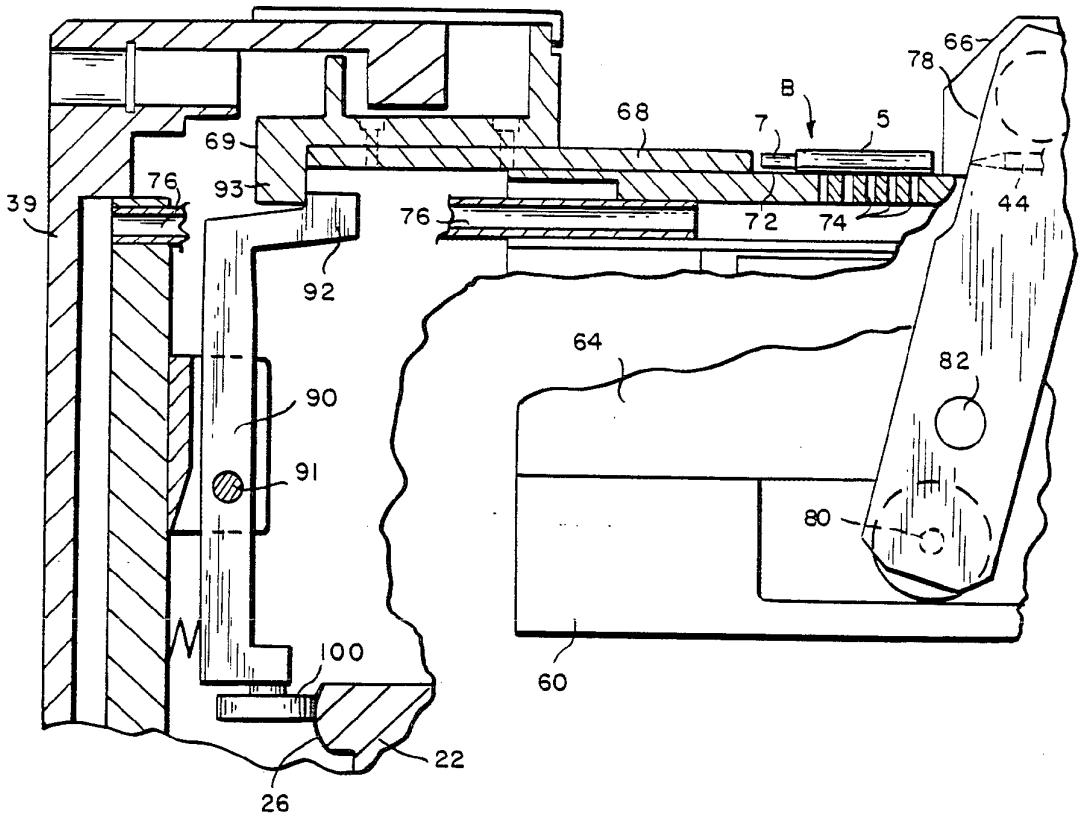

FIG. 7

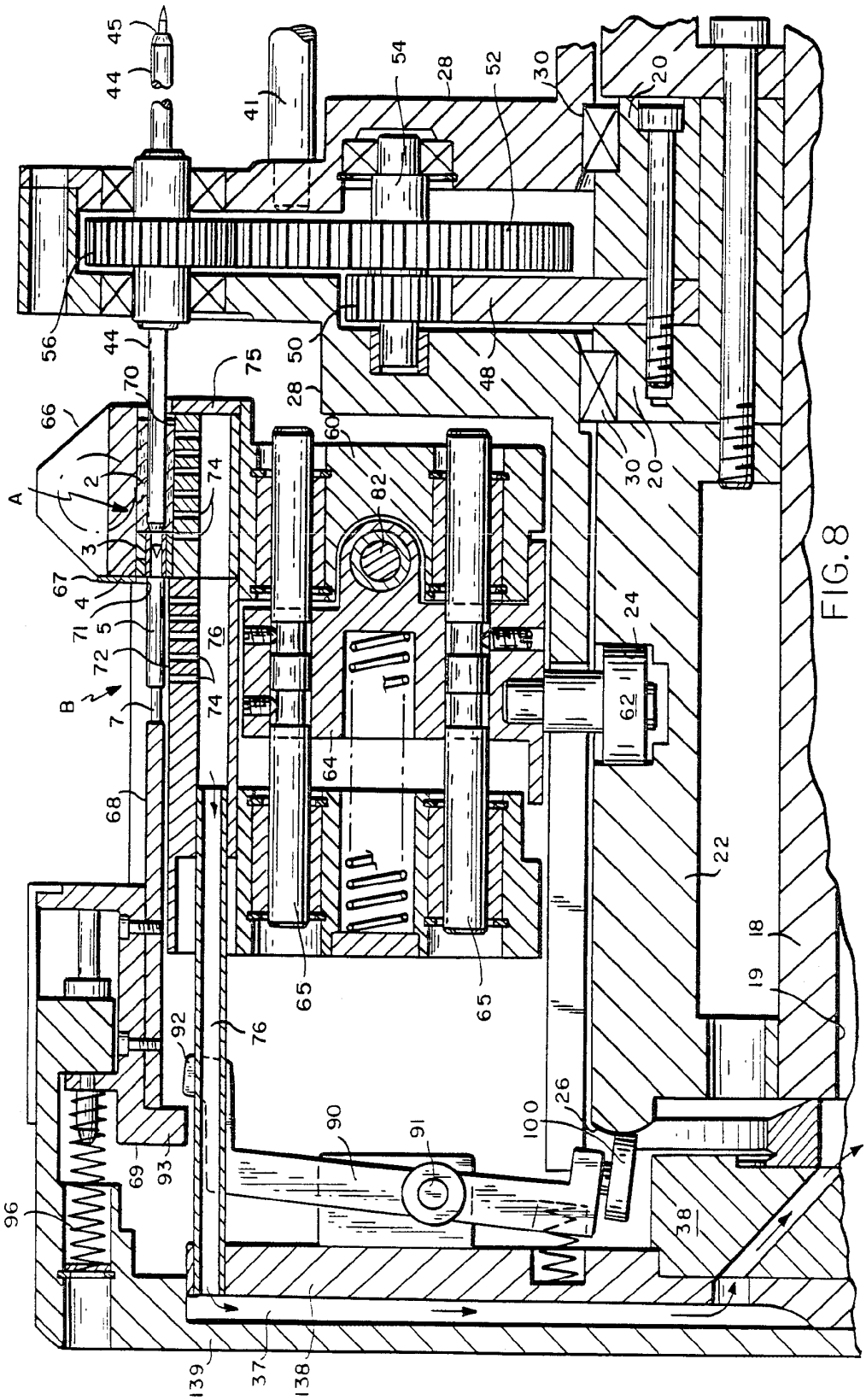
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FIG. 8

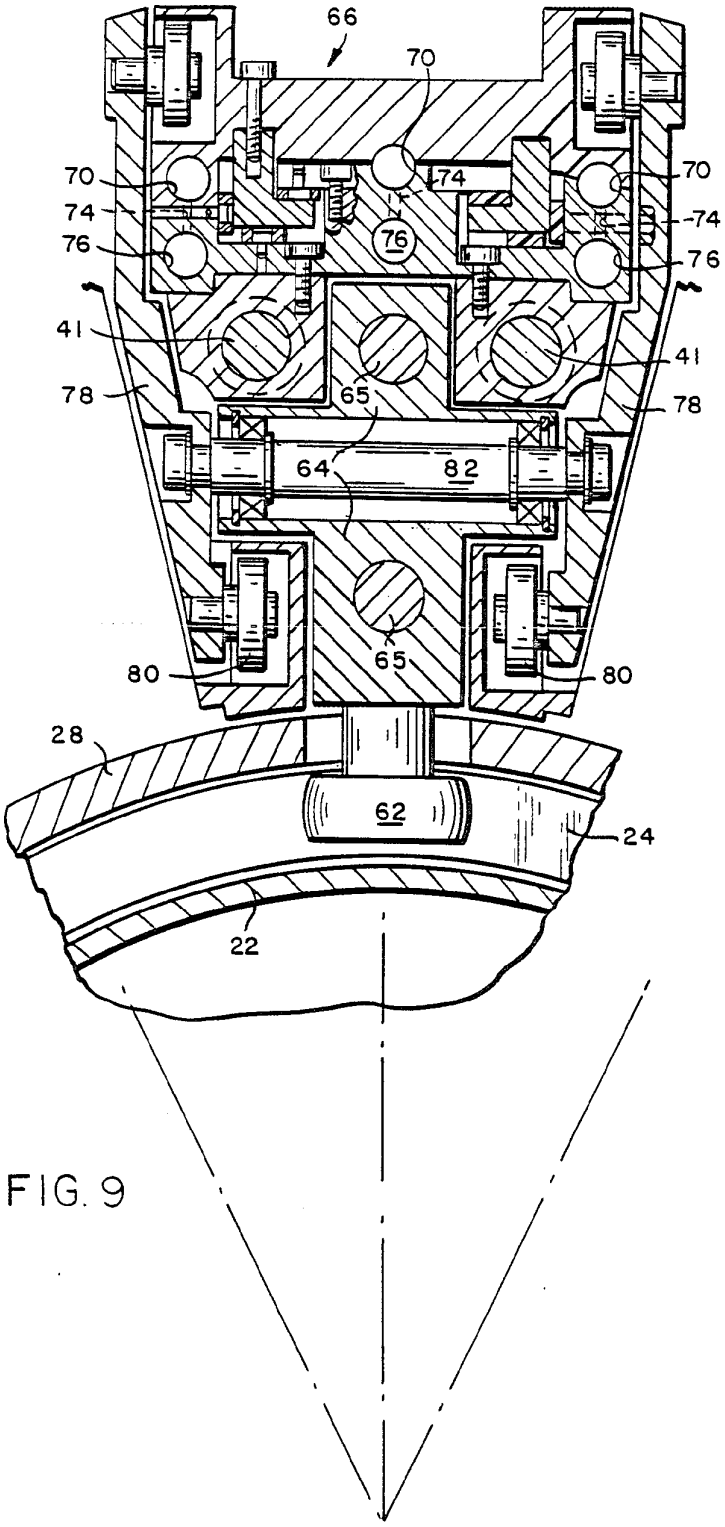


FIG. 9

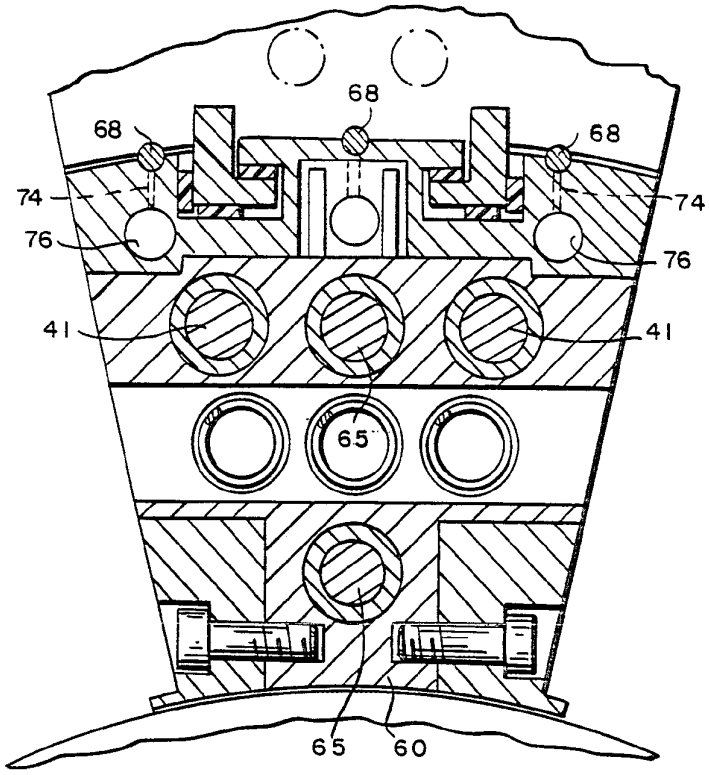


FIG. 10

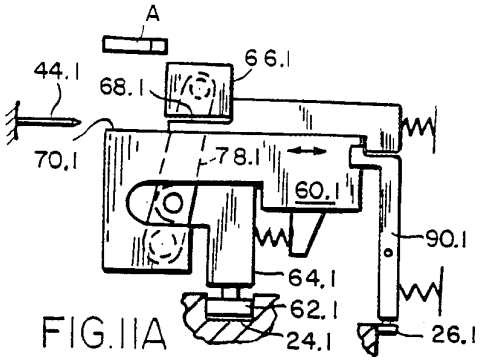


FIG.11A

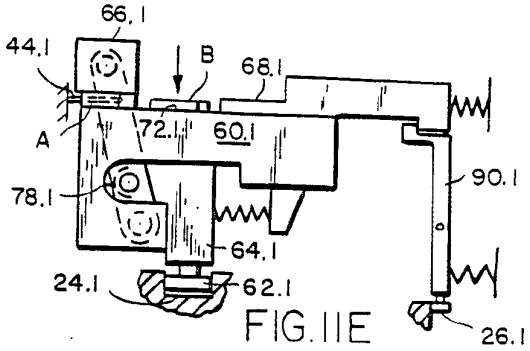


FIG.11E

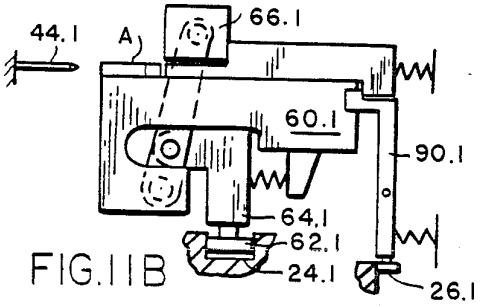


FIG.11B

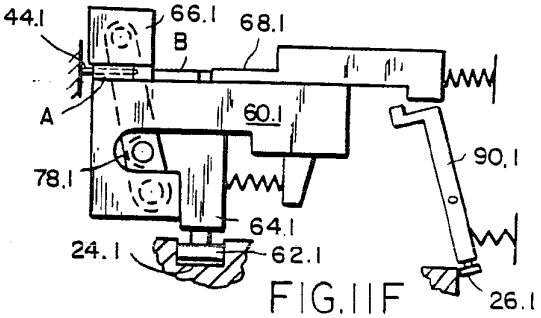


FIG.11F

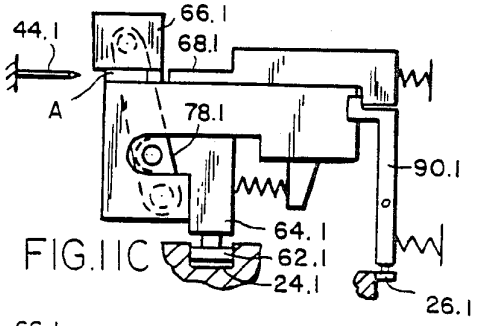


FIG.11C

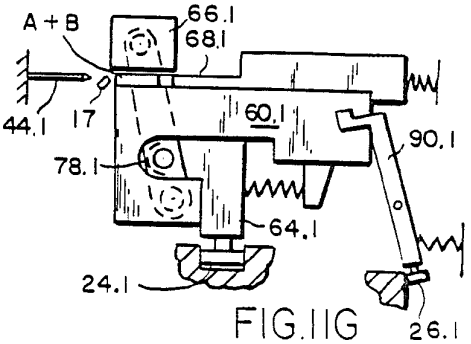


FIG.11G

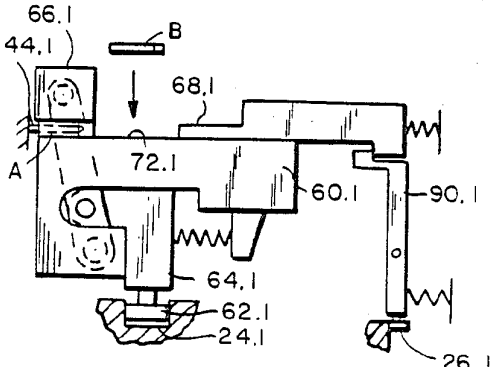


FIG.11D

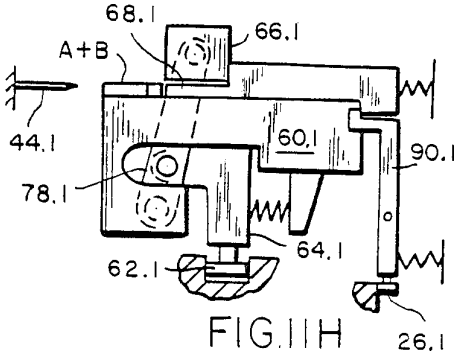


FIG.11H

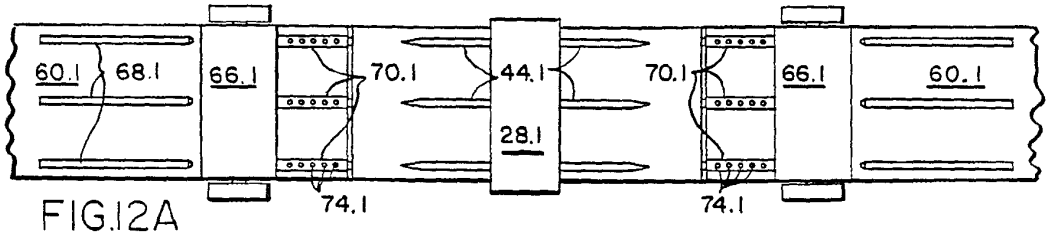


FIG.12A

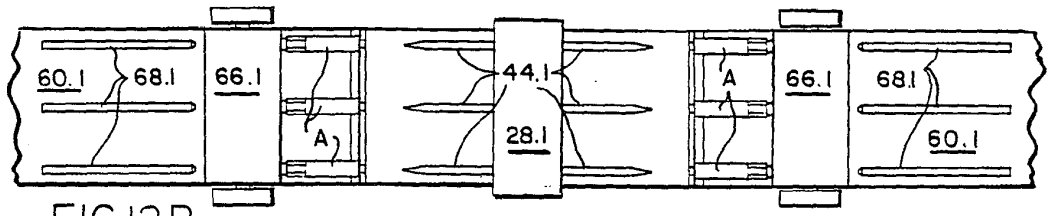


FIG.12B

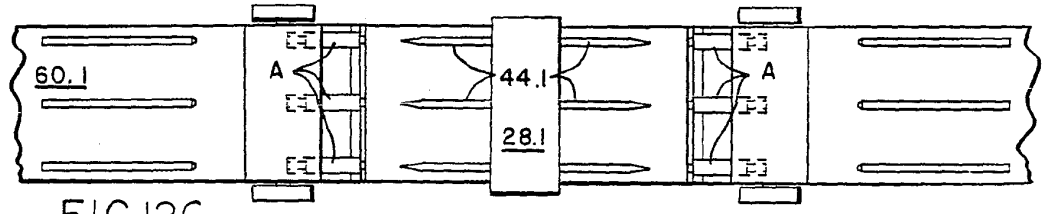


FIG.12C

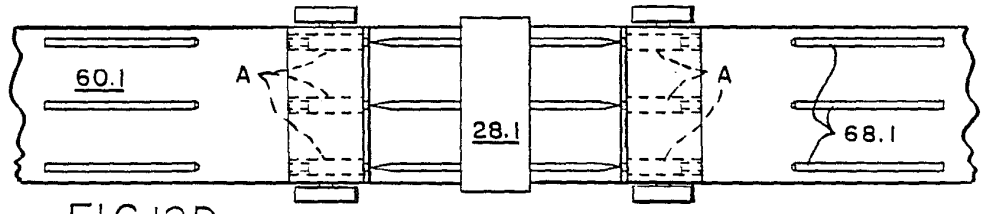


FIG.12D

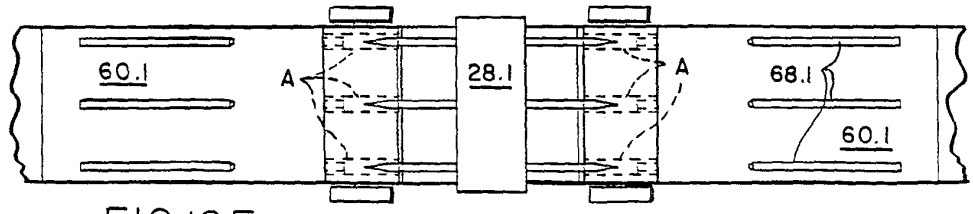


FIG.12E

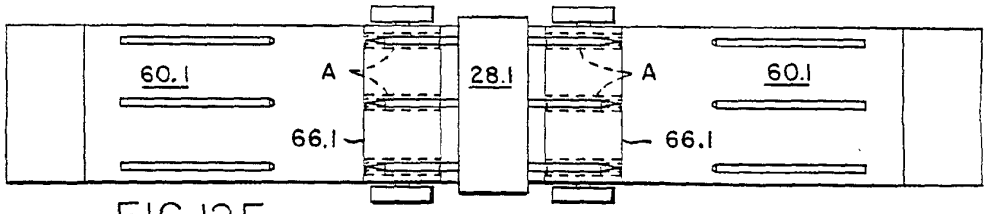
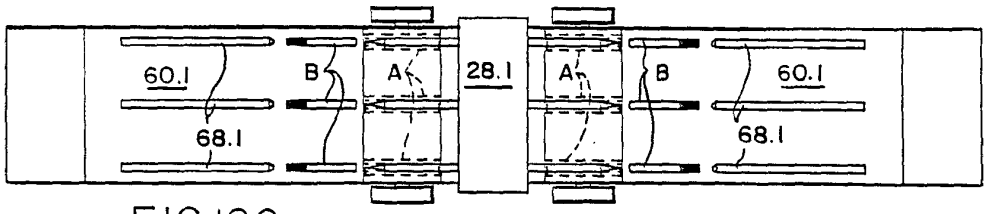


FIG.12F



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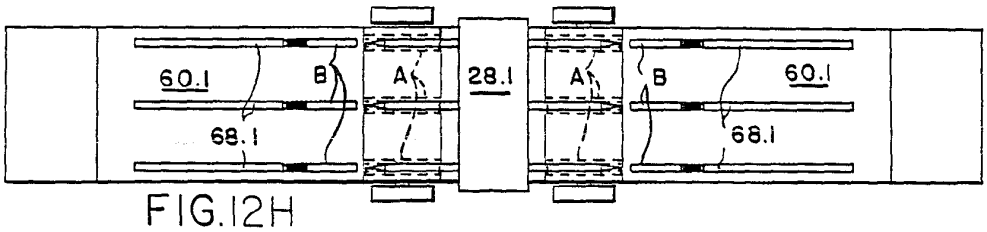


FIG.12H

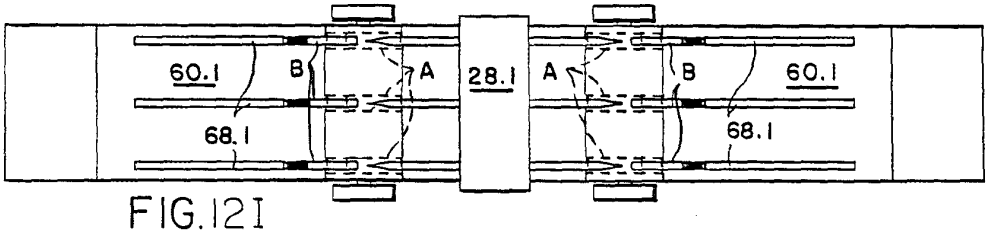


FIG.12I

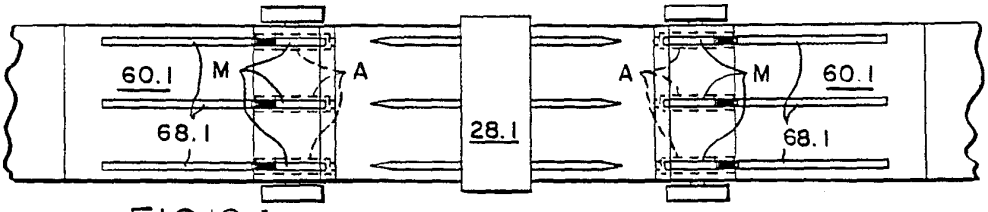


FIG.12J

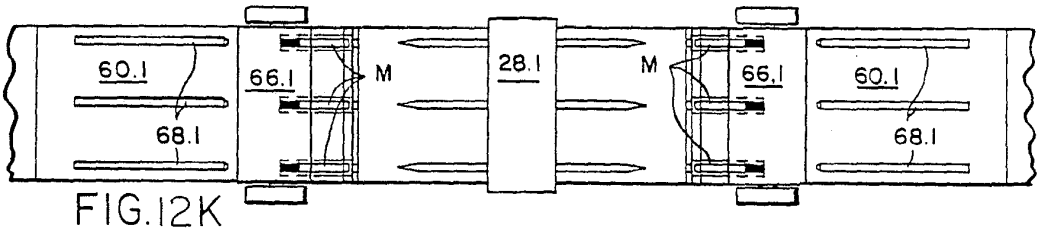


FIG.12K

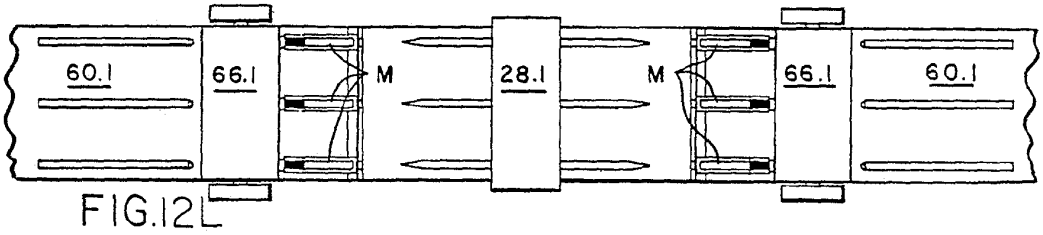
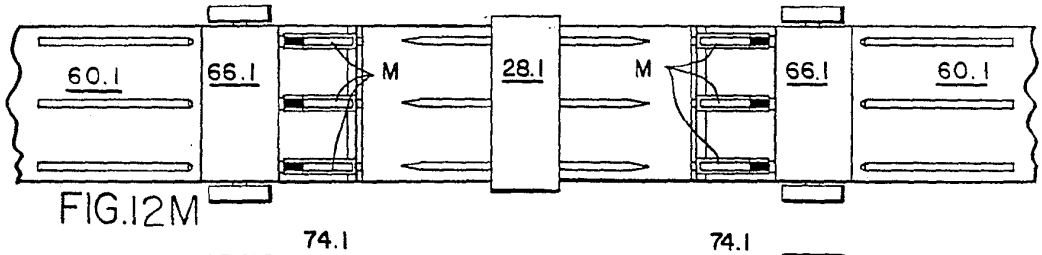


FIG.12L



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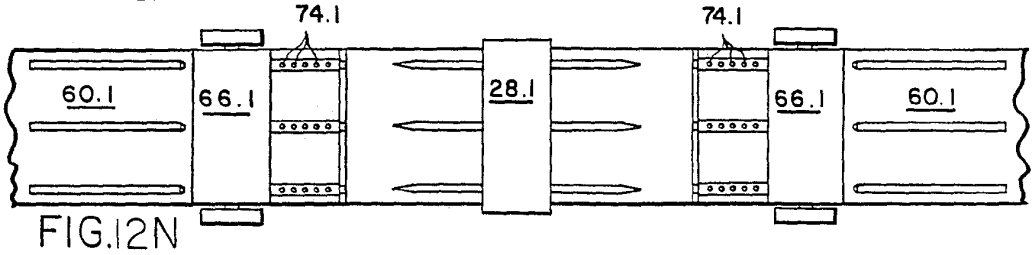

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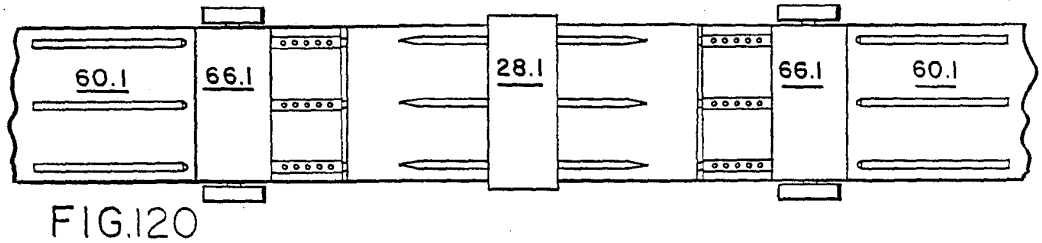

FIG.12O

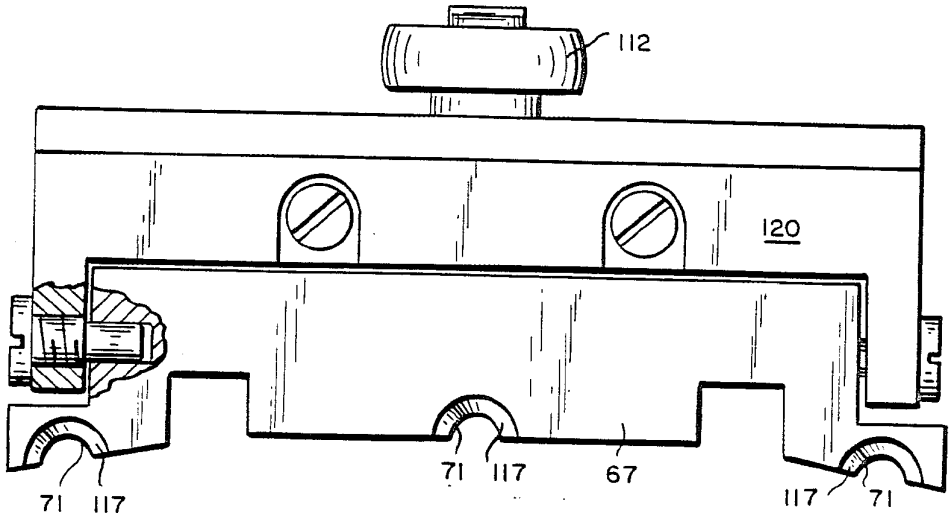

FIG. 14

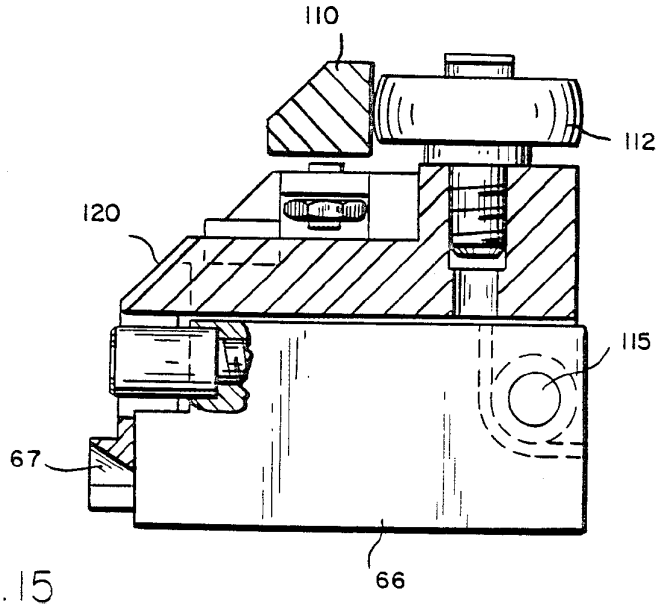

FIG. 15

APPARATUS FOR ASSEMBLING ELEMENTS OF A SMOKING ARTICLE

BACKGROUND OF THE INVENTION

In European Patent Publication Nos. 0174645(A2) and 0212234(A2), the disclosures of which are hereby incorporated by reference, there are disclosed a number of alternative forms of smoking articles which typically embody (1) an aerosol generating cartridge comprising a fuel element for generating heat for transfer to an aerosol forming material which may contain a tobacco flavoring material, (2) a sleeve or jacket circumscribing the cartridge, the sleeve preferably including an insulating material around the fuel element and a tobacco containing material around the aerosol forming material and, optionally, (3) a mouthend piece, which may contain a filter element. Generally, the aerosol generating cartridge of the smoking article comprises a capsule containing an aerosol generating material with a fuel element at one end.

It is a purpose of this invention to provide high speed production apparatus for combining such aerosol generating cartridges and sleeves to form aerosol generating modules.

SUMMARY OF THE INVENTION

In accord with the present invention, an apparatus for making modules, particularly aerosol generating modules for smoking articles is provided. The apparatus comprises (1) a rotatable drum, (2) a plurality of stations mounted around the drum, each station comprising jacket holding means for receiving and holding at least one jacket segment, and cartridge holding means for receiving and holding at least one cartridge or capsule, and (3) means for inserting cartridges into jacket segments, thereby forming modules for smoking articles. Preferably, the jacket segments comprise tobacco and the cartridges contain an aerosol generating material. Typically, the apparatus comprises jacket supply means for supplying jacket segments and cartridge supply means for supplying aerosol generating cartridges to the stations and means for removing the aerosol generating modules from each of the stations, in seriatim. Preferably, each station forms a plurality of aerosol generating modules in parallel.

In one preferred embodiment of the invention, the stations are preferably arranged in axially aligned mirror image pairs or tandem pairs around the periphery of the drum so that operations can take place in parallel at each pair of stations as the drum rotates. The stations preferably each include means for inserting cartridges into jacket segments.

In certain preferred embodiments in which the jacket segments comprise a sleeve of material preformed around a support member, such as a tube, the apparatus includes means for ejecting the support member from the jacket segments, preferably while an aerosol generating cartridge is being inserted into the jacket segment.

In another preferred embodiment, the apparatus further comprises means for forming a passage lengthwise in the jacket segment, and the aerosol generating cartridge is inserted into the passage.

In a particularly preferred embodiment, the passage is formed in the jacket segment by a passage forming member and the apparatus has means for withdrawing the passage forming member and simultaneously inserting the aerosol generating cartridge. In instances where a portion of the jacket segment is formed around a support member, such as a tube, the withdrawing and inserting means also preferably includes means for ejecting the support member from the jacket segment while the cartridge is being inserted therein.

In the preferred drum configuration, means for ejecting a support member, insertion means and passage forming means, if required, are located at each station. Each station also preferably includes a slidable support means, which supports the jacket holding means and the cartridge holding means, and means cooperating with the jacket holding means for restraining movement of the jacket segment during passage formation and/or insertion of the cartridge. Preferably, the insertion means comprises an abutment member located proximate the cartridge holding means during insertion and means for effecting relative movement between the slidable support means and the abutment member to accomplish insertion of the cartridge at least partially into the jacket segment.

In one embodiment of the invention, means operable in connection with the rotation of the drum position the jacket segment and cartridge on the drum for insertion of the cartridge into the jacket segment and accomplish the insertion. When the jacket segment comprises a rod of material without a preformed passage, each station includes a passage forming means which forms a passage in the rod as the drum rotates. The aerosol generating cartridge is then inserted into the passage, and the completed module is removed from the station upon further rotation of the drum, leaving the station ready to receive another jacket segment and begin the cycle once again. When the jacket segment comprises a tube surrounded by a sleeve of material, each station includes means for rejecting the tube, preferably as the cartridge is inserted.

More specifically, one preferred embodiment of an apparatus for assembling components of a preferred smoking article according to this invention comprises a drum and a plurality of stations mounted on the drum, the stations preferably mounted in axially aligned pairs around the drum. Each of the stations comprises at least one spindle, means supporting the spindle for rotation about its longitudinal axis, a slidable abutment member, means supporting the abutment member in axially-spaced alignment with the axis of the spindle, transport means comprising a reciprocally movable support means or carriage embodying axially aligned recesses for receiving first and second components of the smoking article, and a restraining means or clamp movable in unison with, and relative to, the carriage. Preferably, each station includes two or more spindles, abutment members and sets of aligned recesses for the components, so that a plurality of sets of components may be simultaneously assembled at each station.

The restraining means or clamp is preferably operable, by movement relative to the carriage, to enclose the first components on the carriage. The clamp then moves with the carriage toward the spindle and into engagement with the spindle whereby the spindle pierces the first component. Thereafter, the clamp moves with the first component in an opposite direction, in unison with the carriage toward the abutment member to withdraw the pierced first component from the spindle, and impaling it on the second component. Thereafter, the clamp moves relative to the carriage to release the composite structure comprising the first

component with the second component inserted therein.

Rotation of the drum effects movement of the carriage and clamp as aforesaid. Desirably, the spindle is rotated, and there is means operable by rotation of the drum relative to the supporting frame to effect rotation of the spindle such as, for example, a train of gears.

Apparatus in accord with the present invention may additionally comprise means for supplying a mouthend piece and means for joining the mouthend piece to the aerosol generating module to form a cigarette type smoking article. In another embodiment, the apparatus may include means for inserting mouthend piece modules between two aerosol generating modules to make a composite structure that, when cut in half, forms two smoking articles.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in detail with reference to the accompanying drawings, wherein:

FIG. **1** is a longitudinal section of a jacket segment A comprising a rod of tobacco, at one end of which there is a sleeve of insulating material surrounding a tubular support member;

FIG. **2** is an elevation, partly in section, of an aerosol generating cartridge B comprising a capsule containing an aerosol forming material, at one end of which there is a fuel element;

FIG. **3** is a longitudinal section illustrating an aerosol generating module M consisting of aerosol generating cartridge B of FIG. **2** incorporated in jacket segment A of FIG. **1**.

FIG. **4** diagrammatically shows one embodiment of an apparatus in accord with the present invention, comprising a rotating drum, with rotary transfer drums D1 and D2 for depositing smoking article components (e.g., jacket segments A and aerosol generating cartridges B) thereon, and rotary transfer drum D3 for removing the composite structure M therefrom;

FIG. **5** is a fragmentary longitudinal view of an adjacent or tandem pair of stations in a preferred embodiment of the apparatus, having various sectional views rotated about the axis to more clearly illustrate various features of the apparatus, and showing jacket segments A positioned thereon;

FIG. **6** is an enlarged fragmentary section showing one station of the apparatus of FIG. **5** in its initial position and having a jacket segment A positioned thereon;

FIG. **7** is an enlarged fragmentary section showing the station of FIG. **6** in the position having the jacket segment impaled on the spindle and having a cartridge deposited thereon;

FIG. **8** is an enlarged fragmentary section showing the station of FIG. **6** with the jacket segment impaled on the spindle, and with the abutment member engaged with the cartridge, just prior to insertion of the cartridge into the jacket segment;

FIG. **9** is a fragmentary section taken along the line **9—9** of FIG. **6**;

FIG. **10** is a fragmentary section taken along the line **10—10** of FIG. **6**;

FIGS. **11**-A to **11**-H are partial elevational views that schematically illustrate the successive operations of one station of the apparatus of FIG. **5** entailed in combining the jacket segment and cartridge; and

FIGS. **12**-A to **12**-0 are partial plan views schematically illustrating the successive operations of one station of the apparatus of FIG. **5** entailed in combining the jacket segment and the cartridge.

FIG. **13** diagrammatically shows, in relation to the transfer drums, the openings in mounting plate **12** that provide vacuum or low pressure air to the stations.

FIG. **14** is an elevation of a preferred structure for lifting retaining member **67** on clamp **66** for the step of inserting the cartridge "B" into jacket segment "A".

FIG. **15** is a side view, partly in section, of the structure of FIG. **14** illustrating the cam follower in contact with a cam surface to lift the retaining member.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS OF THE INVENTION

The apparatus of the present invention is designed to insert an aerosol generating cartridge in a jacket segment, thereby forming an aerosol generating module, of the type as generally illustrated in FIG. **3**.

Referring to the drawings, FIGS. **1**, **2**, and **3**, and in accordance with the invention, a preferred apparatus is structured to form a longitudinal opening or axial passage **1** (FIG. **3**) in an elongate jacket segment "A" and insert an aerosol generating cartridge "B" into opening **1**.

As illustrated in FIG. **1**, a preferred jacket segment "A" comprises a rod **2** of fibrous material, such as tobacco, volume expanded tobacco, reconstituted tobacco materials, combinations thereof, or other materials. At one end of rod **2** there is a sleeve **3** of insulating material, in this case non-combustible fibers, such as glass fibers. Within the sleeve, there is a tubular support member **4**. The rod **2** and sleeve **3** are circumscribed and joined by means of paper wrappers **6A**, **6B**, and **6C**, such as customarily used in the manufacture of smoking articles such as cigarettes.

Although the jacket segment illustrated in FIG. **1** comprises a preformed sleeve portion and a rod of fibrous material portion, jacket segments for smoking articles that may be combined by apparatus of the present invention may also comprise (1) only a sleeve portion preformed about a support member, (2) a sleeve without a support member, (3) only a rod, or (4) other variations having portions that comprise a sleeve, which may be preformed, a rod, or combinations thereof. In such cases, the apparatus of the present invention can be modified in accord with the teachings herein. For instance, if the jacket segment comprises only a rod portion, a spindle or other passage forming means would normally be used to form a passage suitable for inserting the cartridge therein. Alternatively, the cartridge itself may be suitably shaped to be inserted into the rod without prior forming of a passage. If the jacket segment comprises only a sleeve portion, the apparatus of the invention would be modified accordingly, for instance, to eliminate the spindle and to eject any support member, preferably as the aerosol generating cartridge is inserted into the jacket segment.

The preferred aerosol generating cartridge "B" (FIG. **2**) is an elongate capsule **5**, advantageously of circular cross section, containing an aerosol forming material and having one or more holes **8** at one end for release of aerosol. A heat generating element **7**, preferably in the form of a carbon plug, is inserted in the other end of capsule **5**. Other configurations of the aerosol generating cartridge, such as the various aerosol generating means described in the aforesaid European Patent Publications, may also be used.

As used herein, and only for the purposes of this application, "aerosol" is defined to include vapors, gases, particles, and the like, both visible and invisible, and especially those components perceived by the user to be "smoke-like", generated by action of the heat from the burning fuel element upon substances contained within the aerosol generating cartridge or capsule, or elsewhere in the article. As so defined, the term "aerosol" also includes volatile or sublimeable flavoring agents and/or pharmacologically or physiologically active agents, irrespective of whether they produce a visible aerosol.

A preferred apparatus in accord with the invention generally comprises a rotating assembly drum, generally indicated by reference numeral 27 of FIG. 4. Referring specifically to FIG. 5, the apparatus has a plurality of stations "S" typically designed in essentially axially aligned mirror image pairs forming parallel tracks of stations, each station comprising a carriage 60 and a clamp 66, and a plurality of spindles 44, recesses 70, 72, abutment members 68, etc., so that two sets of aerosol generating modules may be assembled in parallel. As shown in the illustrated embodiment, each station is designed to simultaneously assemble three aerosol generating modules. (See FIG. 10 and FIG. 12-A–12-0)

As shown in FIG. 4, preferably there are transfer drums D1, D2 and D3 disposed about the assembly drum 27 for rotation in timed relation to drum 27 for depositing the components "A" and "B" in the recesses 70 and 72 on each station, in timed relation with the movement of the carriage 60 and clamp 66, and for removing the aerosol generating modules M from the drum after assembly. Transfer drum D1 is preferably located on the upgoing side of drum 27 for depositing jacket segments "A" in recesses 70. Transfer drum D2 is preferably located near the top of drum 27 for depositing cartridges "B" in recesses 72. Transfer drum D3 is preferably located on the downgoing side of the drum 27 for removing the combined aerosol generating modules "M." The transfer drums are provided with recesses 106 for receiving the components and vacuum means depicted by the arrows for holding them in place on the transfer drums before or after transfer.

Typically, the jacket segments are fed directly from a suitably modified conventional type segment combining machine (not shown), such as a Hauni MULFI, by a series of vacuum assisted transfer drums D1. Such drums are used to position two or more jacket segments laterally to line up with the parallel tracks of stations on drum 27. The jacket segments can also be fed from trays or hoppers using suitably arranged vacuum assisted rotary devices or equivalent means.

Typically, the cartridges are fed from trays or hoppers positioned above assembly drum 27 using transfer drum D2, or other suitably arranged vacuum assisted rotary devices or equivalent means.

The completed aerosol generating modules "M" may be deposited on a belt as in FIG. 4 and transported for packaging. Alternatively, the modules can be transferred to a tipping machine by a series of rotary transfer drums or other equivalent means (not shown, where they are combined with mouthend pieces to form cigarette-type smoking articles.

Again referring to FIG. 5, the drum apparatus comprises a supporting structure 10 to which is mounted a horizontally-disposed, tubular support 14 defining interiorly thereof an axial opening 16. A vertical mounting plate 12 is mounted on support 14 and attached to supporting structure 10 near the periphery of the drum (not shown). Mounting plate 12 consists of flat plate 11 and stepped plate 13. Flat plate 11 has grooves 15 radially formed in its inner surface, which in combination with stepped plate 13, provide passageways for low pressure air. Between supporting structure 10 and mounting plate 12 is a vacuum chamber 25. Passageways through mounting plate 12 at suitable locations provide vacuum to the stations "S". See 84, 86, in FIG. 13. A cylindrical sleeve 18 is mounted to the tubular support 14 in concentric relation thereto and attached to the stepped plate 13 of the mounting plate 12. Sleeve 18 has conduits 19 for communication of vacuum or low pressure air to the outside end of the drum. Passageways through plate 13 at suitable locations (85, 87) provide communication between chamber 25 and conduits 19. (FIG. 13)

A hub 20 is non-rotatably mounted to the sleeve 18 midway between its opposite ends, and cam sleeves 22 are bolted to opposite sides of the hub. The cam sleeves 22 have on their cylindrical surfaces cam grooves 24 and at their ends profile cam surfaces 26. The hub 20 is conveniently made in two pieces to hold the annular ring gear 48 which is bolted thereto. (FIG. 8)

An annular support 28 is mounted to the hub 20 on axially-spaced annular bearing rings 30 for rotation about a horizontal axis. Rotation of the support 28 about the hub 20 is effected by a drive shaft 31 rotatably supported in bearings 32 within the tubular support 14. The shaft 31 has fixed to one end a drive gear 34 by means of which it can be rotated. At the other end of the shaft 31, there is fixed a radial flange 36. The radial flange 36 has bolted thereto a disk 38 and this, in turn, has bolted to it an outer end plate 39. The end plate 39 is conveniently formed in two sections. Plate 138 is attached to disk 38 and contains grooves 37 for forming passageways for vacuum and/or low pressure air to each outer station. Plate 139 is attached to plate 138 and completes the passageways. The passageways connect with conduit 19 in sleeve 18 for communication with mounting plate 12 and the source of vacuum or low pressure air.

An inner end plate 40 is rotatably mounted on sleeve 18 on ring bearing 140, adjacent to the stationary mounting plate 12. Vacuum and low pressure air are supplied to each of the inner stations directly through passageways 84, 85, 86, 87 in plate 13. See FIG. 13. Conduits 76 at each inner station extend through inner end plate 40 to a point in close proximity, preferably about 0.1 mm, to plate 13. This provides communication between the passageways in plate 13 and conduits 76 for the transmission of vacuum or low pressure air to the stations "S".

At each station, two shafts 41 are connected at one end to an end plate 39 (or 40) and at the other end to the support 28. These shaft 41 aid in providing structural support to the rotating components of the drum as rotation of the central shaft 31 effects rotation of the support 28.

Between each longitudinal or tandem pair of stations, the annular support 28 has peripherally thereof three rotatable bearing sleeves 42, in which there are mounted oppositely-facing rotatable spindles 44 having conical ends 46. Preferably, the conical end 46 of each spindle 44 has a shoulder 45 (as shown in FIG. 6) which is dimensioned to abut the edge of tube 4 in the jacket segment.

As best shown in FIG. 5, an annular ring gear 48 is mounted to the fixed hub 20, and between the station pairs, three annularly spaced spur gears 50 are mounted

to the rotatable support 28 in mesh with the annular ring gear 48. The spur gears 50 are each fixed to a drive gear 52 which, in turn, is fixed to a shaft 54 journalled on the support 28 so that rotation of the support 28 about the hub 20 and ring gear 48 rotates each of the three drive gears 52. Each drive gear 52 meshes with one spindle gear 56 in a train of fourteen spindle gears 56, and thereby drives all fourteen spindle gears simultaneously. Each spindle gear 56 is mounted on a bearing sleeve 42 and thereby rotates a set of opposite-facing spindles 44. The spindle gears 56 at the end of each train of fourteen gears do not mesh with the end gear in the adjacent train of gears. To accomplish this, the gear teeth on these end gears are less than half the width of the gear and the partial width teeth on one end gear are on one side of the gear while the partial width teeth on the adjacent end gear are on the other side so that they do not mesh. Thus, rotation of the support 28 relative to the fixed hub 20, by way of the aforesaid gears, effects rotation of three trains of fourteen sets of spindles 44 about their horizontal axes which, as illustrated, are parallel to the axis of rotation of the drum.

At each station, a transport comprising a carriage 60 and a clamp 66 is slidably mounted on two horizontally-disposed shafts 41. The carriages 60 are movable axially along the shafts 41 relative to the spindles 44. To effect reciprocal movement, the carriages 60 are each provided with an internal coupling member 64, which is slidably mounted in carriage 60 on spindles 65 and spring biased toward rotating spindles 44. Each coupling member 64 has a cam follower 62 journalled in the cam groove 24 in cam sleeve 22. The cam grooves 24 are contoured so as to effect axial reciprocal movement of the coupling members 64 and, thus, carriages 60 when the assembly drum is rotated.

The clamps 66 are mounted to carriages 60 on support arms 78 which are pivotally coupled to the clamp at 79, to the carriages at 80, and to the coupling members 64 at shaft 82, FIGS. 6 and 7, for movement relative to the carriages 60 parallel to the axis of the spindles 44. Thus clamp movement also is effected by the contour of cam groves 24. Each clamp 66 has a retaining member 67, preferably vertically movable, located distally from the spindles to restrain lateral movement of the jacket segment as it is impaled on a spindle. The retaining member 67 can be mounted to clamp 66 on a leaf spring to permit movement in the upward direction when the cartridge moves under the retaining member, thereby avoiding jamming and breakage if there exists slight misalignment.

FIGS. 14 and 15 illustrate a preferred structure for lifting retaining member 67 for the step of inserting cartridge "B" into jacket segment "A". The structure has a support bridge 120 to which is mounted retaining member 67 and a cam follower 112. The support bridge 120 is pivotally mounted at 115 to clamp 66. Preferably, the retaining member 67 has tapered surfaces 117 from its outward face to the openings 71 that align with the recesses 70, 72 on carriage 60. When the cam follower 112 contacts cam surface 110 (which is stationary, mounted (not shown) e.g. to the frame for drum 27) for the insertion step, cam surface 110 moves cam follower 112 (to the right in FIG. 15) to cause support bridge 120 to pivot at 115 thereby lifting retaining member 67 to permit cartridge "B" to pass through opening 71 without hitting the retaining member.

Each carriage 60 includes a first support area, defined by three outwardly-facing recesses 70 (FIGS. 6, 9 and 10), the axes of which coincide with the axes of the spindles 44. Recesses 70 are dimensioned to receive and support jacket segments "A" (FIG. 1), each preferably comprising a jacketed rod 2 of tobacco, at one end of which is the sleeve 3 of insulating fibers surrounding a plastic tube 4. See FIG. 8. Each clamp 66 also has complementary recesses of the same dimensions as recesses 70 which are aligned with and cooperate with recesses 70 to restrain movement of the jacket segment. The retaining member 67 on clamp 66 has openings 71 aligned with the recesses. Openings 71 are dimensioned to restrain lateral movement of the jacket segment but to permit the aerosol generating cartridges to pass through to be inserted into the jacket segments.

At the spindle end of recesses 70 is a retaining plate 75 to restrain lateral movement of the jacket segment when it is impaled onto the cartridge. Retaining plate 75 has holes 73 aligned with recesses 70 and dimensioned to permit the spindle 44 to pass through to make a passage in jacket segment and to permit tube 4 to pass through to be ejected from the jacket segment while restraining movement of the jacket segment toward the spindle.

Each carriage 60 also includes a second support area defined by three outwardly-facing recesses 72 which are concentric with recesses 70, and which are dimensioned to receive and support the aerosol generating cartridges "B" (FIG. 2), each preferably comprising capsule 5, at one end of which is the heat-generating element 7, in alignment with the axes of the jacket segments. See FIG. 8.

Each cylindrical recess 70 contains a plurality of orifices 74 which are in communication with a passage 76 extending lengthwise of the carriage, and mounted in end plate 39, 40 in flow communication with the passageways therein. Each recess 72 is also provided with a plurality of orifices 74 in communication with the passage 76. Orifices 74 provide vacuum for holding the components in the recesses 70 and 72 in axial alignment and also provide bursts of low pressure air at suitable intervals to remove any debris from the recesses.

In the preferred embodiment, grooves 84 and 86 in mounting plate 12 provide communication to vacuum chamber 25 to provide vacuum to orifices 74 and openings 85 and 87 in mounting plate 12 provide low pressure air to orifices 74, as illustrated in FIG. 13 with reference to the position of the transfer drums. Preferably, low pressure air is provided at about 4 barr and vacuum is provided at about 70 to 80 mbarr.

In the illustrated embodiment, each station also includes three abutment members 68, one for each of the modules to be assembled at that station. The abutment members 68, FIGS. 5 and 8, are bolted to brackets 69 slidably mounted to an end plate 39, 40, and are movable axially relative to the spindles 44. Each abutment member 68 is spring-biased by spring 300 (FIG. 8), and is held retracted by a latch 90 engaged at 92 with extension 93 of bracket 69 (FIG. 7), and is released at appropriate times as will appear hereinafter. Latch 90 is pivotally mounted on a support member 91, which is mounted on the end plate 39, 40. See FIG. 7. Movement of the latch 90 is effected by engagement of a cam follower 100 mounted thereon with the profile cam surface 26 at the end of the cam sleeve 22.

In operation, as the assembly drum 27 rotates, a jacket segment "A" is placed in a recess 70 (FIG. 5), preferably by transfer drum D1. Due to the action of coupling member 64, following cam groove 24, and support arms 78, the clamp 66 is moved relative to the

carriage 60 toward the spindle 44 to enclose the jacket segment A in recess 70. Thereafter, the clamp and carriage move in unison toward the rotating spindle due to the action of coupling member 64 following cam groove 24, to impale the jacket segment A, restrained by retaining member 67, on the spindle 44. At this position, an aerosol generating cartridge "B" (FIG. 2) is placed on the carriage in the recess 72, preferably by transfer drum D2 (FIG. 4). Following deposit of the cartridge "B" on the carriage, the abutment member 68 is released by the latch 90, due to the contour of cam surface 26, so that the abutment member is moved into engagement with the cartridge "B" and pushes it against jacket module A. See FIG. 8.

Movement of the clamp 66, together with the carriage 60, away from the spindle 44, as effected by coupling member 64 in combination with cam groove 24, withdraws jacket segment A and the pierced rod of tobacco 2 from the spindle and, with the aid of abutment member 68, impales the jacket segment A on the cartridge "B" disposing the capsule 5 within rod 2 and the fuel element 7 within sleeve 3 as shown in FIG. 3. During this movement, the plastic tube support member for sleeve 3 is held between capsule 5 and the shoulder 45 on the conical tip 46 of spindle 44, and is eventually ejected from sleeve 3 by passage through the pierced tobacco rod 2. Retaining member 67 has a hole 71 of sufficient size to permit the cartridge "B" to pass through and to restrain axial movement of jacket segment A when it is impaled on the spindle. Further movement of the clamp 66 and carriage 60 relative to the abutment member 68 removes clamp 66 from the resulting aerosol generating module "M" (FIG. 3) and reengages the latch 90 with the abutment member 68. The aerosol generating module "M" is then removed from the carriage by disengagement of the vacuum and transfer to transfer drum D3 (FIG. 4).

FIGS. 11-A to 11-H and 12-A through 12-0 schematically depict the sequence of operation of the stations on assembly drum 27. FIGS. 11-A to 11-H diagramatically show the interaction of carriages 60.1 with cam surfaces 24.1 and 26.1 and the relative movements of the carriages 60.1, the clamps 66.1 and the abutment members 68.1. FIGS. 12-A through 12-0 diagramatically show the movements of clamps 66.1, carriages 60.1 and abutment members 68.1 for the illustrated preferred embodiment which makes three aerosol generating modules at each station. These figures are presented solely for the purpose of illustrating relative movements and relative positions of the various parts of the carriages as shown.

FIGS. 11-A and 12-A show the clamp 66.1 displaced away from the spindles, for loading jacket segments A. At this position, the recesses 70.1 on the carriage 60.1 are exposed. Jacket segments A, preferably comprising a rod of tobacco, the sleeve of insulating fibers and the support tube, are now deposited in the recesses 70.1, as shown in FIGS. 11-B and 12-B, in alignment with the axis of the spindles 44.1. The clamp 66.1 is now moved by the are 78.1, by movement of coupling member 64.1 in conjunction with cam follower 62.1 following cam groove 24.1, as shown in FIG. 11-C, to a position to enclose the jacket segments A in recesses 70.1. See FIGS. 12-C and D.

Following movement of the clamp relative to enclosing segments A, the carriage 60.1 is moved toward the spindles, by means of coupling member 64.1 and cam follower 62.1 in conjunction with cam groove 24.1. Carriage 60.1 carries with it jacket segments A, enclosed by the clamp 66.1, to a position to impale the jacket segments on the rotating spindles 44.1, as shown in FIGS. 11-D, 12-E and 12-F. At this position (FIGS. 11-D and 12-F), the recesses 72.1 are exposed between the clamp 66.1 and the abutment members 68.1.

The cartridges B, comprising the capsule and fuel element, are now deposited between the clamp 66.1 and the abutment members 68.1 (FIG. 11-E and 12-G) with the fuel elements facing abutment members 68.1. The abutment members are then released by retraction of the latch 90.1 through the action of cam follower 100.1. Thus the spring biased abutment members move into engagement with the cartridges "B" and press the latter into engagement with jacket segments A (FIG. 11-F and 12-H).

Now the carriage 60.1 and clamp 66.1 are moved away from the spindles, which withdraws the jacket segments A from the spindles, expels the tubes 4 after passing through the openings in the tobacco rods, and impales the jacket segments A on the cartridges "B" (FIG. 11-G, 12-I to J). Finally, the carriage 60.1, clamp 66.1 and abutment members 68.1 are moved to their initial positions, as shown in FIGS. 11-H and 12-K to O, to free the composite structures "M" for pickoff, and to reengage latch 90.1.

Thus, in sequence, the aforesaid apparatus operates to pierce a rod of tobacco, one end of which has been attached to a sleeve of insulating fibers disposed about a plastic tube, to form a longitudinal passage through the rod of tobacco corresponding to the inside diameter of the sleeve, and thereafter insert an aerosol generating cartridge into the formed passage and the sleeve.

It should be understood that the present disclosure is for the purpose of illustration only and the invention includes all modifications or improvements which are within the scope of the appended claims. The invention is not limited by particular materials, which are described only for purposes of illustration. For example, other materials may be used to form the jacket segment in place of tobacco and glass fibers, such as other fibrous materials and/or non-fibrous materials. Materials other than fibrous materials may also be used to form the sleeve. Other configurations of the aerosol generating cartridge may be employed.

It should also be understood that those skilled in the art, upon considering the present disclosure including the drawings, can readily modify the apparatus to insert cartridges in a sleeve (i.e. without a spindle), to make more or less aerosol generating modules simultaneously at each station, etc.

What is claimed is:

1. Apparatus for making aerosol generating modules for smoking articles, the apparatus comprising: a rotatable drum; a plurality of stations mounted on the drum, each station comprising jacket holding means for receiving and holding at least one jacket segment and cartridge holding means for receiving and holding at least one aerosol generating cartridge; and means for inserting the cartridges into the jacket segments.

2. The apparatus of claim 1 wherein the stations are arranged in axially aligned pairs.

3. The apparatus of claim 1 or 2 wherein each station includes means for inserting.

4. The apparatus of claim 1 or 2 wherein each station comprises passage forming means for forming a passage lengthwise through at least a portion of each jacket segment.

5. The apparatus of claim 4, wherein each station further comprises means for ejecting a support member from within the jacket segment.

6. The apparatus of claim 4 wherein the passage forming means comprises a passage forming member, each station further comprising means for withdrawing the passage forming member from each jacket segment and simultaneously inserting an aerosol generating cartridge into the jacket segment.

7. The apparatus of claim 6, each station further comprising means for ejecting a support member from within the jacket segment.

8. The apparatus of claim 7, wherein the means for simultaneously withdrawing the passage forming member and inserting the cartridge includes the means for ejecting the support member.

9. The apparatus of claim 1 or 2 wherein each station further comprises means for ejecting a support member from within the jacket segment.

10. The apparatus of claim 9 wherein each station further comprises means for simultaneously inserting an aerosol generating cartridge into the jacket segment while the support member is being ejected.

11. The apparatus of claim 1 or 2 wherein at each station the jacket holding means is in axial alignment with the cartridge holding means.

12. The apparatus of claims 1 or 2 wherein each station further comprises: a slidable support means having thereon the jacket holding means and the cartridge holding means; and means cooperating with the jacket holding means for restraining movement of the jacket segment during insertion.

13. The apparatus of claim 12 wherein the insertion means comprises: an abutment member proximate the cartridge holding means; and means for effecting relative movement between the slidable support means and the abutment member to insert the cartridge into the jacket segment.

14. The apparatus of claim 12 wherein the insertion means comprises an abutment member proximate the cartridge holding means and means for moving the slidable support means toward the abutment member to effect the insertion of the cartridge into the jacket segment.

15. The apparatus of claim 12 further comprising means for restraining movement of the abutment member while the support means is moving toward the abutment member to effect insertion of the cartridge into the jacket.

16. The apparatus of claim 12, wherein each station comprises passage forming means for forming a passage lengthwise through at least a portion of each jacket segment.

17. The apparatus of claim 1 or 2 wherein each station further comprises: a support means having fixed thereto the jacket holding means and the cartridge holding means; and means cooperating with the jacket holding means for restraining movement of the jacket segment during insertion; and wherein the insertion means comprises: an abutment member proximate the cartridge holding means; and means for effecting relative movement between the support means and the abutment member to insert the cartridge into the jacket segment.

18. The apparatus of claim 17, wherein each station comprises passage forming means for forming a passage lengthwise through at least a portion of each jacket segment.

19. The apparatus of claim 1 or 2 wherein each station comprises a plurality of corresponding jacket holding and cartridge holding means.

20. The apparatus of claim 1 or 2 wherein each station comprises

passage forming means for forming a passage lengthwise through at least a portion of each jacket segment;

a slidable support means which carries the jacket holding means and cartridge holding means, the jacket holding means being mounted proximate to the passage forming means; the jacket holding means comprises a first recess shaped to receive a jacket segment, and the cartridge holding means comprises a second recess adjacent to the first recess and shaped to receive a cartridge, the recesses being in axial alignment for insertion of the cartridge into the jacket segment; the jacket holding means further including means for restraining movement of the jacket segment during passage formation and insertion; the passage forming means comprising a spindle in axial alignment with the recesses; the insertion means comprises an abutment member proximate the cartridge holding means;

means for moving the slidable support means toward the spindle to effect formation of the passage in the jacket segment; and

means for moving the support means away from the spindle, cooperating with means for restraining movement of the abutment member while the support means is moving away from the spindle, to withdraw the jacket segment from the spindle, engage the cartridge with the abutment member, and insert the cartridge into the jacket segment.

21. The apparatus of claim 20 wherein each station comprises a plurality of corresponding pairs of first and second recesses.

22. The apparatus of claim 20 wherein the spindle, the means for moving the support means away from the spindle, and the means for restraining movement of the abutment member comprise a means for ejecting a support member from within the jacket segment.

23. The apparatus of claim 1 or 3, wherein the jacket holding means and cartridge holding means are mounted adjacent each other on a support means, the jacket holding means includes a means for restraining movement of the jacket segment during insertion, the insertion means comprises an abutment member adjacent the cartridge holding means, and the apparatus further comprises means for effecting relative motion between the abutment member and the support means to effect insertion of the cartridge into the jacket segment.

24. The apparatus of claim 23 wherein the apparatus comprises passage forming means for forming a passage lengthwise through at least a portion of the jacket segment.

25. The apparatus of claim 24 wherein the passage forming means comprises a passage forming member and each station comprises means for withdrawing the passage forming member from the jacket segment and simultaneously inserting the aerosol generating cartridge.

26. The apparatus of claim 1 or 2 wherein the jacket segment comprises a sleeve of insulating material preformed about a tubular member and wherein the inser-

tion means includes means for ejecting the tubular member from the sleeve.

27. The apparatus of claim 1 or 2 wherein the jacket segment comprises a rod of tobacco material and each station comprises passage forming means for forming a passage lengthwise in the rod.

28. Apparatus for making aerosol generating segments for smoking articles, said apparatus comprising:

a rotatable drum;

a plurality of stations located on the drum, each station comprising: jacket holding means for receiving and holding jacket segments; cartridge holding means for receiving and holding aerosol generating cartridges; and means for inserting the cartridges into the jacket segments, thereby forming aerosol generating modules;

jacket supply means for supplying jacket segments and cartridge supply means for supplying aerosol generating cartridges to each of the stations in seriatim; and

means for removing the aerosol generating modules from each station, in seriatim.

29. The apparatus of claim 28 wherein the jacket supply means comprises a rotatable member.

30. The apparatus of claim 28 wherein the cartridge supply means comprises a rotatable member.

31. The apparatus of claim 28 wherein the stations are arranged in axially aligned pairs around the periphery of the drum.

32. The apparatus of claim 28 wherein each station comprises passage forming means for forming a passage lengthwise through at least a portion of each jacket segment.

33. The apparatus of claim 32 wherein each station further comprises means for ejecting a support member from within the jacket segment.

34. The apparatus of claim 32 wherein the passage forming means comprises a passage forming member, each station further comprising means for withdrawing the passage forming member from each jacket segment and simultaneously inserting an aerosol generating cartridge into the jacket segment.

35. Apparatus for assembling components of a smoking article, the apparatus comprising a rotatable drum containing a plurality of peripheral movably mounted supports for receiving first and second components in alignment; means associated with the drum and operable as the drum is rotated to form an axial passage in one component and impale the first component on the second component to produce a composite structure.

36. Apparatus according to claim 35 wherein there are peripherally-spaced spindles on the drum aligned with the supports and movable clamps associated with the supports for enclosing the first components on the supports and moving them onto the spindles and thereafter removing pierced first components from the spindles and impaling them on the second components.

37. Apparatus according to claim 35 wherein the means for forming the axial passage includes spindles in alignment with the supports and the supports comprise recesses for receiving the components and are movable in a first direction to impale the first components on the spindles and thereafter in a second direction to withdraw the first components from the spindles and impale them on the second components.

38. Apparatus according to claim 37 wherein there are abutment means for constraining axial movement of the second components as the first components are been impaled thereon.

39. Apparatus according to claim 35 wherein the supports on the drum are arranged in a series of adjacent axial pairs, and the drum further comprises a pair of opposite-facing spindles located between each pair of supports.

40. The apparatus of claim 39 wherein the supports are mounted in sets on slidably mounted carriages and each carriage has a slidably mounted clamp associated with it for enclosing first components on the support.

41. The apparatus of claim 35 wherein the means for forming the axial passages in the first components comprises pairs of opposite-facing spindles on the drum and wherein the supports are arranged in pairs on both sides of the spindles and comprise sets of axially aligned, corresponding recesses for first and second components.

42. The apparatus of claim 41 wherein the sets of recesses are located in groups on slidably mounted carriages and each carriage has a slidably mounted clamp associated with it for enclosing first components on the support.

43. The apparatus of claim 40 or 42 wherein the drum is mounted on a support member having a contoured cam groove and wherein the carriages and the clamps move in response to the contour of the cam groove.

44. The apparatus of claim 40 or 42 further comprising a releasable, slidable abutment member for constraining movement of the second components while the first components are being impaled on the second components.

45. The apparatus of claim 44 wherein the abutment member is released and latched in response to the contour of a cam surface on a support member for the rotatable drum.

46. The apparatus of claim 39, 40, 41 or 42, further comprising means for rotating the spindles.

47. The apparatus of claim 46 wherein the spindles are rotated by the rotation of the drum.

48. The apparatus of claim 47 wherein the means for rotating the spindles comprise gear means mounted between the pair of supports.

49. Apparatus for assembling components of a smoking article, the apparatus comprising a support member having contoured cam surfaces; and a rotatable drum mounted on the support member and having a plurality of movably mounted assembly stations arranged in tandem around the periphery of the drum, each station comprising a slidably mounted carriage having aligned sets of recesses for receiving a plurality of first and second components of the smoking article, a slidably mounted clamp associated with the carriage for enclosing the first components on the carriage, a slidable abutment member aligned with each set of recesses for constraining axial movement of a second component, and means responsive to cam surfaces on the support member to move the clamp relative to the carriage and abutment members to enclose the first components on the carriage, to move the abutment members from a retracted position to an engaged position for constraining axial movement of the second components on the carriage, to move the carriage and clamp toward the abutment members to insert the second components in the first components, to move the carriage relative to the clamp to release the assembled first and second components, and to move the abutment members from their engaged position to their retracted position.

50. Apparatus for assembling components of a smoking article, comprising a rotatable drum, a plurality of assembly stations mounted on the drum, each station comprising a spindle, means supporting the spindle for rotation about its longitudinal axis, a slidable abutment member, means supporting the abutment member in axially-spaced alignment with the axis of the spindle, a transport means comprising a reciprocal carriage having aligned recesses for receiving first and second components of the smoking article and a clamp movable in unison with the carriage relative to the spindle and the abutment member and movable relative to the carriage, the clamp being operable by movement relative to the carriage and abutment member to enclose a first component in the recess on the carriage for movement with the carriage in a direction toward the spindle into engagement with the spindle to pierce the first component and thereafter in an opposite direction toward the abutment member, initially in unison with the carriage to withdraw the pierced first component, from the spindle and impale it on the second component, and then relative to the carriage to release the composite structure comprising the first component with the second component contained therein, the abutment member being movable from a retracted position while the carriage is moving toward the spindle to an engaged position to restrain the second component while the carriage is moving away from the spindle and the first component is being impaled on the second component.

51. The apparatus of claim 50 wherein each station comprises an equal number of spindles, abutment members, and sets of aligned recesses for receiving first and second components, for the assembly of a plurality of corresponding components simultaneously at each station.

52. The apparatus of claim 50 wherein the stations are mounted in tandem pairs around the rotatable drum and wherein each station comprises an equal number of spindles, abutment members, and sets of aligned recesses for receiving first and second components, for the assembly of a plurality of corresponding components simultaneously at each station.

53. The apparatus of claim 52 wherein the spindles are rotatably mounted in opposite-facing pairs between the carriages of each tandem pair of stations and wherein the means for rotating the spindles comprise gear means mounted between the carriages of each tandem pair of stations.

54. Apparatus according to claim 50 wherein there are orifices in communication with the recesses and means connecting the orifices to a vacuum.

55. Apparatus according to claim 50 wherein there is cam-actuated means for effecting movement of the carriage relative to the spindle and for effecting movement of the clamp relative to the carriage.

56. Apparatus according to claim 50 wherein the abutment member is slidably mounted and is spring-biased toward the spindle and wherein the apparatus further comprises latch means to constrain movement of the abutment member prior to deposit of the second component on the carriage and means operable for releasing the latch means following deposit of the second component on the carriage, to permit the abutment member to engage the second component.

57. Apparatus according to claim 50 further comprising first supply means for depositing the first component on the carriage in its recess prior to movement of the clamp to the enclosing position and second supply means for depositing the second component on the carriage in its recess following movement of the carriage and clamp to the position of impalement of the first component on the spindle.

58. Apparatus for the manufacture of a smoking article, the apparatus comprising a rotatable drum, a plurality of stations mounted on the drum, each station comprising a spindle; an abutment member disposed in spaced alignment with the spindle; a carriage structured to support a first component comprising a jacketed rod of tobacco, at one end of which there is a sleeve of non-combustible material formed around a support member, in alignment with the spindle and the abutment member; and means for effecting movement of the carriage in a direction toward the spindle to pierce the jacketed rod of tobacco; means for supporting a second component comprising an aerosol generating cartridge, at one end of which there is a fuel element, on the carriage between the first component and the abutment members, for constraining movement of the second component relative to the carriage; and means for moving the carriage in a direction away from the spindle to withdraw the fist components from the spindle, impale it on the second component and expel the support member.

59. Apparatus for making smoking articles, the apparatus comprising a drum rotatable about a horizontal axis, a series of spindles mounted on the drum for rotation about horizontal axes parallel to the axis of rotation of the drum, a drive shaft supported by the drum for rotation about a horizontal axis parallel with the axes of the spindles; a train of gears operable by rotation of the drive shaft to effect rotation of the spindles; means for effecting rotation of the drive shaft by rotation of the drum; an abutment member mounted on the drum in axially-spaced alignment with each spindle; a carriage structured to support first and second components positioned between and in alignment with a corresponding number of spindles and abutment members, the carriage being mounted on the drum for reciprocal movement relative to and parallel to the axes of the spindle and the abutment member; and means operable by rotation of the drum to effect reciprocal movement of the carriage to move the carriage in a direction to impale first components on the spindles and in the opposite direction toward the abutment member to withdraw the first components from the spindles and move them toward the abutment members to impale the pierced first components on second components supported by the carriage and constrained by abutment members.

60. Apparatus according to claim 59 wherein there is a clamp mounted on the carriage for movement therewith and relative thereto, to enclose and release the first component on the carriage, and cam-actuated means for effecting movement of the clamp.

61. Apparatus according to claim 59 or 60 wherein the carriage embodies recesses for receiving the first and second components and vacuum means for restraining movement of the components within the recesses.

62. Apparatus according to claim 61 wherein there are a plurality of sets of recesses on the drum and a spindle and abutment member mounted to the drum in peripherally-spaced relation about the axis of rotation of the drum corresponding to each set of recesses.

63. Apparatus according to claim 59 comprising means yieldably biasing the abutment member in a direction toward the spindle, a latch constraining movement of the abutment relative to the carriage and means

for releasing the latch following deposit of the second component on the carriage.

64. Apparatus according to claim 59 comprising means for retracting the abutment member relative the carriage to facilitate placing the second component on the carriage between the abutment member and the first component.

65. Apparatus for making smoking articles, the apparatus comprising a support frame; a drum disposed on the frame for rotation about a horizontal axis; a spindle mounted to the drum for rotation therewith about a horizontal axis spaced from and parallel to the axis of rotation of the drum; spindle rotating means operable by rotation of the drum relative to the frame to effect rotation of the spindle; an abutment member mounted to the drum in axially-spaced alignment with the spindle; a carriage movably mounted to the drum between the spindle and the abutment member and in alignment therewith; carriage movement means on the frame and drum cooperable by rotation of the drum relative to the frame to effect movement of the carriage to move a component supported by the carriage onto the spindle to pierce the same and to withdraw the pierced component from the spindle and impale it on a second component supported by the carriage between the first component and the abutment member.

66. Apparatus according to claim 65 wherein the spindle rotating means for effecting rotation of the spindle comprises a ring gear mounted to the frame, a spur gear mounted to the drum in mesh with the ring gear and meshing gears, one of which is engaged with the spur gear and another of which is mounted to the spindle.

67. Apparatus according to claim 66 wherein the carriage movement means comprise a cam cylinder containing a cam groove mounted to the frame and a cam follower mounted on the carriage for engagement with the cam groove.

68. Apparatus according to claim 67 wherein the cam cylinder is provided with a profile cam at one end and a lever is pivotally mounted to the frame with one end engaged with the profile cam and the other end engageable at times with the abutment member to effect retraction and release of the abutment member and there is spring means for yieldably holding the abutment member in contact with the profile cam.

69. Apparatus for making smoking articles comprising a first component comprising a rod of tobacco, at one end of which there is a sleeve of non-combustible material and a second component comprising an aerosol generating cartridge, the apparatus comprising a frame; a drum disposed on the frame for rotation about a horizontal axis; circumferentially-spaced spindles mounted to the drum about the axis of rotation of the drum; means operable by rotation of the drum relative to the frame to effect rotation of the spindles; an abutment member mounted to the drum in axial alignment with each spindle; carriages slidably mounted to the drum between the spindles and abutment members structured to receive the components in alignment with a spindle and an abutment member; and means for effecting axial movement of each carriage relative to the aligned spindle and abutment member to move the first component onto the spindle to pierce the same and then from the spindle and onto the second component to dispose the first component on the second component.

70. Apparatus according to claim 69 wherein the means for effecting axial movement of the carriages comprise a cam cylinder mounted to the frame and a cam follower mounted to each carriage in engagement with the cam cylinder, operable by relative rotation of the frame and drum to effect reciprocal movement of the carriages.

71. Apparatus according to claim 70 wherein each carriage embodies first and second concentric recesses for receiving, respectively, the first and second components, the apparatus having means for depositing the first components on the carriage; and means for depositing the second component on the carriage while the first component is on the spindle.

72. Apparatus according to claim 70 wherein the cam cylinder embodies a cam groove and the cam follower is in the groove.

73. Apparatus according to claim 72 wherein the cam cylinder further comprises a cam track, wherein the abutment members are spring-biased toward the spindles, wherein there are latch means constraining movement of the abutment members, and wherein there are cam levers yieldably engaged with the cam track operable at times to release the abutment members.

74. The apparatus of claim 69, 70, 71 or 73 wherein the spindles, abutment members, and carriages are arranged in tandem around the drum, the spindles are arranged in opposite-facing pairs located between tandem carriages, and each carriage is structured to receive a plurality of first and second components, for the assembly of a plurality of corresponding components of smoking articles simultaneously on each carriage.

* * * * *

Electronic Patent Application Fee Transmittal

Application Number:	14925968
Filing Date:	28-Oct-2015
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Filer:	Richard Douglas Shoop/Brian Flick
Attorney Docket Number:	13211-713.303

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($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	25212635
Application Number:	14925968
International Application Number:	
Confirmation Number:	2707
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Customer Number:	66854
Filer:	Richard Douglas Shoop/Brian Flick
Filer Authorized By:	Richard Douglas Shoop
Attorney Docket Number:	13211-713.303
Receipt Date:	16-MAR-2016
Filing Date:	28-OCT-2015
Time Stamp:	14:03:24
Application Type:	Utility under 35 USC 111(a)

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Payment Type	Deposit Account
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Deposit Account	504050
Authorized User	SHOOP, RICHARD D
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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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.

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on 3-16-2016.

Brian Tick
Name

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 14/925,968	Confirmation No.: 2707
First Named Inventor	: Adam Bowen	
Filed	: October 28, 2015	
Art Unit	: 1747	
Examiner	: Mayes, Dionne Walls	
Title	: NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF	
Customer No.	: 66854	

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☐ **37 CFR §1.97(b)**
This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:

- ☐ **1).** Within 3 months of the application filing date, or
- ☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or
- ☐ **3).** Before the mail date of a first Office Action on the merits, or
  - ☐ **3a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below
- ☐ **4).** Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.
  - ☐ **4a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below

☒ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☒ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☒ **A).** A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

or

☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under §1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☒ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☒ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☒ **3).** Items identified by a double asterisk (**) on the SB08A are *commonly-owned U.S. patents and U.S. patent application publications.

☒ **37 CFR §1.98 (a)(2)(iii) and (d), *Commonly-owned, unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s), and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **3).** A copy of each application specification is not submitted because the application is stored in the IFW. Cite no(s): 484 and 485

Applicant(s) assume the Examiner has access to the file histories of these items. However, if the Examiner would like to receive copies of Office Actions in any of the commonly-owned applications, publications and/or patents identified on the attached SB08, please inform the undersigned and copies will be provided.

☒ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☒ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☒ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and 609.04(a)III, Foreign patent(s) or other foreign documents not in English cited. Either:**

☒ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☒ **2a).** An English language abstract or an English language copy of a foreign search report or other action by a foreign patent office is provided herewith to fulfill the requirement for a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language: Cite no(s): 375-381, 390, 396-408, 411, 412, and 453

--AND/OR--

☒ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached: Cite no(s): 375, 376, 378, 380, 381, 396-398, 404, 405, 407, and 408

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. Cite no(s):

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement. Cite no(s):

STATEMENT UNDER 37 CFR § 1.704(d)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 3/16/2014

By: _____
Richard D. Shoop, Reg. No. 45,763

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(650) 212-1700
Customer No. 66854

Electronic Acknowledgement Receipt

EFS ID:	25213043
Application Number:	14925968
International Application Number:	
Confirmation Number:	2707
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Customer Number:	66854
Filer:	Richard Douglas Shoop/Brian Flick
Filer Authorized By:	Richard Douglas Shoop
Attorney Docket Number:	13211-713.303
Receipt Date:	16-MAR-2016
Filing Date:	28-OCT-2015
Time Stamp:	14:20:51
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	WO2014187770A2.pdf	1996472 95d18139b6c97de4d596c214a2350293e6d54c06	no	29
Warnings:					
Information:					

2	Foreign Reference	WO2015006652A1.pdf	3520366 f5e8ae815018e0b78579051aacf298084aace898	no	74
Warnings:					
Information:					
3	Foreign Reference	WO2015040180A2.pdf	1559547 5140731366310f120c4eb5a07dc1befebff112bf	no	28
Warnings:					
Information:					
4	Foreign Reference	WO2015082652A1.pdf	1000555 38d3d280f701a43c92f3674e0613c274ce9c1f02	no	19
Warnings:					
Information:					
5	Foreign Reference	WO2015084544A1.pdf	5708151 c729a79e36c588d51c358d8a2c5051009d4fc060	no	96
Warnings:					
Information:					
6	Foreign Reference	WO2015101651A1.pdf	1921727 bf1134ae94cc5a88aca71c27ffb1e9a971c7f73b	no	33
Warnings:					
Information:					
7	Foreign Reference	WO2015124878A1.pdf	1336991 f2bfc1e32fbedd0fb8fadca37d2b4576b37609f4	no	38
Warnings:					
Information:					
8	Foreign Reference	WO2015148547A1.pdf	1438191 5b2a6c6a43b3afe40ecee71e8616fedc543bd6a3	no	40
Warnings:					
Information:					
9	Foreign Reference	WO2015175979A1.pdf	1119240 0dd652d7668462d8e3d3db8ac6c821153f76a199	no	23
Warnings:					
Information:					
10	Non Patent Literature	ECF-AnyInterestInDeterminingNicotine.pdf	945899 f45d4738ac20cd0f4cfda305be518eb16c4556ce	no	8
Warnings:					
Information:					

11	Non Patent Literature	Bombick_et_al-Part2ChemicalAndBiological.pdf	478386 14ab76e4ed74bdec4d3e3071a6ad5df4c6421cdc	no	8
Warnings:					
Information:					
12	Non Patent Literature	Bombick_et_al-Part3ChemicalAndBiological.pdf	392773 5fa2131a60b3a540bbc3e44e70466aec6b1d8385	no	7
Warnings:					
Information:					
13	Non Patent Literature	Borgerding_et_al-Part1ChemicalAndBiological.pdf	1370908 fd584d757c9d92460d2fcdddde06d50b5a8a34ca	no	13
Warnings:					
Information:					
14	Non Patent Literature	Mirriam-Webster_Lighter.pdf	217877 f7c501314ae49e09f1fbf39a5ba2e80245b35dc6	no	2
Warnings:					
Information:					
15	Non Patent Literature	Baker_et_al-ThePyrolysisOfTobacco.pdf	2879309 4b0893691633ed9d79e393be947f5f87354315b5	no	89
Warnings:					
Information:					
16	Non Patent Literature	Torikai_et_al-EffectOfTemperature.pdf	711044 6bdde6d5e43171f769eed5db35224f150206102e	no	9
Warnings:					
Information:					
17	Non Patent Literature	Ward-GreenLeafThreshing.pdf	1277487 b28df6ab57bb5892d621fa45fb6d06e65361d3a0	no	7
Warnings:					
Information:					
18	Non Patent Literature	Ingebrethsen_et_al-ElectronicCigaretteAerosol.pdf	878285 9adfa01d50eceb11167a85a8d4a1358640f3d752	no	9
Warnings:					
Information:					
19	Non Patent Literature	McCann_et_al-DetectionOfCarcinogens.pdf	589865 2c765bee4e459ebc6a924f04ff346bd9923c85f5	no	5
Warnings:					
Information:					

20	Non Patent Literature	Wells-GlycerinAsAConstituent.pdf	400896 55e15a965e5197a0ada0588565d1024ad9fd2e01	no	7
Warnings:					
Information:					
21	Non Patent Literature	Kuo_et_al-AppendixDParticleSize.pdf	118553 bd6edf7f6957d7459bbfb02198723c3f321c8596	no	3
Warnings:					
Information:					
22	Non Patent Literature	HarvestVapour-AmericanBlendTobacco.pdf	192959 aa2d2ce86dbb83eaaeb0de6e2b01175fc928da9e	no	2
Warnings:					
Information:					
23	Non Patent Literature	INCHEM-LevulinicAcid-Mar2003.pdf	38840 696c8649b74fe2ad08053b5ad55ed838a8a081cb	no	1
Warnings:					
Information:					
24	Non Patent Literature	INCHEM-BenzoicAcid-May2005.pdf	73915 e2fb66054fa0822703fa47b589f6ac3442871681	no	2
Warnings:					
Information:					
25	Non Patent Literature	FoodAndDrugAdministration-TheCompoundingPharmacy.pdf	279626 415c15ba5cefff8c9d29ccf15e295ff317e5f752	no	3
Warnings:					
Information:					
26	Non Patent Literature	INCHEM-PyruvicAcid-Jan2003.pdf	33530 7371b9d02c93cafe786924332b0f6ee89b7a6475	no	1
Warnings:					
Information:					
27	Non Patent Literature	INCHEM-SorbicAcid-May2005.pdf	53872 57875ff939c0f0bf06c9f35643f5c751691e2d16	no	1
Warnings:					
Information:					
28	Non Patent Literature	Flouris_et_al-AcuteImpactOfActive.pdf	1250365 0edc97cbd42bb7257ff660febd681ff100c9d6dc	no	12
Warnings:					
Information:					

29	Non Patent Literature	Goniewicz_et_al-NicotineLevelsInElectronic.pdf	785815 93f15bd1715bdf7fc9a2652cca5774ec1e9ff715	no	9
Warnings:					
Information:					
30	Non Patent Literature	Seeman_et_al-TheFormOfNicotine.pdf	1326537 b591d90db200c24ab2b64f48266210d4da82fc58	no	13
Warnings:					
Information:					
31	Non Patent Literature	Vansickel_et_al-AClinicalLaboratory.pdf	759955 df7d5b89aecd44cdc34a84ccc7a3b315de4aae75	no	9
Warnings:					
Information:					
32	Non Patent Literature	Zhang_et_al-InVitroParticleSize.pdf	625228 e1cbf9ec3cb441b965b7a2fb3424a796b2b5c4a9	no	8
Warnings:					
Information:					
33	Non Patent Literature	Nicoli_et_al-MammalianTumorXenografts.pdf	1881086 01dec3636aa89952d4adaf56f48082fea27ec89a	no	5
Warnings:					
Information:					
34	Non Patent Literature	YouTube-FireflyVaporizorReview.pdf	128746 19ccc5a77bdfaca405e07ddee58a341f6fb28ec7	no	1
Warnings:					
Information:					
35	Non Patent Literature	Perfetti_StructuralStudyNicotineSalts_1983.pdf	1995767 2c689cfbc458ce980fd57948bada4be583c1e834	no	12
Warnings:					
Information:					
			Total Files Size (in bytes):	39288763	

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.

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on March 16, 2016.
/Mary Buggie/ 3/16/2016
Mary Buggie Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	14/925,968	Confirmation No.	: 2707
First Named Inventor	:	Adam BOWEN		
Filing Date	:	October 28, 2015		
Art Unit	:	1747		
Examiner	:	Mayes, Dionne Walls		
Title	:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF		
Customer No.	:	66854		

AMENDMENT IN RESPONSE TO NON-FINAL OFFICE ACTION

This reply is in response to the non-final Office Action mailed December 16, 2015 for which a response is due March 16, 2016, and is therefore timely filed. The Commissioner is hereby authorized to charge any fees to make this filing timely to Deposit Account No. 50-4050 and to credit any overpayments to Deposit Account No. 50-4050.

Amendments to the Claims are shown in the listing of claims that begins on page 2.
Interview Summary begins on page 6.
Remarks begin on page 7.

Reconsideration and allowance of the pending claims, in light of the amendments and remarks presented herein is respectfully requested.

SG Docket No.: 13211-713.303

AMENDMENTS TO THE CLAIMS

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

1. (Currently amended) A method of delivering nicotine to a user comprising:

deploying ~~an electronic cigarette~~ a low-temperature vaporizer comprising a nicotine formulation that comprises nicotine, ~~an organic~~ lactic acid, and a biologically acceptable liquid carrier, wherein:

a. the nicotine concentration is from about 0.5% (w/w) to about 20% (w/w);

~~b. the nicotine formulation comprises nicotine lactate;~~

[c.]b. the biologically acceptable liquid carrier comprises propylene glycol and 90%-30% vegetable glycerol; and

[d.]c. operation of the ~~electronic cigarette~~ low-temperature vaporizer comprises heating at least a portion of the nicotine formulation to generate an inhalable aerosol between about 100°C and about 300°C;

wherein inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min and further wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength.

2. (Original) The method of claim 1, wherein a molar ratio of nicotine to organic acid is between about 1:1 and 1:3.

3. (Original) The method of claim 1, wherein the nicotine formulation further comprises at least one flavorant.

4. (Original) The method of claim 1, wherein the nicotine concentration is about 4.5%.

5. (Cancelled)

6. (Original) The method of claim 1, wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns.

7. (Currently amended) A method of delivering nicotine to a user comprising:

deploying ~~an electronic cigarette~~ a low-temperature vaporizer comprising a nicotine formulation that comprises nicotine, ~~a carboxylic acid, wherein the carboxylic acid comprises~~ lactic acid, and a biologically acceptable liquid carrier, wherein:

a. the nicotine concentration is from about 0.5% (w/w) to about 20% (w/w);

b. the nicotine formulation comprises protonated nicotine;

c. the biologically acceptable liquid carrier comprises propylene glycol and 90%-30% vegetable glycerol;

d. the lactic acid does not decompose at room temperature and does not decompose at the operating temperature of the ~~electronic cigarette~~ low-temperature vaporizer; and

e. operation of the ~~electronic cigarette~~ low-temperature vaporizer comprises heating at least a portion of the nicotine formulation between about 100°C and 300°C to generate an inhalable aerosol;

wherein inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min and further wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength.

8. (Original) The method of claim 7, wherein a molar ratio of nicotine to organic acid is between 1:1 and 1:3.

9. (Original) The method of claim 7, wherein the nicotine formulation further comprises at least one flavorant.

10. (Original) The method of claim 7, wherein the nicotine concentration is about 4.5%.

11. (Cancelled)

12. (Original) The method of claim 7, wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns.

13. (Currently amended) ~~An electronic cigarette~~ A low-temperature vaporizer, comprising:

a liquid reservoir;

a nicotine formulation within the liquid reservoir, the nicotine formulation comprising:

nicotine lactate;

propylene glycol; and

90%-30% vegetable glycerol;

wherein a concentration of nicotine in the nicotine formulation is from about 0.5% (w/w) to about 20% (w/w);

a vaporizing component configured to produce an aerosol from the nicotine formulation by heating at least a portion of the nicotine formulation between 100°C and 300°C; and

a mouthpiece configured to connect to the reservoir for inhalation of the aerosol;

wherein inhalation of the aerosol into the user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 min to about 8 min and further wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength.

14. (Original) The electronic cigarette of claim 13, further comprises a battery configured to provide power to the vaporizing component.

15. (Original) The electronic cigarette of claim 13, wherein a molar ratio of nicotine to organic acid is between 1:1 and 1:3.

16. (Original) The electronic cigarette of claim 13, wherein the nicotine formulation further comprises at least one flavorant.

17. (Original) The electronic cigarette of claim 13, wherein the vaporizing component comprises a heating element in fluid communication with the nicotine formulation.

18. (Original) The electronic cigarette of claim 13, wherein the nicotine concentration is about 4.5%.

19. (Cancelled)

20. (Original) The electronic cigarette of claim 13, wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns.

INTERVIEW SUMMARY

Applicants thank the Examiner for the courtesies extended during the telephone interview of March 10, 2016. During the interview Applicants discussed the amendments made herein in light of the cited prior art, as discussed below. Agreement was reached that these amendments would overcome the cited art, although the Examiner indicated that further searching would need to be performed.

REMARKS

Claims 1-20 were pending. No claims were previously withdrawn from consideration, and no claims had been previously cancelled. By this response, claims 1, 7 and 13 have been amended, claims 5, 11 and 19 have been cancelled, and no claims have been added. Support for these amendments, and for any new claims, may be found throughout the specification, but especially in paragraphs [110], [112], [113], [115], [121] and [132]. Cancellation or amendment of any claim is not to be considered a dedication to the public of any subject matter.

Thus, claims 1-4, 6-10, 12-18 and 20 are currently under consideration.

DOUBLE PATENTING

Claims 1-12

Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 9,215,895 to Bowen et al. ("Bowen'895") in view of U.S. Patent Application Publication No. 2014/0261474 to Igor Gonda ("Gonda").

By this response, claims 1-12 have been amended. Upon an indication that the claims are otherwise allowable, should the Examiner maintain the rejection of claims 1-12 for double patenting over Bowen '895 an Gonda, Applicants will likely file a terminal disclaimer, as suggested by the Examiner. In light of the amendments to the claims, a terminal disclaimer at this point would be premature.

Claims 1-4, 6-10 and 12

Claims 1-4, 6-10 and 12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 105-122 of copending U.S. Patent Application No. 14/271,071.

By this response, claims 1-4, 6-10 and 12 have been amended. Upon an indication that the claims are otherwise allowable, should the Examiner maintain the rejection of claims 1-4, 6-

10 and 12 for double patenting over copending U.S. Patent Application No. 14/271,071, Applicants will likely file a terminal disclaimer, as suggested by the Examiner. In light of the amendments to the claims, a terminal disclaimer at this point would be premature.

Claims 5 and 11

Claims 5 and 11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 105-122 of copending U.S. Patent Application No. 14/271,071 in view of Gonda and U.S. Patent Application Publication No. 2009/0151717 to Bowen et al. ("Bowen'717").

By this response, claims 5 and 11 have been cancelled, though their subject matter has been incorporated into the independent claims. Upon an indication that the claims are otherwise allowable, should the Examiner maintain the rejection of the claims for double patenting over Bowen '717, Applicants will likely file a terminal disclaimer, as suggested by the Examiner. In light of the amendments to the claims, a terminal disclaimer at this point would be premature.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103

Claims 1-4, 7-10 and 13-18

Claims 1-4, 7-10 and 13-18 currently stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent Application Publication No. 2006/0196518 to Lik Hon ("Hon") in view of Gonda.

The Applicants respectfully disagree.

The combination of Hon and Gonda does not suggest all of the features of claims 1-4, 7-10 and 13-18. In addition, the combination of Hon with Gonda in the manner suggested by the Office Action of December 16, 2016 is improper because it relies on impermissible hindsight.

As described in the Applicants' specification and discussed during the telephone interview of March 10, 2016, the claimed invention solves a long standing problem in the field electronic cigarettes --- that is, how to convincingly mimic the experience of a traditional

cigarette using a nicotine vaporizer --- by applying previously unrecognized discoveries. Specifically, the Applicants have discovered that some, but not all, nicotine salts, when properly formulated, may produce a nicotine plasma concentration (Cmax) and time course (Tmax) that most closely resembles that of traditional cigarettes. Further, when formulated as recited in the claims, including formulating in between 30%-90% vegetable glycerol and a glycol (such as propylene glycol), the user experience is surprisingly similar in "taste" and "feel", and therefore overall satisfaction, to that of a traditional cigarette. Importantly, when using other nicotine salts and other formulations, the user experience is not sufficiently similar to that of a traditional cigarette.

The Applicants' instant claims are directed in particular, to one particular nicotine salt, present in a solution of nicotine (e.g., freebase nicotine) and lactic acid in a biologically acceptable liquid carrier including propylene glycol and 90%-30% vegetable glycerol. This nicotine salt formulation, when vaporized using a low-temperature vaporizer between about 100°C and 300°C, results in a user experience that closely mimics a traditional cigarette even within the first 3-8 minutes of inhaling. The combination of nicotine and lactic acid in the carrier including propylene glycol and 90%-30% vegetable glycerol for use in a low-temperature vaporization device operating between 100°C and 300°C is based, in part, on the Applicants' unique discovery that only certain nicotine salts (e.g., and therefore only certain organic acids forming these salts) have a nicotine Cmax and Tmax in blood plasma of a user inhaling the vapor that is similar to that of inhaling smoke from a traditional cigarette. For example, the Applicants' disclosure (see, e.g., figures 1-5 and accompanying description) describes for the first time the plasma Tmax and Cmax of a variety of nicotine formulations, and teaches which formulations (and specifically which nicotine salts) do and do not have this desired effect.

As will be described in greater detail below, without the Applicant's teachings, one of skill in the art would not be motivated to provide a nicotine formulation and method of using it as described herein, and therefore it would not be obvious to combine references, including the Hon and Gonda references raised by the Office Action of December 16, 2015.

A. The combination of Hon and Gonda does not suggest all of the features of the claims.

The combination of Hon and Gonda does not suggest all of the features recited by the pending claims including claims 1-4, 7-10 and 13-18. Specifically, the combination of Hon and Gonda does not suggest: (1) a low-temperature vaporization device or a method of using a low-temperature vaporizing device *wherein inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min*; (2) *a low-temperature vaporizer* or a method of using a *low-temperature vaporizer* to heat a nicotine formulation *to generate an inhalable aerosol between about 100°C and about 300°C*; (3) a low-temperature vaporizer device or a method of using a low-temperature vaporizer device to heat a nicotine solution *including a biologically acceptable liquid carrier comprises propylene glycol and 90%-30% vegetable glycerol*; or (4) a low-temperature vaporization device *wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength.*

First, the combination of Hon and Gonda does not suggest a low-temperature vaporization device or a method of using a low-temperature vaporizing device wherein inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min. Hon and Gonda are silent as to the Tmax profiles of any of the nicotine formulations described in either Hon or Gonda. Further, it would not be obvious to modify the combination of Hon and Gonda to include this feature. Applicants note that this limitation was originally present in dependent claims 5, 11 and 19, but has now been included in each of the independent claims. In the Office Action of December 16, 2015, the Hon and Gonda were combined with Bowen et al. (US patent App. Pub. 2009/0151717, hereafter "Bowen '717"). The Office Action argues that this feature would be obvious, because the "collective disclosure [of Hon, Gonda and Bowen '717] indicates that the parameter of pH, aerosolized nicotine particle size and even nicotine concentration in the liquid formulation and inhalation rate are all 'results-effective variables'..." As such, only routine experimentation would be needed to optimize these variables to achieve the "recognized result" (see. Office Action, page 10), and therefore it would be obvious to one of ordinary skill "to have undergone routine experimentation and fabricated the nicotine formulation of Hon in the form of a liquid nicotine lactate salt solution and, in so

doing, arrived at the claimed particle size and inhalation rate which result in the claimed Tmax parameters…"

Applicants disagree. In order to be obvious for optimization, a variable must be first recognized as a results-effective variable in the prior art. See, e.g., *In re Antonie,* 559 F.2d 618, 195 USPQ 6 (CCPA 1977). In this case, neither the result (e.g., that the Tmax of nicotine in the plasma was between 3 and 8 minutes) nor the variables that Applicants have shown critically effect this result (e.g., the type of nicotine salt), are known in the prior art, and therefore it could not be obvious to optimize. Applicant point out that, as described in the Applicants' specification for the first time, the type of nicotine salt and therefore the organic acid used to form the salt in the formulation, is critical to achieving the recited Tmax. The variables cited by the Office Action in reference to Gonda (e.g., pH, particle size, nicotine concentration) are irrelevant if the wrong acid and therefore salt is generated, as described in the Applicants' specification (e.g., see paragraph [115] "… not all nicotine salts perform similarly to each other or to a traditional cigarette with respect to the rate of nicotine uptake in the blood at early time periods (0-1.5 minutes). These results are unexpected."). Without knowing what variables must be optimized (e.g., which acid and therefore nicotine salt to use), it could not be obvious to optimize the combination of Hon and Gonda, which each described a laundry list of acids and nicotine salts, including many that could not be optimized as recited in the claims.

Second, the combination of Hon and Gonda does not suggest a low-temperature vaporizer or a method of using a low-temperature vaporizer to heat a nicotine formulation to generate an inhalable aerosol between about 100°C and about 300°C. Hon describes only "high temperature vaporization." See, e.g., Hon, abstract ("high temperature vaporization nozzle", [006] ("a high temperature vaporization nozzle"), [021] ("the nicotine solution is then vaporized into high temperature vapor"), and [025] ("vaporized and condensed subsequently to form a puff of smoke at high temperature"). Gonda does not apply heat to form the vapor, but describes instead the use of a filter. Thus, the combination of Hon and Gonda does not suggest a low-temperature vaporizer or a method of using one.

Third, the combination of Hon and Gonda does not suggest a low-temperature vaporizer device or a method of using a low-temperature vaporizer device to heat a nicotine solution

including a biologically acceptable liquid carrier comprises propylene glycol and 90%-30% vegetable glycerol. Hon describes only propylene glycol content of between 80%-90% (where the "rest is glycerol", Hon, paragraph [020]). Similarly, Gonda suggests only that "Glycerin and glycols have been also used in inhalation products." Gonda, paragraph [078]. Neither reference alone or in combination suggests the combination of propylene glycol and 90%-30% vegetable glycerol.

Finally, the combination of Hon and Gonda does not suggest a low-temperature vaporization device wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength. Both Hon and Gonda are metered delivery devices in which the amount of material applied per puff is metered or determined by the device. In Hon, the dose of nicotine vapor is applied by spraying the high-temperature vapor that is actively pumped out of the electronic cigarette. See, e.g., Hon, paragraph [006] ("...an electronic pump or a valve connected with a metering cavity…"). Similarly in Gonda, the device partitions the volume inhaled into parts, so that vapor including nicotine is delivered as a bolus only during a portion of the inhalation. See, e.g., Gonda paragraph [021] and [094], which is taught as being important in controlling the rate of entry of nicotine to the blood and/or brain. Gonda, paragraph [025]. Neither Hon nor Gonda, nor the combination of the two, are configured to modify the amount of nicotine delivered by adjusting the inhalation strength.

B. Impermissible Hindsight is required to modify Hon (or Gonda) to obviate the pending claims.

It would not be obvious to modify Hon, Gonda, or the combination of Hon and Gonda to include all of the features recited in the claims, at least because this modification would require the knowledge found only in the Applicant's disclosure, which is impermissible hindsight. Specifically, the Applicants' instant claims are directed to a particular nicotine salt formulation, present in a solution of nicotine (e.g., freebase nicotine) and lactic acid in a biologically acceptable liquid carrier including propylene glycol and 90%-30% vegetable glycerol. It was Applicant's unique finding that only certain nicotine salt formulations, (including this one) when vaporized using a low-temperature vaporizer between about 100°C and 300°C, results in a user experience that closely mimics a traditional cigarette and produces a nicotine Tmax within the

first 3-8 minutes of inhaling. Thus, combination of nicotine and lactic acid in the carrier including propylene glycol and 90%-30% vegetable glycerol for use in a low-temperature vaporization device operating between 100°C and 300°C is based, in part, on the Applicants' unique discovery that only certain nicotine salts (e.g., and therefore only certain organic acids forming these salts) have a nicotine Tmax in blood plasma of that is similar to that of inhaling smoke from a traditional cigarette.

Applicants respectfully submit that the combination of Hon and Gonda is improper because the Office Action relies on information gleaned solely from Applicant's specification. In this case, The Office Action is incorrect in suggesting that it would be obvious to modify Hon to include lactic acid from Gonda. Hon mentions only the use of a nicotine mixture "including an organic acid" and describes as an example of the organic acid only citric acid. Gonda mentions a long list of organic acids that may be combined with nicotine, including lactic acid, but also include many others, in including many (such as citric acid) that do not produce a nicotine Tmax within the first 3-8 minutes of inhaling. It is only the Applicant's teaching of which acids and resulting nicotine salts, particularly in the context of a mixture of propylene glycol and 90%-30% vegetable glycerol, which result in the recited features, including the unexpected result of producing a plasma nicotine Tmax of between 3 and 8 minutes. It is only the Applicants' own teaching that suggests the use of lactic acid with a solution of nicotine having a concentration from about 0.5% (w/w) to about 20% (w/w) in a carrier of propylene glycol and 90%-30% vegetable glycerol to produce a nicotine Tmax of 3-8 minutes.

MPEP § 2142 states that "impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art" Any judgment on obviousness "is, in a sense, necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper" (MPEP § 2145(X)(A), quoting *In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971).

In the present case, the Office Action argues that it would be obvious to modify Hon to include lactic acid because "the Gonda reference teaches that administering an aerosolized,

liquid nicotine-containing formulation via inhalation (i.e., pulmonary administration) in order to effectuate a peak level of nicotine in the blood plasma after a very short time period – mimicking that which is typically achieve during actual cigarette smoking – is known." However, this is is not accurate. The prior art, Gonda included, did not realize that the some, but not all, nicotine salt formulations result in a peak (Tmax) blood plasma level within 3-8 minutes. This information was known only to the Applicants. Instead, Gonda taught that peak nicotine concentration was set only by the concentration, particle size, and pH which effect the deposition profile in the user's airway. Gonda, as indeed all of the prior art, was not aware that the type of nicotine salt (and therefore the included acid) was important, and therefore could provide no guidance suggesting which acid and resulting salt from those known in the art (including those listed by Gonda) would work, or what formulation of this acid and nicotine would work. It was only the Applicant's teaching that provides this suggestion.

As discussed in detail in the Applicants' specification, some, but not all, nicotine nicotine salts and formulations of nicotine salts have the recited property of producing a nicotine Tmax within 3-8 minutes, and providing a user experience that mimic's traditional cigarettes. See, e.g., paragraphs [111], [114], and Example 6. Due to the lack of suggestion in the prior art to this effect, and the fact that this discovery is only present on the record in Applicant's specification, it logically follows that this suggestion has been improperly gleaned from Applicant's own specification and that the combination of Hon and Gonda (with or without Bowen'717) is an exercise of impermissible hindsight. Accordingly, it is respectfully submitted that the combination is improper and respectfully requested that the rejection be withdrawn.

Since the combination of Hon and Gonda does not suggest all of the features of claims 1-4, 7-10 and 13-18, and since the combination of Hon and Gonda to include even some of these features requires the use of impermissible hindsight, these claims cannot be obvious in light of these references. Applicants respectfully request withdrawal of the 35 U.S.C. § 103 rejection of claims 1-4, 7-10 and 13-18 and allowance of all of the currently pending claims.

Claims 5-6, 11-12 and 19-20

Claims 5-6, 11-12 and 19-20 currently stand rejected under 35 U.S.C. § 103 as being unpatentable over Hon in view of Gonda and Bowen'717.

The Applicants respectfully disagree.

Bowen '717 cannot cure the deficiencies discussed above. As already discussed above, the combination of Hon, Gonda and Bowen '717 does not suggest the recited formulation, and specifically does not suggest, without the use of hindsight based on the Applicant's disclosure: (1) a low-temperature vaporization device or a method of using a low-temperature vaporizing device *wherein inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min*; (2) *a low-temperature vaporizer* or a method of using a *low-temperature vaporizer* to heat a nicotine formulation *to generate an inhalable aerosol between about 100°C and about 300°C*; (3) a low-temperature vaporizer device or a method of using a low-temperature vaporizer device to heat a nicotine solution *including a biologically acceptable liquid carrier comprises propylene glycol and 90%-30% vegetable glycerol*; or (4) a low-temperature vaporization device *wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength.*

Since the combination of Hon, Gonda and Bowen '717 does not suggest all of the features recited in the claims, these claims cannot be obvious in light of these references. The Applicants respectfully request withdrawal of the 35 U.S.C. § 103 rejection of claims 5-6, 11-12 and 19-20, and allowance of the currently pending claims.

CONCLUSION

Applicants respectfully request that the Examiner expedite the prosecution of this patent application to issuance. If the Patent Office determines that an extension of time and/or other relief is required, Applicants petition for any required relief including extension of time, and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-4050**, referencing 13211-713.303. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Date: March 16, 2016

Richard D. Shoop
Reg. No. 45,763

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Electronic Acknowledgement Receipt

EFS ID:	25219659
Application Number:	14925968
International Application Number:	
Confirmation Number:	2707
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Customer Number:	66854
Filer:	Richard Douglas Shoop/Mary Buggie
Filer Authorized By:	Richard Douglas Shoop
Attorney Docket Number:	13211-713.303
Receipt Date:	16-MAR-2016
Filing Date:	28-OCT-2015
Time Stamp:	19:41:31
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		13211-713-303_Response_NFOA_3-16-2016.pdf	751188 c6ed14172f0008fbba12e51031548c83095cf687	yes	16

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	5
	Applicant summary of interview with examiner	6	6
	Applicant Arguments/Remarks Made in an Amendment	7	16
Warnings:			
Information:			
	Total Files Size (in bytes):	751188	

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.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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 14/925,968	Filing Date 10/28/2015	☐ 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), (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 $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ 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	03/16/2016	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 17	Minus	** 20	= 0	X $80 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $420 =	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**

		(Column 1)		(Column 2)	(Column 3)		
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	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.

LIE
/STELLA LITTLE/

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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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/925,968	10/28/2015	Adam BOWEN	13211-713.303	2707

66854 7590 03/17/2016

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EXAMINER	
MAYES, DIONNE WALLS	

ART UNIT	PAPER NUMBER
1747	

NOTIFICATION DATE	DELIVERY MODE
03/17/2016	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):

info@shayglenn.com

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	14/925,968	BOWEN ET AL.	
	Examiner	Art Unit	
	DIONNE WALLS MAYES	1747	

All participants (applicant, applicant's representative, PTO personnel):

(1) *DIONNE WALLS MAYES*. (3) *ADAM BOWEN*.

(2) *RICHARD SHOOP*. (4)_____.

Date of Interview: *10 March 2016*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☐103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *Those of Record*.

Identification of prior art discussed: *Hon (2006/0196518) and Gonda (2014/0261474)*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Applicants Representative, Mr. Shoop, and Inventor, Mr. Bowen, presented proposed amendments to the instant claims along with arguments supporting their position that the claims now clearly define over the prior art of record, sepcifically Hon and Gonda. Examiner Mayes indicated that while she could not definitively indicate that the proposed claims would be allowable, she did believe Applicant's arguments to be strong and would consider them favorably, in addition to performing an updated prior art search. Applicant indicated a quick response to the outstanding Office Action would be filed .

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☒ Attachment

/DIONNE WALLS MAYES/ Examiner, Art Unit 1747	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

———

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

PTO/SB/08A (04-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number / Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	579	US- 4,648,393	3/10/1987	Landis et al.	
		US-			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document / Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*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. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] 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 37 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, 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 (1-800-786-9199) and select option 2.

Electronic Acknowledgement Receipt

EFS ID:	25583557
Application Number:	14925968
International Application Number:	
Confirmation Number:	2707
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Customer Number:	66854
Filer:	Kathleen R. Kelleher/Brian Flick
Filer Authorized By:	Kathleen R. Kelleher
Attorney Docket Number:	13211-713.303
Receipt Date:	25-APR-2016
Filing Date:	28-OCT-2015
Time Stamp:	12:43:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		13211-713-303_IDS_Filing_4-25-2016.pdf	272362 bee2683fa11dca624f97df95db9ce37b0c0511cc	yes	4

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Transmittal Letter	1	3
	Information Disclosure Statement (IDS) Form (SB08)	4	4
Warnings:			
Information:			
	Total Files Size (in bytes):	272362	

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.

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on 4-25-2016.

Brian Flak
Name

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 14/925,968	Confirmation No.: 2707
First Named Inventor	: Adam Bowen	
Filed	: October 28, 2015	
Art Unit	: 1747	
Examiner	: Mayes, Dionne Walls	
Title	: NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF	
Customer No.	: 66854	

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☐ **37 CFR §1.97(b)**
This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:
- ☐ **1).** Within 3 months of the application filing date, or
- ☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or
- ☐ **3).** Before the mail date of a first Office Action on the merits, or
  - ☐ **3a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below
- ☐ **4).** Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.
  - ☐ **4a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below

☒ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☒ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☐ **A).** A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

or

☒ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under §1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☒ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☒ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☐ **3).** Items identified by a double asterisk (**) on the SB08A are *commonly-owned U.S. patents and U.S. patent application publications.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), *Commonly-owned, unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s), and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **3).** A copy of each application specification is not submitted because the application is stored in the IFW. Cite no(s):

Applicant(s) assume the Examiner has access to the file histories of these items. However, if the Examiner would like to receive copies of Office Actions in any of the commonly-owned applications, publications and/or patents identified on the attached SB08, please inform the undersigned and copies will be provided.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☐ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and 609.04(a)III, Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** An English language abstract or an English language copy of a foreign search report or other action by a foreign patent office is provided herewith to fulfill the requirement for a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language: Cite no(s):

--AND/OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached: Cite no(s):

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

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

STATEMENT UNDER 37 CFR § 1.704(d)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 4/25/16

By: _____
Kathleen R. Kelleher, Reg. No. 62,230

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

PTO/SB/08A (04-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	581	US- 2015/0128967	5/14/2015	Robinson et al.	
		US-			
		US-			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*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. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] 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 37 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, 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 (1-800-786-9199) and select option 2.

Electronic Acknowledgement Receipt

EFS ID:	25762843
Application Number:	14925968
International Application Number:	
Confirmation Number:	2707
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Customer Number:	66854
Filer:	Kathleen R. Kelleher/Brian Flick
Filer Authorized By:	Kathleen R. Kelleher
Attorney Docket Number:	13211-713.303
Receipt Date:	12-MAY-2016
Filing Date:	28-OCT-2015
Time Stamp:	15:52:01
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		13211-713-303_IDS_Filing_5-12-2016.pdf	271221 f5873d971498ec862ff4262dafec35d259f9ded1	yes	4

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Transmittal Letter	1	3
	Information Disclosure Statement (IDS) Form (SB08)	4	4
Warnings:			
Information:			
	Total Files Size (in bytes):	271221	

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.

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on 5-12-2016.

Brian Tick
Name

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 14/925,968	Confirmation No.: 2707
First Named Inventor	: Adam Bowen	
Filed	: October 28, 2015	
Art Unit	: 1747	
Examiner	: Mayes, Dionne Walls	
Title	: NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF	
Customer No.	: 66854	

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☐ **37 CFR §1.97(b)**
This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:
- ☐ **1).** Within 3 months of the application filing date, or
- ☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or
- ☐ **3).** Before the mail date of a first Office Action on the merits, or
  - ☐ **3a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below
- ☐ **4).** Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.
  - ☐ **4a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below

☒ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☒ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☐ **A).** A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

or

☒ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under §1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☒ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☒ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☐ **3).** Items identified by a double asterisk (**) on the SB08A are *commonly-owned U.S. patents and U.S. patent application publications.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), *Commonly-owned, unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s), and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **3).** A copy of each application specification is not submitted because the application is stored in the IFW. Cite no(s):

Applicant(s) assume the Examiner has access to the file histories of these items. However, if the Examiner would like to receive copies of Office Actions in any of the commonly-owned applications, publications and/or patents identified on the attached SB08, please inform the undersigned and copies will be provided.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☐ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and 609.04(a)III, Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** An English language abstract or an English language copy of a foreign search report or other action by a foreign patent office is provided herewith to fulfill the requirement for a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language: Cite no(s):

--AND/OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached: Cite no(s):

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

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

STATEMENT UNDER 37 CFR § 1.704(d)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 5/12/16

By: _____
Kathleen R. Kelleher, Reg. No. 62,230

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/925,968	10/28/2015	Adam BOWEN	13211-713.303	2707

66854 7590 05/13/2016

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

EXAMINER	
MAYES, DIONNE WALLS	

ART UNIT	PAPER NUMBER
1747	

NOTIFICATION DATE	DELIVERY MODE
05/13/2016	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):

info@shayglenn.com

PTOL-90A (Rev. 04/07)

Office Action Summary	Application No. 14/925,968	Applicant(s) BOWEN ET AL.	
	Examiner DIONNE WALLS MAYES	Art Unit 1747	AIA (First Inventor to File) Status Yes

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/16/2016*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-4,6-10,12-18 and 20* is/are pending in the application.

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

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-4,6-10,12-18 and 20* is/are rejected.

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

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Claim Rejections - 35 USC § 112

2. 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.

3. Claims 2, 8 and 15 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Each of the above-recited claims recite the phrase “organic acid”; however, because of the amendments to the claims, filed on March 16, 2016, there is now insufficient antecedent basis for this limitation in the claims.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least

one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

5. Claims 1-4, 6-10 and 12 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-15 of Bowen '895 (U.S. Patent No. 9,215,895) in view of Griffith, Jr. et al (US. Pat. App. Pub. 2013/0255702).

Regarding the instant independent claim 1, the Bowen '895 patent claims recites a method of delivering nicotine to a user comprising deploying an electronic cigarette comprising a nicotine formulation which comprises nicotine, an acid and a biologically acceptable carrier, wherein inhalation of the aerosol is formed by heating the nicotine formulation and inhaling it into the user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma T_{max} from about 3 min to about 8 min. Bowen '895 fails, however, to recite that the electronic cigarette is a "low-temperature" one which operates by heating the nicotine formulation to between about 100-300 degrees C, wherein the nicotine formulation comprises nicotine in combination with the specific acid of lactic acid and the specific biologically acceptable carrier of propylene glycol and 90%-30% glycerol. However, the Griffith, Jr. et al reference teaches a low temperature electronic cigarette operating at the claimed temperature ranges to heat a nicotine formulation which also includes lactic acid, and a glycerin/90-30% glycerol solution (see paras.[0014],[0019],[0086]-[0088]). Hence, it would have been obvious to one having ordinary skill in the art to have included the nicotine formulation of Griffith, Jr. et al, operating at the designated temperatures, in the device of Bowen '895 as such is already known in the art.

Regarding claim 2, Griffith, Jr. et al discloses that its nicotine formulation can include about 0.5 moles of lactic acid per one mole of nicotine (see para. [0086]), so it

would have been obvious to one having ordinary skill in the art to have chosen this molar ratio for the Bowen '895 nicotine formulation.

Regarding claim 3, it would have been obvious to one having ordinary skill in the art to have added a flavorant to the modified nicotine formulation in order to enhance the organoleptic quality of the same for the benefit of the user.

Regarding claim 4, independent claim 1 of Bowen '925 recites a nicotine concentration of between 2% to 6% (w/w).

Regarding claim 6, independent claim 1, Bowen '925 recites a nicotine formulation that generates an aerosol comprising particles sizes from about 0.1 microns to about 5 microns.

Regarding the instant independent claim 7, the Bowen '895 patent claims recites a method of delivering nicotine to a user comprising deploying an electronic cigarette comprising a nicotine formulation which comprises nicotine, an acid and a biologically acceptable carrier, wherein inhalation of the aerosol is formed by heating the nicotine formulation and inhaling it into the user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma T_{max} from about 3 min to about 8 min. The nicotine may not be disclosed as being "protonated", but given that it is provided in a carrier with lactic acid, it follows that a nicotine salt (i.e., nicotine lactate) would be formed, thus rendering the nicotine "protonated". Further, it fails, however, to recite that the electronic cigarette is a "low-temperature" one which operates by heating the nicotine formulation to between about 100-300 degrees C, wherein the nicotine formulation comprises nicotine in combination with the specific acid

of lactic acid and the specific biologically acceptable carrier of propylene glycol and 90%-30% glycerol. However, the Griffith, Jr. et al reference teaches a low temperature electronic cigarette operating at the claimed temperature ranges to heat a nicotine formulation which also includes lactic acid, and a glycerin/90-30% glycerol solution (see paras.[0014],[0019],[0086]-[0088]). Hence, it would have been obvious to one having ordinary skill in the art to have included the nicotine formulation of Griffith, Jr. et al, operating at the designated temperatures, in the device of Bowen '895 as such is already known in the art.

Regarding claim 8, Griffith, Jr. et al discloses that its nicotine formulation can include about 0.5 moles of lactic acid per one mole of nicotine (see para. [0086]), so it would have been obvious to one having ordinary skill in the art to have chosen this molar ratio for the Bowen '895 nicotine formulation.

Regarding claim 9, it would have been obvious to one having ordinary skill in the art to have added a flavorant to the modified nicotine formulation in order to enhance the organoleptic quality of the same for the benefit of the user.

Regarding claim 10, independent claim 1 of Bowen '925 recites a nicotine concentration of between 2% to 6% (w/w).

Regarding claim 12, independent claim 1, Bowen '925 recites a nicotine formulation that generates an aerosol comprising particles sizes from about 0.1 microns to about 5 microns.

Claim Rejections - 35 USC § 103

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

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102 of this title, 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.

7. 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.

8. 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.

9. Claims 1-4, 6-10, 12-18 and 20 are rejected under 35 U.S.C. 103 as being unpatentable over Griffith, Jr. et al (US. Pat. App. Pub. 2013/0255702) - as evidenced

by www.e-cigarette-forum.com's PG-VG-PEG Discussion Posting (hereinafter referred to as "the PG-VG-PEG Internet Posting") - in view of Gonda (US. Pat. No. 2014/0261474) and Bowen '717 et al (US. Pat. App. Pub. 2009/0151717).

Regarding independent claim 1, Griffith, Jr. et al discloses an aerosol delivery article, and its use, for yielding materials in an inhalable form. Specifically, Griffith, Jr. et al discloses the oral delivery of inhalable materials comprising a resistive heating element formed of a substrate wherein an electrically conductive material is integrally formed with a carrier material that can be coated or impregnated with materials that can be aerosolized for inhalation, i.e. aerosol precursor material. The aerosol precursor can comprise any materials that are volatilizable at the disclosed working temperatures (ranging from 50-300 degrees C), an example of which is 75-80% by weight glycerol (Note: "The PG-VG-PEG Internet Posting" serves as evidence that the terms "glycerol" and "vegetable glycerol/glycerin" are synonymous), 1-10% by weight propylene glycol, 2-3% by weight nicotine and 0.1-0.5% by weight of one or more flavors. Griffith, Jr. et al also discloses that an organic acid (such as lactic acid) can be added as the "flavor" in said aerosol precursor (see paras.[0009], [0014],[0019],[0086]-[0088])(corresponding to the claimed "A method of delivering nicotine to a user comprising: deploying a low-temperature vaporizer comprising a nicotine formulation that comprises nicotine, lactic acid, and a biologically acceptable liquid carrier, wherein: a. the nicotine concentration is from about 0.5% (w/w) to about 20% (w/w); b. the biologically acceptable liquid carrier comprises propylene glycol and 90%-30% vegetable glycerol; and c. operation of the

low-temperature vaporizer comprises heating at least a portion of the nicotine formulation to generate an inhalable aerosol between about 100°C and about 300°C").

Griffith, Jr. et al is silent as to the peak amount and timeframe of nicotine delivery into a user's bloodstream upon inhalation of its aerosolized materials. However, the Gonda reference teaches that administering an aerosolized, liquid nicotine-containing formulation via inhalation (i.e., pulmonary administration) in order to effectuate a peak level of nicotine in the blood plasma after a very short period of time - mimicking that which is typically achieved during actual cigarette smoking - can be accomplished. Specifically, Gonda teaches that a nicotine formulation in solution, can be prepared so as to be inhaled to emulate the effects of smoking wherein the aerosol is delivered in a relatively small volume at the beginning of a puff and a low puff rate to enhance deposition and rapid absorption in the lungs which results in rapid delivery of nicotine. (see paras. [0043], [0052], [0064], [0067], [0078], [0091]-[0092]). Also, Gonda states that adjustments in pH, in combination with changing the particle size of the aerosol, can be carried out to create a different experience for the user. For example, by decreasing the pH of the nicotine formulation, the likelihood of airway irritation and cough is reduced, and/or by decreasing the particle size of the inhaled material, the aerosolized particles of nicotine will deposit deeper in the lungs, which increases the rate of absorption of the nicotine and leads to an increase in peak nicotine plasma levels (see para. [0007],[0033]-[0036], [0052], [0064], [0086]). Further, Gonda states that, during inhalation of aerosolized nicotine formulations, a satisfactory dose of nicotine is achieved in a small number of breaths, spaced by short periods, preferably

less than 2 minutes (see para. [0017]). (Note: To this point, the Bowen '717 et al reference further discloses that, typically, when smokers "puff" on cigarettes they may take a puff every 30 seconds (i.e., in an intense smoking regime. Bowen '717 et al then shows that aerosol devices used to inhale a nicotine substance can also be "smoked" in such manner (see para. [0107])). The afore-mentioned *collective* disclosure indicates that the parameters of pH, aerosolized nicotine particle size, nicotine concentration in the liquid formulation and even inhalation rate, are all "result-effective variables". Once a particular parameter is recognized as a result-effective variable, i.e., a variable which achieves a recognized result, the determination of the optimum or workable ranges of said variable can be characterized by routine experimentation. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) MPEP 2144.05. Hence, it would have been obvious to one having ordinary skill in the art at the time of the invention to have undergone routine experimentation and fabricated the nicotine formulation of Griffith, Jr. et al in the form of a liquid nicotine solution and, in so doing, arrived at the claimed inhalation rate which result in the claimed T_{max} parameters, after determining that these values provided, as close as possible, the same nicotine blood levels achieved by smoking a conventional cigarette. Hence, it would have been obvious to one having ordinary skill in the art to have operated the device of Griffith, Jr. et al such that it delivers nicotine to a user per the teachings of Gonda in order to achieve the benefits described above (corresponding to the claimed "wherein inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma T_{max} from about 3 minutes to about 8 min and

further wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength").

Regarding claim 2, Griffith, Jr. et al discloses that its aerosol precursor can include about 0.5 moles of lactic acid per one mole of nicotine (see para. [0086])(corresponding to the claimed "wherein a molar ratio of nicotine to organic acid is between about 1:1 and 1:3")

Regarding claim 3, Griffith, Jr. et al discloses that its aerosol precursor material can be combined with more than one flavorant (see para. [0049])(corresponding to the claimed "wherein the nicotine formulation further comprises at least one flavorant").

Regarding claim 4, Griffith, Jr. et al discloses that a specific non-limiting example of the nicotine content in its aerosol precursor may be about 2-3% by weight (see para. [00888]). However, it would have been obvious to one having ordinary skill in the art to have adjusted this amount to be a bit higher - corresponding to the claimed amount - in order to satisfy the particular organoleptic preferences of the user (corresponding to the claimed "wherein the nicotine concentration is about 4.5%").

Regarding claim 6, based on the disclosure of Gonda, as discussed above, that by decreasing the particle size, the aerosolized particles of nicotine will deposit deeper in the lungs, which increases the rate of absorption of the nicotine and leads to an increase in peak nicotine plasma levels, it would have been obvious to one having ordinary skill in the art to have optimized the particle size of its aerosol to fall between 0.1 - 5 microns (Corresponding to the claimed "wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns").

Regarding independent claim 7, Griffith, Jr. et al discloses an aerosol delivery article, and its use, for yielding materials in an inhalable form. Specifically, Griffith, Jr. et al discloses the oral delivery of inhalable materials comprising a resistive heating element formed of a substrate wherein an electrically conductive material is integrally formed with a carrier material that can be coated or impregnated with materials that can be aerosolized for inhalation, i.e. aerosol precursor material. The aerosol precursor can comprise any materials that are volatilizable at the disclosed working temperatures (ranging from 50-300 degrees C), an example of which is 75-80% by weight glycerol, 1-10% by weight propylene glycol, 2-3% by weight nicotine and 0.1-0.5% by weight of one or more flavors. Griffith, Jr. et al also discloses that an organic acid (such as lactic acid) can be added as the "flavor" in said aerosol precursor (Note: The nicotine of Griffith, Jr. et al may not be disclosed as being "protonated", but given that it is provided in a carrier with lactic acid, it is reasonable to presume that a nicotine salt (i.e., nicotine lactate) would be formed in the solution, thus rendering the nicotine "protonated")(see paras.[0009], [0014],[0019],[0086]-[0088])(corresponding to the claimed "A method of delivering nicotine to a user comprising: deploying a low-temperature vaporizer comprising a nicotine formulation that comprises nicotine, lactic acid, and a biologically acceptable liquid carrier, wherein: a. the nicotine concentration is from about 0.5% (w/w) to about 20% (w/w); b. the nicotine formulation comprises protonated nicotine; c. the biologically acceptable liquid carrier comprises propylene glycol and 90%-30% vegetable glycerol; d. the lactic acid does not decompose at room temperature and does not decompose at the operating temperature of the low temperature vaporizer;

and e. operation of the low-temperature vaporizer comprises heating at least a portion of the nicotine formulation between about 100°C and about 300°C to generate an inhalable aerosol").

Griffith, Jr. et al is silent as to the peak amount and timeframe of nicotine delivery into a user's bloodstream upon inhalation of its aerosolized materials. However, the Gonda reference teaches that administering an aerosolized, liquid nicotine-containing formulation via inhalation (i.e., pulmonary administration) in order to effectuate a peak level of nicotine in the blood plasma after a very short period of time - mimicking that which is typically achieved during actual cigarette smoking - can be accomplished. Specifically, Gonda teaches that a nicotine formulation in solution, can be prepared so as to be inhaled to emulate the effects of smoking wherein the aerosol is delivered in a relatively small volume at the beginning of a puff and a low puff rate to enhance deposition and rapid absorption in the lungs which results in rapid delivery of nicotine. (see paras. [0043], [0052], [0064], [0067], [0078], [0091]-[0092]). Also, Gonda states that adjustments in pH, in combination with changing the particle size of the aerosol, can be carried out to create a different experience for the user. By decreasing the pH of the nicotine formulation, the likelihood of airway irritation and cough is reduced. By decreasing the particle size of the inhaled material, the aerosolized particles of nicotine will deposit deeper in the lungs, which increases the rate of absorption of the nicotine and leads to an increase in peak nicotine plasma levels (see para. [0007],[0033]-[0036], [0052], [0064], [0086]). Further, Gonda states that, during inhalation of aerosolized nicotine formulations, a satisfactory dose of nicotine is achieved in a small number of

breaths, spaced by short periods, preferably less than 2 minutes (see para. [0017]). (Note: To this point, the Bowen '717 et al reference further discloses that, typically, when smokers "puff" on cigarettes they may take a puff every 30 seconds (i.e., in an intense smoking regime. Bowen '717 et al then shows that aerosol devices used to inhale a nicotine substance can also be "smoked" in such manner (see para. [0107])). The afore-mentioned *collective* disclosure indicates that the parameters of pH, aerosolized nicotine particle size, nicotine concentration in the liquid formulation and even inhalation rate, are all "result-effective variables". Once a particular parameter is recognized as a result-effective variable, i.e., a variable which achieves a recognized result, the determination of the optimum or workable ranges of said variable can be characterized by routine experimentation. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) MPEP 2144.05. Hence, it would have been obvious to one having ordinary skill in the art at the time of the invention to have undergone routine experimentation and fabricated the nicotine formulation of Griffith, Jr. et al in the form of a liquid nicotine solution and, in so doing, arrived at the claimed inhalation rate which result in the claimed T_{max} parameters, after determining that these values provided, as close as possible, the same nicotine blood levels achieved by smoking a conventional cigarette. Hence, it would have been obvious to one having ordinary skill in the art to have operated the device of Griffith, Jr. et al such that it delivers nicotine to a user per the teachings of Gonda in order to achieve the benefits described above (corresponding to the claimed "wherein inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine

plasma T_{max} from about 3 minutes to about 8 min and further wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength").

Regarding claim 8, Griffith, Jr. et al discloses that its aerosol precursor can include about 0.5 moles of lactic acid per one mole of nicotine (see para. [0086])(corresponding to the claimed "wherein a molar ratio of nicotine to organic acid is between about 1:1 and 1:3")

Regarding claim 9, Griffith, Jr. et al discloses that its aerosol precursor material can be combined with more than one flavorant (see para. [0049])(corresponding to the claimed "wherein the nicotine formulation further comprises at least one flavorant").

Regarding claim 10, Griffith, Jr. et al discloses that a specific non-limiting example of the nicotine content in its aerosol precursor may be about 2-3% by weight (see para. [00888]). However, it would have been obvious to one having ordinary skill in the art to have adjusted this amount to be a bit higher - corresponding to the claimed amount - in order to satisfy the particular organoleptic preferences of the user (corresponding to the claimed "wherein the nicotine concentration is about 4.5%").

Regarding claim 12, based on the disclosure of Gonda, as discussed above, that by decreasing the particle size, the aerosolized particles of nicotine will deposit deeper in the lungs, which increases the rate of absorption of the nicotine and leads to an increase in peak nicotine plasma levels, it would have been obvious to one having ordinary skill in the art to have optimized the particle size of its aerosol to fall between 0.1 - 5 microns (Corresponding to the claimed "wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns").

Regarding independent claim 13, Griffith, Jr. et al discloses an aerosol delivery article (10) for yielding materials in an inhalable form having a mouth-end (11) with an opening (18) to allow for withdrawal of an aerosol, from an inside cavity, which has been vaporized by a resistive heating element (50) that heats an aerosol precursor material loaded on a substrate (53). The aerosol precursor can comprise any materials that are volatilizable at the disclosed working temperatures (ranging from 50-300 degrees C), an example of which is 75-80% by weight glycerol, 1-10% by weight propylene glycol, 2-3% by weight nicotine and 0.1-0.5% by weight of one or more flavors. Griffith, Jr. et al also discloses that an organic acid (such as lactic acid) can be added as the "flavor" in said aerosol precursor (Note: The nicotine of Griffith, Jr. et al may not be disclosed as also being in the form of its salt "nicotine lactate", but given that it is provided in a carrier with lactic acid, it is reasonable to presume that the nicotine salt (i.e., nicotine lactate) would be formed in the solution (see paras.[0009], [0014],[0019],[0086]-[0088],[0137])(corresponding to the claimed "A low-temperature vaporizer comprising a liquid reservoir; a nicotine formulation within the liquid reservoir, the nicotine formulation comprising: nicotine lactate; propylene glycol; and 90%-30% vegetable glycerol; wherein the concentration of nicotine in the nicotine formulation is from about 0.5% (w/w) to about 20%(w/w); a vaporizing component configured to produce an aerosol from the nicotine formulation by heating at least a portion of the nicotine formulation between 100 degrees C and 300 degrees C; and a mouthpiece configured to connect to the reservoir for inhalation of the aerosol").

Griffith, Jr. et al is silent as to the peak amount and timeframe of nicotine delivery into a user's bloodstream upon inhalation of its aerosolized materials. However, the Gonda reference teaches that administering an aerosolized, liquid nicotine-containing formulation via inhalation (i.e., pulmonary administration) in order to effectuate a peak level of nicotine in the blood plasma after a very short period of time - mimicking that which is typically achieved during actual cigarette smoking - can be accomplished. Specifically, Gonda teaches that a nicotine formulation in solution, can be prepared so as to be inhaled to emulate the effects of smoking wherein the aerosol is delivered in a relatively small volume at the beginning of a puff and a low puff rate to enhance deposition and rapid absorption in the lungs which results in rapid delivery of nicotine. (see paras. [0043], [0052], [0064], [0067], [0078], [0091]-[0092]). Also, Gonda states that adjustments in pH, in combination with changing the particle size of the aerosol, can be carried out to create a different experience for the user. By decreasing the pH of the nicotine formulation, the likelihood of airway irritation and cough is reduced. By decreasing the particle size of the inhaled material, the aerosolized particles of nicotine will deposit deeper in the lungs, which increases the rate of absorption of the nicotine and leads to an increase in peak nicotine plasma levels (see para. [0007],[0033]-[0036], [0052], [0064], [0086]). Further, Gonda states that, during inhalation of aerosolized nicotine formulations, a satisfactory dose of nicotine is achieved in a small number of breaths, spaced by short periods, preferably less than 2 minutes (see para. [0017]). (Note: To this point, the Bowen ‘717 et al reference further discloses that, typically, when smokers “puff” on cigarettes they may take a puff every 30 seconds (i.e., in an

intense smoking regime. Bowen '717 et al then shows that aerosol devices used to inhale a nicotine substance can also be "smoked" in such manner (see para. [0107])). The afore-mentioned *collective* disclosure indicates that the parameters of pH, aerosolized nicotine particle size, nicotine concentration in the liquid formulation and even inhalation rate, are all "result-effective variables". Once a particular parameter is recognized as a result-effective variable, i.e., a variable which achieves a recognized result, the determination of the optimum or workable ranges of said variable can be characterized by routine experimentation. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) MPEP 2144.05. Hence, it would have been obvious to one having ordinary skill in the art at the time of the invention to have undergone routine experimentation and fabricated the nicotine formulation of Griffith, Jr. et al in the form of a liquid nicotine solution and, in so doing, arrived at the claimed inhalation rate which result in the claimed T_{max} parameters, after determining that these values provided, as close as possible, the same nicotine blood levels achieved by smoking a conventional cigarette. Hence, it would have been obvious to one having ordinary skill in the art to have operated the device of Griffith, Jr. et al such that it delivers nicotine to a user per the teachings of Gonda in order to achieve the benefits described above (corresponding to the claimed "wherein inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma T_{max} from about 3 minutes to about 8 min and further wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength").

Regarding claim 14, the aerosol delivery article of Griffith, Jr. et al may include a battery (40)(see Fig. 1, para. [0134])(corresponding to the claimed "further comprises a battery configured to provide power to the vaporizing component").

Regarding claim 15, Griffith, Jr. et al discloses that its aerosol precursor can include about 0.5 moles of lactic acid per one mole of nicotine (see para. [0086])(corresponding to the claimed "wherein a molar ratio of nicotine to organic acid is between about 1:1 and 1:3")

Regarding claim 16, Griffith, Jr. et al discloses that its aerosol precursor material can be combined with more than one flavorant (see para. [0049])(corresponding to the claimed "wherein the nicotine formulation further comprises at least one flavorant").

Regarding claim 17, as stated above, Griffith, Jr. et al discloses that the aerosol, from an inside cavity, is vaporized by a resistive heating element (50) that heats the nicotine-containing aerosol precursor material located on a substrate (53)(see para. [0137])(corresponding to the claimed "wherein the vaporizing component comprises a heating element in fluid communication with the nicotine formulation").

Regarding claim 18, Griffith, Jr. et al discloses that a specific non-limiting example of the nicotine content in its aerosol precursor may be about 2-3% by weight (see para. [00888]). However, it would have been obvious to one having ordinary skill in the art to have adjusted this amount to be a bit higher - corresponding to the claimed amount - in order to satisfy the particular organoleptic preferences of the user (corresponding to the claimed "wherein the nicotine concentration is about 4.5%").

Regarding claim 20, based on the disclosure of Gonda, as discussed above, that by decreasing the particle size, the aerosolized particles of nicotine will deposit deeper in the lungs, which increases the rate of absorption of the nicotine and leads to an increase in peak nicotine plasma levels, it would have been obvious to one having ordinary skill in the art to have optimized the particle size of its aerosol to fall between 0.1 - 5 microns (Corresponding to the claimed "wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns").

Response to Arguments

10. Applicant's arguments with respect to the claims have been considered but are moot in view of the new grounds for rejection, presented above, involving a new combination of prior art references, which were necessitated because of the amendments made to the claims, filed on March 16, 2016.

Conclusion

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

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

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

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIONNE WALLS MAYES whose telephone number is (571)272-5836. The examiner can normally be reached on Tuesday and Thursday, 8:00A - 6:30P EST.

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.

/DIONNE WALLS MAYES/
Examiner, Art Unit 1747

/MICHAEL H WILSON/
Supervisory Patent Examiner, Art Unit 1747

Notice of References Cited	Application/Control No. 14/925,968	Applicant(s)/Patent Under Reexamination BOWEN ET AL.	
	Examiner DIONNE WALLS MAYES	Art Unit 1747	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-2013/0255702 A1	10-2013	Griffith, Jr. et al.	A24F47/008	131/328
	B	US-				
	C	US-				
	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	E-Cigarette Forum - PG-VG-PEG Discussion Posting - https://www.e-cigarette-forum.com/forum/threads/pg-vg-peg.177551/, dated April 8, 2011.
	V	
	W	
	X	

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

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14925968	BOWEN ET AL.
	Examiner	Art Unit
	DIONNE W MAYES	1747

CPC- SEARCHED		
Symbol	Date	Examiner
a24f47/00; a24f47/008	4/27/2016	DWM

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Search conducted (see attached search strategy)	12/10/2015	DWM
Inventor search conducted	12/10/2015	DWM
EAST Search conducted (see attached search strategy)	4/27/2016	DWM
Inventor search updated	4/27/2016	DWM

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 20

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number / Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	US- 374,584	12/13/1887	Cook	
	2	US- 576,653	2/9/1897	Bowlby	
	3	US- 595,070	12/7/1897	Oldenbusch	
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	6	US- 968,160	8/23/1910	Johnson	
	7	US- 969,076	8/30/1910	Pender	
	8	US- 1,067,531	7/15/1913	MacGregor	
	9	US- 1,163,183	12/7/1915	Stoll	
	10	US- 1,299,162	4/1/1919	Fisher	
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	12	US- 1,552,877	9/8/1925	Phillipps et al.	
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	14	US- 1,706,244	3/19/1929	Louis	
	15	US- 1,845,340	2/16/1932	Ritz	
	16	US- 1,972,118	9/4/1934	McDill	
	17	US- 1,998,683	4/23/1935	Montgomery	
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	374	CA2641869A1	5/6/2010	Xia, Hao Ran		
	375	CN101869356A(w/EngTrans)	10/27/2010	Liu Zheqi		
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Examiner Signature	/Dionne Walls Mayes/	Date Considered	03/31/2016

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 20

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

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	21	US- 2,231,909	2/18/1941	Hempel	
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	32	US- 3,258,015	6/28/1966	Drummond et al.	
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	380	DE19854012A1(w/EngTrans)	5/18/2000	Reemtsma Gmbh		
	381	DE4200639A1(w/EngEquiv)	7/23/1992	Brown & Williamson Tob.		
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	383	EP0535695A2	4/7/1993	Phillips Petroleum Co		
	384	EP1458388A(asWO03/055486)	9/22/2004	McNeil AB		
	385	EP2325093B1	6/20/2012	Imperial Tobacco Ltd		

Examiner Signature	/Dionne Walls Mayes/	Date Considered	03/31/2016

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 20

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

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	39	US- 3,792,704	2/19/1974	Parker	
	40	US- 3,861,523	1/21/1975	Fountain et al.	
	41	US- 3,941,300	3/2/1976	Troth	
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	43	US- 4,049,005	9/20/1977	Hernandez et al.	
	44	US- 4,066,088	1/3/1978	Ensor	
	45	US- 4,207,976	6/17/1980	Herman	
	46	US- 4,215,708	8/5/1980	Bron	
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	50	US- 4,595,024	6/17/1986	Greene et al.	
	51	US- 4,708,151	11/24/1987	Shelar	
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	386	EP2609821A1	7/3/2013	Philip Morris Prod S.A		
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	392	GB1065678A	4/19/1967	Super Temp Corp		
	393	IE-S2005-0051	2/2/2005	Oglesby & Butler R&D Ltd		
	394	IE-S2005-0563	8/24/2005	Oglesby & Butler R&D Ltd		

Examiner Signature	/Dionne Walls Mayes/	Date Considered	03/31/2016

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 20

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

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	58	US- 4,819,665	4/11/1989	Roberts et al.	
	59	US- 4,830,028	5/16/1989	Lawson et al.	
	60	US- 4,836,224	6/6/1989	Lawson et al.	
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	64	US- 4,893,639	1/16/1990	White	
	65	US- 4,907,606	3/13/1990	Lilja et al.	
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	71	US- 5,020,548	6/4/1991	Farrier et al.	
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	395	IE-S2005-0615	9/19/2005	Oglesby & Butler R&D Ltd		
	396	JP02-145179A(w/EngEquiv)	6/4/1990	Hercules Inc		
	397	JP03-049671(w/EngEquiv)	3/4/1991	Brown & Williamson Tob.		
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	400	JP11-178563(w/EngAbs)	7/6/1999	Japan Tobacco Inc		

Examiner Signature	/Dionne Walls Mayes/	Date Considered	03/31/2016

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Sheet 5 of 20

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Art Unit	1747
Examiner Name	Mayes, Dionne Walls
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	77	US- 5,105,831	4/21/1992	Banerjee et al.	
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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	401	JP2000-203639(w/EngAbs)	7/25/2000	S & B Foods Inc		
	402	JP2000-236865A(w/EngAbs)	9/5/2000	Seiko Kogyo KK		
	403	JP2001-165437A(wEngAbs)	6/22/2001	Tsubota Pearl Co Ltd		
	404	JP2005-034021A(w/EngCorres)	2/10/2005	Seiko Epson Corp		
	405	JP2006-504430A(w/EngEquiv)	2/9/2006	R J Reynolds Tobacco Co		
	406	JP62-278975(w/EngAbs)	12/3/1987	Watabe, Isamu		

Examiner Signature	/Dionne Walls Mayes/	Date Considered	03/31/2016

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 6 of 20

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	96	US- 5,666,978	9/16/1997	Counts et al.	
	97	US- 5,708,258	1/13/1998	Counts et al.	
	98	US- 5,730,118	3/24/1998	Hermanson	
	99	US- 5,730,158	3/24/1998	Collins et al.	
	100	US- 5,746,587	5/5/1998	Racine et al.	
	101	US- 5,810,164	9/22/1998	Rennecamp	
	102	US- 5,819,756	10/13/1998	Mielordt	
	103	US- 5,845,649	12/8/1998	Saito et al.	
	104	US- 5,865,185	2/2/1999	Collins et al.	
	105	US- 5,881,884	3/16/1999	Podosek	
	106	US- 5,931,828	8/3/1999	Durkee	
	107	US- 5,934,289	8/10/1999	Watkins et al.	
	108	US- 5,938,018	8/17/1999	Keaveney et al.	
	109	US- 5,944,025	8/31/1999	Cook et al.	
	110	US- 5,954,979	9/21/1999	Counts et al.	
	111	US- 5,967,310	10/19/1999	Hill	
	112	US- 5,975,415	11/2/1999	Zehnal	
	113	US- 5,979,460	11/9/1999	Matsumura	
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	407	JP64-37276A(w/EngEquiv)	2/7/1989	R J Reynolds Tobacco Co		
	408	KR0193885B1(w/EngEquiv)	6/15/1999	Philip Morris Prod Inc		
	409	WO95/01137A1	1/12/1995	Voges Innovation Pty Ltd.		
	410	WO97/12639A1	4/10/1997	Slutsky, Arthur		
	411	WO00/28842A1(EngAbs)	5/25/2000	Reemtsma Gmbh		
	412	WO03/056948A1(EngAbs)	7/17/2003	Japan Tobacco Inc.		

Examiner Signature	/Dionne Walls Mayes/	Date Considered	03/31/2016

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 7 of 20

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

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	115	US- 5,996,589	12/7/1999	St. Charles	
	116	US- 6,053,176	4/25/2000	Adams et al.	
	118	US- 6,095,153	8/1/2000	Kessler et al.	
	119	US- 6,102,036	8/15/2000	Slutsky et al.	
	120	US- 6,125,853	10/3/2000	Susa et al.	
	121	US- 6,155,268	12/5/2000	Takeuchi	
	122	US- 6,164,287	12/26/2000	White	
	123	US- 6,234,169	5/22/2001	Bulbrook et al.	
	124	US- 6,269,966	8/7/2001	Pallo et al.	
	125	US- 6,349,728	2/26/2002	Pham	
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	127	US- 6,386,371	5/14/2002	Parsons	
	128	US- 6,431,363	8/13/2002	Hacker	
	129	US- 6,446,793	9/10/2002	Layshock	
	130	US- 6,510,982	1/28/2003	White et al.	
	131	US- 6,532,965	3/18/2003	Abhulimen et al.	
	132	US- 6,536,442	3/25/2003	St. Charles et al.	
	133	US- 6,557,708	5/6/2003	Polacco	
	134	US- 6,598,607	7/29/2003	Adiga et al.	

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	413	WO03/082031A1	10/9/2003	Steinberg, Dan A.		
	414	WO03/094900A1	11/20/2003	Alexza Molecular Delivery		
	415	WO2004/064548A1	8/5/2004	Netzer, Omry		
	417	WO2005/020726A1	3/10/2005	Lee, Seunghyun		
	418	WO2006/015070A1	2/9/2006	Brown & Williamson Tob.		
	419	WO2007/026131A1	3/8/2007	Acetate Products Ltd		

Examiner Signature	/Dionne Walls Mayes/	Date Considered	03/31/2016

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 8 of 20

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

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	135	US- 6,606,998	8/19/2003	Gold	
	136	US- 6,615,840	9/9/2003	Fournier et al.	
	137	US- 6,622,867	9/23/2003	Menceles	
	138	US- 6,655,379	12/2/2003	Clark et al.	
	139	US- 6,672,762	1/6/2004	Faircloth et al.	
	140	US- 6,688,313	2/10/2004	Wrenn et al.	
	141	US- 6,726,006	4/27/2004	Funderburk et al.	
	142	US- 6,772,756	8/10/2004	Shayan	
	143	US- 6,799,576	10/5/2004	Farr	
	144	US- 6,803,545	10/12/2004	Blake et al.	
	145	US- 6,805,545	10/19/2004	Slaboden	
	146	US- 6,810,883	11/2/2004	Felter et al.	
	147	US- 6,827,573	12/7/2004	St. Charles et al.	
	148	US- 6,954,979	10/18/2005	Logan	
	149	US- 7,000,775	2/21/2006	Gelardi et al.	
	151	US- 7,488,171	2/10/2009	St. Charles et al.	
	152	US- 7,546,703	6/16/2009	Johnske et al.	
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	154	US- 7,644,823	1/12/2010	Gelardi et al.	

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	421	WO2010/023561A1	3/4/2010	Actavis Group Ptc		
	422	WO2011/033396A2	3/24/2011	Minilogic Device Corp Ltd		
	423	WO2011/117580A2	9/29/2011	Kind Consumer Ltd		
	424	WO2012/021972A1	2/23/2012	Cogestor Inc.		
	425	WO2012/027350A2	3/1/2012	Alelov, Eli		
	426	WO2012/085207A1	6/28/2012	Philip Morris Prod S.A		

Examiner Signature	/Dionne Walls Mayes/	Date Considered	03/31/2016

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Sheet 9 of 20

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Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

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	155	US- 7,767,698	8/3/2010	Warchol et al.	
	156	US- 7,815,332	10/19/2010	Smith	
	157	US- 7,832,410	11/16/2010	Hon	
	158	US- 7,886,507	2/15/2011	McGuinness Jr.	
	159	US- 7,988,034	8/2/2011	Pezzoli	
	160	US- 8,141,701	3/27/2012	Hodges	
	161	US- 8,156,944	4/17/2012	Hon	
	162	US- 8,322,350	12/4/2012	Lipowicz	
	163	US- 8,371,310	2/12/2013	Brenneise	
	164	US- 8,381,739	2/26/2013	Gonda	
	165	US- 8,387,612	3/5/2013	Damani et al.	
	166	US- 8,443,534	5/21/2013	Goodfellow et al.	
	167	US- 8,490,629	7/23/2013	Shenassa et al.	
	168	US- 8,539,959	9/24/2013	Scatterday	
	169	US- 8,541,401	9/24/2013	Mishra et al.	
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	171	US- 8,671,952	3/18/2014	Winterson et al.	
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	428	WO2013/050934A1	4/11/2013	SIS Resources Ltd.		
	429	WO2013/083635A1	6/13/2013	Philip Morris Prod S.A		
	431	WO2013/098398A2	7/4/2013	Philip Morris Prod S.A		
	432	WO2013/142678A1	9/26/2013	Njoy Inc.		
	434	WO2014/093127A2	6/19/2014	Fuisz, Richard C.		
	436	WO2014/118286A2	8/7/2014	Philip Morris Prod S.A		

Examiner Signature	/Dionne Walls Mayes/	Date Considered	03/31/2016

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First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

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	176	US- 8,925,555	1/6/2015	Monsees et al.	
	354	US- 2015/0157056**	6/11/2015	Bowen et al.	
	179	US- 9,215,895**	12/22/2015	Bowen et al.	
	180	US- D590990	4/21/2009	Hon	
	181	US- D590991	4/21/2009	Hon	
	182	US- D624238	9/21/2010	Turner	
	183	US- D642330	7/26/2011	Turner	
	184	US- D644375	8/30/2011	Zhou	
	185	US- D653803	2/7/2012	Timmermans	
	186	US- D691324	10/8/2013	Saliman	
	187	US- D695450	12/10/2013	Benassayag et al.	
	188	US- D707389	6/17/2014	Liu	
	189	US- 2001/0015209	8/23/2001	Zielke	
	190	US- 2001/0032643	10/25/2001	Hochrainer et al.	
	191	US- 2001/0032795	10/25/2001	Weinstein et al.	
	192	US- 2001/0052480	12/20/2001	*Kawaguchi et al.*	
	193	US- 2002/0078951	6/27/2002	Nichols et al.	
	194	US- 2002/0175164	11/28/2002	Dees et al.	
	195	US- 2003/0005926	1/9/2003	Jones et al.	

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	437	WO2014/139611A1	9/18/2014	Philip Morris Prod S.A		
	438	WO2014/140087A1	9/18/2014	Philip Morris Prod S.A		
	440	WO2014/187763A1	11/27/2014	Philip Morris Prod S.A		
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	443	WO2015/006652A1	1/15/2015	Alexza Pharm. Inc.		
	445	WO2015/040180A2	3/26/2015	Philip Morris Prod S.A		

Examiner Signature	/Dionne Walls Mayes/	Date Considered	03/31/2016

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 11 of 20

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	360	US- 2015/0208729**	7/30/2015	Monsees et al.	
	196	US- 2003/0089377	5/15/2003	Hajaligol et al.	
	197	US- 2004/0031495	2/19/2004	Steinberg	
	198	US- 2004/0099266	5/27/2004	Cross et al.	
	199	US- 2004/0149296	8/5/2004	Rostami et al.	
	200	US- 2004/0149624	8/5/2004	Wischusen et al.	
	201	US- 2004/0173229	9/9/2004	Crooks et al.	
	202	US- 2004/0182403	9/23/2004	Andersson et al.	
	203	US- 2004/0221857	11/11/2004	Dominguez	
	204	US- 2004/0237974	12/2/2004	Min	
	205	US- 2005/0016549	1/27/2005	Banerjee et al.	
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	207	US- 2005/0034723	2/17/2005	Bennett et al.	
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	210	US- 2005/0145533	7/7/2005	Seligson	
	211	US- 2005/0172976	8/11/2005	Newman et al.	
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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	448	WO2015/082652A1	6/11/2015	Philip Morris Prod S.A		
	449	WO2015/084544A1	6/11/2015	Pax Labs, Inc.		
	451	WO2015/101651A1	7/9/2015	Philip Morris Prod S.A		
	453	WO2015/124878A1(EngAbs)	8/27/2015	Smokio		
	454	WO2015/148547A1	10/1/2015	Nicotech LLC		
	455	WO2015/175979A1	11/19/2015	Pax Labs, Inc.		

Examiner Signature	/Dionne Walls Mayes/	Date Considered	03/31/2016

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Sheet 12 of 20

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

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	214	US- 2006/0018840	1/26/2006	Lechuga Ballesteros et al.	
	215	US- 2006/0054676	3/16/2006	Wischusen	
	216	US- 2006/0102175	5/18/2006	Nelson	
	217	US- 2006/0150991	7/13/2006	Lee	
	218	US- 2006/0191546	8/31/2006	Takano et al.	
	219	US- 2006/0191548	8/31/2006	Strickland et al.	
	371	US- 2015/0313285	11/5/2015	Waller et al.	
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Sheet 13 of 20

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Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

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	239	US- 2008/0149118	6/26/2008	Oglesby et al.	
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	247	US- 2009/0133691	5/28/2009	Yamada et al.	
	248	US- 2009/0230117	9/17/2009	Fernando et al.	
	249	US- 2009/0255534	10/15/2009	Paterno	
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	251	US- 2009/0272379	11/5/2009	Thorens et al.	

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Sheet 14 of 20

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Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

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	254	US- 2009/0293892	12/3/2009	Williams et al.	
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	262	US- 2010/0186757	7/29/2010	Crooks et al.	
	264	US- 2010/0236562	9/23/2010	Hearn et al.	
	265	US- 2010/0242974	9/30/2010	Pan	
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Sheet 15 of 20

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Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

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	273	US- 2011/0049226	3/3/2011	Moreau et al.	
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	293	US- 2012/0227753	9/13/2012	Newton	
	294	US- 2012/0255567	10/11/2012	Rose et al.	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature	/Dionne Walls Mayes/	Date Considered	03/31/2016

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PTO/SB/08A (04-07)
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 17 of 20

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	315	US- 2014/0041655	2/13/2014	Barron et al.	
	317	US- 2014/0060552**	3/6/2014	Cohen	
	325	US- 2014/0190503	7/10/2014	Li et al.	
	326	US- 2014/0196731	7/17/2014	Scatterday	
	372	US- 2016/0044967**	2/18/2016	Bowen et al.	
	334	US- 2014/0345631**	11/27/2014	Bowen et al.	
	335	US- 2014/0345635	11/27/2014	Rabinowitz et al.	
	337	US- 2014/0366898**	12/18/2014	Monsees et al.	
	338	US- 2014/0378790**	12/25/2014	Cohen	
	339	US- 2015/0020823	1/22/2015	Lipowicz et al.	
	342	US- 2015/0027468	1/29/2015	Li et al.	
	350	US- 2015/0128966	5/14/2015	Lord	
	353	US- 2015/0150308**	6/4/2015	Monsees et al.	
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NON PATENT 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.	T[2]
	456	ECF; Any interest in determining nicotine--by DVAP; (https://www.e-cigarette-forum.com/forum/threads/any-interest-in-determining-nicotine-by-dvap.35922/); blog posts dated: 2009; 8 pgs.; print/retrieval date: July 31, 2014	
	457	BOMBICK et al.; Chemical and biological studies of a new cigarette that primarily heats tobacco; Part 2: In vitro toxicology of mainstream smoke condesnsate; Food and Chemical Toxicology; 36(3); pp. 183-190; March 1998	
	458	BOMBICK et al.; Chemcal and biological studies of a new cigarette that primarily heats tobacco; Part 3: In vitro toxicity of whole smoke; Food and Chemical Toxicology; 36(3); pp. 191-197; March 1998	
	459	BORGERDING et al.; Chemcal and biological studies of a new cigarette that primarily heats tobacco; Part 1: Chemical composition of mainstream smoke; Food and Chemical Toxicology; 36(3); pp. 169-182; March 1998	
	460	MIRRIAM-WEBSTER Online Dictionary; Lighter; retrieved 1/4/2013 from the internet: (http://www.merriam-webster.com/dictionary/lighter?show=0&t=1357320593); 2 pgs.; print date: 1/4/2013	
	461	BAKER et al.; The pyrolysis of tobacco ingredients; J. Anal. Appl. Pyrolysis; 71(1); pp. 223-311; March 2004	
	462	TORIKAI et al.; Effects of temperature, atmosphere and pH on the generation of smoke compounds duriung tobacco pyrolysis; Food and Chemical Toxicology; 42(9); pp. 1409-1417; September 2004	
	463	WARD; Green leaf threshing and redrying tobacco; Section 10B; in TOBACCO Production, Chemistry and Technology; Davis and Nielsen (Eds.); Blackwell Science Ltd.; pp. 330-333; July 15, 1999	
	464	INGEBRETHSEN et al.; Electronic cigarette aerosol particle size distribution measurements; Inhalation Toxicology; 24(14); pp. 976-984; December 2012	
	465	McCANN et al.; Detection of carcinogens as mutagens in the salmonella/microsome test: Assay of 300 chemicals: Discussion; Proc. Nat. Acad. Sci.; 73(3); pp. 950-954; March 1976	

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	466	WELLS; Glycerin as a constituent of cosmetics and toilet preparations; Journal of the Society of Cosmetic Chemists; 9(1); pp. 19-25; January 1958	
	467	KUO et al.; Appendix D: Particle size-U.S. sieve size and tyler screen mesh equivalents; Applications of Turbulent and Multiphase Combustion; John Wiley & Sons, Inc.; pp. 541-543; May 1, 2012	
	468	HARVEST VAPOR; American Blend Tobacco (product info.); retrieved from the internet (http://harvestvapor.com/); 2 pgs.; print/retrieval date: 10/10/2014	
	469	INCHEM; Levulinic Acid; JECFA Evaluation Summary; retrieved 10/10/2014 from http://www.inchem.org/documents/jecfa/feceval/jec_1266.htm; 1 pg.; March 10, 2003	
	470	INCHEM; Benzoic Acid; JECFA Evaluation Summary; retrieved 10/10/2014 from http://www.inchem.org/documents/jecfa/feceval/jec_184.htm; 2 pgs..; May 28, 2005	
	471	FOOD & DRUG ADMINISTRATION; Warning letter to The Compounding Pharmacy; retrieved 10/10/2014 from http://www.fda.gov/ICECI/EnfocementActions/WarningLetters/2002/ucm144843.htm; 3 pgs.; April 9, 2002	
	472	INCHEM; Pyruvic Acid; JECFA Evaluation Summary; retrieved 10/10/2014 from http://www.inchem.org/documents/jecfa/feceval/jec_2072.htm; 1 pg.; January 29, 2003	
	473	INCHEM; Sorbic Acid; JECFA Evaluation Summary; retrieved 10/10/2014 from http://www.inchem.org/documents/jecfa/feceval/jec_2181.htm; 1 pg.; May 29, 2005	
	474	FLOURIS et al.; Acute impact of active and passive electronic cigarette smoking on serum cotinine and lung function; Inhal. Toxicol.; 25(2); pp. 91-101; Feb 2013	
	475	GONIEWICZ et al.; Nicotine levels in electronic cigarettes; Nicotine Tobacco Research; 15(1); pp. 158-166; Jan 2013	

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	476	SEEMAN et al.; The form of nicotine in tobacco. Thermal transfer of nicotine and nicotine acid salts to nicotine in the gas phase; J Aric Food Chem.; 47(12); pp. 5133-5145; Dec 1999	
	477	VANSICKEL et al.; A clinical laboratory model for evaluating the acute effects of electronic cigarettes: Nicotine delivery profile and cardiovascular and subjective effects; Cancer Epidemiology Biomarkers Prevention; 19(8); pp. 1945-1953; (online) July 20, 2010	
	478	ZHANG et al.; In vitro particle size distributions in electronic and conventional cigarette aerosols suggest comparable deposition patterns; Nicotine Tobacco Research; 15(2); pp. 501-508; Feb 2013	
	479	NICOLI et al.; Mammalian tumor xenografts induce neovascularization in Zebrafish embryos; Cancer Research; 67(7); pp. 2927-2931; April 1, 2007	
	480	YouTube; Firefly Vaporizor Review w/ Usage Tips by The Vape Critic; retrieved from the internet (http://www.youtube.com/watch?v=1J38N0AV7wI); 1 pg.; published 12/10/2013; download/print date: 2/18/2015	
	483	PERFETTI; Structural study of nicotine salts; Beitrage zur Tabakforschung International; Contributions to Tobacco Research; 12(2); pp. 43-54; June 1983	
	484	MONSEES, J.; U.S. Pat. App. # 12/115,400 entitled "Method And System For Vaporization Of A Substance", filed 5/5/2008	
	485	BOWEN et al.; U.S. Pat. App. # 14/960,259 entitled "Calibrated Dose Control", filed 12/4/2015	

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	579	US- 4,648,393	3/10/1987	Landis et al.	
		US-			
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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	389	nicotine near50 (lactic or lactate)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/27 09:16
L2	440	nicotine near50 (lactic or lactate)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/04/27 09:16
L3	65	((a24f47/00)".cpc" or (131/$.ccls.) or (128/$).ccls.) and nicotine near50 (lactic or lactate)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/04/27 09:20
L4	70	((a24f47/00).cpc. or (131/$.ccls.) or (128/$).ccls.) and nicotine near50 (lactic or lactate)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/04/27 09:20
L5	73	((a24f47/00 or a24f47/008).cpc. or (131/$.ccls.) or (128/$).ccls.) and nicotine near50 (lactic or lactate)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/04/27 09:20
L8	1	("9,215,895").PN.	US-PGPUB; USPAT	OR	OFF	2016/04/27 11:18
L9	6717	(a24f47/00 or a24f47/008).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/04/27 18:29
S1	3	(("20060195518") or ("20120256567") or ("20080241255")).PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 11:41
S2	3	(("20060195518") or ("20120255567") or ("20080241255")).PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 11:41
S3	2	(("20120255567") or ("20080241255")).PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 11:42
S4	0	("2006").pn. and (hon).in.	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 11:42

S5	42	(hon).in. and cigarette	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 11:44
S6	25	("131"/$ or "128"/$).ccls. and electronic cigarette and nicotine and plasma	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:06
S7	6	("131"/$ or "128"/$).ccls. and (fuisz).in. and nicotine and plasma	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:06
S8	91	("131"/$ or "128"/$).ccls. and inhal$5 near15 nicotine and plasma	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:15
S9	25	("131"/$ or "128"/$).ccls. and inhal$5 near15 nicotine and plasma and ((max or maxim$3) near25 time)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:16
S10	23	("131"/$ or "128"/$).ccls. and inhal$5 near15 nicotine and (plasma near25 (peak or max or maxim$3) near25 time)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:25
S11	9	("131"/$ or "128"/$).ccls. and inhal$5 same (nicotine same (plasma near25 (peak or max or maxim$3) near25 time))	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:25
S12	9	("131"/$ or "128"/$).ccls. and inhal$5 same (nicotine same (plasma near25 (peak or max or maxim$3) near25 time))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:26
S13	32	("131"/$ or "128"/$).ccls. and inhal$5 and (nicotine same (plasma near25 (peak or max or maxim$3) same time))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:28
S14	2	("131"/$ or "128"/$).ccls. and nicotine benzoate	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:51
S15	2	(vaporiz$3 or electronic cigarette) and nicotine benzoate	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:52
S16	346	("131"/$ or "128"/$).ccls. and (salt near5 nicotine)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:53
S17	230	("131"/$ or "128"/$).ccls. and (salt near5 nicotine) same (acid)	US-PGPUB; USPAT; USOCR; FPRS;	ADJ	ON	2015/01/20 15:54

			EPO; JPO; DERWENT; IBM_TDB			
S18	210	("131"/$ or "128"/$).ccls. and (salt near5 nicotine) near35 (acid)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:55
S19	17	("131"/$ or "128"/$).ccls. and (salt near5 nicotine) near35 (carboxylic or citric)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 16:08
S20	1	("2356185").PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 16:32
S21	1	("2356185").PN.	USOCR	OR	OFF	2015/01/20 16:33
S22	4	nicotine benzoate	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 16:38
S23	1	("20010029959").PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 16:43
S24	0	electronic cigarette and inhal$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 16:47
S25	1	nicotine and inhal$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 16:48
S26	1	nicotine and inhal$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 16:59
S27	53	inhal$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 17:33
S28	222	puff$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 17:37
S29	207	("131"/$ or "128"/$ or cigarette) and puff$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR;	ADJ	ON	2015/01/20 17:40

			FPRS; EPO; JPO; DERWENT; IBM_TDB			
S30	179	("131"/$ or "128"/$) and puff$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 17:40
S31	28	(("20070163610") or ("20090293895") or ("20130186416") or ("7832410") or ("8,156,944") or ("8,511,318") or ("20140345631") or ("20140345635") or ("20040191322") or ("20060018840") or ("20060196518") or ("20080241255") or ("20090004249") or ("20100242976") or ("20110268809") or ("20120255567") or ("4,830,028") or ("4,836,224") or ("6,102,036") or ("6,234,169") or ("6,799,576") or ("6,874,507") or ("7,767,698") or ("8,079,371") or ("8,322,350") or ("8,375,957") or ("8,381,739") or ("8,741,348")).PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 20:10
S32	1	(14/512311).APP.	US-PGPUB; USPAT	OR	OFF	2015/03/23 22:03
S33	1	(14/512311).APP.	US-PGPUB; USPAT	OR	OFF	2015/05/14 15:25
S34	1605	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:07
S35	237	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:08
S36	221	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5 or mouth or oral$4)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:08
S37	191	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5 or mouth or oral$4) and (plasma or blood)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:08
S38	163	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5 or mouth or oral$4) and (plasma or blood) and ph	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:09
S39	108	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5 or mouth or oral$4) and (plasma or blood) and ph and ((drop$4 or vapor$4 or aerosol$4 or particle) near25 size)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:10
S40	87	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5 or mouth or oral$4) and (plasma or blood) and ph and ((drop$4 or vapor$4 or	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:11

		aerosol$4 or particle) near25 size) and heat$4				
S41	77	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5) and (plasma or blood) and ph and ((drop$4 or vapor$4 or aerosol$4 or particle) near25 size) and heat$4	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:12
S42	4	("2004076289").PN.	FPRS; EPO; JPO	OR	OFF	2015/05/14 18:13
S43	15	ANDERSSON near3 SVEN-BORJE	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:15
S44	13	ANDERSSON near3 SVEN-BORJE and nicotine	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:15
S45	71	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5) and (plasma or blood) and ph and ((drop$4 or vapor$4 or aerosol$4 or particle) near25 size) and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:26
S46	21	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5) and (plasma or blood) and (ph near5 "7") and ((drop$4 or vapor$4 or aerosol$4 or particle) near25 size) and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:27
S47	26	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5) and (plasma or blood) and (ph near5 "7") and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:28
S48	38	("128"/$ or "131"/$ or "424"/$ or "514"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5) and (plasma or blood) and (ph near5 "7") and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:31
S49	1	("20060196518").PN.	US-PGPUB; USPAT	OR	OFF	2015/05/14 19:32
S50	34	("128"/$ or "131"/$ or "424"/$ or "514"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and (salicylic or sorbic or lauric or levulinic or citric or benzoic or pyruvic) and (inhal$5) and ((plasma or blood or peek or peak) near10 concentration) and (ph near5 "7") and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 08:30
S51	1	("8831739").PN.	US-PGPUB; USPAT	OR	OFF	2015/05/15 08:43
S52	1	("8381739").PN.	US-PGPUB; USPAT	OR	OFF	2015/05/15 08:43
S53	14	(igor near3 gonda) and nicotine and ng/ml	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 10:42
S54	13	(igor near3 gonda) and nicotine near50	US-PGPUB;	ADJ	ON	2015/05/15

		concentration near50 ng/ml	USPAT; USOCR			10:42
S55	0	(igor near3 gonda) and nicotine near50 concentration near50 ng/ml near50 salt	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 10:43
S56	64	(igor near3 gonda) and ((blood or plasma or nicotine) near50 concentration)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 10:46
S57	13	(igor near3 gonda) and ((blood or plasma or nicotine) near50 concentration) same nicotine	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 10:46
S58	1	("20030136404").PN.	US-PGPUB; USPAT	OR	OFF	2015/05/17 15:16
S59	1	(14/512311).APP.	US-PGPUB; USPAT	OR	OFF	2015/07/14 09:12
S60	1	("20140261474").PN.	US-PGPUB; USPAT	OR	OFF	2015/07/14 10:27
S61	1	(14/512311).APP.	US-PGPUB; USPAT	OR	OFF	2015/09/17 14:40
S62	934	(A24F47/008).cpc.	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/09/17 14:46
S63	78	("128"/$ or "131"/$ or "424"/$ or "514"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and acid and (inhal$5) and (plasma or blood) and (ph near5 "7") and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/09/17 14:46
S64	367	("128"/$ or "131"/$ or "424"/$ or "514"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and acid and (inhal$5) and (plasma or blood) and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/09/17 14:47
S65	283	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and (levulinic or pyruvic or salicylic or sorbic or lauric or benzoic) and (inhal$5 or mouth or oral$4) and (plasma or blood)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/09/17 14:48
S69	2	(("20060196518") or ("20140261474")).PN.	US-PGPUB; USPAT	OR	OFF	2015/12/10 16:09
S70	1	("9215895").PN.	US-PGPUB; USPAT	OR	OFF	2016/03/30 20:38
S71	0	(14/925958).APP.	US-PGPUB; USPAT	OR	OFF	2016/04/24 10:41
S72	1	(14/925968).APP.	US-PGPUB; USPAT	OR	OFF	2016/04/24 10:41
S73	2	(12/236439).APP.	US-PGPUB; USPAT	OR	OFF	2016/04/24 10:56
S74	120	(A24F47/008).cpc. and temperature near25 ("100" or "200" or "300")	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 12:53
S75	34	(A24F47/008).cpc. and temperature near25 ("100" or "200" or "300") near25 degrees	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 12:56
S76	35	(A24F47/008 or A24F47/00 or A24F47/002).cpc. and temperature near25	US-PGPUB; USPAT;	ADJ	ON	2016/04/25 12:57

		("100" or "200" or "300") near25 degrees	USOCR			
S77	0	((128/$ or 131/$).ccls. or (A24F47/008 or A24F47/00 or A24F47/002).cpc.) and low tempereture and ("100" or "200" or "300") near25 degrees	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 13:27
S78	1787	((128/$ or 131/$).ccls. or (A24F47/008 or A24F47/00 or A24F47/002).cpc.) and low temperature	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 13:28
S79	118	((128/$ or 131/$).ccls. or (A24F47/008 or A24F47/00 or A24F47/002).cpc.) and low temperature and ("100" or "200" or "300") near25 degrees	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 13:28
S80	29	((128/$ or 131/$).ccls. or (A24F47/008 or A24F47/00 or A24F47/002).cpc.) and low temperature and ("100" or "200" or "300") near25 degrees and nicotine	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 13:29
S81	2	(12/336439).APP.	US-PGPUB; USPAT	OR	OFF	2016/04/25 13:38
S82	1	("5,544,646").PN.	US-PGPUB; USPAT	OR	OFF	2016/04/25 19:16
S83	10	(rose).in. and pyruvic and nicotine	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 19:18
S84	1	(12/481908).APP.	US-PGPUB; USPAT	OR	OFF	2016/04/25 21:20

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S66	723	(A24F47/008).cpc.	US-PGPUB	ADJ	ON	2015/09/17 14:46
S67	246	("128"/$ or "131"/$ or "424"/$ or "514"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and acid and (inhal$5) and (plasma or blood) and heat$4 and lung	US-PGPUB	ADJ	ON	2015/09/17 14:47
S68	196	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and (levulinic or pyruvic or salicylic or sorbic or lauric or benzoic) and (inhal$5 or mouth or oral$4) and (plasma or blood)	US-PGPUB	ADJ	ON	2015/09/17 14:49

4/27/2016 6:29:31 PM
C:\Users\dmayes\Documents\EAST\Workspaces\14925968.wsp

FAX COVER SHEET

FAX No: 571-273-5836

ATTN: Examiner Mayes (Dionne Walls Mayes)

Date: June 8, 2016

Number of pages (including cover sheet): 3

RE: Telephone interview on Thursday, June 9, 2016 for App. no. 14/925,968

From: Rick Shoop

Return Fax: 1-650-212-7562

Direct Dial: 1-650-283-2092 (cell)

NOTES

See attached

June 8, 2016

RE: Telephone interview on Thursday, June 9, 2016 at 10 am PT (1pm ET) for App. no. 14/925,968

Dear Examiner Mayes:

Thank you for making time to talk about this application; I'm looking forward to talking with you tomorrow at 1pm ET (10 am PT). I'll give you a call then. During the call I'd like to discuss the new principle reference (Griffith) and the combination with Gonda. For our discussion, I'm attaching some claim amendment language.

Please let me know if there are any changes in your schedule, or if you need anything ahead of the call. Thanks again!

Best,
Rick Shoop

FOR DISCUSSION ONLY
--- DO NOT ENTER ---

1. (POSSIBLE AMENDMENTS - DO NOT ENTER) A method of delivering nicotine to a user comprising:

deploying a low-temperature vaporizer comprising a nicotine formulation that comprises nicotine, lactic acid, and a biologically acceptable liquid carrier, wherein:

a. the nicotine concentration is from about 0.5% (w/w) to about 20% (w/w);

b. the biologically acceptable liquid carrier comprises propylene glycol and 90%-30% vegetable glycerol; and

c. operation of the low-temperature vaporizer comprises wicking the nicotine formulation from a fluid storage reservoir to an atomizer and heating at least a portion of the nicotine formulation to generate an inhalable aerosol between about 100°C and about 300°C;

wherein inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min and further wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength.

7. (POSSIBLE AMENDMENTS - DO NOT ENTER) A method of delivering nicotine to a user comprising:

deploying a low-temperature vaporizer comprising a nicotine formulation that comprises nicotine, lactic acid, and a biologically acceptable liquid carrier within a fluid storage reservoir connected to a heating element by a wick, wherein:

a. the nicotine concentration is from about 0.5% (w/w) to about 20% (w/w);

b. the nicotine formulation comprises protonated nicotine;

c. the biologically acceptable liquid carrier comprises propylene glycol and 90%-30% vegetable glycerol;

d. the lactic acid does not decompose at room temperature and does not decompose at the operating temperature of the low-temperature vaporizer; and

e. operation of the low-temperature vaporizer comprises wicking the nicotine formulation from the fluid storage reservoir to the heating element and heating at least a portion of the nicotine formulation between about 100°C and 300°C to generate an inhalable aerosol;

wherein inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min and further wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/925,968	10/28/2015	Adam BOWEN	13211-713.303	2707

66854 7590 06/14/2016

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

EXAMINER	
MAYES, DIONNE WALLS	

ART UNIT	PAPER NUMBER
1747	

NOTIFICATION DATE	DELIVERY MODE
06/14/2016	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):

info@shayglenn.com

PTOL-90A (Rev. 04/07)

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	14/925,968	BOWEN ET AL.	
	Examiner	Art Unit	
	DIONNE W. MAYES	1747	

All participants (applicant, applicant's representative, PTO personnel):

(1) *DIONNE W. MAYES*. (3)_____.

(2) *RICHARD SHOOP*. (4)_____.

Date of Interview: *09 June 2016*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☒103 ☒Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *Those of Record*.

Identification of prior art discussed: *Griffith, Jr. et al (20130255702) and Gonda (2014/0261474)*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Applicant's representative, Mr. Richard Shoop, proposed claim amendments, to the independent claims, which include recitation related to "wicking" of the nicotine formulation from a fluid reservoir to an atomizer/heating element. Examiner Mayes indicated that, after a cursory look of the primary reference, Griffith, Jr. et al, this "wicking" feature/structure did not appear to be apparent and further consdieration would need to be taken to determine whether modifiying the Griffith, Jr reference to include this feature would even be obvious. The Examiner also indicated that an updated search would need to be conducted. Lastly, Examiner Mayes emphasized the fact that Applicant needed to show that the instant specification supported the new recitation and, if so, that this was clearly made of record. Mr. Shoop said that he would take everything under consideration and file an amendment in the very near future..

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☒ Attachment

/DIONNE W MAYES/ Examiner, Art Unit 1747	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

———

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

PTO/SB/08A (04-07)
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	585	JP10-501999A(w/EngEquiv)	2/24/1998	Boehringer Ingelheim		

Examiner Signature		Date Considered	

*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. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] 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 37 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, 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 (1-800-786-9199) and select option 2.

Electronic Patent Application Fee Transmittal

Application Number:	14925968
Filing Date:	28-Oct-2015
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Filer:	Richard Douglas Shoop/Brian Flick
Attorney Docket Number:	13211-713.303

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($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	26075293
Application Number:	14925968
International Application Number:	
Confirmation Number:	2707
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Customer Number:	66854
Filer:	Richard Douglas Shoop/Brian Flick
Filer Authorized By:	Richard Douglas Shoop
Attorney Docket Number:	13211-713.303
Receipt Date:	15-JUN-2016
Filing Date:	28-OCT-2015
Time Stamp:	15:56:59
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	2820
Deposit Account	504050
Authorized User	SHOOP, RICHARD D
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		13211-713-303_IDS_Filing_6-15-2016.pdf	272546 7e9a162af5aa29b2260b3d40190f940541ad5464	yes	4
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Transmittal Letter		1	3	
	Information Disclosure Statement (IDS) Form (SB08)		4	4	
Warnings:					
Information:					
2	Foreign Reference	JP10-501999AwEngEquiv.pdf	3881257 9f5f4be56c683c9397af0c0f9f521e95b21f35e6	no	32
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30802 38ee338e6843acce2e3e83608cea6f7251c71d1c	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	4184605		

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.

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on 6-15-2016.

Brian Flick
Name

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 14/925,968	Confirmation No.: 2707
First Named Inventor	: Adam Bowen	
Filed	: October 28, 2015	
Art Unit	: 1747	
Examiner	: Mayes, Dionne Walls	
Title	: NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF	
Customer No.	: 66854	

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☐ **37 CFR §1.97(b)**

This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:

- ☐ **1).** Within 3 months of the application filing date, or
- ☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or
- ☐ **3).** Before the mail date of a first Office Action on the merits, or
  - ☐ **3a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below
- ☐ **4).** Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.
  - ☐ **4a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below

☐ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☐ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☐ **A).** A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

or

☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☒ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under §1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☐ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☐ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☐ **3).** Items identified by a double asterisk (**) on the SB08A are *commonly-owned U.S. patents and U.S. patent application publications.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), *Commonly-owned, unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s), and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **3).** A copy of each application specification is not submitted because the application is stored in the IFW. Cite no(s):

Applicant(s) assume the Examiner has access to the file histories of these items. However, if the Examiner would like to receive copies of Office Actions in any of the commonly-owned applications, publications and/or patents identified on the attached SB08, please inform the undersigned and copies will be provided.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☐ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and 609.04(a)III, Foreign patent(s) or other foreign documents not in English cited. Either:**

☒ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☒ **2a).** An English language abstract or an English language copy of a foreign search report or other action by a foreign patent office is provided herewith to fulfill the requirement for a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language: Cite no(s): 585

--AND/OR--

☒ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached: Cite no(s): 585

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☒ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. Cite no(s): 585

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement. Cite no(s):

STATEMENT UNDER 37 CFR § 1.704(d)

☒ Each item of information contained in the information disclosure statement was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: June 15, 2016

By: _____
Richard D. Shoop, Reg. No. 45,763

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

Doc Code: A.NE.AFCP
Document Description: After Final Consideration Pilot Program Request

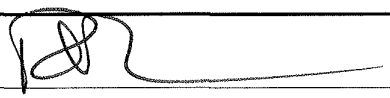
PTO/SB/434 (05-13)

CERTIFICATION AND REQUEST FOR CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0

Practitioner Docket No.:	Application No.:	Filing Date:
13211-713.303	14/925,968	October 28, 2015
First Named Inventor:	**Title:**	
Adam BOWEN	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF	

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0 (AFCP 2.0) OF THE ACCOMPANYING RESPONSE UNDER 37 CFR 1.116.

1. The above-identified application is (i) an original utility, plant, or design nonprovisional application filed under 35 U.S.C. 111(a) [a continuing application (*e.g.*, a continuation or divisional application) is filed under 35 U.S.C. 111(a) and is eligible under (i)], or (ii) an international application that has entered the national stage in compliance with 35 U.S.C. 371(c).
2. The above-identified application contains an outstanding final rejection.
3. Submitted herewith is a response under 37 CFR 1.116 to the outstanding final rejection. The response includes an amendment to at least one independent claim, and the amendment does not broaden the scope of the independent claim in *any* aspect.
4. This certification and request for consideration under AFCP 2.0 is the only AFCP 2.0 certification and request filed in response to the outstanding final rejection.
5. Applicant is willing and available to participate in any interview requested by the examiner concerning the present response.
6. This certification and request is being filed electronically using the Office's electronic filing system (EFS-Web).
7. Any fees that would be necessary consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, extension of time fees, are being concurrently filed herewith. [There is no additional fee required to request consideration under AFCP 2.0.]
8. By filing this certification and request, applicant acknowledges the following:
   - Reissue applications and reexamination proceedings are not eligible to participate in AFCP 2.0.
   - The examiner will verify that the AFCP 2.0 submission is compliant, *i.e.*, that the requirements of the program have been met (see items 1 to 7 above). For compliant submissions:
     - The examiner will review the response under 37 CFR 1.116 to determine if additional search and/or consideration (i) is necessitated by the amendment and (ii) could be completed within the time allotted under AFCP 2.0. If additional search and/or consideration is required but cannot be completed within the allotted time, the examiner will process the submission consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, by mailing an advisory action.
     - If the examiner determines that the amendment does not necessitate additional search and/or consideration, or if the examiner determines that additional search and/or consideration is required and could be completed within the allotted time, then the examiner will consider whether the amendment places the application in condition for allowance (after completing the additional search and/or consideration, if required). If the examiner determines that the amendment does not place the application in condition for allowance, then the examiner will contact the applicant and request an interview.
       - The interview will be conducted by the examiner, and if the examiner does not have negotiation authority, a primary examiner and/or supervisory patent examiner will also participate.
       - If the applicant declines the interview, or if the interview cannot be scheduled within ten (10) calendar days from the date that the examiner first contacts the applicant, then the examiner will proceed consistent with current practice concerning responses after final rejection under 37 CFR 1.116.

Signature	Date
	June 15, 2016
Name (Print/Typed)	**Practitioner Registration No.**
Richard D. Shoop	45,763

***Note**: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.*

☐ * Total of _____ forms are submitted.

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. § 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on June 15, 2016.
/Mary Buggie/ 6/15/2016
Mary Buggie Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	14/925,968	Confirmation No.	: 2707
First Named Inventor:	:	Adam BOWEN		
Filing Date	:	October 28, 2015		
Art Unit	:	1747		
Examiner	:	Mayes, Dionne Walls		
Title	:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF		
Customer No.	:	66854		

AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.116

This communication is in response to the final Office Action dated May 13, 2016, for which a response is due August 13, 2016. Thus, this response is timely filed. Applicants submit herewith a Certification and Request for Consideration Under the After Final Consideration Pilot Program (2.0) in order for the Examiner to fully consider the amendments made herein. Finally, a Declaration Under 37 C.F.R. § 1.132 providing support and evidence of commercial success is also submitted herewith.

The Commissioner is authorized to charge any fees to make this filing timely to Deposit Account No. 50-4050.

Amendments to the Claims are shown in the listing of claims that begins on page 2.

Remarks/Arguments begin on page 6 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 method of delivering nicotine to a user comprising:

deploying a low-temperature vaporizer comprising a nicotine formulation that comprises nicotine, lactic acid, and a biologically acceptable liquid carrier within a fluid storage compartment connected to a heating element by a wick, wherein:

a. the nicotine concentration is from about 0.5% (w/w) to about 20% (w/w);

b. the biologically acceptable liquid carrier comprises propylene glycol and 90%-30% vegetable glycerol; and

c. operation of the low-temperature vaporizer comprises wicking the nicotine formulation from the fluid storage compartment to the heating element and heating at least a portion of the nicotine formulation to generate an inhalable aerosol between about 100°C and about 300°C;

wherein inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min and a Cmax of over 10 ng/mL on average, and further wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength.

2. (Currently amended) The method of claim 1, wherein a molar ratio of nicotine to ~~organic~~ lactic acid is between about 1:1 and 1:3.

3. (Original) The method of claim 1, wherein the nicotine formulation further comprises at least one flavorant.

4. (Original) The method of claim 1, wherein the nicotine concentration is about 4.5%.

5. (Cancelled)

6. (Original) The method of claim 1, wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns.

7. (Currently amended) A method of delivering nicotine to a user comprising:

deploying a low-temperature vaporizer comprising a nicotine formulation that comprises nicotine, lactic acid, and a biologically acceptable liquid carrier within a fluid storage compartment connected to a heating element by a wick, wherein:

a. the nicotine concentration is from about 0.5% (w/w) to about 20% (w/w);

b. the nicotine formulation comprises protonated nicotine;

c. the biologically acceptable liquid carrier comprises propylene glycol and 90%-30% vegetable glycerol;

d. the lactic acid does not decompose at room temperature and does not decompose at the operating temperature of the low-temperature vaporizer; and

e. operation of the low-temperature vaporizer comprises wicking the nicotine formulation from the fluid storage compartment to the heating element and heating at least a portion of the nicotine formulation between about 100°C and 300°C to generate an inhalable aerosol;

wherein inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min and further wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength.

8. (Currently amended) The method of claim 7, wherein a molar ratio of nicotine to ~~organic~~ lactic acid is between 1:1 and 1:3.

9. (Original) The method of claim 7, wherein the nicotine formulation further comprises at least one flavorant.

10. (Original) The method of claim 7, wherein the nicotine concentration is about 4.5%.

11. (Cancelled)

12. (Original) The method of claim 7, wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns.

13. (Currently amended) A low-temperature vaporizer, comprising:

a liquid reservoir;

a nicotine formulation within the liquid reservoir, the nicotine formulation comprising:

nicotine lactate;

propylene glycol; and

90%-30% vegetable glycerol;

wherein a concentration of nicotine in the nicotine formulation is from about 0.5% (w/w) to about 20% (w/w);

a vaporizing component configured to produce an aerosol from the nicotine formulation by heating at least a portion of the nicotine formulation between 100°C and 300°C, wherein the liquid reservoir is connected to the vaporizing component by a wick; and

a mouthpiece configured to connect to the reservoir for inhalation of the aerosol;

wherein inhalation of the aerosol into the user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 min to about 8 min and a Cmax of over 10 ng/mL on average, and further wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength.

14. (Original) The electronic cigarette of claim 13, further comprises a battery configured to provide power to the vaporizing component.

15. (Currently amended) The electronic cigarette of claim 13, wherein a molar ratio of nicotine to ~~organic~~ lactic acid is between 1:1 and 1:3.

16. (Original) The electronic cigarette of claim 13, wherein the nicotine formulation further comprises at least one flavorant.

17. (Original) The electronic cigarette of claim 13, wherein the vaporizing component comprises a heating element in fluid communication with the nicotine formulation.

18. (Original) The electronic cigarette of claim 13, wherein the nicotine concentration is about 4.5%.

19. (Cancelled)

20. (Original) The electronic cigarette of claim 13, wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns.

REMARKS

Claims 1-4, 6-10, 12-18 and 20 were pending in this application. By this response, claims 1, 2, 7, 8, 13 and 15 have been amended. No new claims have been added, and no claims have been cancelled. The amendments to the claims and the new claims are supported throughout the specification, and particularly:

(a) Support for the amendments to claims 1 and 7, reciting: "a nicotine formulation… within a fluid storage compartment," may be found at least in paragraphs [0040]-[0066] (e.g., "[p]rovided herein is a cartridge in an electronic cigarette comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation…").

(b) Support for the amendments to claims 1 and 7 reciting: "…connected to a heating element by a wick" may be found at least in paragraphs [0640]-[0642] (e.g., "heater comprises a heater chamber, a fluid wick, and a resistive heating element in contact with the fluid wick"). One of skill in the art would understand, based on at least this disclosure, that the inventors had adequately described the recited use of a wick connecting the liquid nicotine formulation to the heater (heating element).

(c) Support for the amendments to claims 1 and 7 reciting: "wicking the nicotine formulation from the fluid storage compartment to the heating element" may be found at least in paragraphs [0640]-[0642], as mentioned above describing devices in which the fluid storage compartment is in fluid communication with a heater (heating element) (see [0030]-[0031] ("…a heating element in fluid communication with the nicotine salt liquid formulation… a fluid storage compartment that stores the nicotine salt liquid formulation"), wherein the connection to the heater is a wick (see, e.g., paragraph [0642], "heater comprises a heater chamber, a fluid wick, and a resistive heating element in contact with the fluid wick"). One of skill in the art would understand, based on at least this disclosure, that the inventors had described the recited wicking of nicotine, using the wick, from the fluid storage compartment to the heater (heating element).

(d) Support for the amendment to claims 1 and 13 to recite that "wherein inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in … a Cmax of over 10 ng/mL on average" may be found at least in paragraph [0290].

(e) Support for the amendment to claim 13, reciting "wherein the liquid reservoir is connected to the vaporizing component by a wick" may be found at least in paragraph [0642], "heater comprises a heater chamber, a fluid wick, and a resistive heating element in contact with the fluid wick"). One of skill in the art would understand, based on at least this disclosure, that the inventors had described the recited connection between the liquid reservoir and the vaporizer (e.g., heater).

Thus, no new matter has been added. Amendment of the claims is not to be considered a dedication to the public of any subject matter.

Thus, claims 1-4, 6-10, 12-18 and 20 are currently under consideration. Reconsideration of these claims is requested in view of the amendments and the following remarks.

INFORMATION DISCLOSURE STATEMENT

Applicant notes that a Supplemental Information Disclosure Statement was filed 5/12/2016. A Supplemental Information Disclosure Statement is also filed herewith. It is respectfully requested that these Supplemental Information Disclosure Statements be considered and the PTO Forms 1449/SB08 be initialed and returned with the next Action.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112

Claims 2, 8 and 15

Claims 2, 8 and 15 currently stand 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.

By this response, Applicants have amended claims 2, 8 and 15 to fully address the objections mentioned above (e.g., by amending "organic acid" to "lactic acid"). Thus, this rejection has been fully addressed and rendered moot.

DOUBLE PATENTING

Claims 1-4, 6-10 and 12

Claims 1-4, 6-10 and 12 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 9,215,895 to Bowen et al. ("Bowen '895") in view of U.S. Patent Application Publication No. 2013/0255702 to Griffith, Jr. et al. ("Griffith").

The Applicants respectfully disagree.

By this response, independent claims 1, 7 and 13 have been amended, emphasizing the lack of obvious subject matter between pending claims 1-4, 6-10 and 12 and the cited Griffith references. Should the Examiner maintain the nonstatutory double patenting rejection but otherwise indicate the claims are allowable, the Applicants with favorably consider filing a terminal disclaimer to overcome this rejection; filing such a terminal disclaimer earlier would be premature.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103

Claims 1-4, 6-10, 12-18 and 20

Claims 1-4, 6-10, 12-18 and 20 currently stand rejected under 35 U.S.C. § 103 as being unpatentable over Griffith as evidenced by www.e-cigarette-forum.corn's PG-VG-PEG Discussion Posting ("the PG-VG-PEG Internet Posting") in view of U.S. Patent Application Publication No. 2014/0261474 to Gonda ("Gonda") and U.S. Patent Application Publication No. 2009/0151717 to Bowen et al. ("Bowen '717").

The Applicants respectfully disagree. The combination of Griffith, PG-VG-PEG Internet Posting, Gonda and the Bowen '717 does not suggest all of the features recited in the currently pending claims. Further, there is a substantial objective indicia of non-obviousness, as evidenced by the 37 C.F.R. § 1.132 Declaration by Dr. Gal Cohen submitted herewith, which provides significant evidence of commercial success that is attributable to the features recited in the Applicants' pending claims.

A. The combination of Griffith, the PG-VG-PEG Internet Posting, Gonda and Bowen does not suggest all of the features of claims 1-4, 6-10, 12-18 and 20

The combination of Griffith, PG-VG-PEG Internet Posting, Gonda and the Bowen '717 does not suggest all of the features recited in the claims. In particular, this combination of references does not suggest:

(1) deploying a low-temperature vaporizer comprising a nicotine formulation that comprises nicotine, lactic acid, and a biologically acceptable liquid carrier *within a fluid storage compartment connected to a heating element by a wick;*
(2) operation of the low-temperature vaporizer comprises *wicking the nicotine formulation from the fluid storage compartment to the heating element* and heating at least a portion of the nicotine formulation to generate an inhalable aerosol;
(3) wherein inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min and a Cmax of over 10 ng/mL on average.

Regarding the first and second elements, none of Griffith, PG-VG-PEG Internet Posting, Gonda or the Bowen '717, alone or in combination, suggests deploying a low-temperature vaporizer comprising a nicotine formulation that comprises nicotine, lactic acid, and a biologically acceptable liquid carrier within a fluid storage compartment connected to a heating element by a wick or wicking the nicotine formulation from the fluid storage compartment to the heating element. Griffith teaches a solid-state device in which nicotine formulation, and particularly the vapor precursor material, is incorporated (e.g., coated on, absorbed by or adsorbed) in or on a carbonized substrate, so that they are "integral with the carbonized

substrate". See Griffith, paragraphs [0009], [0014], [0089], and [0122]. Griffith does not teach or suggest keeping the biological material within a fluid compartment and connecting to the heating element by a wick. Instead, Griffith suggests that the vapor precursor material is saturated onto the substrate that has been carbonized. It goes counter to Griffiths' teaching of the benefit of using a carbonized substrate to directly integrate with the vapor forming material to include an intervening wick. Griffith emphasizes the importance of the improved-resistivity of the carbonized substrate. It would not make sense to include an intermediate structure, such as a wick, between the vapor precursor material and the carbonized substrate of Griffith.

Similarly, none of PG-VG-PEG Internet Posting, Gonda and the Bowen '717 suggests deploying a low-temperature vaporizer comprising a nicotine formulation that comprises nicotine, lactic acid, and a biologically acceptable liquid carrier within a fluid storage compartment connected to a heating element by a wick or wicking the nicotine formulation from the fluid storage compartment to the heating element. The PG-VG-PEG Internet Posting is silent as to this feature. Gonda describes devices and methods using solids (e.g., powdered material) or filtering a liquid through a membrane to form vapor. Finally, Bowen '717 teaches heating a viscous material in an oven.

In addition, the combination of Griffith, PG-VG-PEG Internet Posting, Gonda and the Bowen '717 does not suggest a method or apparatus in which inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min, and a Cmax of over 10 ng/mL on average.

As previously described, the Applicants' claims are directed a particular nicotine salt that results from combining a solution of nicotine (e.g., freebase nicotine) and lactic acid in a biologically acceptable liquid carrier including propylene glycol and 90%-30% vegetable glycerol. This nicotine salt formulation, when vaporized using a low-temperature vaporizer between about 100°C and 300°C, results in a user experience that closely mimics a traditional cigarettes; e.g., having a Tmax that is between 3-8 minutes and a Cmax greater than 10 ng/mL. The combination of nicotine and lactic acid in a carrier including propylene glycol and 90%-30%

vegetable glycerol for use in a low-temperature vaporization device operating between 100°C and 300°C is based, in part, on the Applicants' unique discovery that only certain nicotine salts (e.g., and therefore only certain organic acids forming these salts) have a nicotine Cmax and Tmax in blood plasma of a user inhaling the vapor that is similar to that of inhaling smoke from a traditional cigarette. For example, the Applicants' disclosure (see, e.g., figures 1-5 and accompanying description) describes for the first time the plasma Tmax and Cmax of a variety of nicotine formulations, and teaches which formulations (and specifically which nicotine salts) do and do not have this desired effect.

Without the Applicant's teachings, one of skill in the art would not be motivated to select the correct nicotine formulation and method of using it as described herein, and therefore it would not be obvious to combine references, including the Griffith, PG-VG-PEG Internet Posting, Gonda and the Bowen '717 references raised by the Office Action. Specifically, without the Applicant's teaching, one of skill in the art would not know to select, from the universe of possible nicotine formulations, the proper nicotine, lactic acid and PG/VG carrier at the recited concentrations, and how to use this nicotine formulation to achieve the Tmax of nicotine in the blood between 3-8 minutes (and a Cmax of over 10 ng/mL).

The combination of Griffith, PG-VG-PEG Internet Posting, Gonda and the Bowen '717 does not suggest a method of using a low-temperature vaporizing device wherein inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min and a Cmax of over 10 ng/mL on average. Further, it would not be obvious to modify the combination of Griffith, PG-VG-PEG Internet Posting, Gonda and the Bowen '717 to achieve the recited invention.

The final Office Action of May 13, 2016 argues that Griffith, PG-VG-PEG Internet Posting, Gonda and the Bowen '717 suggest a method of using a nicotine formulation that achieves a blood nicotine Tmax of between 3-8 min (and a Cmax of over 10 ng/mL), because this method would be obvious since "Gonda teaches that administering an aerosolized, liquid nicotine-containing formulation via inhalation (i.e., pulmonary administration) in order to

effectuate a peak level of nicotine in the blood plasma after a very short period of time – mimicking that which is typically achieved during actual cigarette smoking – can be accomplished."

Applicants respectfully disagree. A suggestion that a recited feature could be accomplished is not sufficient to show obviousness. Although Gonda mentions the Tmax of nicotine due to cigarettes (Gonda [092]), Gonda stops short of teaching that this was actually achieved. More importantly, although Gonda provides a long list of factors that may affect the rate of absorption (e.g., Tmax), including: amount or concentration of nicotine, pH, duration of particle generation, and particle size (see Gonda [0032], [0064] and [0099]), none of these variables are responsible for the Tmax and Cmax effect recited in the Applicant's claims. As described in the Applicants' specification, it is the unexpected combination of nicotine, lactic acid, and PG/VG in a liquid solution that is vaporized by heating between 100 and 300 °C and inhaled to provide a Tmax of between 3-8 min (and a Cmax over 10 ng/mL) as recited in the Applicant's claims. While Gonda suggests that for some formulations could be tweaked by adjusting pH and/or particle size to modify their absorption, Gonda does not show the recited Tmax levels are actually achieved. This is because, as described in the Applicant's disclosure, particle size and pH (and any of the other factors mentioned by Gonda) are not sufficient by themselves, to achieve the proper Tmax, particularly when wicking a liquid reservoir onto a heater that is heated between 100-300 °C to vaporize. Importantly this ability to achieve the target Tmax with a nicotine formulation is not dependent on mere pH, but surprisingly depends on the type of acid included in the formulation, which was not known in the art until the Applicant's invention. The variables referenced by Gonda (e.g., nicotine concentration, pH, etc.) alone or in combination are not sufficient. As Applicants have described, the type of organic acid (including, in particular, lactic acid) is also critical.

Without this essential knowledge, or without the use of hindsight, it cannot be obvious to modify the Griffith reference to achieve the recited Tmax and Cmax values, even if Gonda suggests that it may be beneficial. Although the Office Action asserts that it would be routine for one of skill in the art, given the known "results oriented parameters" of Gonda (e.g., pH,

nicotine concentration, particle size) to modify Griffith to achieve the claimed Tmax features, since only "routine experimentation would be needed" to optimize these variables to achieve the "recognized result" (see, e.g., Office Action, page 10). Applicants disagree. The variables being 'optimized' in the instant claims are not the same as the variables identified as "results oriented" variables by Gonda. Instead, these variables are the liquid mixture, containing nicotine, the correct carrier mixture (PG/VG) and correct acid (e.g., lactic acid). In order to be obvious for optimization, a variable (or as here, a combination of variables) must be *recognized* as a results-effective variable in the prior art. See, e.g., *In re Antonie,* 559 F.2d 618, 195 USPQ 6 (CCPA 1977). In this case, none of these variables were recognized by the Gonda as relevant to the desired result (e.g., a Tmax of nicotine in the plasma between 3 and 8 minutes), and therefore it could not be obvious to optimize to achieve them. The "results oriented variables" cited by the Office Action in reference to Gonda (e.g., pH, particle size, nicotine concentration) are irrelevant if the wrong acid and therefore salt is generated (e.g., see paragraph [115] "... not all nicotine salts perform similarly to each other or to a traditional cigarette with respect to the rate of nicotine uptake in the blood at early time periods (0-1.5 minutes). These results are unexpected."). Without knowing what variables must be optimized (e.g., which acid and therefore nicotine salt to use), it could not be obvious to optimize the combination Griffith and Gonda together or with any other reference.

Since the combination of Griffith, PG-VG-PEG Internet Posting, Gonda and the Bowen '717 does not suggest all of the features recited in claims 1-4, 6-10, 12-18 and 20, these claims cannot be obvious in light of these references.

B. Commercial Success of the Products attributable to the Claimed Features shows objective indicia of non-obviousness

The Supreme Court has recognized commercial success as a possible determinant of patent validity since 1876. Smith v. Goodyear Dental Vulcanite Co., 93 U.S. 486, 495-96 (1876). In 1966, with the landmark decision of *Graham v. John Deere Co.*, the Court reaffirmed the vitality of secondary considerations "[a]s indicia of obviousness or nonobviousness." (*Graham v. John Deere Co.*, 383 U.S. 1, 17-18). The Court listed commercial success as the first secondary

consideration. The commercial success of a product is highly probative of obviousness where the commercial success is attributable to the claimed features that are allegedly obvious; if a product commercially successful product was obvious to invent, then other competitors likely would have already developed it and the market for subsequent entrants to achieve commercial success would be depleted. The potential for achieving commercial success is thought to drive inventors to formulate solutions to existing problems to satisfy marketplace demands. Such evidence of commercial success may help prevent improper hindsight bias when comparing the claimed invention to a combination of prior art.

Applicants respectfully submit that the claimed invention, as supported by the attached declaration under 37 C.F.R. § 1.132, has had great commercial success directly resulting from the incorporation of the all of the features of the claimed invention.

Prior to the Applicants' invention, existing electronic cigarettes for delivering nicotine to a user did not include a nicotine formulation comprising nicotine, lactic acid, and a carrier of propylene glycol and 90%-30% vegetable glycerol that was vaporized so that inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min. A new vaporizer product incorporating all of the features recited in the Applicants' claims in the fall of 2015. In the eight months since its introduction, this product has exhibited nearly exponential sales growth. This commercial success is directly attributable to the features claimed by the Applicant's claims.

Attached hereto is a 37 C.F.R. § 1.132 Declaration by Dr. Gal Cohen. Dr. Cohen's declaration describes the NJOY Daily commercial electronic cigarette product, a low-temperature vaporizer (electronic cigarette). The NJOY Daily product incorporates all of the features recited in the claims. As established in Dr. Cohen's declaration and the associated exhibits, sales of the NJOY Daily product have grown rapidly since its introduction, eclipsing the sales of other electronic cigarettes, including other newly introduced and heavily advertised products that do not include the recited features. This commercial success is directly attributable to the claimed features, including in particular, the use of a nicotine mixture including lactic acid

and PG/VG, and the ability to achieve a Tmax within approximately the same time as a traditional cigarette (e.g., "wherein inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min") and a Cmax of greater than 10 ng/mL.

(a) *The NJOY Daily product includes all of the features recited in the claims*

Paragraphs 7 and 8 of Dr. Cohen's exhibit establish that the NJOY Daily electronic cigarette embodies all of the features recited in the claims. The NJOY product is an electronic cigarette including a liquid reservoir; a nicotine formulation within the liquid reservoir, in which the nicotine formulation includes: nicotine lactate (nicotine and lactic acid), and a carrier including propylene glycol and 90%-30% vegetable glycerol. The concentration of nicotine in the nicotine formulation is 4.5% (between 0.5% to about 20%) w/w. The fluid storage compartment is connected to a heating element by a wick. In operation, the NJOY Daily device produces an aerosol from the nicotine formulation by heating at least a portion of the nicotine formulation between 100°C and 300°C so that inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min and a Cmax of over 10 ng/mL. This is explicitly shown for the NJOY Daily product in Exhibit G ("Nicotine Delivery" graph).

(b) *The NJOY Daily Product has Been Commercially Successful Because It Includes the Features Recited in the Applicants' Claims.*

The NJOY Product has enjoyed commercial success which has increased since its introduction into the market in the fall of 2015, as described by Dr. Cohen in detail in paragraphs 5 and 6. For evidence of commercial success to be probative of non-obviousness, there must be a nexus between the commercial success and the features recited in the claims. There are multiple lines of evidence showing that the commercial success of the NJOY Daily product is due (at least in part) to the feature recited in the claims. First, the NJOY Daily product has been specifically advertised as including the features recited in the claims, identifying these features key selling points to consumers. Second, consumer self-reporting data (testimonials) indicate that consumers are purchasing the NJOY daily product precisely because it includes the features

recited in the claims. Finally, the company selling the NJOY Daily device (NJOY Inc.) has itself stated that the recited features, in particular the Tmax properties ("nicotine absorption") are at responsible for the commercial success. These points are all described in paragraphs 9-11 of Dr. Cohen's declaration.

Although in many cases it may be difficult to attribute commercial success to particular recited features and not simply advertising (see, e.g., MPEP §716.03(B), citing *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 227 USPQ 766 (Fed. Cir. 1985)), that is not the case here. Instead, advertisements for the NJOY Daily product explicitly touted the claimed features as selling points to the consumer. Thus, the success of this advertisement campaign itself hinged on the incorporation of the the recited features into the NJOY Daily product. See the Declaration of Dr. Gal Cohen, Exhibits F and G. As shown in electronic and print advertisements marketed to consumers and distributers, the NJOY Daily product was explicitly described as embodying the Applicants claimed features. For example, the NJOY Daily product was described as including nicotine solution including 4.5% nicotine, lactic acid, and 50/50 PG/VG that can provide "over 90%" of the satisfaction as a cigarette "during the first seven minutes," based on a "clinical trial conducted by [an] independent lab measuring nicotine absorption in blood stream [Tmax]…". Some advertisements went so far as to include a graph showing the Tmax and Cmax values for the NJOY Daily (compared to other products and a traditional cigarette) as shown by the flyer in Exhibit G.

The nexus between the recited features, including the nicotine solution with nicotine, lactic acid and PG/VG that results in a nicotine plasma Tmax from about 3 minutes to about 8 min and a Cmax of over 10 ng/mL, is also shown by consumer testimonials (Exhibit H of Dr. Cohen's declaration). Consumers have self-reported that they purchase and prefer the NJOY Daily product because of the recited features, compared to other commercial products that do not include these features. The rapid blood absorption (Tmax) is typically expressed by consumers as a nicotine satisfaction or "fix" similar or identical to traditional cigarettes.

Finally, as shown in Exhibit A of Dr. Cohen's Declaration, the company offering the NJOY Daily product (NJOY, Inc.) directly attributes the commercial success to the rapid blood

absorption (Tmax) ("NJOY attributes the Daily's early success to the product's accessible $5.99 MSRP, as well as its ability to create a bridge to familiarity for adult smokers through its lightweight, soft touch design *and superior nicotine absorption.*").

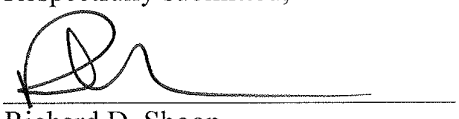
In light of this commercial success, which is directly attributable to the recited features of the Applicants' claims, as evidenced by the attached 37 C.F.R. § 1.132 Declaration and as shown above, the Applicant's respectfully request withdrawal of the 35 U.S.C. § 103 rejection of claims 1-4, 6-10, 12-18 and 20 and allowance of all of the currently pending claims.

CONCLUSION

In light of the remarks set forth above, Applicants respectfully request the Examiner expedite the prosecution of this patent application to issuance. If it is determined that a telephone conference would aid in the prosecution of this application, the Examiner is invited to telephone the undersigned at (650) 287-2164.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-4050** referencing docket no. 13211-713.303. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



Date: June 15, 2016

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	: 14/925,968	Confirmation No.	: 2707
Inventor(s)	: Adam BOWEN		
Filing Date	: October 28, 2015		
Art Unit	: 1747		
Examiner	: Mayes, Dionne Walls		
Title	: NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF		
Customer No.	: 66854		

DECLARATION UNDER 37 C.F.R. § 1.132

I, Dr. Gal Cohen, declare as follows:

(1) I hold a PhD in Molecular and Cellular Physiology from Stanford University.

(2) I am the Head of Scientific and Regulatory Affairs at PAX Labs, Inc. ("PAX"), a market leader in vaporization (including electronic cigarette) technology, where I have been employed or affiliated since 2008.

(3) PAX Labs is the applicant and owner of U.S. patent application no. 14/925,968, for which this declaration is being submitted.

(4) As part of my employment at PAX, I monitor the sales and marketing of other electronic cigarette manufacturers, including NJOY, Inc.

(5) In or around September of 2015, NJOY, Inc. released a new product, called the "NJOY Daily". Since its introduction, sales of the NJOY Daily product have grown substantially and the NJOY Daily has experienced a significant commercial success, particularly as compared to other electronic cigarettes. Exhibit A, attached hereto is a copy of an article from the June 10, 2016 edition of "Convenience Store Decisions." The article, dated March 30, 2016, is entitled "NJOY Daily E-Cig Sales Soar." As reported in the article, the NJOY Daily "is currently the fastest turning new e-vapor product, outselling other new products such as JTI's Logic Pro and Pax Labs' JUUL."

(6) I have also monitored the sales of the NJOY Daily product using Information Resources, Inc. (IRI), a syndication service that tracks consumer product sales and marketing. IRI analysis of NJOY, Inc. shows that since its introduction, 4 week sales in all convenience store channels of NJOY Daily have grown from $0 a year ago to just

under a million dollars ($908,604). In the same time period, sales of other, established NJOY, Inc., products (including "NJOY Vaping" and "NJOY Bold") have decreased in sales by an aggregate of just over $700,000. This data is shown in Exhibit B. NJOY, Inc. has included a graphic illustrating unit sales of the NJOY Daily product as part of its advertisement material promoting the product to distributers, which is shown in Exhibit C. The graphic shows the exponential growth of NJOY Daily sales based on IRI data using four week sales data for sales in all channels ending on January 3, 2016.

(7) I have purchased and examined the NJOY Daily product. The NJOY Daily embodies all of the features of the pending claims of the U.S. patent application no. 14/925,968. The NJOY Daily is an electronic cigarette that includes a liquid nicotine formulation of nicotine, lactic acid, and a carrier of 50/50 propylene glycol (PG) and vegetable glycerin (VG). Exhibit D, attached hereto, is a description of the NJOY Daily product that is provided on the NJOY website (www.njoy.com/faq, last visited June 10, 2016). I have also requested and reviewed a chemical analysis of the liquid nicotine composition of a purchased NJOY Daily product, and have confirmed that the composition of this product is the same as recited in the claims of U.S. patent application no. 14/925,968. Specifically, the NJOY Daily nicotine formulation is a liquid solution of nicotine (between 46.8 and 47.3 mg/mL) and lactic acid (between 22.6 and 22.4 mg/mL) with a biologically acceptable liquid carrier of propylene glycol and glycerin (vegetable glycerol). The vegetable glycerol is between 90% and 30% of the liquid carrier. The chemical analysis was performed by a commercial chemical lab, Enthalpy Analytical, Inc., and a copy of this report is attached as Exhibit E. The liquid solution of the NJOY Daily product saturates a sponge that is held within a fluid storage compartment, and the liquid solution within the storage compartment is connected to a heating element by a wick. During operation of the NJOY Daily product, the nicotine formulation is wicked from the fluid storage compartment to the heating element and heated to between about 100°C and about 300°C to generate an inhalable aerosol.

(8) The use of the NJOY Daily product also results in the nicotine plasma Tmax from about 3 min to about 8 minutes and a Cmax of over 10 ng/ml when the aerosol produced by the NJOY Daily is inhaled into the user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds. Exhibit G shows an example of advertising material promoting the NJOY Daily product which describes the product as "over 90 percent as satisfying as a cigarette during the first 7 minutes of use," based on the Tmax and Cmax profile for the NJOY Daily. In Exhibit G, the statements referring to the increased satisfaction in strength and timing of the nicotine delivery refer to a clinical trial "conducted by [an] independent lab measuring nicotine absorption in [the] blood stream represented by mean of test subjects assessed on day 8 of use following 12 hours of abstinence." Exhibit F shows two screen captures of the advertisement aimed at consumers for the NJOY Daily that describe the peak blood nicotine concentration (Tmax) occurring within the first seven minutes of use, which is describes as providing a satisfaction similar to what is achieved by a traditional cigarette. In addition, the Tmax and Cmax resulting from the NJOY Daily product is also described in advertising material targeting distributers, as shown in Exhibit G. Exhibit G is an advertising flyer distributed by NJOY Inc, targeting distributers and

customers of NJOY Daily. In Exhibit G, the graph titled "Nicotine Delivery" at the bottom right shows that the NJOY Daily has a Tmax between 3 minutes and 8 minutes, and a Cmax of greater than 10 ng/ml (mean nicotine concentration). The "Chart Notes" provided at the bottom of the flyer indicate that the graph represents a "[c]linical trial conducted by independent lab measuring nicotine absorption in blood stream represented by mean of test subjects assessed on day 8 of use following 12 hours of abstinence. N=18-20 per product. Subjects smokers aged 18-65 not currently attempting to quit. Products puffed (starting at time zero) every 30 seconds for 5 minutes."

(9) It is my opinion that the commercial success of the NJOY Daily product is attributed to the features recited in the claims of U.S. patent application no. 14/925,968. The Tmax and Cmax values of the NJOY Daily product which result from the nicotine solution including nicotine, lactic acid and the PG/VG carrier provide a cigarette-like satisfaction. The rapid onset (e.g., Tmax between 3 and 8 minutes) of a relatively high blood nicotine level (e.g., Cmax over 10 ng/mL) result in a user experience and satisfaction that is closer to the experience provided by a traditional cigarette. It has long been the goal of electronic cigarette manufactures to provide an electronic cigarette that can mimic the experience of a traditional cigarette, because of the potential for tremendous commercial success. There are numerous user-reported testimonials available online in which users discuss their reasons for purchasing the NJOY Daily product; the majority of such self-reporting comments refer to the cigarette-like experience that it provides.

(10) In addition, the features recited in the claims, and particularly the Tmax and Cmax profiles, are used extensively in the NJOY Daily marketing and advertisement materials to drive consumer purchases. For example, the consumer advertisements show in Exhibit F tout the Cmax and Tmax properties as providing a user experience that is most similar to cigarettes. In Exhibit F, on the top left ("Meet NJOY Daily"), the advertisement claims that "over 90 percent as satisfying as a cigarette," and on bottom of ("IT'S THAT SATISFYING"), a similar advertisement states "[o]ur latest innovation is now delivering the most authentic 'smoking' experience to date. We're proud (and really freakin excited) to introduce the Daily – a labor of love that blends Satisfaction, Performance, Authenticity, Flavor and Design for an experience that's more than 90% as satisfying as a cigarette during the first 7 minutes of use." The advertisement of Exhibit G is even more explicit, graphically showing the Tmax and Cmax curves and describing the NJOY Daily as providing "[q]uick & strong satisfaction more like a cigarette".

(11) Finally, the NJOY company itself credits the nicotine absorption into the blood, the Tmax and Cmax properties of the NJOY Daily, as at least partially responsible for the commercial success. The recent article ("NJOY Daily E-Cig Sales Soar") in Exhibit A cites NJOY as attributing the early success of the NJOY Daily product to "its lightweight, soft touch design and superior nicotine absorption."

(12) I declare that all statements made herein 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 were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under the provisions of 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of any patent issuing upon U.S. Application Serial No. 14/632,161, or any continuing application thereof.

Signature: _____ Date: 6/15/16
Gal A. Cohen, PhD

EXHIBIT A

Convenience Store Decisions
June 10, 2016

NJOY Daily E-Cig Sales Soar

March 30, 2016 CSD Staff : 0 Comments

Accessible pricing and lightweight, soft touch design help spur consumer demand for NJOY Daily.

E-cigarette manufacturer NJOY shared the latest IRI FDMxC ("All-Channel") data, revealing that the NJOY Daily disposable e-cig is currently the fastest-turning new e-vapor product, outselling other new products such as JTI's Logic Pro and Pax Labs' Juul.

The data indicates that NJOY Daily is finding a home in the hands of adult smokers looking for an introductory e-vapor product that delivers nicotine satisfaction more like a cigarette.

According to IRI data, NJOY Daily's 3 SKUs moved more than 37,000 units in the single week ending Feb. 21, 2016. This amounts to 23% greater unit sales per week when compared with Logic Pro and 281% greater unit sales per week than Juul.

NJOY attributes Daily's early success to the product's accessible $5.99 MSRP, as well as its ability to create a bridge to familiarity for adult smokers through its lightweight, soft touch design and superior nicotine absorption. Thanks to their valued retail partners, NJOY has been able to leverage promotional support, merchandising, signage, and marketing assets to drive trial among adult smokers.

An early e-vapor pioneer, NJOY is currently the largest independent e-cigarette and vaping company in the USA. NJOY has heavily invested in R&D and market studies to further its ongoing commitment to product innovation based on consumer research and leading-edge science.

EXHIBIT B
IRI Data

NJOY, Inc. sells 3 product lines:

(1) NJOY vaping (vape pen and e-liquid bottles with a traditional nicotine formulation)
(2) NJOY Bold (cigalikes with a traditional nicotine formulation)
(3) NJOY Daily (cigalike with a lactic acid based formulation)

Based on data provided by Information Resources, Inc (IRI), in the past year, 4 week sales in all convenience store channels for all NJOY products have increased from $2,079,734 to $2,274,610. However, the proportion of sales represented by NJOY Daily has increased from 0% to 40%, while sales of all other products (NJOY vaping and NJOY Bold) have decreased by 60%.

	4 weeks ending 5/15/16		year ago		change y/y
vaping	$879,301	39%	$1,015,091	49%	($135,789)
Bold	$486,705	21%	$1,064,644	51%	($577,939)
Daily	$908,604	40%	$0	0%	$908,604
Total	$2,274,610		$2,079,734		$194,876

INTRODUCING

NJOY® DAILY

THE DIFFERENTIATED DISPOSABLE

REINVIGORATING CONSUMER TRIAL

BY DELIVERING SATISFACTION MORE LIKE A CIGARETTE.

DESIGNED WITH RETAILERS IN MIND

REINVIGORATING CONSUMER TRIAL	• Everyday value - approximately 300 puffs for $5.99 per stick • Quick & strong satisfaction more like a cigarette • Disposable lightweight stick
MAXIMIZE PURCHASE FREQUENCY & PROFITS	• ~40% margins* • 1 count configuration to maximize purchase frequency • Compact 5 count cartons for limited investment and optimal turns • Flavor freshness seal for extended shelf life • ~ 70% higher gross profit per week vs. leading rechargeable refills**
SELL THROUGH RATE SUPPORT	• Multi-million dollar consumer advertising campaign • Robust introductory price promotions • Modular merchandising displays and impactful signage • Trial generating activations • Targeted coupon delivery to adult smokers

IRI UNIT SALES
ALL CHANNEL***

NJOY®
DAILY

Source:

*Assumes assorted MSRP and cost = ~$2.01 per pack

**Assumes 50.2% Gross Profit per leading rechargeable 2.0 refill and assumes 1 week per month of consumption, 1 Unit Deluxe Disposable = 1 Unit; Advantage = 1 refillpod/week. Assumes 1 refillpod purchased per store visit.

***IRI All Outlets Ending 12/29/19, All Channels = FMUC + C-Store

EXHIBIT C

EXHIBIT D

Screen captures from www.njoy.com/faq (taken 6/10/2016):

What is e-liquid?

The main ingredients by volume in NJOY's vape e-liquids are propylene glycol (PG) and vegetable glycerin (VG). The secondary ingredients are nicotine and flavors.

All of NJOY's e-liquids are made in the USA with domestic and imported ingredients, and contain pharmaceutical grade PG, VG and nicotine. The e-liquid in the following products also contain lactic acid: NJOY Daily (all flavors) and our Classic Tobacco and Menthol vaping e-liquids.

NJOY Vape e-liquids contain 50% vegetable glycerin (VG) and 50% propylene glycol (PG).

The VG/PG ratios in the Artist Collection:

Paramour: 50/50 Hedon's Bite: 60/40 Sacré Coeur: 50/50 Dragon Scape: 70/30 Samba Sun: 60/40

Daily, the disposable e-cig that offers the most authentic 'smoking' experience is available in Rich Tobacco, Cool Menthol, Blue + Black Berry and Classic Tobacco (online only...coming soon).

Kings, the disposable e-cig that started it all, comes in bold, gold and menthol flavors.

Recharge comes in a range of flavors beyond menthol and traditional, including vanilla bean and pomegranate.

NJOY Vaping e-liquids come in a wide variety of flavors. You can see the all here.

Artist Collection is an exclusive line of complex e-liquids crafted by five leading artists in the vape industry in partnership with NJOY.

Check out all of our flavor chambers and e-liquids today.

How much nicotine is in NJOY products?

Ask and you shall receive:

NJOY Daily

- Rich Tobacco: 4.5% nicotine by weight
- Cool Menthol: 4.5% nicotine by weight
- Blue + Black Berry: 4.5% nicotine by weight

Some of your products now list lactic acid in the ingredient list, why?

Lactic acid is used in certain products to optimize the throat hit as well as your overall experience.

What is the difference between the NJOY King and the NJOY Daily?

There are several differences between the King and Daily, besides its size. NJOY Daily has been innovated to deliver quick & strong satisfaction more like a cigarette, it features a new longer lasting battery with QuickVapor technology delivering significantly longer battery life (approx. 300 puffs), has new upgraded flavors, more vapor volume and a discreet but stylish new design.

EXHIBIT E

PAX Labs, Inc.

660 Alabama Street, Second Floor
San Francisco, CA 94110

E-Liquid Analysis

Electronic Cigarette (eC) Liquid Testing

Analysis Report
(1115-553)

GC/FID Analysis (ENT184)

Nicotine, Propylene glycol, Vegetable glycerin, Water

HPLC/UV Analysis (ENT301-Mod)

Lactic Acid

Enthalpy Analytical, Inc.

Phone: (919) 850 - 4392 / Fax: (919) 850 - 9012 / www.enthalpy.com
800-1 Capitola Drive Durham, NC 27713-4385

I certify that to the best of my knowledge all analytical data presented in this report summary:

- Have been checked for completeness
- Are accurate, error-free, and legible
- Have been conducted in accordance with approved protocol

This analytical report was prepared in Portable Document Format (.PDF) and contains 10 pages.

Jennifer B. Feller

QA Review Performed by: Jennifer B. Feller

Report Issued: 1/6/2016

Summary of Results

ACCREDITED
Testing Cert. # 3198.01

Report for: PAX Labs, Inc.
Client Project: Electronic Cigarette (eC) Liquid Testing
Sample Type: e-Liquid

Project Code: 1115-553
Project Start Date: 11/13/15
Analysis Method: ENT184

Enthalpy Code	Client Code	Nicotine (mg/mL)	Propylene glycol (mg/mL)	Glycerin (mg/mL)	Water # (mg/mL)
1115-553-01-01	PO-J1-1511112A1	46.8	491	487	57.6
1115-553-01-02		47.3	497	489	59.9

#: Water results are blank corrected.

503

Report for: PAX Labs, Inc.
Client Project: Electronic Cigarette (eC) Liquid Testing
Sample Type: e-Liquid

Project Code: 1115-553
Project Start Date: 11/13/15
Analysis Method: ENT301-Mod

Enthalpy Code	Client Code	Notes	Lactic Acid (ug/mL)
1115-553-01 (DF 1010) 1	PO-J1-1511112A1	--	22,597
1115-553-01 (DF 1010) 2			22,389
		Average	**22,493**
		%DIFF	**0.9**

Narrative Summary

Enthalpy Analytical Narrative Summary

Company	PAX Labs, Inc.
Analysts	KEH, BJB/ABP
Parameters	ENT184, ENT301-Mod

Client Proj	Electronic Cigarette (eC) Liquid Testing
Job #	1115-553
# Samples	1 eC Liquid Sample

Custody	A scintillation vial labeled "*E-Liquid test nicotine, Lactic acid PG. Glycerin PO-J1-151112A1*" was used for this project. It was prepared and analzyed in duplicate. Prior to, during, and after analysis, the sample was kept under lock with access only to authorized personnel by Enthalpy Analytical, Inc.
ENT184 (Primary Constituents)	The e-Liquid sample was prepared and analyzed in duplicate for nicotine, propylene glycol (PG), and vegetable glycerin (aka VG, glycerin, or glycerol), and water following the analytical procedures in Enthalpy SOP ENT184. The samples were analyzed on the Hewlett Packard Model 6890 Gas Chromatograph "BMO" equipped with a Flame Ionization Detector (FID) and an appropriate column.
ENT301-Mod (Lactic Acid)	The e-Liquid sample was prepared and analyzed in duplicate for lactic acid following the general analytical procedures in Enthalpy SOP ENT301. The samples were analyzed using the Agilent Model 1100, High Performance Liquid Chromatograph "Selma," equipped with an Ultraviolet (UV) Detector operating at 360 nm and an appropriate column.
QC Notes	All QC samples were within acceptance criteria unless otherwise noted. As the lactic acid analysis was not a standard laboratory method, a second source standard was not available to verify the calibration for lactic acid. A continuing calibration sample was analyzed after the samples, and had a recovery of 98.7% of the expected concentration.
Reporting Notes	Sample and calibration curve chromatograms are available upon request. The results presented in this report are representative of the samples as provided to the laboratory.

General Reporting Notes

The following are general reporting notes that are applicable to all Enthalpy Analytical, Inc. data reports, unless specifically noted otherwise.

- Any analysis which referrs to the method as *"Type"* represents a planned deviation from the reference method. For instance a Hydrogen Sulfide assay from a Tedlar bag would be labeled as "EPA Method 16-Type" because Tedlar bags are not mentioned as one of the collection options in EPA Method 16.
- The acronym ***MDL*** represents the Minimum Detection Limit. Below this value the laboratory cannot determine the presence of the analyte of interest reliably.
- The acronym ***LOQ*** represents the Limit of Quantification. Below this value the laboratory cannot quantitate the analyte of interest within the criteria of the method.
- The acronym ***ND*** following a value indicates a non-detect or analytical result below the MDL.
- The letter ***J*** in the Qualifier or Flag column in the results indicates that the value is between the MDL and the LOQ. The laboratory can positively identify the analyte of interest as present, but the value should be considered an estimate.
- The letter ***E*** in the Qualifier or Flag column indicates an analytical result exceeding 100% of the highest calibration point. The associated value should be considered as an estimate.
- The acronym ***DF*** represents Dilution Factor. This number represents dilution of the sample during the preparation and/or analysis process. The analytical result taken from a laboratory instrument is multiplied by the DF to determine the final undiluted sample results.
- The addition of ***MS*** to the Sample ID represents a Matrix Spike. An aliquot of an actual sample is spiked with a known amount of analyte so that a percent recovery value can be determined. The MS analysis indicates what effect the sample matrix may have on the target analyte, i.e. whether or not anything in the sample matrix interferes with the analysis of the analyte(s).
- The addition of ***MSD*** to the Sample ID represents a Matrix Spike Duplicate. Prepared in the same manner as an MS, the use of duplicate matrix spikes allows further confirmation of laboratory quality by showing the consistency of results gained by performing the same steps multiple times.
- The addition of ***LD*** to the Sample ID represents a Laboratory Duplicate. The analyst prepares an additional aliquot of sample for testing and the results of the duplicate analysis are compared to the initial result. The result should have a difference value of within 10% of the initial result (if the results of the original analysis are greater than the LOQ).
- The addition of ***AD*** to the Sample ID represents an Alternate Dilution. The analyst prepares an additional aliquot at a different dilution factor (usually double the initial factor). This analysis helps confirm that no additional compound is present and coeluting or sharing absorbance with the analyte of interest, as they would have a different response/absorbance than the analyte of interest.
- The Sample ID ***LCS*** represents a Laboratory Control Sample. Clean matrix, similar to the client sample matrix, prepared and analyzed by the laboratory using the same reagents, spiking standards and procedures used for the client samples. The LCS is used to assess the control of the laboratory's analytical system. Whenever spikes are prepared for our client projects, two spikes are retained as LCSs. The LCSs are labeled with the associated project number and kept in-house at the appropriate temperature conditions. When the project samples are received for analysis, the LCSs are analyzed to confirm that the analyte could be recovered from the media, separate from the samples which were used on the project and which may have been affected by source matrix, sample collection and/or sample transport.

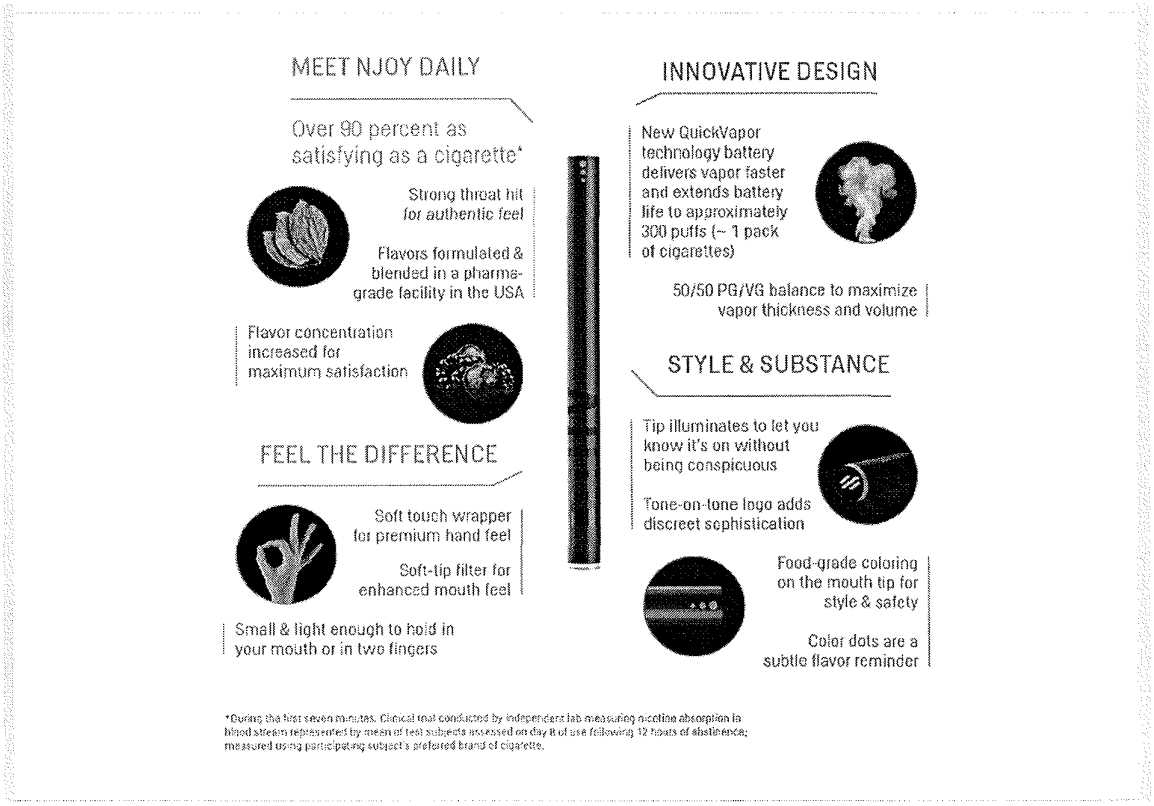
General Reporting Notes

(continued)

- **Significant Figures**: Where the reported value is much greater than unity (1.00) in the units expressed, the number is rounded to a whole number of units, rather than to 3 significant figures. For example, a value of 10,456.45 ug catch is rounded to 10,456 ug. There are five significant digits displayed, but no confidence should be placed on more than two significant digits.
- **Manual Integration**: The data systems used for processing will flag manually integrated peaks with an "M". There are several reasons a peak may be manually integrated. These reasons will be identified by the following two letter designations. The peak was ***not integrated*** by the software "NI", the peak was ***integrated incorrectly*** by the software "II" or the ***wrong peak*** was integrated by the software "WP". These codes will accompany the analyst's manual integration stamp placed next to the compound name on the chromatogram.

This Is The Last Page Of This Report.

EXHIBIT F



IT'S THAT SATISFYING

Our latest innovation is now delivering the most authentic "smoking" experience to date. We're proud (and really freakin excited) to introduce the Daily – a labor of love that blends Satisfaction, Performance, Authenticity, Flavor and Design for an experience that's more than 90% as satisfying as a cigarette during the first 7 minutes of use.

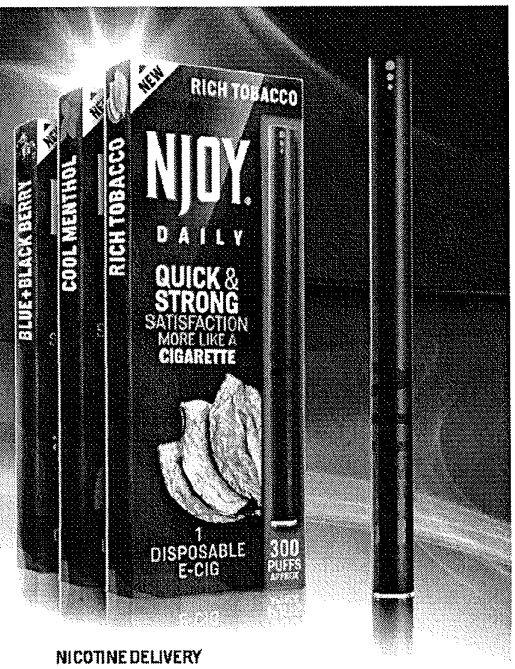
*June 2015 in-home consumer study consisting of adult smokers using tobacco and menthol flavor of both brands.

(Screen capture from https://www.njoy.com/daily, last visited June 13, 2016)

INTRODUCING

NJOY® DAILY

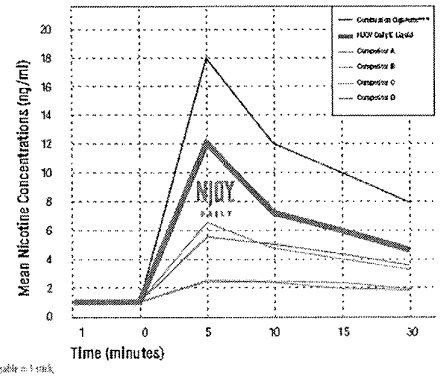
THE DIFFERENTIATED DISPOSABLE



DESIGNED WITH RETAILERS IN MIND

REINVIGORATING CONSUMER TRIAL	• Everyday value - approximately 300 puffs for $5.99 per stick • Quick & strong satisfaction more like a cigarette • Disposable lightweight stick
MAXIMIZE PURCHASE FREQUENCY & PROFITS	• ~40% margins* • 1 count configuration to help restore purchase frequency • Compact 5 count cartons for limited investment and optimal turns • Flavor freshness seal for extended shelf life • ~70% higher gross profit per week vs. leading rechargeable refills**
SELL THROUGH RATE SUPPORT	• Robust introductory pricing promotions • Modular merchandising displays and impactful signage • Multi-million dollar consumer advertising campaign • Trial generating activations • Targeted coupon delivery to adult smokers

NICOTINE DELIVERY
CIGARETTE VS TOP C STORE BRANDS



Source:
*Margins assume NDS retail and NJOY list price
** Assumes "Converted users" (Users completely switching from pack-a-day of cigarettes to E-Vapor Products. Assumes 2 units per week of consumption. Unit Definition: Disposable = 1 stick, Rechargeable = 1 cartridge, E-Liquid = 1 5 mL E-Liquid bottle assumes 1 unit purchased per visit
*** Measured using participating subjects preferred brand of cigarette
Clinical Notes: Clinical trial conducted by independent lab measuring nicotine absorption in blood serum represented by mean of test subjects assessed over day 8 of use following 12 hours of abstinence. N= 18-20 per product. Subjects smokers aged 18-55 not currently attempting to quit. Products puffed (drawing at own pace) every 30 seconds for 5 minutes.

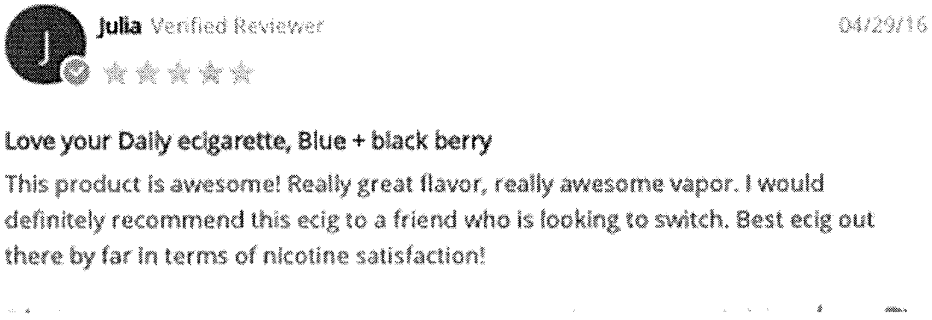
WARNING: NJOY® products are not nothing tobacco products and have not been tested as such, or have the long-term effects of using the product been established. NJOY® products are intended for use by adults of legal smoking age (18 or older in California), and not by children who are under age, pregnant or breastfeeding, or persons with or at risk of heart disease, high blood pressure, diabetes or taking medicine for depression or asthma. NJOY® products contain nicotine – a chemical known to the State of California to cause birth defects or other reproductive harm. Nicotine is addictive and habit forming, and it is very toxic by inhalation, in contact with the skin, or if swallowed. Ingestion of the non-vaporized concentrated ingredients in the liquid components of NJOY® products can be poisonous. If any liquid is swallowed, seek medical assistance immediately.

NJOY VAPING

EXHIBIT H

Consumer Testimonials

Sampling of customer testimonials from www.njoy.com/ (last visited 6/10/2016)



Customer testimonials from http://www.vaporauthority.com/products/genuine-njoy-daily-disposable-e-cig (last visited June 10, 2016):

★★★★★ (5/5)

Steven P from **Philly** on **May 17, 2016**

Great disposable here, probably the best one I've ever tried. Got one a while ago just for shits but now I pick a couple of em up every time I place an order here. These are so easy for out and about or stealthy vaping. Damn close to an analog too!

Report this review

★★★★★ (5/5)

Morgan from **Denver** on **Apr 29, 2016**

Unbelievable! It's like I'm smoking a cigarette again, but I'm not... I have been vaping instead of smoking for like a year now and this is a great way to revisit that without feeling like shit afterwards! Whooo Hoooo!

Report this review

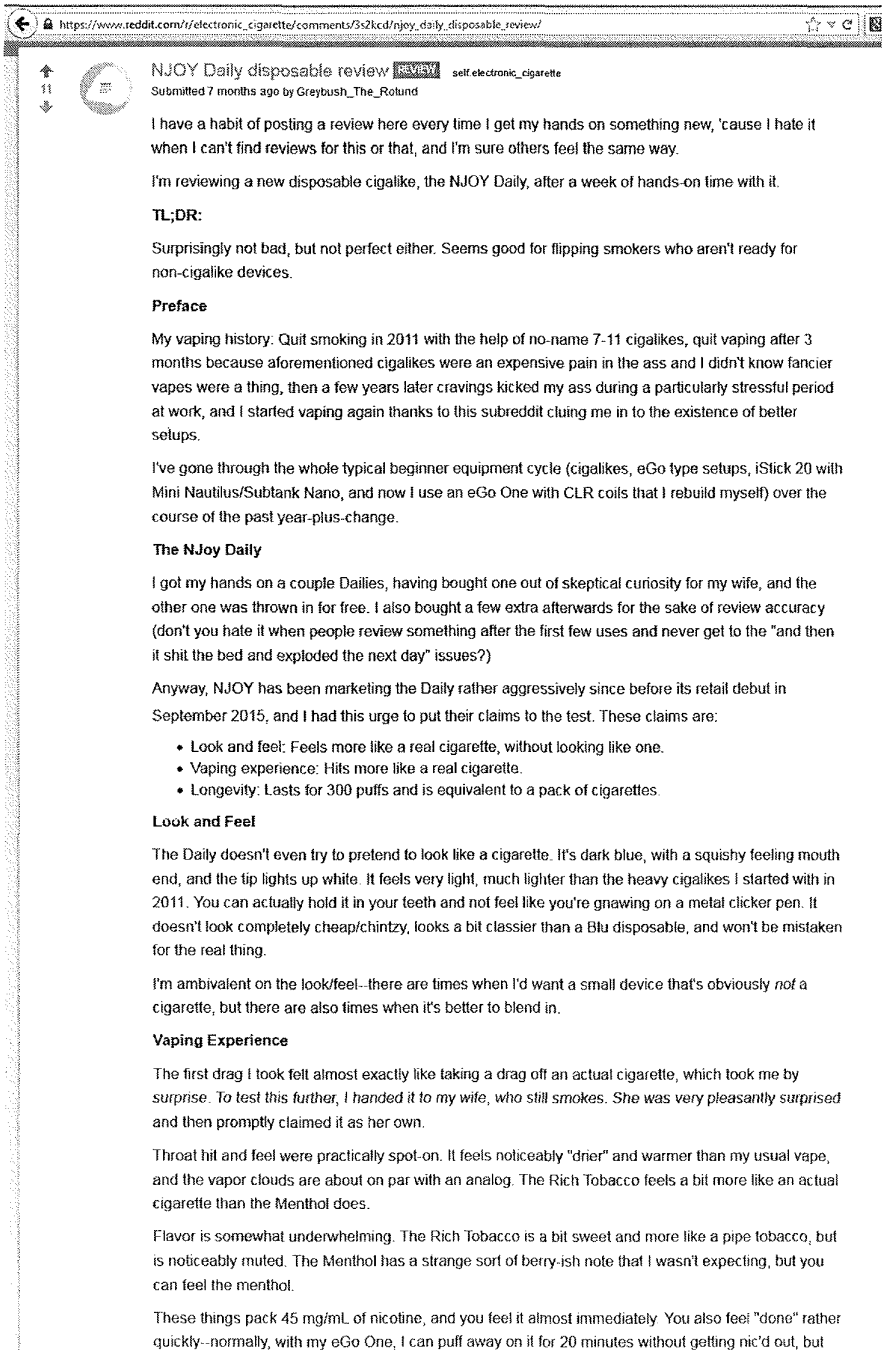
★★★★★ (5/5)

Alana B from **Austin Tx** on **Apr 11, 2016**

Oh Wow! I've tried other ecigs like this from the gas station and they were disappointing, but I'd never seen these Daily before. Now this is the closest thing to a real cigarette that I've ever had! I mean, if its this good I don't know why anyone would smoke real cigs.. Completely satisfying!! I actually have a nice vape set up and I just ordered these out of curiosity and I wanted an emergency go-to if my vape broke or got lost or something. Really good on the out and about. I'm definitely going to keep a stock of these around for rough times. Would be great for someone just trying to quit cigarettes, but it could get costly if you just relied on these. Get these and also a good mod and tank - and your golden! Much appreciated Vapor Authority!

Report this review

Exemplary Customer review from Reddit:
https://www.reddit.com/r/electronic_cigarette/comments/3s2kcd/njoy_daily_disposable_review/ (last visited June 10, 2016):



https://www.reddit.com/r/electronic_cigarette/comments/3s2kcd/njoy_daily_disposable_review/

11

NJOY Daily disposable review REVIEW self.electronic_cigarette

Submitted 7 months ago by Greybush_The_Rotund

I have a habit of posting a review here every time I get my hands on something new, 'cause I hate it when I can't find reviews for this or that, and I'm sure others feel the same way.

I'm reviewing a new disposable cigalike, the NJOY Daily, after a week of hands-on time with it.

TL;DR:

Surprisingly not bad, but not perfect either. Seems good for flipping smokers who aren't ready for non-cigalike devices.

Preface

My vaping history: Quit smoking in 2011 with the help of no-name 7-11 cigalikes, quit vaping after 3 months because aforementioned cigalikes were an expensive pain in the ass and I didn't know fancier vapes were a thing, then a few years later cravings kicked my ass during a particularly stressful period at work, and I started vaping again thanks to this subreddit cluing me in to the existence of better setups.

I've gone through the whole typical beginner equipment cycle (cigalikes, eGo type setups, iStick 20 with Mini Nautilus/Subtank Nano, and now I use an eGo One with CLR coils that I rebuild myself) over the course of the past year-plus-change.

The NJoy Daily

I got my hands on a couple Dailies, having bought one out of skeptical curiosity for my wife, and the other one was thrown in for free. I also bought a few extra afterwards for the sake of review accuracy (don't you hate it when people review something after the first few uses and never get to the "and then it shit the bed and exploded the next day" issues?)

Anyway, NJOY has been marketing the Daily rather aggressively since before its retail debut in September 2015, and I had this urge to put their claims to the test. These claims are:

- Look and feel: Feels more like a real cigarette, without looking like one.
- Vaping experience: Hits more like a real cigarette.
- Longevity: Lasts for 300 puffs and is equivalent to a pack of cigarettes.

Look and Feel

The Daily doesn't even try to pretend to look like a cigarette. It's dark blue, with a squishy feeling mouth end, and the tip lights up white. It feels very light, much lighter than the heavy cigalikes I started with in 2011. You can actually hold it in your teeth and not feel like you're gnawing on a metal clicker pen. It doesn't look completely cheap/chintzy, looks a bit classier than a Blu disposable, and won't be mistaken for the real thing.

I'm ambivalent on the look/feel--there are times when I'd want a small device that's obviously *not* a cigarette, but there are also times when it's better to blend in.

Vaping Experience

The first drag I took felt almost exactly like taking a drag off an actual cigarette, which took me by *surprise. To test this further, I handed it to my wife, who still smokes. She was very pleasantly surprised* and then promptly claimed it as her own.

Throat hit and feel were practically spot-on. It feels noticeably "drier" and warmer than my usual vape, and the vapor clouds are about on par with an analog. The Rich Tobacco feels a bit more like an actual cigarette than the Menthol does.

Flavor is somewhat underwhelming. The Rich Tobacco is a bit sweet and more like a pipe tobacco, but is noticeably muted. The Menthol has a strange sort of berry-ish note that I wasn't expecting, but you can feel the menthol.

These things pack 45 mg/mL of nicotine, and you feel it almost immediately. You also feel "done" rather quickly--normally, with my eGo One, I can puff away on it for 20 minutes without getting nic'd out, but

with the Daily, I'm done within 5-10 minutes.

Hilariously, I also frequently caught myself absentmindedly flicking/tapping it like the real thing.

Short form, it feels and hits like a real cigarette, but falls short in the flavor department.

Longevity

Normally, whenever a cigalike claims that it's equivalent to a whole pack of cigarettes, I usually bust out laughing because I've never gotten anywhere near that kind of performance out of cigalikes in the past.

The "300 puffs" type of marketing statement is also probably based on the work of an unpaid intern with a small squeeze bulb and a click counter. Hardly anyone I know smokes or vapes like a small squeeze bulb, so puff count is a metric that I usually dismiss as irrelevant.

The more practical metric I'd use instead, when judging whether or not a cigalike is equivalent to a pack of cigarettes, starts with how long that pack would last me if I were still smoking. When I quit, I was smoking about a pack per day. So, in order to meet that threshold for me, a Daily would need to last an entire day from morning to bedtime, assuming I maintained a typical schedule of stepping outside roughly every other hour or so for 5-10 minutes.

For the sake of science, I've gone through 6 of them over the past week, and am still working on number seven. So far, they all have consistently lasted about 24 hours before giving up the ghost, give or take an hour or two.

Mind you, I'm not chain vaping the things, just using them in the same manner that I used to smoke--stepping outside every hour or hour and a half for 5 to 10 minutes during the 16-ish hours that I'm awake. The drags I took were about 2-4 seconds long, with about the same amount of suction that I used as a smoker, and I took one to three drags per minute.

If I tried to chain-vape a Daily, I doubt they'd last more than 3 hours (and I'd either have the mother of all nic buzzes or be puking my guts out).

They deliver. I'm impressed. They're a step up from the other disposables I've tried.

Price

MSRP for a Daily is $5.99. For me, given my week-long pack-a-day simulation for this review, that puts the Daily on par with buying a pack a day. So, it's not cheap, but if you smoke a pack or less a day, it's competitive with buying cigarettes, yet still more expensive over the medium to long term than going straight to something like a basic eGo setup with decent clearomizers.

From a practical standpoint, the cigalikes I've tried before had a much worse bang-for-the-buck factor, costing anywhere from 1.5x to over twice what you'd spend on cigarettes and failing to come anywhere close to the stated longevity.

The Daily seems to be an okay middle ground as far as disposables go--not too expensive relative to a pack of cigarettes, and noticeably more reliable and consistent than the junky stuff.

Verdict

Smokers trying to quit through vaping tend to run into a number of pain points in the critical earliest days. At this point, they're usually trying to replace smoking with something that feels *like* smoking, and they're transitioning through not just a nicotine addiction, but also the physical/psychological aspect of the habit.

So, what they generally want is something that gives them the same feeling as smoking *without* being a gigantic pain in the ass or requiring a level of acclimatization that exceeds their threshold of frustration.

I think this is a good device for flipping smokers, especially those who choke on larger setups. My wife, for example, has tried several different devices and they all seem to make her cough or simply don't satisfy when dialed down. This device, she actually likes.

Supplemental Application Data Sheet

Application Information

Application number::	14/925,968
Filing Date::	October 28, 2015
Title::	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
Attorney Docket Number::	13211-713.303

- Please update the Applicant Information as follows:

Applicant Information

Assignee?::	YES
Organization name::	PAX Labs, Inc.
Street of mailing address::	660 Alabama Street, Second Floor
City of mailing address::	San Francisco
State or Province of mailing address::	CA
Postal or Zip Code of mailing address::	94110
Country of mailing address::	US

- Please update the Assignee Information as follows:

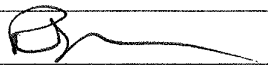
Assignee Information

Assignee name::	PAX Labs, Inc.
Street of mailing address::	660 Alabama Street, Second Floor
City of mailing address::	San Francisco
State or Province of mailing address::	CA
Postal or Zip Code of	

mailing address:: 94110

Country of mailing address:: US

Signature:

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature.			
Signature		**Date**	June 15, 2016
Name	Richard D. Shoop	**Registration No.**	45,763

Doc Code: PA..
Document Description: Power of Attorney

Attorney No.: 13211-713.303

PTO/AIA/82B (07-13)
Approved for use through 11/30/2014. OMB 0651-0051
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date
14/925,968	October 28, 2015

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 66854

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

PAX LABS, INC.

☐ *Inventor or Joint Inventor (title not required below)*

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	3-30-2016
Name	Adam Bowen		
Title	Chief Technology Officer and Co-Founder		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☑ Total of one forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. 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 3 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.

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. OMB 0651-0031
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STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: PAX LABS, INC.

Application No./Patent No.: 14/925,968 Filed/Issue Date: October 28, 2015

Titled: NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF

PAX LABS, INC., a Corporation

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☑ The assignee of the entire right, title, and interest.

2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):

   ☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

   ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (*e.g.*, bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

A. ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

B. ☑ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: Adam BOWEN and Chenyue XING To: PLOOM, INC.

   The document was recorded in the United States Patent and Trademark Office at Reel 037990, Frame 0969, or for which a copy thereof is attached.

2. From: PLOOM, INC. To: PAX LABS, INC.

   The document was recorded in the United States Patent and Trademark Office at Reel 037991, Frame 0005, or for which a copy thereof is attached.

This collection of information is required by 37 CFR 3.73(b). 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: 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.

PTO/AIA/96 (08-12)
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STATEMENT UNDER 37 CFR 3.73(c)

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

4. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

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5. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☑ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

[signature]	3-30-2016
Signature	Date
Adam Bowen	CTO and Co-Founder
Printed or Typed Name	Title or Registration Number

Electronic Acknowledgement Receipt

EFS ID:	26076217
Application Number:	14925968
International Application Number:	
Confirmation Number:	2707
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Customer Number:	66854
Filer:	Richard Douglas Shoop/Mary Buggie
Filer Authorized By:	Richard Douglas Shoop
Attorney Docket Number:	13211-713.303
Receipt Date:	15-JUN-2016
Filing Date:	28-OCT-2015
Time Stamp:	16:29:05
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		13211-713-303_AFCP_ResponseFOA_Decl_1-132_6-15-2016.pdf	3578368 028c580780e1fb3369afdfb01d85e7cb65eb430c	yes	50

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	After Final Consideration Program Request	1	1
	Response After Final Action	2	2
	Claims	3	6
	Applicant Arguments/Remarks Made in an Amendment	7	19
	Affidavit-traversing rejectns or objectns rule 132	20	45
	Application Data Sheet	46	47
	Power of Attorney	48	48
	Assignee showing of ownership per 37 CFR 3.73	49	50
Warnings:			
Information:			
	Total Files Size (in bytes):	3578368	

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.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/925,968	Filing Date 10/28/2015	☐ 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), (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 $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ 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	06/15/2016	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 17	Minus	** 20	= 0	X $80 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $420 =	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**

		(Column 1)		(Column 2)	(Column 3)		
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	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.

LIE
/PHYLLIS CANTY/

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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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/925,968	10/28/2015	Adam BOWEN	13211-713.303

CONFIRMATION NO. 2707

66854
SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

POA ACCEPTANCE LETTER

OC000000083864686

Date Mailed: 06/24/2016

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 06/15/2016.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/byemane/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
14/925,968	10/28/2015	1747	1600	13211-713.303	20	3

CONFIRMATION NO. 2707

CORRECTED FILING RECEIPT

66854
SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

Date Mailed: 06/24/2016

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Adam BOWEN, San Francisco, CA;
Chenyue XING, San Francisco, CA;

Applicant(s)

PAX Labs, Inc., San Francisco, CA;

Assignment For Published Patent Application

PAX Labs, Inc., San Francisco, CA

Power of Attorney: The patent practitioners associated with Customer Number 66854

Domestic Priority data as claimed by applicant

This application is a CON of 14/512,311 10/10/2014 PAT 9215895
which is a CON of 14/271,071 05/06/2014
which claims benefit of 61/820,128 05/06/2013
and claims benefit of 61/912,507 12/05/2013

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: No

Permission to Access Search Results: No

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 11/09/2015

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/925,968**

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

Title

NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF

Preliminary Class

131

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific

countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

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PTO/SB/08A (04-07)
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant *Figures Appear*
	595	US- 9,220,302	12/29/2015	DePiano et al.	
	596	US- 9,226,526	1/5/2016	Liu	
	597	US- 9,271,525	3/1/2016	Liu	
	598	US- 9,271,529	3/1/2016	Alima	
	599	US- 9,272,103	3/1/2016	Storz	
	600	US- 9,277,769	3/8/2016	Liu	
	601	US- 9,282,772	3/15/2016	Tucker et al.	
	602	US- 9,282,773	3/15/2016	Greim et al.	
	603	US- 9,289,014	3/22/2016	Tucker et al.	
	604	US- 9,308,336	4/12/2016	Newton	
	605	US- 9,326,547	5/3/2016	Tucker et al.	
	606	US- 9,351,522	5/31/2016	Safari	
	590	US- 2013/0199528	8/8/2013	Goodman et al.	
	591	US- 2014/0144429	5/29/2014	Wensley et al.	
	592	US- 2015/0272220	10/1/2015	Spinka et al.	
	608	US- 2015/0282525	10/8/2015	Plojoux et al.	
	609	US- 2015/0313275	11/5/2015	Andersonet al.	
	611	US- 2015/0351456	12/10/2015	Johnson et al.	
	614	US- 2016/0021931	1/28/2016	Haweset al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	639	WO2015/149647A1(w/ Eng Abs)	10/8/2015	Kimree Hi-Tech Inc.		
	640	WO2015/168828A1(w/ Eng Abs)	11/12/2015	Kimree Hi-Tech Inc.		

Examiner Signature		Date Considered	

*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. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]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 37 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, 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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PTO/SB/08A (04-07)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	607	US- 2016/0058071	3/3/2016	Hearn	
	618	US- 2016/0058072	3/3/2016	Liu	
	621	US- 2016/0081395	3/24/2016	Thorens et al.	
	623	US- 2016/0106154	4/21/2016	Lord	
	624	US- 2016/0106155	4/21/2016	Reevell	
	627	US- 2016/0120218	5/5/2016	Schennum et al.	
	630	US- 2016/0135503	5/19/2016	Liu	
	632	US- 2016/0143359	5/26/2016	Xiang	
	635	US- 2016/0143365	5/26/2016	Liu	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*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. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] 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 37 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, 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 (1-800-786-9199) and select option 2.

Electronic Patent Application Fee Transmittal

Application Number:	14925968
Filing Date:	28-Oct-2015
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Filer:	Richard Douglas Shoop/Brian Flick
Attorney Docket Number:	13211-713.303

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($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	26322723
Application Number:	14925968
International Application Number:	
Confirmation Number:	2707
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Customer Number:	66854
Filer:	Richard Douglas Shoop/Brian Flick
Filer Authorized By:	Richard Douglas Shoop
Attorney Docket Number:	13211-713.303
Receipt Date:	12-JUL-2016
Filing Date:	28-OCT-2015
Time Stamp:	12:51:13
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$180
RAM confirmation Number	071216INTEFSW00011347504050
Deposit Account	504050
Authorized User	Richard Shoop
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		13211-713-303_IDS_Filing_7-12-2016.pdf	368505 49db8cab8b70ba2fa94a2301c7196a74079d99e1	yes	5
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Transmittal Letter		1	3	
	Information Disclosure Statement (IDS) Form (SB08)		4	5	
Warnings:					
Information:					
2	Foreign Reference	WO2015149647A1wEngAbs.pdf	4126062 5befb950204f07116668f0505bde16b475a60b4c	no	30
Warnings:					
Information:					
3	Foreign Reference	WO2015168828A1wEngAbs.pdf	3569086 5ee87f51ce7ac3a070eabc7220a3d17100792211	no	30
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	30801 64f4946aa153fa64a44ecd4b4490c28cf440066b	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	8094454		

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.

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on 7-12-2016.

Brian Flick
Name

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 14/925,968	Confirmation No.: 2707
First Named Inventor	: Adam Bowen	
Filed	: October 28, 2015	
Art Unit	: 1747	
Examiner	: Mayes, Dionne Walls	
Title	: NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF	
Customer No.	: 66854	

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☐ **37 CFR §1.97(b)**
This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:
- ☐ **1).** Within 3 months of the application filing date, or
- ☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or
- ☐ **3).** Before the mail date of a first Office Action on the merits, or
  - ☐ **3a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below
- ☐ **4).** Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.
  - ☐ **4a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below

☐ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☐ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☐ **A).** A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement. or

☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☒ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under §1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☒ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☒ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☐ **3).** Items identified by a double asterisk (**) on the SB08A are *commonly-owned U.S. patents and U.S. patent application publications.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), *Commonly-owned, unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s), and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **3).** A copy of each application specification is not submitted because the application is stored in the IFW. Cite no(s):

Applicant(s) assume the Examiner has access to the file histories of these items. However, if the Examiner would like to receive copies of Office Actions in any of the commonly-owned applications, publications and/or patents identified on the attached SB08, please inform the undersigned and copies will be provided.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☐ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and 609.04(a)III, Foreign patent(s) or other foreign documents not in English cited. Either:**

☒ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☒ **2a).** An English language abstract or an English language copy of a foreign search report or other action by a foreign patent office is provided herewith to fulfill the requirement for a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language: Cite no(s): 639 and 640

--AND/OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached: Cite no(s):

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

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

STATEMENT UNDER 37 CFR § 1.704(d)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 7/12/16

By: _____

Richard D. Shoop, Reg. No. 45,763

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/925,968	10/28/2015	Adam BOWEN	13211-713.303	2707

66854 7590 07/28/2016

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

EXAMINER	
MAYES, DIONNE WALLS	

ART UNIT	PAPER NUMBER
1747	

NOTIFICATION DATE	DELIVERY MODE
07/28/2016	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):

info@shayglenn.com

PTOL-90A (Rev. 04/07)

Examiner-Initiated Interview Summary	Application No. 14/925,968	Applicant(s) BOWEN ET AL.	
	Examiner DIONNE W. MAYES	Art Unit 1747	

All participants (applicant, applicant's representative, PTO personnel):

(1) *DIONNE W. MAYES*. (3)_____.

(2) *RICHARD SHOOP*. (4)_____.

Date of Interview: *12 July 2016*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☐103 ☒Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *Those of Record*.

Identification of prior art discussed: *Collett et al (US. Pat. No. 8,881,737), Gonda (US. Pat. App. Pub. 2014/0261474) and Bowen '717 (US. Pat. App.Pub. 2009/0151717)* .

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Examiner Mayes contacted Applicant's representative, Mr. Shoop, pursuant to the Request, filed on 6/15/2016, under the AFCP 2.0 Program. In the Request, Applicant proposed amending the independent claims, in a substantial manner, so as to require further search/consideration. After review of the proposed amendments, and a quick prior art search, Examiner Mayes determined that a new prior art reference, such as Collett et al, could be used (in lieu of existing primary reference Griffith, Jr. et al) to address the proposed new recitation regarding "wick/wicking". Examiner Mayes then submitted that the existing references to Gonda and Bowen '717 were still proper to reject the proposed new claim recitation regarding "Cmax". As such, Examiner Mayes indicated that the proposed claim amendments would not be entered, as they do no appear to render the claimed invention definable over the prior art, but that she'd be happy to further consider the claimed invention, officially, - as well as the Declaration filed under 37 CFR 1.132 - upon the filing of a Continued application, i.e. an RCE. Mr. Shoop stood firm on Applicant's position that the proposed claims defined over the prior art of record, but indicated that he would take what was discussed into consideration and file an official response to the Final Rejection accordingly.

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☒ Attachment

/DIONNE W MAYES/ Examiner, Art Unit 1747	

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 14/925,968	**Applicant(s)** BOWEN ET AL.	
	Examiner DIONNE W. MAYES	**Art Unit** 1747	**AIA (First Inventor to File) Status** Yes

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

THE REPLY FILED 15 June 2016 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

NO NOTICE OF APPEAL FILED

1. ☐ The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   c) ☐ A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection. The current period for reply expires months from the mailing date of *the prior Advisory Action* or SIX MONTHS from the mailing date of the final rejection, whichever is earlier.

   Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANT'S FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) or (c) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   b) ☐ They raise the issue of new matter (see NOTE below);
   c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): (a) ☒ will not be entered, or (b) ☐ will be entered, and an explanation of how the new or amended claims would be rejected is provided below or appended.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
9. ☒ The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
10. ☐ The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
11. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

12. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
13. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
14. ☒ Other: See attached PTO-2323 and PTO-413B forms.

STATUS OF CLAIMS

15. The status of the claim(s) is (or will be) as follows:
    Claim(s) allowed: .
    Claim(s) objected to: .
    Claim(s) rejected: 1-4,6-10,12-18 and 20.
    Claim(s) withdrawn from consideration: .

/MICHAEL H WILSON/ Supervisory Patent Examiner, Art Unit 1747	/DIONNE W MAYES/ Examiner, Art Unit 1747

Continuation of 3. NOTE: Applicant has proposed substantially amending the independent claims in a manner that significantly changes the scope of said claims. Specifically, it proposes the addition, in independent claims 1 and 13 of "a Cmax of over 10 ng/mL on average" and, also, in independent claims 1, 7 and 13 of "wick/wicking" recitation. Such amendment would raise new issues that would require further consideration and/or search, and would most likely require the application of new prior art references to reject the claims. As such, the proposed amendment has not been entered.

Examiner-Initiated Interview Summary	Application No. 14/925,968	Applicant(s) BOWEN ET AL.	
	Examiner DIONNE W. MAYES	Art Unit 1747	

All participants (applicant, applicant's representative, PTO personnel):

(1) *DIONNE W. MAYES*. (3)_____.

(2) *RICHARD SHOOP*. (4)_____.

Date of Interview: *12 July 2016*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☐103 ☒Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *Those of Record*.

Identification of prior art discussed: *Collett et al (US. Pat. No. 8,881,737), Gonda (US. Pat. App. Pub. 2014/0261474) and Bowen '717 (US. Pat. App.Pub. 2009/0151717)* .

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Examiner Mayes contacted Applicant's representative, Mr. Shoop, pursuant to the Request, filed on 6/15/2016, under the AFCP 2.0 Program. In the Request, Applicant proposed amending the independent claims, in a substantial manner, so as to require further search/consideration. After review of the proposed amendments, and a quick prior art search, Examiner Mayes determined that a new prior art reference, such as Collett et al, could be used (in lieu of existing primary reference Griffith, Jr. et al) to address the proposed new recitation regarding "wick/wicking". Examiner Mayes then submitted that the existing references to Gonda and Bowen '717 were still proper to reject the proposed new claim recitation regarding "Cmax". As such, Examiner Mayes indicated that the proposed claim amendments would not be entered, as they do no appear to render the claimed invention definable over the prior art, but that she'd be happy to further consider the claimed invention, officially, - as well as the Declaration filed under 37 CFR 1.132 - upon the filing of a Continued application, i.e. an RCE. Mr. Shoop stood firm on Applicant's position that the proposed claims defined over the prior art of record, but indicated that he would take what was discussed into consideration and file an official response to the Final Rejection accordingly.

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☒ Attachment

/DIONNE W MAYES/ Examiner, Art Unit 1747	

AFCP 2.0 Decision	Application No.	Applicant(s)
	14/925,968	BOWEN ET AL.
	Examiner	Art Unit
	DIONNE W. MAYES	1747

This is in response to the After Final Consideration Pilot request filed 15 June 2016.

1. **Improper Request** – The AFCP 2.0 request is improper for the following reason(s) and the after final amendment submitted with the request will be treated under pre-pilot procedure.

   ☐ An AFCP 2.0 request form PTO/SB/434 (or equivalent document) was not submitted.

   ☐ A non-broadening amendment to at least one independent claim was not submitted.

   ☐ A proper AFCP 2.0 request was submitted in response to the most recent final rejection.

   ☐ Other:

2. **Proper Request**

   A. After final amendment submitted with the request will not be treated under AFCP 2.0.
   The after final amendment cannot be reviewed and a search conducted within the guidelines of the pilot program.

   ☐ The after final amendment will be treated under pre-pilot procedure.

   B. Updated search and/or completed additional consideration.
   The examiner performed an updated search and/or completed additional consideration of the after final amendment within the time authorized for the pilot program. The result(s) of the updated search and/or completed additional consideration are:

   ☐ 1. All of the rejections in the most recent final Office action are overcome and a Notice of Allowance is issued herewith.

   ☒ 2. The after final amendment would not overcome all of the rejections in the most recent final Office action. See attached interview summary for further details.

   ☐ 3. The after final amendment was reviewed, and it raises a new issue(s). See attached interview summary for further details.

   ☐ 4. The after final amendment raises new issues, but would overcome all of the rejections in the most recent final Office action. A decision on determining allowability could not be made within the guidelines of the pilot. See attached interview summary for further details, including any newly discovered prior art.

   ☐ 5. Other:

   Examiner Note: Please attach an interview summary when necessary as described above.

AMENDMENTS TO THE CLAIMS

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

1. (Currently amended) A method of delivering nicotine to a user comprising:

deploying a low-temperature vaporizer comprising a nicotine formulation that comprises nicotine, lactic acid, and a biologically acceptable liquid carrier within a fluid storage compartment connected to a heating element by a wick, wherein:

a. the nicotine concentration is from about 0.5% (w/w) to about 20% (w/w);

b. the biologically acceptable liquid carrier comprises propylene glycol and 90%-30% vegetable glycerol; and

c. operation of the low-temperature vaporizer comprises wicking the nicotine formulation from the fluid storage compartment to the heating element and heating at least a portion of the nicotine formulation to generate an inhalable aerosol between about 100°C and about 300°C;

wherein inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min and a Cmax of over 10 ng/mL on average, and further wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength.

2. (Currently amended) The method of claim 1, wherein a molar ratio of nicotine to ~~organic~~ lactic acid is between about 1:1 and 1:3.

3. (Original) The method of claim 1, wherein the nicotine formulation further comprises at least one flavorant.

4. (Original) The method of claim 1, wherein the nicotine concentration is about 4.5%.

5. (Cancelled)

6. (Original) The method of claim 1, wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns.

7. (Currently amended) A method of delivering nicotine to a user comprising:

deploying a low-temperature vaporizer comprising a nicotine formulation that comprises nicotine, lactic acid, and a biologically acceptable liquid carrier within a fluid storage compartment connected to a heating element by a wick, wherein:

a. the nicotine concentration is from about 0.5% (w/w) to about 20% (w/w);

b. the nicotine formulation comprises protonated nicotine;

c. the biologically acceptable liquid carrier comprises propylene glycol and 90%-30% vegetable glycerol;

d. the lactic acid does not decompose at room temperature and does not decompose at the operating temperature of the low-temperature vaporizer; and

e. operation of the low-temperature vaporizer comprises wicking the nicotine formulation from the fluid storage compartment to the heating element and heating at least a portion of the nicotine formulation between about 100°C and 300°C to generate an inhalable aerosol;

wherein inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min and further wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength.

8. (Currently amended) The method of claim 7, wherein a molar ratio of nicotine to ~~organic~~ lactic acid is between 1:1 and 1:3.

9. (Original) The method of claim 7, wherein the nicotine formulation further comprises at least one flavorant.

10. (Original) The method of claim 7, wherein the nicotine concentration is about 4.5%.

11. (Cancelled)

12. (Original) The method of claim 7, wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns.

13. (Currently amended) A low-temperature vaporizer, comprising:

a liquid reservoir;

a nicotine formulation within the liquid reservoir, the nicotine formulation comprising:

nicotine lactate;

propylene glycol; and

90%-30% vegetable glycerol;

wherein a concentration of nicotine in the nicotine formulation is from about 0.5% (w/w) to about 20% (w/w);

a vaporizing component configured to produce an aerosol from the nicotine formulation by heating at least a portion of the nicotine formulation between 100°C and 300°C, wherein the liquid reservoir is connected to the vaporizing component by a wick; and

a mouthpiece configured to connect to the reservoir for inhalation of the aerosol;

wherein inhalation of the aerosol into the user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 min to about 8 min and a Cmax of over 10 ng/mL on average, and further wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength.

14. (Original) The electronic cigarette of claim 13, further comprises a battery configured to provide power to the vaporizing component.

15. (Currently amended) The electronic cigarette of claim 13, wherein a molar ratio of nicotine to ~~organic~~ lactic acid is between 1:1 and 1:3.

16. (Original) The electronic cigarette of claim 13, wherein the nicotine formulation further comprises at least one flavorant.

17. (Original) The electronic cigarette of claim 13, wherein the vaporizing component comprises a heating element in fluid communication with the nicotine formulation.

18. (Original) The electronic cigarette of claim 13, wherein the nicotine concentration is about 4.5%.

19. (Cancelled)

20. (Original) The electronic cigarette of claim 13, wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY.DOCKET NO./TITLE	REQUEST ID
14/925,968	10/28/2015	PAX Labs, Inc.	13211-713.303	23382

Acknowledgement of Change to Small Entity Status

The entity status change request below filed through Private PAIR on 08/17/2016 has been accepted.

CERTIFICATIONS:

Change of Entity Status:

X Applicant asserting small entity status. See 37 CFR 1.27.

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.

This portion must be completed by the signatory or signatories making the entity status change in accordance with 37 CFR 1.4(d)(4).

Signature:	/Richard D. Shoop/
Name:	Richard D. Shoop
Registration Number:	45763

PTO/SB/30 (07-14)
Approved for use through 07/31/2016 OMB 0651-0031
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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	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam BOWEN
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

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, to any international application that does not compy with the requirements of 35 U.S.C 371, 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

      ii. ☑ Affidavit(s)/ Declaration(s)

      iii. ☑ Information Disclosure Statement (IDS)

      iv. ☑ Other Pet. Ext. of Time, Track 1 Request

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. 50-4050 .

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

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

      iii. ☑ Other Track 1 Request ($2,000) and Processing Fee ($70)

   b. ☐ Check in the amount of $ _____ enclosed

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

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		Date	August 19, 2016
Name (Print/Type)	Richard D. Shoop	Registration No.	45,763

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being 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 U.S. Patent and Trademark Office on the date shown below.

Signature	/Mary Buggie/		
Name (Print/Type)	Mary Buggie via EFS	Date	August 19, 2016

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.

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (03-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Adam BOWEN	Nonprovisional Application Number (if known):	14/925,968
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1), the prioritized examination fee set forth in 37 CFR 1.17(c), and if not already paid, the publication fee set forth in 37 CFR 1.18(d) have been filed with the request. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims.

3. The applicable box is checked below:

I. ☐ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

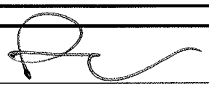
---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, **or** the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☑ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature 	Date August 19, 2016
Name (Print/Typed) Richard D. Shoop	Practitioner Registration Number 45,763

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☐ *Total of _____ forms are submitted.

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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional): 13211-713.303

Application Number: 14/925,968

Filed: October 28, 2015

For: NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF

Art Unit: 1747

Examiner: Mayes, Dionne Walls

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	Micro Entity Fee	
☑ One month (37 CFR 1.17(a)(1))	$200	$100	$50	$ 100
☐ Two months (37 CFR 1.17(a)(2))	$600	$300	$150	$
☐ Three months (37 CFR 1.17(a)(3))	$1,400	$700	$350	$
☐ Four months (37 CFR 1.17(a)(4))	$2,200	$1,100	$550	$
☐ Five months (37 CFR 1.17(a)(5))	$3,000	$1,500	$750	$

☑ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 50-4050.

☑ Payment made via 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.

I am the

☐ applicant.

☑ attorney or agent of record. Registration number 45,763.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.

Signature

August 19, 2016
Date

Richard D. Shoop
Typed or printed name

(650) 212-1700
Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☐ * Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.136(a). 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 6 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 PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. § 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on August 19, 2016.
/Mary Buggie/ 8/19/2016
Mary Buggie Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	14/925,968	Confirmation No.	: 2707
First Named Inventor:	:	Adam BOWEN		
Filing Date	:	October 28, 2015		
Art Unit	:	1747		
Examiner	:	Mayes, Dionne Walls		
Title	:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF		
Customer No.	:	66854		

AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.114

This communication is in response to the Advisory Action of July 28, 2016, which in turn responded to the Response to the final Office Action of May 13, 2016 mailed on June 15, 2016. A response to the final Office action was due August 13, 2016. A one-month Petition for Extension of Time is filed herewith, extending the due date up to and including September 13, 2016. Therefore, this response is timely filed.

Applicants submit herewith a Request for Continued Examination (RCE) and the fees for Prioritized Examination - Track 1 status. Finally, a Declaration Under 37 C.F.R. § 1.132 providing support and evidence of commercial success is also submitted herewith.

The Commissioner is authorized to charge any fees to make this filing timely to Deposit Account No. 50-4050.

Amendments to the Claims are shown in the listing of claims that begins on page 2.

Remarks/Arguments begin on page 6 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 method of delivering nicotine to a user comprising:

deploying a low-temperature vaporizer comprising a nicotine formulation that comprises nicotine, lactic acid, and a biologically acceptable liquid carrier in conditions sufficient to form nicotine lactate salt, wherein:

a. the nicotine concentration is from about 0.5% (w/w) to about 20% (w/w);

b. the biologically acceptable liquid carrier comprises propylene glycol and 90%-30% vegetable glycerol; and

c. operation of the low-temperature vaporizer comprises wicking the nicotine formulation to a heating element and heating at least a portion of the nicotine formulation to generate an inhalable aerosol of nicotine lactate between about 100°C and about 300°C;

wherein inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min and a Cmax of over 10 ng/mL on average, and further wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength.

2. (Currently amended) The method of claim 1, wherein a molar ratio of nicotine to ~~organic~~ lactic acid is between about 1:1 and 1:3.

3. (Original) The method of claim 1, wherein the nicotine formulation further comprises at least one flavorant.

4. (Original) The method of claim 1, wherein the nicotine concentration is about 4.5%.

5. (Cancelled)

6. (Original) The method of claim 1, wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns.

7. (Currently amended) A method of delivering nicotine to a user comprising:

deploying a low-temperature vaporizer comprising a nicotine formulation that comprises nicotine, lactic acid, and a biologically acceptable liquid carrier in conditions sufficient to form nicotine lactate salt, wherein:

a. the nicotine concentration is from about 0.5% (w/w) to about 20% (w/w);

b. the nicotine formulation comprises protonated nicotine;

c. the biologically acceptable liquid carrier comprises propylene glycol and 90%-30% vegetable glycerol;

d. the lactic acid does not decompose at room temperature and does not decompose at the operating temperature of the low-temperature vaporizer; and

e. operation of the low-temperature vaporizer comprises wicking the nicotine formulation to the heating element and heating at least a portion of the nicotine formulation between about 100°C and 300°C to generate an inhalable aerosol;

wherein inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min and further wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength.

8. (Currently amended) The method of claim 7, wherein a molar ratio of nicotine to ~~organic~~ lactic acid is between 1:1 and 1:3.

9. (Original) The method of claim 7, wherein the nicotine formulation further comprises at least one flavorant.

10. (Original) The method of claim 7, wherein the nicotine concentration is about 4.5%.

11. (Cancelled)

12. (Original) The method of claim 7, wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns.

13. (Currently amended) A low-temperature vaporizer, comprising:

a liquid reservoir;

a nicotine formulation within the liquid reservoir, the nicotine formulation comprising:

nicotine lactate;

propylene glycol; and

90%-30% vegetable glycerol;

wherein a concentration of nicotine in the nicotine formulation is from about 0.5% (w/w) to about 20% (w/w);

a vaporizing component configured to produce an aerosol from the nicotine formulation by heating at least a portion of the nicotine formulation between 100°C and 300°C, wherein the liquid reservoir is connected to the vaporizing component by a wick; and

a mouthpiece configured to connect to the reservoir for inhalation of the aerosol;

wherein inhalation of the aerosol into the user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 min to about 8 min and a Cmax of over 10 ng/mL on average, and further wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength.

14. (Original) The electronic cigarette of claim 13, further comprises a battery configured to provide power to the vaporizing component.

15. (Currently amended) The electronic cigarette of claim 13, wherein a molar ratio of nicotine to ~~organic~~ lactic acid is between 1:1 and 1:3.

16. (Original) The electronic cigarette of claim 13, wherein the nicotine formulation further comprises at least one flavorant.

17. (Original) The electronic cigarette of claim 13, wherein the vaporizing component comprises a heating element in fluid communication with the nicotine formulation.

18. (Original) The electronic cigarette of claim 13, wherein the nicotine concentration is about 4.5%.

19. (Cancelled)

20. (Original) The electronic cigarette of claim 13, wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns.

21. (New) The method of claim 1, wherein the nicotine formulation comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

22. (New) The method of claim 7, wherein the nicotine formulation comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

REMARKS

Claims 1-4, 6-10, 12-18 and 20 were pending in this application. By this response, claims 1, 2, 7, 8, 13 and 15 have been amended. New claims 21-22 have been added, and no claims have been cancelled. The amendments to the claims and the new claims are supported throughout the specification, and particularly:

(a) Support for the amendments to claims 1 and 7 reciting: "...in conditions sufficient to form nicotine lactate salt" may be found at least in paragraphs [0131] and in provisional patent application 61/820,128, incorporated by reference in its entirety.

(b) Support for the amendments to claims 1 and 7 reciting: "wicking the nicotine to the heating element" may be found at least in paragraphs [0640]-[0642], as mentioned above describing devices in which the fluid storage compartment is in fluid communication with a heater (heating element) and provisional patent application 61/820,128 (illustrating use of eGO-C cartridge which includes a wick).

(c) Support for the amendment to claims 1 and 13 to recite that "wherein inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in ... a Cmax of over 10 ng/mL on average" may be found at least in paragraph [0290].

(d) Support for the amendment to claim 13, reciting "wherein the liquid reservoir is connected to the vaporizing component by a wick" may be found at least in paragraph [0642].

Thus, no new matter has been added. Amendment of the claims is not to be considered a dedication to the public of any subject matter.

Claims 1-4, 6-10, 12-18 and 20 are currently under consideration. Reconsideration of these claims is requested in view of the amendments and the following remarks.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112

Claims 2, 8 and 15

Claims 2, 8 and 15 currently stand 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.

By this response, Applicants have amended claims 2, 8 and 15 to fully address the objections mentioned above (e.g., by amending "organic acid" to "lactic acid"). Thus, this rejection has been fully addressed and rendered moot.

DOUBLE PATENTING

Claims 1-4, 6-10 and 12

Claims 1-4, 6-10 and 12 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 9,215,895 to Bowen et al. ("Bowen '895") in view of U.S. Patent Application Publication No. 2013/0255702 to Griffith, Jr. et al. ("Griffith").

The Applicants respectfully disagree.

By this response, independent claims 1, 7 and 13 have been amended, emphasizing the lack of obvious subject matter between pending claims 1-4, 6-10 and 12 and the cited references. Should the Examiner maintain the nonstatutory double patenting rejection but otherwise indicate the claims are allowable, the Applicants with likely file a terminal disclaimer to overcome this rejection; filing such a terminal disclaimer earlier would be premature.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103

Claims 1-4, 6-10, 12-18 and 20 currently stand rejected under 35 U.S.C. § 103 as being unpatentable over Griffith (or alternatively Collett et. al, U.S. 8,881,737, hereafter "Collett") as evidenced by www.e-cigarette-forum.corn's PG-VG-PEG Discussion Posting ("the PG-VG-PEG Internet Posting") in view of U.S. Patent Application Publication No. 2014/0261474 to Gonda ("Gonda") and U.S. Patent Application Publication No. 2009/0151717 to Bowen et al. ("Bowen '717"). Collett was raised in the Advisory Action of July 28th, 2016 as an alternative to Griffith.

The pending claims are alleged to be obvious in view of the combination of Griffith or Collett, the PG-VG-PEG Internet Posting, Gonda and Bowen '717, because these references, in aggregate, include all of the features recited in the claims.

The Applicants respectfully disagree.

The specific and particular arrangement of these features as recited in the claims is not suggested without the use of impermissible hindsight. Further, compelling evidence of commercial success due to the recited features (secondary considerations) is definitive evidence of non-obviousness.

A. IMPERMISSIBLE HINDSIGHT

The Griffith, or alternatively Collett, reference describes a nicotine formulation in which an organic acid (such as lactic acid) is used as a flavorant; neither reference suggests the recited application of a nicotine formulation including lactic acid in a particular PG/VG carrier solution to form nicotine lactate salt solution for vaporization at low temperature and evoking a nicotine plasma Tmax from about 3 minutes to about 8 min and a Cmax of over 10 ng/mL. Instead, the final Office Action relies on the combination with Gonda to suggest this as "Gonda… teaches that administering an aerosolized, liquid nicotine-containing formulation via inhalation (i.e., pulmonary administration) in order to effectuate at peak level of nicotine in the blood plasma…can be accomplished." (final Office Action, page 9). The final Office Action points to a list of allegedly "results-effective" variables in Gonda involving only routine experimentation to accomplish this recited feature.

Applicants respectfully disagree. Without the use of hindsight, one of skill in the art would not chose a lactic acid formulation from out of the various formulations suggested by Griffith and Collett (which are primarily directed to novel vaporization devices that only very broadly a large variety of vaporization formulations). The results-oriented variables identified by Gonda are not in fact, responsible for the recited Tmax and Cmax features recited in the Applicants' claims. Although Gonda provides a long list of factors that may affect the rate of absorption (e.g., Tmax), including: amount or concentration of nicotine, pH, duration of particle generation, and particle size (see Gonda [0032], [0064] and [0099]), none of these variables are sufficient to achieve the Tmax and Cmax effect recited in the Applicant's claims. As described in the Applicants' specification, it is the unexpected combination of nicotine, lactic acid, and PG/VG in a liquid solution that is vaporized by heating between 100 and 300 °C and inhaled to provide a Tmax of between 3-8 min (and a Cmax over 10 ng/mL). While Gonda suggests that for some formulations could be tweaked by adjusting pH and/or particle size to modify their absorption, Gonda does not show the recited Tmax levels are actually achieved. This is because, as described in the Applicant's disclosure, particle size and pH (and any of the other factors mentioned by Gonda) are not sufficient by themselves, to achieve the proper Tmax, particularly when wicking a liquid reservoir onto a heater that is heated between 100-300 °C to vaporize. Importantly this ability to achieve the target Tmax with a nicotine formulation is not dependent on mere pH, but surprisingly depends on the type of acid included in the formulation, which was not known in the art until the Applicant's invention. The variables referenced by Gonda (e.g., nicotine concentration, pH, etc.) alone or in combination are not sufficient. As Applicants have described, the type of organic acid (including, in particular, lactic acid) is also critical.

Without this essential knowledge, or without the use of hindsight, it cannot be obvious to modify the Griffith reference to achieve the recited Tmax and Cmax values, even if Gonda suggests that it may be beneficial. Although the Office Action asserts that it would be routine for one of skill in the art, given the known "results oriented parameters" of Gonda (e.g., pH, nicotine concentration, particle size) to modify Griffith to achieve the claimed Tmax features, since only "routine experimentation would be needed" to optimize these variables to achieve the "recognized result" (see, e.g., Office Action, page 10). Applicants disagree. The variables being

'optimized' in the instant claims are not the same as the variables identified as "results oriented" variables by Gonda. Instead, these variables are the liquid mixture, containing nicotine, the correct carrier mixture (PG/VG) and correct acid (e.g., lactic acid). In order to be obvious for optimization, a variable (or as here, a combination of variables) must be *recognized* as a results-effective variable in the prior art. See, e.g., *In re Antonie,* 559 F.2d 618, 195 USPQ 6 (CCPA 1977). In this case, none of these variables were recognized by the Gonda as relevant to the desired result (e.g., a Tmax of nicotine in the plasma between 3 and 8 minutes), and therefore it could not be obvious to optimize to achieve them. The "results oriented variables" cited by the Office Action in reference to Gonda (e.g., pH, particle size, nicotine concentration) are irrelevant if the wrong acid and therefore salt is generated (e.g., see paragraph [115] "… not all nicotine salts perform similarly to each other or to a traditional cigarette with respect to the rate of nicotine uptake in the blood at early time periods (0-1.5 minutes). These results are unexpected."). Without knowing what variables must be optimized (e.g., which acid and therefore nicotine salt to use), it could not be obvious to optimize the combination Griffith and Gonda together or with any other reference.

MPEP § 2142 states that "impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art" (emphasis added). "'Any judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper'" (MPEP § 2145(X)(A), quoting *In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971). In this case, the Office Action has use the teachings of the Applicants' disclosure, showing that the recited composition of nicotine lactate can be optimized to mimic the Tmax and Cmax of traditional tobacco, to select the particular composition from Griffith or Collett for combining with Collette. Without the Applicants' disclosure, there is no suggestion to combine Griffith and Collett.

B. SECONDARY CONSIDERATIONS

In addition to the arguments presented above, Applicants hereby submit a Rule 1.132 Declaration to present evidence of commercial success and long-felt but unsolved needs that together weigh against a finding of obviousness.

Objective indicia of nonobviousness play a critical role in the obviousness analysis. They are "not just a cumulative or confirmatory part of the obviousness calculus but constitute[ ] independent evidence of nonobviousness." *Ortho–McNeil Pharm., Inc. v. Mylan Labs., Inc.,* 520 F.3d 1358, 1365 (Fed. Cir. 2008). Objective indicia "can be the most probative evidence of nonobviousness in the record, and enables the court to avert the trap of hindsight." *Crocs, Inc. v. Int'l Trade Comm'n*, 598 F.3d 1294, 1310 (Fed. Cir. 2010) (internal quotation marks omitted). In particular, the objective indicia of nonobviousness are crucial in avoiding the trap of hindsight when reviewing, what otherwise seems like, a combination of known elements.

Applicants respectfully submit that the claimed invention, as supported by the attached declaration under 37 C.F.R. § 1.132, has had great commercial success directly resulting from the incorporation of the all of the features of the claimed invention.

The Supreme Court has recognized commercial success as a possible determinant of patent validity since 1876. Smith v. Goodyear Dental Vulcanite Co., 93 U.S. 486, 495-96 (1876). In 1966, with the landmark decision of *Graham v. John Deere Co.*, the Court reaffirmed the vitality of secondary considerations "[a]s indicia of obviousness or nonobviousness." (*Graham v. John Deere Co.*, 383 U.S. 1, 17-18). The Court listed commercial success as the first secondary consideration. The commercial success of a product is highly probative of obviousness where the commercial success is attributable to the claimed features that are allegedly obvious; if a product commercially successful product was obvious to invent, then other competitors likely would have already developed it and the market for subsequent entrants to achieve commercial success would be depleted. The potential for achieving commercial success is thought to drive inventors to formulate solutions to existing problems to satisfy marketplace demands. Such evidence of commercial success may help prevent improper hindsight bias when comparing the claimed invention to a combination of prior art.

Prior to the Applicants' invention, existing electronic cigarettes for delivering nicotine to a user did not include a nicotine formulation comprising nicotine, lactic acid, and a carrier of propylene glycol and 90%-30% vegetable glycerol that was vaporized so that inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min. A new vaporizer product incorporating all of the features recited in the Applicants' claims in the fall of 2015. In the eight months since its introduction, this product has exhibited nearly exponential sales growth. This commercial success is directly attributable to the features claimed by the Applicant's claims.

Attached hereto is a 37 C.F.R. § 1.132 Declaration by Dr. Gal Cohen. Dr. Cohen's declaration describes the NJOY Daily commercial electronic cigarette product, a low-temperature vaporizer (electronic cigarette). Neither the Applicants nor Dr. Cohen are affiliated with the NJOY Daily product. The NJOY Daily product incorporates all of the features recited in the claims. As established in Dr. Cohen's declaration and the associated exhibits, sales of the NJOY Daily product have grown rapidly since its introduction, eclipsing the sales of other electronic cigarettes, including other newly introduced and heavily advertised products that do not include the recited features. This commercial success is directly attributable to the claimed features, including in particular, the use of a nicotine mixture including lactic acid and PG/VG, and the ability to achieve a Tmax within approximately the same time as a traditional cigarette (e.g., "wherein inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min") and a Cmax of greater than 10 ng/mL.

(a) *The NJOY Daily product includes all of the features recited in the claims*

Paragraphs 7 and 8 of Dr. Cohen's exhibit establish that the NJOY Daily electronic cigarette embodies all of the features recited in the claims. The NJOY product is an electronic cigarette including a liquid reservoir; a nicotine formulation within the liquid reservoir, in which the nicotine formulation includes: nicotine lactate (nicotine and lactic acid), and a carrier including propylene glycol and 90%-30% vegetable glycerol. The concentration of nicotine in the nicotine formulation is 4.5% (between 0.5% to about 20%) w/w. The fluid storage

compartment is connected to a heating element by a wick. In operation, the NJOY Daily device produces an aerosol from the nicotine formulation by heating at least a portion of the nicotine formulation between 100°C and 300°C so that inhalation of the aerosol into a user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min and a Cmax of over 10 ng/mL. This is explicitly shown for the NJOY Daily product in Exhibit G ("Nicotine Delivery" graph).

(b) *The NJOY Daily Product has Been Commercially Successful Because It Includes the Features Recited in the Applicants' Claims.*

The NJOY Product has enjoyed commercial success which has increased since its introduction into the market in the fall of 2015, as described by Dr. Cohen in detail in paragraphs 5 and 6. For evidence of commercial success to be probative of non-obviousness, there must be a nexus between the commercial success and the features recited in the claims. There are multiple lines of evidence showing that the commercial success of the NJOY Daily product is due (at least in part) to the feature recited in the claims. First, the NJOY Daily product has been specifically advertised as including the features recited in the claims, identifying these features key selling points to consumers. Second, consumer self-reporting data (testimonials) indicate that consumers are purchasing the NJOY daily product precisely because it includes the features recited in the claims. Finally, the company selling the NJOY Daily device (NJOY Inc.) has itself stated that the recited features, in particular the Tmax properties ("nicotine absorption") are at responsible for the commercial success. These points are all described in paragraphs 9-11 of Dr. Cohen's declaration.

Although in many cases it may be difficult to attribute commercial success to particular recited features and not simply advertising (see, e.g., MPEP §716.03(B), citing *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 227 USPQ 766 (Fed. Cir. 1985)), that is not the case where, as here, the recited features <u>are</u> what is being advertised. Advertisements for the NJOY Daily product explicitly touted the claimed features as selling points to the consumer. Thus, the success of this advertisement campaign itself hinged on the recited features into the NJOY Daily product. See the Declaration of Dr. Gal Cohen, Exhibits F and G. As shown in electronic and print advertisements marketed to consumers and distributers, the NJOY Daily product was

explicitly described as embodying the Applicants claimed features. For example, the NJOY Daily product was described as including nicotine solution including 4.5% nicotine, lactic acid, and 50/50 PG/VG that can provide "over 90%" of the satisfaction as a cigarette "during the first seven minutes," based on a "clinical trial conducted by [an] independent lab measuring nicotine absorption in blood stream [Tmax]…". Some advertisements went so far as to include a graph showing the Tmax and Cmax values for the NJOY Daily (compared to other products and a traditional cigarette) as shown by the flyer in Exhibit G.

The nexus between the recited features, including the nicotine solution with nicotine, lactic acid and PG/VG that results in a nicotine plasma Tmax from about 3 minutes to about 8 min and a Cmax of over 10 ng/mL, is also shown by consumer testimonials (Exhibit H of Dr. Cohen's declaration). Consumers have self-reported that they purchase and prefer the NJOY Daily product because of the recited features, compared to other commercial products that do not include these features. The rapid blood absorption (Tmax) is typically expressed by consumers as a nicotine satisfaction or "fix" similar or identical to traditional cigarettes.

Finally, as shown in Exhibit A of Dr. Cohen's Declaration, the company offering the NJOY Daily product (NJOY, Inc.) directly attributes the commercial success to the rapid blood absorption (Tmax) ("NJOY attributes the Daily's early success to the product's accessible $5.99 MSRP, as well as its ability to create a bridge to familiarity for adult smokers through its lightweight, soft touch design *and superior nicotine absorption.*").

In light of the strong and unambiguous evidence of commercial success, which is directly attributable to the recited features of the Applicants' claims, as shown in the attached 37 C.F.R. § 1.132 Declaration and discussed above, the Applicant's respectfully request withdrawal of the 35 U.S.C. § 103 rejection of claims 1-4, 6-10, 12-18 and 20 and allowance of all of the currently pending claims.

CONCLUSION

In light of the remarks set forth above, Applicants respectfully request the Examiner expedite the prosecution of this patent application to issuance. If it is determined that a telephone conference would aid in the prosecution of this application, the Examiner is invited to telephone the undersigned at (650) 287-2164.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-4050** referencing docket no. 13211-713.303. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Date: August 19, 2016

Richard D. Shoop
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	: 14/925,968	Confirmation No.	: 2707
Inventor(s)	: Adam BOWEN		
Filing Date	: October 28, 2015		
Art Unit	: 1747		
Examiner	: Mayes, Dionne Walls		
Title	: NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF		
Customer No.	: 66854		

DECLARATION UNDER 37 C.F.R. § 1.132

I, Dr. Gal Cohen, declare as follows:

(1) I hold a PhD in Molecular and Cellular Physiology from Stanford University.

(2) I am the Head of Scientific and Regulatory Affairs at PAX Labs, Inc. ("PAX"), a market leader in vaporization (including electronic cigarette) technology, where I have been employed or affiliated since 2008.

(3) PAX Labs is the applicant and owner of U.S. patent application no. 14/925,968, for which this declaration is being submitted.

(4) As part of my employment at PAX, I monitor the sales and marketing of other electronic cigarette manufacturers, including NJOY, Inc.

(5) In or around September of 2015, NJOY, Inc. released a new product, called the "NJOY Daily". Since its introduction, sales of the NJOY Daily product have grown substantially and the NJOY Daily has experienced a significant commercial success, particularly as compared to other electronic cigarettes. Exhibit A, attached hereto is a copy of an article from the June 10, 2016 edition of "Convenience Store Decisions." The article, dated March 30, 2016, is entitled "NJOY Daily E-Cig Sales Soar." As reported in the article, the NJOY Daily "is currently the fastest turning new e-vapor product, outselling other new products such as JTI's Logic Pro and Pax Labs' JUUL."

(6) I have also monitored the sales of the NJOY Daily product using Information Resources, Inc. (IRI), a syndication service that tracks consumer product sales and marketing. IRI analysis of NJOY, Inc. shows that since its introduction, 4 week sales in all convenience store channels of NJOY Daily have grown from $0 a year ago to just

under a million dollars ($908,604). In the same time period, sales of other, established NJOY, Inc., products (including "NJOY Vaping" and "NJOY Bold") have decreased in sales by an aggregate of just over $700,000. This data is shown in Exhibit B. NJOY, Inc. has included a graphic illustrating unit sales of the NJOY Daily product as part of its advertisement material promoting the product to distributers, which is shown in Exhibit C. The graphic shows the exponential growth of NJOY Daily sales based on IRI data using four week sales data for sales in all channels ending on January 3, 2016.

(7) I have purchased and examined the NJOY Daily product. The NJOY Daily embodies all of the features of the pending claims of the U.S. patent application no. 14/925,968. The NJOY Daily is an electronic cigarette that includes a liquid nicotine formulation of nicotine, lactic acid, and a carrier of 50/50 propylene glycol (PG) and vegetable glycerin (VG). Exhibit D, attached hereto, is a description of the NJOY Daily product that is provided on the NJOY website (www.njoy.com/faq, last visited June 10, 2016). I have also requested and reviewed a chemical analysis of the liquid nicotine composition of a purchased NJOY Daily product, and have confirmed that the composition of this product is the same as recited in the claims of U.S. patent application no. 14/925,968. Specifically, the NJOY Daily nicotine formulation is a liquid solution of nicotine (between 46.8 and 47.3 mg/mL) and lactic acid (between 22.6 and 22.4 mg/mL) with a biologically acceptable liquid carrier of propylene glycol and glycerin (vegetable glycerol). The vegetable glycerol is between 90% and 30% of the liquid carrier. The chemical analysis was performed by a commercial chemical lab, Enthalpy Analytical, Inc., and a copy of this report is attached as Exhibit E. The liquid solution of the NJOY Daily product saturates a sponge that is held within a fluid storage compartment, and the liquid solution within the storage compartment is connected to a heating element by a wick. During operation of the NJOY Daily product, the nicotine formulation is wicked from the fluid storage compartment to the heating element and heated to between about 100°C and about 300°C to generate an inhalable aerosol.

(8) The use of the NJOY Daily product also results in the nicotine plasma Tmax from about 3 min to about 8 minutes and a Cmax of over 10 ng/ml when the aerosol produced by the NJOY Daily is inhaled into the user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds. Exhibit G shows an example of advertising material promoting the NJOY Daily product which describes the product as "over 90 percent as satisfying as a cigarette during the first 7 minutes of use," based on the Tmax and Cmax profile for the NJOY Daily. In Exhibit G, the statements referring to the increased satisfaction in strength and timing of the nicotine delivery refer to a clinical trial "conducted by [an] independent lab measuring nicotine absorption in [the] blood stream represented by mean of test subjects assessed on day 8 of use following 12 hours of abstinence." Exhibit F shows two screen captures of the advertisement aimed at consumers for the NJOY Daily that describe the peak blood nicotine concentration (Tmax) occurring within the first seven minutes of use, which is describes as providing a satisfaction similar to what is achieved by a traditional cigarette. In addition, the Tmax and Cmax resulting from the NJOY Daily product is also described in advertising material targeting distributers, as shown in Exhibit G. Exhibit G is an advertising flyer distributed by NJOY Inc, targeting distributers and

customers of NJOY Daily. In Exhibit G, the graph titled "Nicotine Delivery" at the bottom right shows that the NJOY Daily has a Tmax between 3 minutes and 8 minutes, and a Cmax of greater than 10 ng/ml (mean nicotine concentration). The "Chart Notes" provided at the bottom of the flyer indicate that the graph represents a "[c]linical trial conducted by independent lab measuring nicotine absorption in blood stream represented by mean of test subjects assessed on day 8 of use following 12 hours of abstinence. N=18-20 per product. Subjects smokers aged 18-65 not currently attempting to quit. Products puffed (starting at time zero) every 30 seconds for 5 minutes."

(9) It is my opinion that the commercial success of the NJOY Daily product is attributed to the features recited in the claims of U.S. patent application no. 14/925,968. The Tmax and Cmax values of the NJOY Daily product which result from the nicotine solution including nicotine, lactic acid and the PG/VG carrier provide a cigarette-like satisfaction. The rapid onset (e.g., Tmax between 3 and 8 minutes) of a relatively high blood nicotine level (e.g., Cmax over 10 ng/mL) result in a user experience and satisfaction that is closer to the experience provided by a traditional cigarette. It has long been the goal of electronic cigarette manufactures to provide an electronic cigarette that can mimic the experience of a traditional cigarette, because of the potential for tremendous commercial success. There are numerous user-reported testimonials available online in which users discuss their reasons for purchasing the NJOY Daily product; the majority of such self-reporting comments refer to the cigarette-like experience that it provides.

(10) In addition, the features recited in the claims, and particularly the Tmax and Cmax profiles, are used extensively in the NJOY Daily marketing and advertisement materials to drive consumer purchases. For example, the consumer advertisements show in Exhibit F tout the Cmax and Tmax properties as providing a user experience that is most similar to cigarettes. In Exhibit F, on the top left ("Meet NJOY Daily"), the advertisement claims that "over 90 percent as satisfying as a cigarette," and on bottom of ("IT'S THAT SATISFYING"), a similar advertisement states "[o]ur latest innovation is now delivering the most authentic 'smoking' experience to date. We're proud (and really freakin excited) to introduce the Daily – a labor of love that blends Satisfaction, Performance, Authenticity, Flavor and Design for an experience that's more than 90% as satisfying as a cigarette during the first 7 minutes of use." The advertisement of Exhibit G is even more explicit, graphically showing the Tmax and Cmax curves and describing the NJOY Daily as providing "[q]uick & strong satisfaction more like a cigarette".

(11) Finally, the NJOY company itself credits the nicotine absorption into the blood, the Tmax and Cmax properties of the NJOY Daily, as at least partially responsible for the commercial success. The recent article ("NJOY Daily E-Cig Sales Soar") in Exhibit A cites NJOY as attributing the early success of the NJOY Daily product to "its lightweight, soft touch design and superior nicotine absorption."

(12) I declare that all statements made herein 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 were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under the provisions of 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of any patent issuing upon U.S. Application Serial No. 14/632,161, or any continuing application thereof.

Signature: _____ Date: 6/15/16
Gal A. Cohen, PhD

EXHIBIT A

Convenience Store Decisions
June 10, 2016

NJOY Daily E-Cig Sales Soar

March 30, 2016 CSD Staff : 0 Comments

Accessible pricing and lightweight, soft touch design help spur consumer demand for NJOY Daily.

E-cigarette manufacturer NJOY shared the latest IRI FDMxC ("All-Channel") data, revealing that the NJOY Daily disposable e-cig is currently the fastest-turning new e-vapor product, outselling other new products such as JTI's Logic Pro and Pax Labs' Juul.

The data indicates that NJOY Daily is finding a home in the hands of adult smokers looking for an introductory e-vapor product that delivers nicotine satisfaction more like a cigarette.

According to IRI data, NJOY Daily's 3 SKUs moved more than 37,000 units in the single week ending Feb. 21, 2016. This amounts to 23% greater unit sales per week when compared with Logic Pro and 281% greater unit sales per week than Juul.

NJOY attributes Daily's early success to the product's accessible $5.99 MSRP, as well as its ability to create a bridge to familiarity for adult smokers through its lightweight, soft touch design and superior nicotine absorption. Thanks to their valued retail partners, NJOY has been able to leverage promotional support, merchandising, signage, and marketing assets to drive trial among adult smokers.

An early e-vapor pioneer, NJOY is currently the largest independent e-cigarette and vaping company in the USA. NJOY has heavily invested in R&D and market studies to further its ongoing commitment to product innovation based on consumer research and leading-edge science.

EXHIBIT B
IRI Data

NJOY, Inc. sells 3 product lines:

(1) NJOY vaping (vape pen and e-liquid bottles with a traditional nicotine formulation)
(2) NJOY Bold (cigalikes with a traditional nicotine formulation)
(3) NJOY Daily (cigalike with a lactic acid based formulation)

Based on data provided by Information Resources, Inc (IRI), in the past year, 4 week sales in all convenience store channels for all NJOY products have increased from $2,079,734 to $2,274,610. However, the proportion of sales represented by NJOY Daily has increased from 0% to 40%, while sales of all other products (NJOY vaping and NJOY Bold) have decreased by 60%.

	4 weeks ending 5/15/16		year ago		change y/y
vaping	$879,301	39%	$1,015,091	49%	($135,789)
Bold	$486,705	21%	$1,064,644	51%	($577,939)
Daily	$908,604	40%	$0	0%	$908,604
Total	$2,274,610		$2,079,734		$194,876

INTRODUCING
NJOY® DAILY
THE DIFFERENTIATED DISPOSABLE
REINVIGORATING CONSUMER TRIAL
BY DELIVERING SATISFACTION MORE LIKE A CIGARETTE.
DESIGNED WITH RETAILERS IN MIND
REINVIGORATING CONSUMER TRIAL
• Everyday value – approximately 300 puffs for $5.99 per stick
• Quick & strong satisfaction more like a cigarette
• Disposable lightweight stick
MAXIMIZE PURCHASE FREQUENCY & PROFITS
• ~40% margins*
• 1 count configuration to maximize purchase frequency
• Compact 5 count cartons for limited investment and optimal turns
• Flavor freshness seal for extended shelf life
• ~70% higher gross profit per week vs. leading rechargeable refills**
SELL THROUGH RATE SUPPORT
• Multi-million dollar consumer advertising campaign
• Robust introductory price promotions
• Modular merchandising displays and impactful signage
• Trial generating activations
• Targeted coupon delivery to adult smokers
IRI UNIT SALES
ALL CHANNEL***
NJOY DAILY
JUUL
JUL
AUG
SEP
OCT
NOV
DEC
Source:
*Margins assume MSRP and cost = NJOY list price
** Assumes $2.74 Gross Profit per leading rechargeable 2ct refill and assumes 7 units per week of consumption. "1 Unit" Definition: Disposable = 1 stick; Recharge = 1 carbomizer. Assumes 1 unit purchased per store visit.
***IRI 4WKs Ending 12/3/16 All Channel = FDMx + C-Store
NJOY® DAILY

EXHIBIT D

Screen captures from www.njoy.com/faq (taken 6/10/2016):

What is e-liquid?

The main ingredients by volume in NJOY's vape e-liquids are propylene glycol (PG) and vegetable glycerin (VG). The secondary ingredients are nicotine and flavors.

All of NJOY's e-liquids are made in the USA with domestic and imported ingredients, and contain pharmaceutical grade PG, VG and nicotine. The e-liquid in the following products also contain lactic acid: NJOY Daily (all flavors) and our Classic Tobacco and Menthol vaping e-liquids.

NJOY Vape e-liquids contain 50% vegetable glycerin (VG) and 50% propylene glycol (PG).

The VG/PG ratios in the Artist Collection:

Paramour: 50/50 Hedon's Bite: 60/40 Sacré Coeur: 50/50 Dragon Scape: 70/30 Samba Sun: 60/40

Daily, the disposable e-cig that offers the most authentic 'smoking' experience is available in Rich Tobacco, Cool Menthol, Blue + Black Berry and Classic Tobacco (online only...coming soon).

Kings, the disposable e-cig that started it all, comes in bold, gold and menthol flavors.

Recharge comes in a range of flavors beyond menthol and traditional, including vanilla bean and pomegranate.

NJOY Vaping e-liquids come in a wide variety of flavors. You can see the all here.

Artist Collection is an exclusive line of complex e-liquids crafted by five leading artists in the vape industry in partnership with NJOY.

Check out all of our flavor chambers and e-liquids today.

How much nicotine is in NJOY products?

Ask and you shall receive:

NJOY Daily

- Rich Tobacco: 4.5% nicotine by weight
- Cool Menthol: 4.5% nicotine by weight
- Blue + Black Berry: 4.5% nicotine by weight

Some of your products now list lactic acid in the ingredient list, why?

Lactic acid is used in certain products to optimize the throat hit as well as your overall experience.

What is the difference between the NJOY King and the NJOY Daily?

There are several differences between the King and Daily, besides its size. NJOY Daily has been innovated to deliver quick & strong satisfaction more like a cigarette, it features a new longer lasting battery with QuickVapor technology delivering significantly longer battery life (approx. 300 puffs), has new upgraded flavors, more vapor volume and a discreet but stylish new design.

EXHIBIT E

PAX Labs, Inc.

660 Alabama Street, Second Floor
San Francisco, CA 94110

E-Liquid Analysis

Electronic Cigarette (eC) Liquid Testing

Analysis Report
(1115-553)

GC/FID Analysis (ENT184)

Nicotine, Propylene glycol, Vegetable glycerin, Water

HPLC/UV Analysis (ENT301-Mod)

Lactic Acid

Enthalpy Analytical, Inc.
Phone: (919) 850 - 4392 / Fax: (919) 850 - 9012 / www.enthalpy.com
800-1 Capitola Drive Durham, NC 27713-4385

I certify that to the best of my knowledge all analytical data presented in this report summary:

- Have been checked for completeness
- Are accurate, error-free, and legible
- Have been conducted in accordance with approved protocol

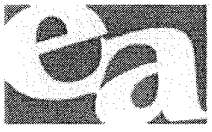
This analytical report was prepared in Portable Document Format (.PDF) and contains 10 pages.

Jennifer B. Feller

QA Review Performed by: Jennifer B. Feller

Report Issued: 1/6/2016

Summary of Results



ACCREDITED
Testing Cert. # 3198.01

Report for: PAX Labs, Inc.
Client Project: Electronic Cigarette (eC) Liquid Testing
Sample Type: e-Liquid

Project Code: 1115-553
Project Start Date: 11/13/15
Analysis Method: ENT184

Enthalpy Code	Client Code	Nicotine (mg/mL)	Propylene glycol (mg/mL)	Glycerin (mg/mL)	Water # (mg/mL)
1115-553-01-01	PO-J1-1511112A1	46.8	491	487	57.6
1115-553-01-02		47.3	497	489	59.9

#: Water results are blank corrected.

581

Report for: PAX Labs, Inc.
Client Project: Electronic Cigarette (eC) Liquid Testing
Sample Type: e-Liquid

Project Code: 1115-553
Project Start Date: 11/13/15
Analysis Method: ENT301-Mod

Enthalpy Code	Client Code	Notes	Lactic Acid (ug/mL)
1115-553-01 (DF 1010) 1	PO-J1-1511112A1	--	22,597
1115-553-01 (DF 1010) 2			22,389
		Average	22,493
		%DIFF	0.9

Narrative Summary

Enthalpy Analytical Narrative Summary

Company	PAX Labs, Inc.
Analysts	KEH, BJB/ABP
Parameters	ENT184, ENT301-Mod

Client Proj	Electronic Cigarette (eC) Liquid Testing
Job #	1115-553
# Samples	1 eC Liquid Sample

Custody	A scintillation vial labeled "*E-Liquid test nicotine, Lactic acid PG. Glycerin PO-J1-151112A1*" was used for this project. It was prepared and analzyed in duplicate. Prior to, during, and after analysis, the sample was kept under lock with access only to authorized personnel by Enthalpy Analytical, Inc.
ENT184 (Primary Constituents)	The e-Liquid sample was prepared and analyzed in duplicate for nicotine, propylene glycol (PG), and vegetable glycerin (aka VG, glycerin, or glycerol), and water following the analytical procedures in Enthalpy SOP ENT184. The samples were analyzed on the Hewlett Packard Model 6890 Gas Chromatograph "BMO" equipped with a Flame Ionization Detector (FID) and an appropriate column.
ENT301-Mod (Lactic Acid)	The e-Liquid sample was prepared and analyzed in duplicate for lactic acid following the general analytical procedures in Enthalpy SOP ENT301. The samples were analyzed using the Agilent Model 1100, High Performance Liquid Chromatograph "Selma," equipped with an Ultraviolet (UV) Detector operating at 360 nm and an appropriate column.
QC Notes	All QC samples were within acceptance criteria unless otherwise noted. As the lactic acid analysis was not a standard laboratory method, a second source standard was not available to verify the calibration for lactic acid. A continuing calibration sample was analyzed after the samples, and had a recovery of 98.7% of the expected concentration.
Reporting Notes	Sample and calibration curve chromatograms are available upon request. The results presented in this report are representative of the samples as provided to the laboratory.

General Reporting Notes

The following are general reporting notes that are applicable to all Enthalpy Analytical, Inc. data reports, unless specifically noted otherwise.

- Any analysis which referrs to the method as *"Type"* represents a planned deviation from the reference method. For instance a Hydrogen Sulfide assay from a Tedlar bag would be labeled as "EPA Method 16-Type" because Tedlar bags are not mentioned as one of the collection options in EPA Method 16.
- The acronym ***MDL*** represents the Minimum Detection Limit. Below this value the laboratory cannot determine the presence of the analyte of interest reliably.
- The acronym ***LOQ*** represents the Limit of Quantification. Below this value the laboratory cannot quantitate the analyte of interest within the criteria of the method.
- The acronym ***ND*** following a value indicates a non-detect or analytical result below the MDL.
- The letter ***J*** in the Qualifier or Flag column in the results indicates that the value is between the MDL and the LOQ. The laboratory can positively identify the analyte of interest as present, but the value should be considered an estimate.
- The letter ***E*** in the Qualifier or Flag column indicates an analytical result exceeding 100% of the highest calibration point. The associated value should be considered as an estimate.
- The acronym ***DF*** represents Dilution Factor. This number represents dilution of the sample during the preparation and/or analysis process. The analytical result taken from a laboratory instrument is multiplied by the DF to determine the final undiluted sample results.
- The addition of ***MS*** to the Sample ID represents a Matrix Spike. An aliquot of an actual sample is spiked with a known amount of analyte so that a percent recovery value can be determined. The MS analysis indicates what effect the sample matrix may have on the target analyte, i.e. whether or not anything in the sample matrix interferes with the analysis of the analyte(s).
- The addition of ***MSD*** to the Sample ID represents a Matrix Spike Duplicate. Prepared in the same manner as an MS, the use of duplicate matrix spikes allows further confirmation of laboratory quality by showing the consistency of results gained by performing the same steps multiple times.
- The addition of ***LD*** to the Sample ID represents a Laboratory Duplicate. The analyst prepares an additional aliquot of sample for testing and the results of the duplicate analysis are compared to the initial result. The result should have a difference value of within 10% of the initial result (if the results of the original analysis are greater than the LOQ).
- The addition of ***AD*** to the Sample ID represents an Alternate Dilution. The analyst prepares an additional aliquot at a different dilution factor (usually double the initial factor). This analysis helps confirm that no additional compound is present and coeluting or sharing absorbance with the analyte of interest, as they would have a different response/absorbance than the analyte of interest.
- The Sample ID ***LCS*** represents a Laboratory Control Sample. Clean matrix, similar to the client sample matrix, prepared and analyzed by the laboratory using the same reagents, spiking standards and procedures used for the client samples. The LCS is used to assess the control of the laboratory's analytical system. Whenever spikes are prepared for our client projects, two spikes are retained as LCSs. The LCSs are labeled with the associated project number and kept in-house at the appropriate temperature conditions. When the project samples are received for analysis, the LCSs are analyzed to confirm that the analyte could be recovered from the media, separate from the samples which were used on the project and which may have been affected by source matrix, sample collection and/or sample transport.

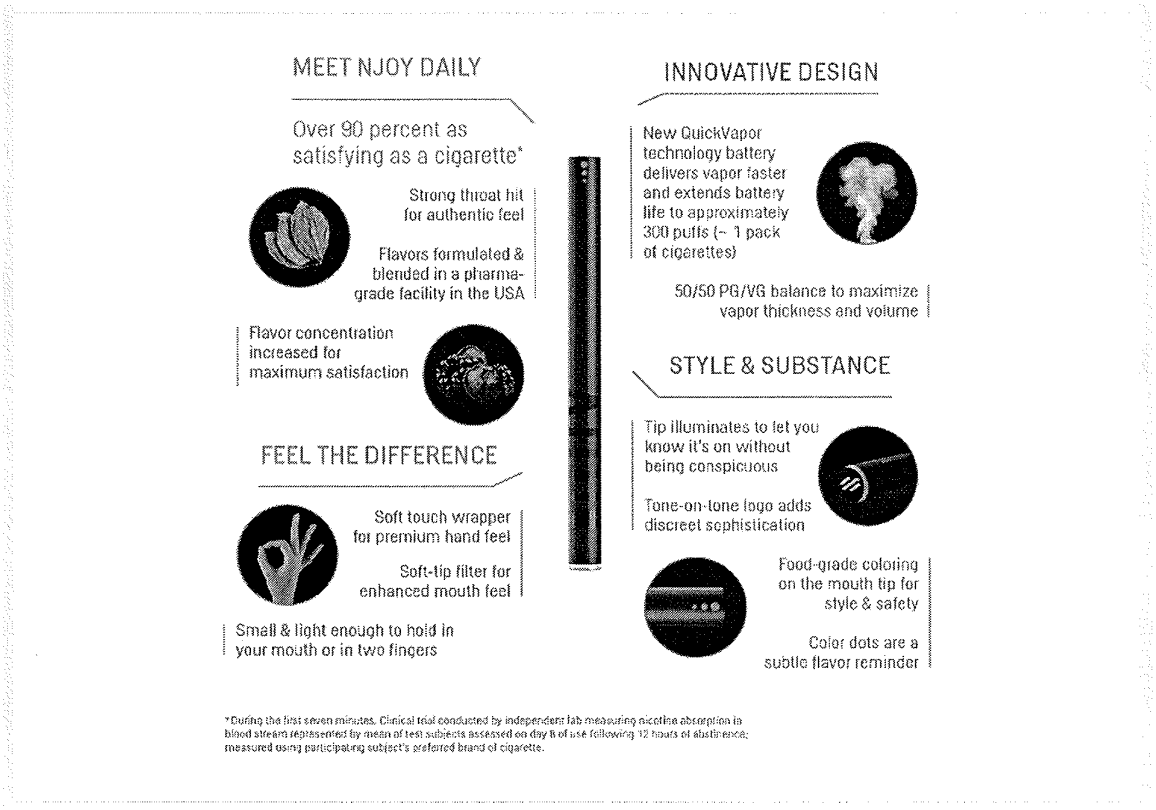
General Reporting Notes

(continued)

- **Significant Figures**: Where the reported value is much greater than unity (1.00) in the units expressed, the number is rounded to a whole number of units, rather than to 3 significant figures. For example, a value of 10,456.45 ug catch is rounded to 10,456 ug. There are five significant digits displayed, but no confidence should be placed on more than two significant digits.
- **Manual Integration**: The data systems used for processing will flag manually integrated peaks with an "M". There are several reasons a peak may be manually integrated. These reasons will be identified by the following two letter designations. The peak was ***not integrated*** by the software "NI", the peak was ***integrated incorrectly*** by the software "II" or the ***wrong peak*** was integrated by the software "WP". These codes will accompany the analyst's manual integration stamp placed next to the compound name on the chromatogram.

This Is The Last Page Of This Report.

EXHIBIT F



IT'S THAT SATISFYING

Our latest innovation is now delivering the most authentic "smoking" experience to date. We're proud (and really freakin excited) to introduce the Daily – a labor of love that blends Satisfaction, Performance, Authenticity, Flavor and Design for an experience that's more than 90% as satisfying as a cigarette during the first 7 minutes of use.

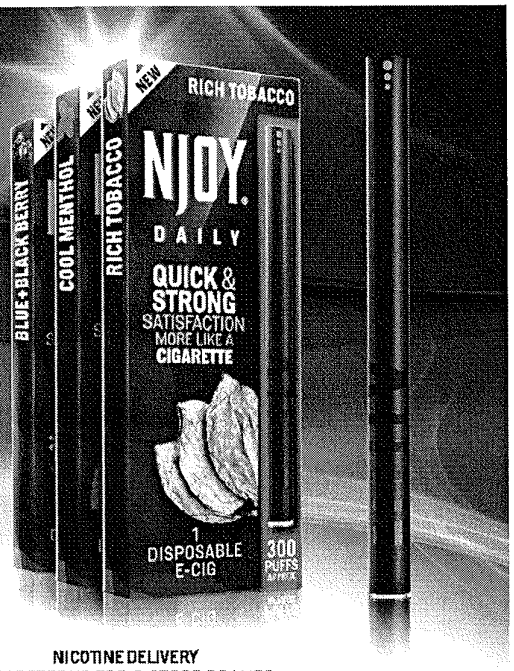
*June 2015 in-home consumer study consisting of adult smokers using tobacco and menthol flavor of both brands.

(Screen capture from https://www.njoy.com/daily, last visited June 13, 2016)

INTRODUCING

NJOY® DAILY

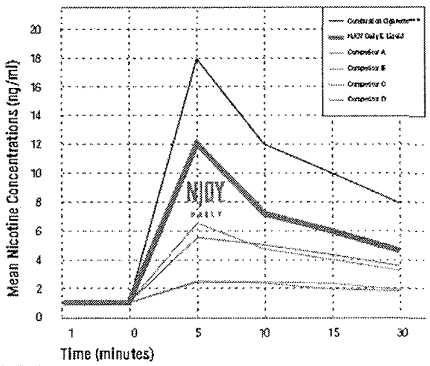
THE DIFFERENTIATED DISPOSABLE



DESIGNED WITH RETAILERS IN MIND

REINVIGORATING CONSUMER TRIAL	• Everyday value - approximately 300 puffs for $5.99 per stick • Quick & strong satisfaction more like a cigarette • Disposable lightweight stick
MAXIMIZE PURCHASE FREQUENCY & PROFITS	• ~40% margins* • 1 count configuration to help restore purchase frequency • Compact 5 count cartons for limited investment and optimal turns • Flavor freshness seal for extended shelf life • ~70% higher gross profit per week vs. leading rechargeable refills**
SELL THROUGH RATE SUPPORT	• Robust introductory pricing promotions • Modular merchandising displays and impactful signage • Multi-million dollar consumer advertising campaign • Trial generating activations • Targeted coupon delivery to adult smokers

NICOTINE DELIVERY
CIGARETTE VS TOP C STORE BRANDS



Source:
*Margins assume MSRP and cost NJOY list price
** Assumes "Committed user": Users completely switching from pack a day of cigarettes to E-Vapor Products. Assumes 2 sticks per week of consumption. 1 Unit Definition: Disposable = 1 stick; Rechargeable 1 cartomizer, 1 Liquid 1 4 mL E-Liquid and assumes 1 unit purchased per visit
*** Measured in leg participating subjects preferred brand of cigarette
Chart Notes: Clinical trial conducted by independent lab measuring nicotine absorption in blood stream represented by mean of test subjects assessed on day 8 of use following 12 hours of abstinence.
N= 18-20 per product. Subjects smokers aged 18-65 not currently attempting to quit. Products puffed (starting at time zero) every 30 seconds for 5 minutes.

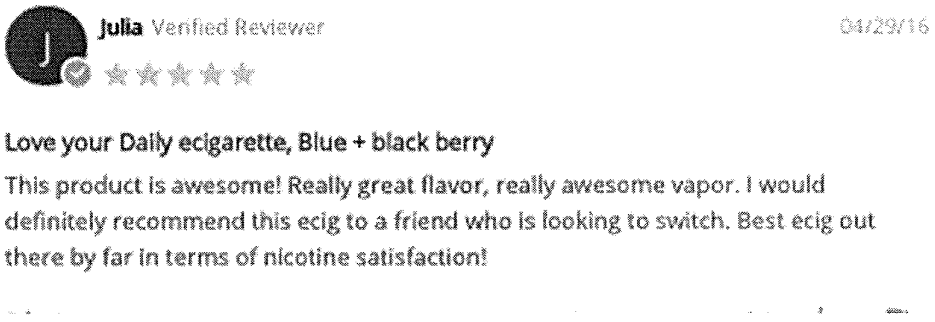
WARNING: NJOY® products are not nothing cessation products and have not been tested as such, nor have the long-term effects of using this product been established. NJOY® products are intended for use by adults of legal smoking age (18 or older in California), and not by children, women who are or are pregnant or breastfeeding, or persons without a risk of heart disease, high blood pressure, diabetes or taking medicine for depression or asthma. NJOY® products contain nicotine. Nicotine is an addictive chemical. Do not use if you are allergic to propylene glycol. Nicotine is addictive and habit forming, and it is very toxic by inhalation, ingestion or skin contact with the skin, or through wounds. Ingestion of the non-vaporized concentrated ingredients in the liquid components of NJOY® products can be poisonous. If any liquid is swallowed, seek medical assistance immediately.

NJOY VAPING

EXHIBIT H

Consumer Testimonials

Sampling of customer testimonials from www.njoy.com/ (last visited 6/10/2016)



Julia Verified Reviewer 04/29/16

Love your Daily ecigarette, Blue + black berry

This product is awesome! Really great flavor, really awesome vapor. I would definitely recommend this ecig to a friend who is looking to switch. Best ecig out there by far in terms of nicotine satisfaction!

Sammy G. Verified Reviewer 02/04/16

The njoy Daily is the best e-cigarette yet!

I've tried them all...well most of them. This is the first e-cigarette that really offers an effective substitute to a real cigarette. Terrific!

Sam J. Verified Reviewer 03/07/16

Best E-cigs in the Game!

NJOY is my go-to e-cig.. I was a long time user of the Kings e-cigarette and I've just recently made the switch to their new Daily electronic cigarette.. The Daily e-cig has the nicotine fix I need and it really does feel like a regular cigarette.. The Blue + Black Berry is my favorite flavor !!

Share | Was This Review Helpful? 4 0

Customer testimonials from http://www.vaporauthority.com/products/genuine-njoy-daily-disposable-e-cig (last visited June 10, 2016):

★★★★★ (5/5)

Steven P from **Philly** on **May 17, 2016**

Great disposable here, probably the best one I've ever tried. Got one a while ago just for shits but now I pick a couple of em up every time I place an order here. These are so easy for out and about or stealthy vaping. Damn close to an analog too!

Report this review

★★★★★ (5/5)

Morgan from **Denver** on **Apr 29, 2016**

Unbelievable! It's like I'm smoking a cigarette again, but I'm not... I have been vaping instead of smoking for like a year now and this is a great way to revisit that without feeling like shit afterwards! Whooo Hoooo!

Report this review

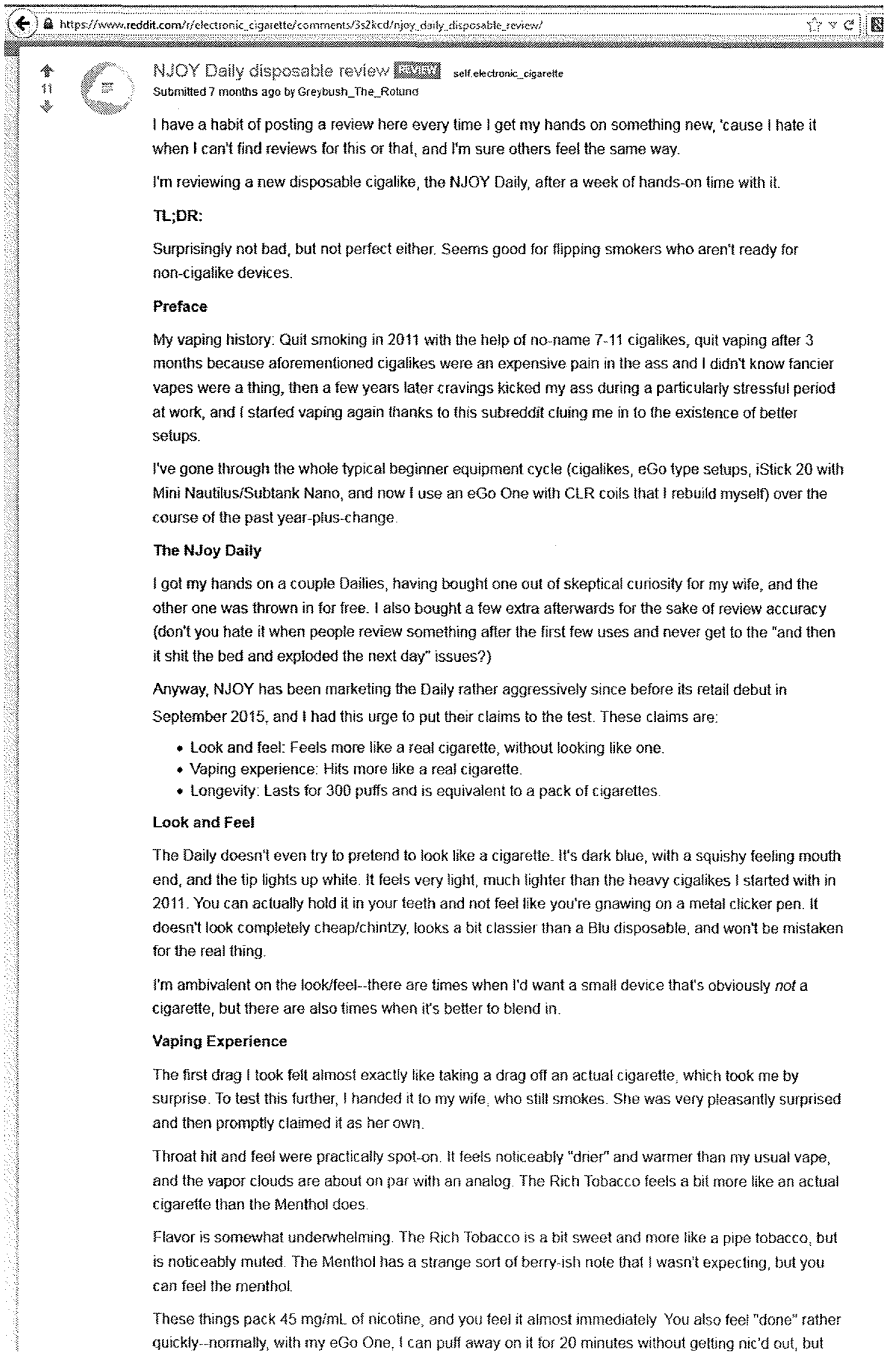
★★★★★ (5/5)

Alana B from **Austin Tx** on **Apr 11, 2016**

Oh Wow! I've tried other ecigs like this from the gas station and they were disappointing, but I'd never seen these Daily before. Now this is the closest thing to a real cigarette that I've ever had! I mean, if its this good I don't know why anyone would smoke real cigs.. Completely satisfying!! I actually have a nice vape set up and I just ordered these out of curiosity and I wanted an emergency go-to if my vape broke or got lost or something. Really good on the out and about. I'm definitely going to keep a stock of these around for rough times. Would be great for someone just trying to quit cigarettes, but it could get costly if you just relied on these. Get these and also a good mod and tank - and your golden! Much appreciated Vapor Authority!

Report this review

Exemplary Customer review from Reddit: https://www.reddit.com/r/electronic_cigarette/comments/3s2kcd/njoy_daily_disposable_review/ (last visited June 10, 2016):



https://www.reddit.com/r/electronic_cigarette/comments/3s2kcd/njoy_daily_disposable_review/

11

NJOY Daily disposable review Review self.electronic_cigarette

Submitted 7 months ago by Greybush_The_Rotund

I have a habit of posting a review here every time I get my hands on something new, 'cause I hate it when I can't find reviews for this or that, and I'm sure others feel the same way.

I'm reviewing a new disposable cigalike, the NJOY Daily, after a week of hands-on time with it.

TL;DR:

Surprisingly not bad, but not perfect either. Seems good for flipping smokers who aren't ready for non-cigalike devices.

Preface

My vaping history: Quit smoking in 2011 with the help of no-name 7-11 cigalikes, quit vaping after 3 months because aforementioned cigalikes were an expensive pain in the ass and I didn't know fancier vapes were a thing, then a few years later cravings kicked my ass during a particularly stressful period at work, and I started vaping again thanks to this subreddit cluing me in to the existence of better setups.

I've gone through the whole typical beginner equipment cycle (cigalikes, eGo type setups, iStick 20 with Mini Nautilus/Subtank Nano, and now I use an eGo One with CLR coils that I rebuild myself) over the course of the past year-plus-change.

The NJoy Daily

I got my hands on a couple Dailies, having bought one out of skeptical curiosity for my wife, and the other one was thrown in for free. I also bought a few extra afterwards for the sake of review accuracy (don't you hate it when people review something after the first few uses and never get to the "and then it shit the bed and exploded the next day" issues?)

Anyway, NJOY has been marketing the Daily rather aggressively since before its retail debut in September 2015, and I had this urge to put their claims to the test. These claims are:

- Look and feel: Feels more like a real cigarette, without looking like one.
- Vaping experience: Hits more like a real cigarette.
- Longevity: Lasts for 300 puffs and is equivalent to a pack of cigarettes.

Look and Feel

The Daily doesn't even try to pretend to look like a cigarette. It's dark blue, with a squishy feeling mouth end, and the tip lights up white. It feels very light, much lighter than the heavy cigalikes I started with in 2011. You can actually hold it in your teeth and not feel like you're gnawing on a metal clicker pen. It doesn't look completely cheap/chintzy, looks a bit classier than a Blu disposable, and won't be mistaken for the real thing.

I'm ambivalent on the look/feel--there are times when I'd want a small device that's obviously *not* a cigarette, but there are also times when it's better to blend in.

Vaping Experience

The first drag I took felt almost exactly like taking a drag off an actual cigarette, which took me by surprise. To test this further, I handed it to my wife, who still smokes. She was very pleasantly surprised and then promptly claimed it as her own.

Throat hit and feel were practically spot-on. It feels noticeably "drier" and warmer than my usual vape, and the vapor clouds are about on par with an analog. The Rich Tobacco feels a bit more like an actual cigarette than the Menthol does.

Flavor is somewhat underwhelming. The Rich Tobacco is a bit sweet and more like a pipe tobacco, but is noticeably muted. The Menthol has a strange sort of berry-ish note that I wasn't expecting, but you can feel the menthol.

These things pack 45 mg/mL of nicotine, and you feel it almost immediately. You also feel "done" rather quickly--normally, with my eGo One, I can puff away on it for 20 minutes without getting nic'd out, but

with the Daily, I'm done within 5-10 minutes.

Hilariously, I also frequently caught myself absentmindedly flicking/tapping it like the real thing.

Short form, it feels and hits like a real cigarette, but falls short in the flavor department.

Longevity

Normally, whenever a cigalike claims that it's equivalent to a whole pack of cigarettes, I usually bust out laughing because I've never gotten anywhere near that kind of performance out of cigalikes in the past.

The "300 puffs" type of marketing statement is also probably based on the work of an unpaid intern with a small squeeze bulb and a click counter. Hardly anyone I know smokes or vapes like a small squeeze bulb, so puff count is a metric that I usually dismiss as irrelevant.

The more practical metric I'd use instead, when judging whether or not a cigalike is equivalent to a pack of cigarettes, starts with how long that pack would last me if I were still smoking. When I quit, I was smoking about a pack per day. So, in order to meet that threshold for me, a Daily would need to last an entire day from morning to bedtime, assuming I maintained a typical schedule of stepping outside roughly every other hour or so for 5-10 minutes.

For the sake of science, I've gone through 6 of them over the past week, and am still working on number seven. So far, they all have consistently lasted about 24 hours before giving up the ghost, give or take an hour or two.

Mind you, I'm not chain vaping the things, just using them in the same manner that I used to smoke--stepping outside every hour or hour and a half for 5 to 10 minutes during the 16-ish hours that I'm awake. The drags I took were about 2-4 seconds long, with about the same amount of suction that I used as a smoker, and I took one to three drags per minute.

If I tried to chain-vape a Daily, I doubt they'd last more than 3 hours (and I'd either have the mother of all nic buzzes or be puking my guts out).

They deliver. I'm impressed. They're a step up from the other disposables I've tried.

Price

MSRP for a Daily is $5.99. For me, given my week-long pack-a-day simulation for this review, that puts the Daily on par with buying a pack a day. So, it's not cheap, but if you smoke a pack or less a day, it's competitive with buying cigarettes, yet still more expensive over the medium to long term than going straight to something like a basic eGo setup with decent clearomizers.

From a practical standpoint, the cigalikes I've tried before had a much worse bang-for-the-buck factor, costing anywhere from 1.5x to over twice what you'd spend on cigarettes and failing to come anywhere close to the stated longevity.

The Daily seems to be an okay middle ground as far as disposables go--not too expensive relative to a pack of cigarettes, and noticeably more reliable and consistent than the junky stuff.

Verdict

Smokers trying to quit through vaping tend to run into a number of pain points in the critical earliest days. At this point, they're usually trying to replace smoking with something that feels *like* smoking, and they're transitioning through not just a nicotine addiction, but also the physical/psychological aspect of the habit.

So, what they generally want is something that gives them the same feeling as smoking *without* being a gigantic pain in the ass or requiring a level of acclimatization that exceeds their threshold of frustration.

I think this is a good device for flipping smokers, especially those who choke on larger setups. My wife, for example, has tried several different devices and they all seem to make her cough or simply don't satisfy when dialed down. This device, she actually likes.

Electronic Patent Application Fee Transmittal

Application Number:	14925968
Filing Date:	28-Oct-2015
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Filer:	Richard Douglas Shoop/Mary Buggie
Attorney Docket Number:	13211-713.303

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Request for Prioritized Examination	2817	1	2000	2000
Pages:				
Claims:				
Miscellaneous-Filing:				
PROCESSING FEE, EXCEPT PROV. APPLS.	2830	1	70	70
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with $0 paid	2251	1	100	100
Miscellaneous:				
Request for Continued Examination	2801	1	600	600
		Total in USD ($)		**2770**

Electronic Acknowledgement Receipt

EFS ID:	26695589
Application Number:	14925968
International Application Number:	
Confirmation Number:	2707
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Customer Number:	66854
Filer:	Richard Douglas Shoop/Mary Buggie
Filer Authorized By:	Richard Douglas Shoop
Attorney Docket Number:	13211-713.303
Receipt Date:	19-AUG-2016
Filing Date:	28-OCT-2015
Time Stamp:	15:33:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$2770
RAM confirmation Number	1957
Deposit Account	504050
Authorized User	SHOOP, RICHARD D

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

Charge any Additional Fees required under 37 CFR 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 CFR 1.17 (Patent application and reexamination processing fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		13211-713-303_RCE_Track1_Ext_Response_Decl_Exhibits.pdf	3225135 1fd1f382fd81fa09f7706292bb4c37116159b7c8	yes	44

Multipart Description/PDF files in .zip description

Document Description	Start	End
Request for Continued Examination (RCE)	1	1
TrackOne Request	2	2
Extension of Time	3	3
Amendment Submitted/Entered with Filing of CPA/RCE	4	4
Claims	5	8
Applicant Arguments/Remarks Made in an Amendment	9	18
Affidavit-traversing rejectns or objectns rule 132	19	44

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	36104 6689f4c2e5a25fe80b50cd5c128c89ce5e8a2a11	no	2

Warnings:

Information:

Total Files Size (in bytes):	3261239

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.

PTO/SB/08A (04-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	666	US- 8,809,261	8/19/2014	Elsohly et al.	
	669	US- 8,881,737	11/11/2014	Collett et al.	
	667	US- 2015/0038567	2/5/2015	Herkenroth et al.	
	580	US- 2016/0174611**	6/23/2016	Monsees et al.	
		US-			
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		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	668	EP2152313B1	9/3/2014	McNeil AB		

Examiner Signature		Date Considered	

*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. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] 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 37 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, 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 (1-800-786-9199) and select option 2.

PTO/SB/08b (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

NON PATENT 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.	T[2]
	587	MONSEES et al.; U.S. Pat. Appl. # 15/165,954 entitled "Devices for vaporization of a substance," filed 5/26/2016	
	588	MONSEES et al.; U.S. Pat. Appl. # 15/166,001 entitled "Electronic vaporization device," filed 5/26/2016	
	589	MONSEES et al.; U.S. Pat. Appl. # 15/165,972 entitled "Portable devices for generating an inhalable vapor," filed 5/26/2016	
	665	BOWEN et al.; U.S. Pat Appl. # 15/101,303 entitled "Nicotine liquid formulations for aerosol devices and methods thereof," filed 6/2/2016	

Examiner Signature		Date Considered	

*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.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 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, 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 (1-800-786-9199) and select option 2.

Electronic Acknowledgement Receipt

EFS ID:	26696046
Application Number:	14925968
International Application Number:	
Confirmation Number:	2707
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Customer Number:	66854
Filer:	Richard Douglas Shoop/Brian Flick
Filer Authorized By:	Richard Douglas Shoop
Attorney Docket Number:	13211-713.303
Receipt Date:	19-AUG-2016
Filing Date:	28-OCT-2015
Time Stamp:	15:50:09
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		13211-713-303_IDS_Filing_8-19-2016.pdf	345145 109e549322c0c28093e728b7d6b9346eec7994d6	yes	5

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Transmittal Letter	1	3
	Information Disclosure Statement (IDS) Form (SB08)	4	5

Warnings:					
Information:					
2	Foreign Reference	EP2152313B.pdf	8630620 b964bc79855e9ccb2a5804467fe593d8436850d8	no	28
Warnings:					
Information:					
		Total Files Size (in bytes):	8975765		

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.

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on August 19, 2016.

/Brian Flick/
Name

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 14/925,968	Confirmation No.: 2707
First Named Inventor	: Adam Bowen	
Filed	: October 28, 2015	
Art Unit	: 1747	
Examiner	: Mayes, Dionne Walls	
Title	: NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF	
Customer No.	: 66854	

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☒ **37 CFR §1.97(b)**

This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:

- ☐ **1).** Within 3 months of the application filing date, or
- ☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or
- ☐ **3).** Before the mail date of a first Office Action on the merits, or
  - ☐ **3a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below
- ☒ **4).** Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.
  - ☐ **4a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below

☐ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☐ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☐ **A).** A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement. or

☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under §1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☒ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☒ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☒ **3).** Items identified by a double asterisk (**) on the SB08A are *commonly-owned U.S. patents and U.S. patent application publications.

☒ **37 CFR §1.98 (a)(2)(iii) and (d), *Commonly-owned, unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s), and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **3).** A copy of each application specification is not submitted because the application is stored in the IFW.

Applicant(s) assume the Examiner has access to the file histories of these items. However, if the Examiner would like to receive copies of Office Actions in any of the commonly-owned applications, publications and/or patents identified on the attached SB08, please inform the undersigned and copies will be provided.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☒ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and 609.04(a)III, Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** An English language abstract or an English language copy of a foreign search report or other action by a foreign patent office is provided herewith to fulfill the requirement for a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language: Cite no(s):

--AND/OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached: Cite no(s):

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. Cite no(s):

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement. Cite no(s):

STATEMENT UNDER 37 CFR § 1.704(d)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: August 19, 2016

By: _____
Richard D. Shoop, Reg. No. 45,763

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO CA 94403

MAILED
AUG 29 2016
OFFICE OF PETITIONS

Doc Code: TRACK1.GRANT

Decision Granting Request for Prioritized Examination (Track I or After RCE)	Application No.: 14/925,968

1. THE REQUEST FILED August 19, 2016 IS **GRANTED**.

The above-identified application has met the requirements for prioritized examination

A. ☐ for an original nonprovisional application (Track I).
B. ☒ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination.** The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

A. filing a **petition for extension of time** to extend the time period for filing a reply;
B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims**, or a multiple dependent claim;
C. filing a **request for continued examination**;
D. filing a notice of appeal;
E. filing a request for suspension of action;
F. mailing of a notice of allowance;
G. mailing of a final Office action;
H. completion of examination as defined in 37 CFR 41.102; or
I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to Brian W. Brown at 571-272-5338.

/Brian W. Brown/
[*Signature*]

Petitions Examiner, Office of Petitions
(Title)

U.S. Patent and Trademark Office
PTO-2298 (Rev. 02-2012)

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on September 12, 2016.
/Mary Buggie/ 9/12/2016
Mary Buggie Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	14/925,968	Confirmation No.	: 2707
First Named Inventor	:	Adam BOWEN		
Filing Date	:	October 28, 2015		
Art Unit	:	1747		
Examiner	:	Mayes, Dionne Walls		
Title	:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF		
Customer No.	:	66854		

Mail Stop 16
Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR REFUND UNDER 37 C.F.R. § 1.28

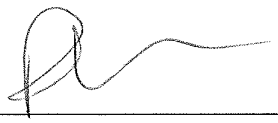
On June 15, 2016 and July 12, 2016, Applicants electronically filed Information Disclosure Statements via the Electronic Filing System (EFS). The undiscounted fees of $180 were paid via Deposit Account No. 50-4050. **Applicants hereby assert small entity status**, as shown in the copy of the Change Entity Status electronically submitted on August 17, 2016. Therefore, Applicants request a refund of $180 to Deposit Account No. 50-4050.

ITEMIZATION			
Fee Description	**Undiscounted Entity Amount Previously Paid**	**Current Small Entity Fees**	**Refund Requested**
Information Disclosure Statement	$180 on June 22, 2016	$90	$90
Information Disclosure Statement	$180 on July 12, 2016	$90	$90
Total Refund Requested to Deposit Account No. 50-4050:			**$180**

SG Docket No.: 13211-713.303

If it is determined that a telephone conference would expedite the processing of this Request, please contact the undersigned at the number given below.

Respectfully submitted,



Date: September 12, 2016

Richard D. Shoop
Reg. No. 45,763

SHAY GLENN LLP
2755 CAMPUS DRIVE, SUITE 210
SAN MATEO, CA 94403
TELEPHONE: 650.212.1700
FACSIMILE: 650.212.7562

Change Entity Status - Confirmation

Request ID	23382
Timestamp	Aug 17, 2016 9:03:31 PM EST
Status	Submitted

The Entity Status of the application has been successfully changed

Application Number	14/925,968
Attorney Docket Number	13211-713.303
Title	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
Updated Entity Status	Small
Micro certification statement	N/A

I certify, in accordance with 37 CFR 1.4(d)(4):

* I am an attorney or agent registered to practice before the Patent and Trademark Office who has been given power of attorney in this application

Filed By	Richard D. Shoop
Registration Number	45763

Signatures

Signature	Name
/Richard D. Shoop/	Richard D. Shoop

Point of Contact Info

Name	Richard D. Shoop
Telephone	(650) 212-1700
Email	rick@shayglenn.com

Electronic Acknowledgement Receipt

EFS ID:	26900696
Application Number:	14925968
International Application Number:	
Confirmation Number:	2707
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Customer Number:	66854
Filer:	Richard Douglas Shoop/Mary Buggie
Filer Authorized By:	Richard Douglas Shoop
Attorney Docket Number:	13211-713.303
Receipt Date:	12-SEP-2016
Filing Date:	28-OCT-2015
Time Stamp:	17:47:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Refund Request	13211-713-303_RequestRefund.pdf	84268 99596b2c375e9deb6c2bd1d6da8800817b0149ff	no	3

Warnings:

Information:	
Total Files Size (in bytes):	84268

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
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USPTO
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DIVISION

2016 SEP 12 AM 9:14

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on September 12, 2016.
/Mary Buggie/ 9/12/2016
Mary Buggie Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	: 14/925,968	Confirmation No.	: 2707
First Named Inventor	: Adam BOWEN		
Filing Date	: October 28, 2015		
Art Unit	: 1747		
Examiner	: Mayes, Dionne Walls		
Title	: NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF		
Customer No.	: 66854		

Mail Stop 16
Director of the United States Patent and Trademark Office
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ITEMIZATION			
Fee Description	**Undiscounted Entity Amount Previously Paid**	**Current Small Entity Fees**	**Refund Requested**
Information Disclosure Statement	$180 on June 22, 2016	$90	$90
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Total Refund Requested to Deposit Account No. 50-4050:			**$180**

SG Docket No.: 13211-713.303

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Respectfully submitted,

Date: September 12, 2016

Richard D. Shoop
Reg. No. 45,763

SHAY GLENN LLP
2755 CAMPUS DRIVE, SUITE 210
SAN MATEO, CA 94403
TELEPHONE: 650.212.1700
FACSIMILE: 650.212.7562

Electronic Acknowledgement Receipt

EFS ID:	26322723
Application Number:	14925968
International Application Number:	
Confirmation Number:	2707
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF 09/20/2016 SSANDARA 00000004 504050 14925968 01 FC:2806 90.00 DA 09/20/2016 SSANDARA 00000005 504050 14925968 01 FC:2806 90.00 DA
First Named Inventor/Applicant Name:	Adam BOWEN
Customer Number:	66854
Filer:	Richard Douglas Shoop/Brian Flick
Filer Authorized By:	Richard Douglas Shoop
Attorney Docket Number:	13211-713.303
Receipt Date:	12-JUL-2016
Filing Date:	28-OCT-2015
Time Stamp:	12:51:13
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$180
RAM confirmation Number	071216INTEFSW00011347504050
Deposit Account	504050
Authorized User	Richard Shoop
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Adjustment date: 09/20/2016 SSANDARA 06/16/2016 INTEFSW 00002820 504050 14925968 01 FC:1806 180.00 CR Adjustment date: 09/20/2016 SSANDARA 07/12/2016 INTEFSW 00011347 504050 14925968 01 FC:1806 180.00 CR	

PTO/SB/08A (04-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	684	US- 5,031,646	7/16/1991	Lippiello et al.	
	685	US- 5,133,368	7/28/1992	Neumann et al.	
	488	US- 8,511,318	8/20/2013	Hon	
	680	US- 5,240,012	8/31/1993	Ehrman et al.	
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		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	687	EP0283672B1	9/22/1993	R J Reynolds Tobacco		
	688	EP2319934B1	9/2/2015	Stichting Dienst		
	689	WO2007/078273A1	7/12/2007	Augite Inc.		
	690	WO2015/009862A2	1/22/2015	Altria Client Services		

Examiner Signature		Date Considered	

*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. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] 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 37 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, 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 (1-800-786-9199) and select option 2.

PTO/SB/08b (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

NON PATENT 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.	T[2]
	683	BURCH et al.; Effect of pH on nicotine absorption and side effects produced by aerosolized nicotine; Journal of Aerosol Medicine: Deposition, Clearance, and Effects in the Lung; 6(1); pp. 45-52; 1993	

Examiner Signature		Date Considered	

*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.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 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, 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 (1-800-786-9199) and select option 2.

Electronic Acknowledgement Receipt

EFS ID:	26969979
Application Number:	14925968
International Application Number:	
Confirmation Number:	2707
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Customer Number:	66854
Filer:	Richard Douglas Shoop/Brian Flick
Filer Authorized By:	Richard Douglas Shoop
Attorney Docket Number:	13211-713.303
Receipt Date:	19-SEP-2016
Filing Date:	28-OCT-2015
Time Stamp:	17:55:50
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		13211-713-303_IDS_Filing_9-19-2016.pdf	337673 d008f657c4cf834b43d1986d6bcf3fef062b8411	yes	5

	Multipart Description/PDF files in .zip description			
	Document Description	**Start**	**End**	
	Transmittal Letter	1	3	
	Information Disclosure Statement (IDS) Form (SB08)	4	5	
Warnings:				
Information:				

2	Foreign Reference	EP283672B1.pdf	1603865 6ade10480ab98bbdbc3f7ab7edea203c1ea317fd	no	23
Warnings:					
Information:					
3	Foreign Reference	WO2007078273A1.pdf	399703 6a9fb5cbeb0bcf9e4930704c0b6aba049a2b71cd	no	13
Warnings:					
Information:					
4	Foreign Reference	WO2015009862A2.pdf	1682368 6e44adca6a616c91976e43fe6417eb350b192f6f	no	29
Warnings:					
Information:					
5	Non Patent Literature	Burch_et_al-EffectOfpHOnNicotineAbsorption.pdf	2286776 75e63872d4e2d57f082dc3da685332142911f433	no	8
Warnings:					
Information:					
6	Foreign Reference	EP2319934B1.pdf	22795970 fc0974973589815821 9f09eea56f7ed742142b35	no	103
Warnings:					
Information:					
		Total Files Size (in bytes):	29106355		

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.

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on September 19, 2016.

/Brian Flick/
Brian Flick

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 14/925,968	Confirmation No.: 2707
First Named Inventor	: Adam Bowen	
Filed	: October 28, 2015	
Art Unit	: 1747	
Examiner	: Mayes, Dionne Walls	
Title	: NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF	
Customer No.	: 66854	

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☒ **37 CFR §1.97(b)**

This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:

- ☐ **1).** Within 3 months of the application filing date, or
- ☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or
- ☐ **3).** Before the mail date of a first Office Action on the merits, or
  - ☐ **3a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below
- ☒ **4).** With or after the filing of a request for continued examination (RCE) under § 1.114 but before the mailing date of a first Office Action (after RCE).
  - ☐ **4a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below

☐ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☐ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☐ **A).** A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

or

☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under §1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☒ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☒ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☐ **3).** Items identified by a double asterisk (**) on the SB08A are *commonly-owned U.S. patents and U.S. patent application publications.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), *Commonly-owned, unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s), and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **3).** A copy of each application specification is not submitted because the application is stored in the IFW. Cite no(s):

Applicant(s) assume the Examiner has access to the file histories of these items. However, if the Examiner would like to receive copies of Office Actions in any of the commonly-owned applications, publications and/or patents identified on the attached SB08, please inform the undersigned and copies will be provided.

☒ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☒ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☒ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and 609.04(a)III, Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** An English language abstract or an English language copy of a foreign search report or other action by a foreign patent office is provided herewith to fulfill the requirement for a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language: Cite no(s):

--AND/OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached: Cite no(s):

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. Cite no(s):

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement. Cite no(s):

STATEMENT UNDER 37 CFR § 1.704(d)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: September 19, 2016

By: _____
Richard D. Shoop, Reg. No. 45,763

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

PTO/SB/08A (04-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	714	US- 2014/0190501	7/10/2014	Liu	
	713	US- 2015/0157054	6/11/2015	Liu	
		US-			
		US-			
		US-			
		US-			
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		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	712	EP3024343A2(WO2015/013327)	1/29/2015	Altria Client Serv. Inc.		
	716	WO 03/103387A2	12/18/2003	S.C. Johnson & Son Inc.		
	715	WO2014/159982A1	10/2/2014	R.J. Reynolds Tobacco Co.		

Examiner Signature		Date Considered	

*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. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] 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 37 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, 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 (1-800-786-9199) and select option 2.

PTO/SB/08b (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

NON PATENT 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.	T[2]
	703	MONSEES et al.; U.S. Pat. Appl. # 15/257,748 entitled "Cartridge for use with a vaporizer device," filed 9/6/2016	
	704	MONSEES et al.; U.S. Pat. Appl. # 15/257,760 entitled "Vaporizer apparatus," filed 9/6/2016	
	705	MONSEES et al.; U.S. Pat. Appl. # 15/257,768 entitled "Vaporizer apparatus," filed 9/6/2016	
	706	MONSEES et al.; U.S. Pat. Appl. # 15/261,823 entitled "Low temperature electronic vaporization device and methods," filed 9/9/2016	

Examiner Signature		Date Considered	

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Electronic Acknowledgement Receipt

EFS ID:	27331565
Application Number:	14925968
International Application Number:	
Confirmation Number:	2707
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Customer Number:	66854
Filer:	Richard Douglas Shoop/Brian Flick
Filer Authorized By:	Richard Douglas Shoop
Attorney Docket Number:	13211-713.303
Receipt Date:	26-OCT-2016
Filing Date:	28-OCT-2015
Time Stamp:	16:36:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		13211-713-303_IDS_Filing_10-26-2016.pdf	344918 4572ac8346f5ef5d286621aa29d1d6aee9e99774	yes	5

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Transmittal Letter	1	3
	Information Disclosure Statement (IDS) Form (SB08)	4	5

Warnings:					
Information:					
2	Foreign Reference	EP3024343_WO2015013327A2.pdf	1551941 38b90b391e5bac610c8ecc13d2064b30bc1cb7b2	no	29
Warnings:					
Information:					
3	Foreign Reference	WO2003103387A2.pdf	2281687 5d69a17bf4b6e3d684a5bc376351096a89b6ca1f	no	57
Warnings:					
Information:					
4	Foreign Reference	WO2014159982A1.pdf	3297006 fd807d68a49865ed1945bd6c5b092fb648c255f7	no	52
Warnings:					
Information:					
		Total Files Size (in bytes):	7475552		

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New Applications Under 35 U.S.C. 111
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National Stage of an International Application under 35 U.S.C. 371
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New International Application Filed with the USPTO as a Receiving Office
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CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on October 26, 2016.

/Brian Flick/
Brian Flick

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 14/925,968	Confirmation No.: 2707
First Named Inventor	: Adam Bowen	
Filed	: October 28, 2015	
Art Unit	: 1747	
Examiner	: Mayes, Dionne Walls	
Title	: NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF	
Customer No.	: 66854	

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

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FILING OF INFORMATION DISCLOSURE STATEMENT

☒ **37 CFR §1.97(b)**
This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:

- ☐ **1).** Within 3 months of the application filing date, or
- ☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or
- ☐ **3).** Before the mail date of a first Office Action on the merits, or
  - ☐ **3a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below
- ☒ **4).** With or after the filing of a request for continued examination (RCE) under § 1.114 but before the mailing date of a first Office Action (after RCE).
  - ☐ **4a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below

☐ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☐ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☐ **A).** A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement. or

☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under §1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☒ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☒ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☐ **3).** Items identified by a double asterisk (**) on the SB08A are *commonly-owned U.S. patents and U.S. patent application publications.

☒ **37 CFR §1.98 (a)(2)(iii) and (d), *Commonly-owned, unpublished U.S. applications cited**

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☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☒ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and 609.04(a)III, Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** An English language abstract or an English language copy of a foreign search report or other action by a foreign patent office is provided herewith to fulfill the requirement for a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language: Cite no(s):

--AND/OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached: Cite no(s):

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. Cite no(s):

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement. Cite no(s):

STATEMENT UNDER 37 CFR § 1.704(d)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: October 26, 2016

By: /Richard D. Shoop/
Richard D. Shoop, Reg. No. 45,763

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

Doc Code: ECOMM.AUTH/ECOMM.WTDW
Doc Description: Internet Communications Authorized/Internet Communications Authorization Withdrawn

PTO/SB/439 (11-15)

AUTHORIZATION FOR INTERNET COMMUNICATIONS IN A PATENT APPLICATION OR REQUEST TO WITHDRAW AUTHORIZATION FOR INTERNET COMMUNICATIONS

Application No.	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam BOWEN
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Practitioner Docket No.	13211-713.303

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

I. To authorize permission for Internet Communications.

☑ Recognizing that Internet communications are not secure, I hereby authorize the USPTO to communicate with the undersigned and practitioners in accordance with 37 CFR 1.33 and 37 CFR 1.34 concerning any subject matter of this application via video conferencing, instant messaging, or electronic mail. I understand that a copy of these communications will be made of record in the application file. (MPEP 502.03)

II. To withdraw authorization for Internet Communications.

☐ The authorization given on _____, to the USPTO to communicate with the undersigned and any practitioner in accordance with 37 CFR 1.33 and 37 CFR 1.34 concerning any subject matter of this application via Internet communications such as video conferencing, instant messaging, or electronic mail is hereby withdrawn. I understand that the withdrawal is effective when approved rather than when received.

I am the

☐ applicant.

☑ attorney or agent of record. Registration number 45,763.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.

/Richard D. Shoop/ — Signature

November 11, 2016 — Date

Richard D. Shoop — Typed or printed name

(650) 287-2164 — Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Juristic entities must be represented by a patent practitioner (see 37 CFR 1.31, which is applicable to any paper filed on or after September 16, 2012, that is presented on behalf of a juristic entity, regardless of application filing date). Submit multiple forms if more than one signature is required, see below*.

☐ * Total of _____ forms are submitted.

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 Acknowledgement Receipt

EFS ID:	27491946
Application Number:	14925968
International Application Number:	
Confirmation Number:	2707
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Customer Number:	66854
Filer:	Richard Douglas Shoop/Mary Buggie
Filer Authorized By:	Richard Douglas Shoop
Attorney Docket Number:	13211-713.303
Receipt Date:	11-NOV-2016
Filing Date:	28-OCT-2015
Time Stamp:	21:04:21
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Internet Communications Authorized	13211-713-303_Authorization_Internet_Communications.pdf	82168 a93b6d2983f549841d771bb9c14364215ef934af	no	2
Warnings:					

Information:	
Total Files Size (in bytes):	82168

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.

PTO/SB/08A (04-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	718	US- 6,603,924	8/5/2003	Brown et al.	
	719	US- 2013/0298905	11/14/2013	Levin et al.	
		US-			
		US-			
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		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*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. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For *Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.* [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] 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 37 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, 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 (1-800-786-9199) and select option 2.

PTO/SB/08b (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

NON PATENT 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.	T[2]
	721	FARSALINOS et al.; Electronic cigarettes do not damage the heart; European Society of Cardiology; 4 pages; retrieved from the internet (http://www.escardio.org/The-ESC/Press-Office/Press-releases/Electronic-cigarettes-do-not-damage-the-heart); August 25, 2012	
	720	VANSICKEL et al.; Electronic cigarettes: effective nicotine delivery after acute administration; Nicotine & Tobacco Research; 15(1); pp. 267-270; January 2013	

Examiner Signature		Date Considered	

*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.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 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, 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 (1-800-786-9199) and select option 2.

Electronic Acknowledgement Receipt

EFS ID:	27548579
Application Number:	14925968
International Application Number:	
Confirmation Number:	2707
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Customer Number:	66854
Filer:	Richard Douglas Shoop/Brian Flick
Filer Authorized By:	Richard Douglas Shoop
Attorney Docket Number:	13211-713.303
Receipt Date:	17-NOV-2016
Filing Date:	28-OCT-2015
Time Stamp:	18:16:43
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		13211-713-303_IDS_Filing_WithResp__11-17-2016.pdf	341552 34f459e934576bebf95d01048404f6e9383c6678	yes	5

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Transmittal Letter	1	3
	Information Disclosure Statement (IDS) Form (SB08)	4	5

Warnings:					
Information:					
2	Non Patent Literature	Farsalinos_et_al_ElectronicCigarettesDoNotDamage_2012.pdf	60065 60439509eb9ffb3386f6b00a5c61f547def2e017	no	4
Warnings:					
Information:					
3	Non Patent Literature	Vansickel_et_al_ElectronicCigarettesEffective_2013.pdf	1994756 6e5877e04f3be9d23e60ca8831e34168e1faf8e8	no	4
Warnings:					
Information:					
		Total Files Size (in bytes):	2396373		

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.

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on November 17, 2016.

/Brian Flick/
Brian Flick

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 14/925,968	Confirmation No.: 2707
First Named Inventor	: Adam Bowen	
Filed	: October 28, 2015	
Art Unit	: 1747	
Examiner	: Mayes, Dionne Walls	
Title	: NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF	
Customer No.	: 66854	

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☒ **37 CFR §1.97(b)**

This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:

- ☐ **1).** Within 3 months of the application filing date, or
- ☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or
- ☐ **3).** Before the mail date of a first Office Action on the merits, or
  - ☐ **3a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below
- ☒ **4).** With or after the filing of a request for continued examination (RCE) under § 1.114 but before the mailing date of a first Office Action (after RCE).
  - ☐ **4a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below

☐ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☐ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☐ **A).** A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

or

☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under §1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☒ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☒ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☐ **3).** Items identified by a double asterisk (**) on the SB08A are *commonly-owned U.S. patents and U.S. patent application publications.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), *Commonly-owned, unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s), and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **3).** A copy of each application specification is not submitted because the application is stored in the IFW. Cite no(s):

Applicant(s) assume the Examiner has access to the file histories of these items. However, if the Examiner would like to receive copies of Office Actions in any of the commonly-owned applications, publications and/or patents identified on the attached SB08, please inform the undersigned and copies will be provided.

☒ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☒ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☐ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and 609.04(a)III, Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** An English language abstract or an English language copy of a foreign search report or other action by a foreign patent office is provided herewith to fulfill the requirement for a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language: Cite no(s):

--AND/OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached: Cite no(s):

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

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

STATEMENT UNDER 37 CFR § 1.704(d)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: November 17, 2016

By: /Richard D. Shoop/
Richard D. Shoop, Reg. No. 45,763

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on November 17, 2016.
/Mary Buggie/ 11/17/20116
Mary Buggie Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	14/925,968	Confirmation No.	: 2707
First Named Inventor:	:	Adam BOWEN		
Filing Date	:	October 28, 2015		
Art Unit	:	1747		
Examiner	:	Mayes, Dionne Walls		
Title	:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF		
Customer No.	:	66854		

SUPPLEMENTAL AMENDMENT AND COMMENTS UNDER 37 C.F.R. § 1.114

This communication is submitted following the Request for Continued Examination (RCE) and the fees for Prioritized Examination - Track 1 status filed on August 19, 2016. A Declaration Under 37 C.F.R. § 1.132 providing support and evidence of Unexpected Results is also submitted herewith

The Commissioner is authorized to charge any fees to make this filing timely to Deposit Account No. 50-4050.

Amendments to the Claims are shown in the listing of claims that begins on page 2.

Remarks/Arguments begin on page 7 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 method of delivering nicotine to a user comprising:

deploying a low-temperature vaporizer comprising a nicotine formulation that comprises nicotine~~, lactic acid~~ lactate, and a biologically acceptable liquid carrier ~~in conditions sufficient to form nicotine lactate salt~~, wherein:

a. the nicotine lactate concentration is ~~from~~ about [[0.5%]] 4% (w/w) ~~to about 20% (w/w)~~;

b. the biologically acceptable liquid carrier comprises ~~propylene glycol and 90%-30% vegetable~~ glycerol; and

c. operation of the low-temperature vaporizer comprises wicking the nicotine formulation to a heating element and heating at least a portion of the nicotine formulation to generate an inhalable aerosol of nicotine lactate ~~between about 100°C and about 300°C~~;

wherein inhalation of the aerosol into a user's lungs increases heart rate comparable to inhaling a traditional burned cigarette in that inhaling 10 puffs of the aerosol over a period of about [[5]]3 minutes results in [[at a]] an increase in heart rate that peaks within about 3.5 minutes from the first puff ~~of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min and a Cmax of over 10 ng/mL on average, and further wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength~~.

2. (Previously presented) The method of claim 1, wherein a molar ratio of nicotine to lactic acid is between about 1:1 and 1:3.

3. (Original) The method of claim 1, wherein the nicotine formulation further comprises at least one flavorant.

4. (Cancelled)

5. (Cancelled)

6. (Original) The method of claim 1, wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns.

7. (Currently amended) A method of delivering nicotine to a user comprising:

deploying a low-temperature vaporizer comprising a nicotine formulation that comprises nicotine~~, lactic acid~~ lactate, and a biologically acceptable liquid carrier ~~in conditions sufficient to form nicotine lactate salt~~, wherein:

a. the nicotine lactate concentration is from about [[0.5]]4% (w/w) to about [[20]]6.5% (w/w);

~~b. the nicotine formulation comprises protonated nicotine;~~

[[c]]b. the biologically acceptable liquid carrier comprises ~~propylene glycol and 90%-30% vegetable~~ glycerol;

~~d. the lactic acid does not decompose at room temperature and does not decompose at the operating temperature of the low-temperature vaporizer;~~ and

[[e]]c. operation of the low-temperature vaporizer comprises wicking the nicotine formulation to the heating element and heating at least a portion of the nicotine formulation ~~between about 100°C and 300°C~~ to generate an inhalable aerosol;

wherein inhalation of the aerosol into a user's lungs increases heart rate comparable to inhaling a traditional burned cigarette in that inhaling 10 puffs of the aerosol over a period of about [[5]]3 minutes results in [[at a]]an increase in heart rate that peaks within about 3.5 minutes from the first puff ~~of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 minutes to about 8 min and further wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength~~.

8. (Previously presented) The method of claim 7, wherein a molar ratio of nicotine to lactic acid is between 1:1 and 1:3.

9. (Original) The method of claim 7, wherein the nicotine formulation further comprises at least one flavorant.

10. (Original) The method of claim 7, wherein the nicotine concentration is about 4.5%.

11. (Cancelled)

12. (Original) The method of claim 7, wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns.

13. (Currently amended) A low-temperature vaporizer, comprising:

a liquid reservoir;

a nicotine formulation within the liquid reservoir, the nicotine formulation comprising:

nicotine lactate;

~~propylene glycol;~~ and

~~90%-30% vegetable~~ glycerol;

wherein a concentration of the nicotine lactate in the nicotine formulation is ~~from~~ about [[0.5]]4% (w/w) to about [[20]]6.5% (w/w);

a vaporizing component configured to produce an aerosol from the nicotine formulation by heating at least a portion of the nicotine formulation ~~between 100°C and 300°C~~, wherein the liquid reservoir is connected to the vaporizing component by a wick; and

a mouthpiece configured to connect to the reservoir for inhalation of the aerosol;

wherein inhalation of the aerosol into the user's lungs increases heart rate comparable to inhaling a traditional burned cigarette in that inhaling 10 puffs of the aerosol over a period of about [[5]]3 minutes results in [[at a]] an increase in heart rate that peaks within about 5 minutes from the first puff ~~of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 min to about 8 min and a Cmax of over 10 ng/mL on average, and further wherein the user may modify the amount of nicotine delivered by adjusting inhalation strength~~.

14. (Original) The electronic cigarette of claim 13, further comprises a battery configured to provide power to the vaporizing component.

15. (Previously presented) The electronic cigarette of claim 13, wherein a molar ratio of nicotine to lactic acid is between 1:1 and 1:3.

16. (Original) The electronic cigarette of claim 13, wherein the nicotine formulation further comprises at least one flavorant.

17. (Original) The electronic cigarette of claim 13, wherein the vaporizing component comprises a heating element in fluid communication with the nicotine formulation.

18. (Original) The electronic cigarette of claim 13, wherein the nicotine concentration is about 4.5%.

19. (Cancelled)

20. (Original) The electronic cigarette of claim 13, wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns.

21. (Previously presented) The method of claim 1, wherein the nicotine formulation comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

22. (Previously presented) The method of claim 7, wherein the nicotine formulation comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

23. (New) A method of delivering nicotine to a user comprising:

deploying a low-temperature vaporizer comprising a nicotine formulation that comprises nicotine lactate, and a biologically acceptable liquid carrier, wherein:

a. the nicotine lactate concentration is about 4.5% (w/w);

b. the biologically acceptable liquid carrier comprises glycerol; and

c. operation of the low-temperature vaporizer comprises wicking the nicotine formulation to a heating element and heating at least a portion of the nicotine formulation to generate an inhalable aerosol of nicotine lactate;

wherein inhalation of the aerosol into a user's lungs increases heart rate comparable to inhaling a traditional burned cigarette in that inhaling 10 puffs of the aerosol over a period of about 3 minutes results in an increase in heart rate that peaks within about 3.5 minutes from the first puff.

REMARKS

Claims 1-4, 6-10, 12-18 and 20-22 were pending in this application. By this response, claims 1, 7 and 13 have been amended, and claim 4 has been cancelled. New claim 23 has been added. The amendments to the claims and the new claims are supported throughout the specification, including in provisional patent application no. 61/820,128.

Thus, claims 1-3, 6-10, 12-18, and 20-24 are pending.

DECLARATION OF ADAM BOWEN

Also submitted herewith is a declaration from Adam Bowen, providing additional experimental evidence in support of the heart rate effect of vaporizing nicotine lactate as well as providing evidence of unexpected results.

UNEXPECTED RESULTS

Applicants respectfully submit that the claimed invention, as supported by the present specification and further supported by the attached declaration under 37 C.F.R. § 1.132, exhibits unexpected results over the cited art and is accordingly nonobvious. Per *Graham v. John Deere Co.*, 383 U.S. 1 (1966), unexpected results are a secondary consideration that may tip the scales towards a conclusion of nonobviousness. Such unexpected results may include:

- Greater than expected results;
- Superiority of a shared property;
- Presence of an unexpected property; and
- Absence of an expected property.

(See MPEP § 716.02(a)). In the present case, the nicotine lactate possesses the unexpected property that inhalation of an aerosol of the claimed nicotine lactate composition into a user's lungs increases heart rate comparable to inhaling a traditional burned cigarette in that inhaling 10 puffs of the aerosol over a period of about 3 minutes results in an increase in heart rate that peaks within about 3.5 minutes from the first puff. As discussed in the present specification, including

FIG. 1 and 2, and as further demonstrated in the attached declaration under 37 C.F.R. § 1.132, this property was surprising.

As described in paragraph [013] of the Provisional Application no. 61/820128, to which the instant application claims priority:

> "This experience of increased heart rate comparable to that of a traditional burned cigarette has not been demonstrated or identified in other electronic cigarette devices. Nor has it been demonstrated or identified in low temperature tobacco vaporization devices that do not burn the tobacco, even when a nicotine salt is used as an additive to the tobacco (typically, the concentration of nicotine salt within the solution as an additive for the tobacco is about 20 weight percent or more). Thus, this experience and combination is surprising and unexpected with regard to any of these types of devices." (emphasis added)

The Declaration of Adam Bowen explains this in additional detail. See in particular, paragraphs 6 and 7, which describes the published prior art, in which inhaling vaporized nicotine was not found to effect heart rate in a manner that is comparable to inhaling smoke from a burned tobacco cigarette. For example, Vansickel et al. ("A Clinical laboratory assessment of the abuse liability of an electronic cigarette described a comparison between vaporized nicotine (as found in commercially available vaporizers) and burned cigarettes and concluded that: "[n]o significant changes in heart rate were observed for the Hydro EC, NPRO EC [electronic cigarettes], or sham conditions."). Thus, the results yielded by the claimed invention are unexpected in view of the cited art. Accordingly, it is respectfully submitted that the claims are allowable over the prior art.

CONCLUSION

Applicants respectfully request that the Examiner expedite the prosecution of this patent application to issuance. If the Patent Office determines that an extension of time and/or other relief is required, Applicants petition for any required relief including extension of time, and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-4050**, referencing 13211-713.303. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Date: November 17, 2016

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	: 14/925,968	Confirmation No.	: 2707
Inventor(s)	: Adam BOWEN		
Filing Date	: October 28, 2015		
Art Unit	: 1747		
Examiner	: Mayes, Dionne Walls		
Title	: NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF		
Customer No.	: 66854		

DECLARATION UNDER 37 C.F.R. § 1.132

I, Adam Bowen, declare as follows:

(1) In January of 2005, I co-founded Ploom, Inc., now PAX Labs, which develops and produces nicotine vaporizers ("electronic cigarettes"), and am currently the Chief Technical Officer (CTO) of the company.

(2) I am also an inventor on the patent application, U.S. Application no. 14/925,968, tiled "NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF" (hereafter "the '968 application"), as well as on U.S. provisional patent application 61/820,128, filed on May 6, 2013 (hereafter "the '128 provisional application"), to which the '968 application claims priority.

(3) The '968 patent application describes the use of liquid nicotine salts formulations in a vaporizer to form an aerosol of nicotine. The nicotine in these formulations is formed by a nicotine salt in a liquid carrier such as a glycerol, glycol or mixture of these. As described in the '128 provisional application, the use of certain nicotine salts, including carboxylic acid nicotine salts such as nicotine lactate, produces a physiological effect when vaporized that is comparable to that from inhaling a traditional burned cigarette. Specifically, the resulting vapor produces an increase in heart rate that peaks within the first five minutes, just as seen when inhaling traditional burned cigarettes. FIG. 1 of the '128 provisional application was provided as an example of this. This figure is reproduced in the attached Exhibit A. The data shown in FIG. 1 of the '128 provisional application was for nicotine levulinate.

(4) Although nicotine lactate was included as an example of a nicotine salt in the '128 provisional application, the experimental data was not explicitly included in FIG. 1. Nicotine lactate also has a physiological effect on the heart rate that closely resembles that of smoking a tobacco cigarette. Specifically, nicotine lactate also causes an increase in heart rate that peaks within about 5 minutes from the first puff. This data is shown in Exhibit B, attached herewith.

(5) The data shown in Exhibit B was collected in the same manner as is shown in FIG. 1 of the '128 provisional application. A 6.5% (w/w) solution of nicotine lactate solution was prepared in glycerol by adding neat nicotine lactate into the glycerol, which was mixed thoroughly. A 4.0% (w/w) solution of nicotine lactate was similarly prepared. Both formulations were administered as to a subject as described for FIG. 1 of the '128 provisional application, and heart rate measurements (e.g., at 30-second intervals) were taken for ten minutes from start of puffing. The test participant took 10 puffs over 3 minutes in each case. The increase in heart rate seen with both the 6.5% and 4.0% nicotine lactate solutions are directly comparable to that seen for nicotine levulinate, and are similar to that seen with a traditional burned cigarette. This is in contrast with freebase nicotine which did not induce a peak in heart rate within the first five minutes, as shown in FIG. 1 of the '128 provisional application.

(6) This result was unexpected. Prior to my work, it was widely believed by those of skill in the art that vaporized nicotine did not evoke the same physiological response as traditional burned cigarettes. This belief was supported by data showing that vaporized nicotine did not evoke the same or similar peak increase in heart rate as traditional burned cigarettes. In FIG 1 of the the '128 provisional, the bottom trace (freebase nicotine) is typical for the heart rate effect of prior art nicotine vaporizers showing a more gradual increase in heart rate. It was surprising and unexpected that nicotine salt formulations such as nicotine lactate instead produce a peak heart rate that matches that produced by traditional burned cigarettes.

(7) Prior to my invention, those of skill in the art believed that vaporized nicotine did not result in an effect on heart rate comparable to that seen with a traditional cigarette. At the time of my invention, published data comparing the physiological effect of vaporized nicotine delivered from an electronic cigarette to that caused by traditional burned cigarettes concluded that vaporized nicotine differed from traditional tobacco cigarettes, and either did not produce any significant change in hear rate, or resulted in only a slowly increasing, sustained increase in heart rate, in contrast to the rapid onset (within 5 minute) peak increase in heart rate that seen with burned cigarettes. For example, Vansickel et al. ("A Clinical laboratory assessment of the abuse liability of an electronic cigarette. Addiction 2012;107:1493–500, attached hereto as Exhibit C) examined the effect on hart rate between vaporized nicotine and burned cigarettes, and reported that there were not any significant changes in heart rate following two 10-puff bouts with a 16 or 18 mg nicotine/cartridge e-cigarette (n=32; n=16). Significant increases in HR were reported with burned cigarettes. Vansickel et al. used a protocol that was similar to what I used in generating the data shown in FIG. 1 of the '128 provisional and Exhibit B. Heart rate was measured every 20 seconds, and subjects were instructed to take 10 puffs with a 30-second interpuff interval. The electronic

cigarettes used included nicotine (16- or 18-mg), propylene glycol, water and flavorants. Vansickel et al. reported that there was a peak in heart rate within the first 5 minutes for the burned cigarettes, while there was no significant peak in the same time period for any of the electronic cigarettes ("Heart rate increased from an average (SD) of 65.7 (10.4) bpm at baseline to a peak of 80.3 (10.9) bpm five minutes after the first administration under the own-brand condition [burned cigarettes]. No significant changes in heart rate were observed for the Hydro EC, NPRO EC [electronic cigarettes], or sham conditions."). Later work by the same researchers (Vansickel AR, Eissenberg T. Electronic cigarettes: Effective nicotine delivery after acute administration. Nicotine Tob Res 2013;15:267–70, attached hereto as Exhibit D) reported that even when higher levels of nicotine were included in the electronic cigarette, such as 18 mg/ml nicotine, 9 mg/ml nicotine and 24 mg/ml nicotine, only a gradual increase in heart rate was seen which did not peak within 5 minutes, but continued to increase and remain elevated over a longer time period ("heart rate increased significantly within 5 min of the first puff and remained elevated throughout the ad lib puffing period."). Similar or identical effects were reported by others (see, e.g., the European Society for Cardiology, http://www.escardio.org/The-ESC/Press-Office/Press-releases/Electronic-cigarettes-do-not-damage-the-heart, attached hereto as Exhibit E), comparing how a heart reacts to cigarette smoke compared to inhaling nicotine vapor, and pointing out that heart rate and blood pressure increases quickly and dramatically when smoking a traditional cigarette, but the inhaling vapor from an electronic cigarette results in only a slight uptick in blood pressure, and "hardly any increase in heart rate." In light of the published literature, it was surprising unexpected that the use of nicotine lactate to form the nicotine in the solution being vaporized would have a physiological effect on a body that closely resembles that of smoking a tobacco cigarette such that inhaling 10 puffs of the aerosol over a period of about 3 minutes would result in an increase in heart rate that peaks within about 5 minutes from the first puff.

(8) I declare that all statements made herein 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 were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under the provisions of 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of any patent issuing upon U.S. Application Serial No. 14/632,161, or any continuing application thereof.

Signature: _____ Date: 11/17/16
Adam Bowen

EXHIBIT A

Figure 1 of U.S. provisional patent application 61/820,128 (filed on May 6, 2013)

FIG. 1

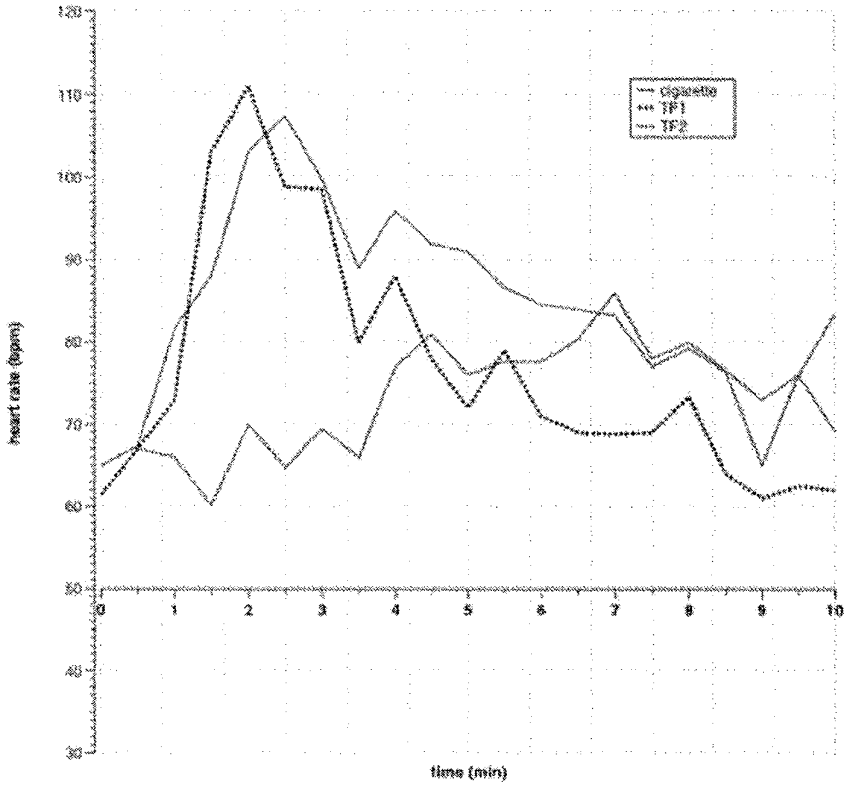
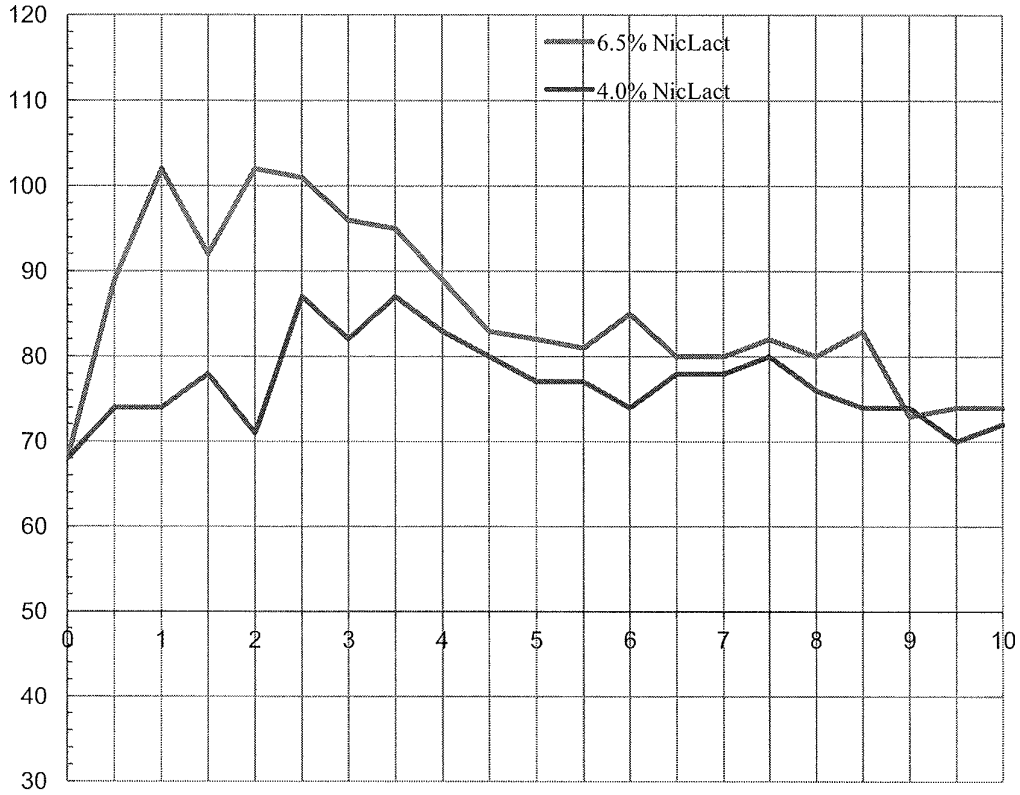


EXHIBIT B

Nicotine Lactate effect on heart rate



Published OnlineFirst on July 20, 2010 as 10.1158/1055-9965.EPI-10-0288

EXHIBIT C

Research Article

Cancer Epidemiology, Biomarkers & Prevention

A Clinical Laboratory Model for Evaluating the Acute Effects of Electronic "Cigarettes": Nicotine Delivery Profile and Cardiovascular and Subjective Effects

Andrea R. Vansickel, Caroline O. Cobb, Michael F. Weaver, and Thomas E. Eissenberg

Abstract

Background: Electronic "cigarettes" are marketed to tobacco users as potential reduced exposure products (PREP), albeit with little information regarding electronic cigarette user toxicant exposure and effects. This information may be obtained by adapting clinical laboratory methods used to evaluate other PREPs for smokers.

Methods: Thirty-two smokers participated in four independent Latin-square ordered conditions that differed by product: own brand cigarette, "NPRO" electronic cigarettes (NPRO EC; 18 mg cartridge), "Hydro" electronic cigarettes (Hydro EC; 16 mg cartridge), or sham (unlit cigarette). Participants took 10 puffs at two separate times during each session. Plasma nicotine and carbon monoxide (CO) concentration, heart rate, and subjective effects were assessed.

Results: Own brand significantly increased plasma nicotine and CO concentration and heart rate within the first five minutes of administration whereas NPRO EC, Hydro EC, and sham smoking did not. Own brand, NPRO EC, and Hydro EC (but not sham) significantly decreased tobacco abstinence symptom ratings and increased product acceptability ratings. The magnitude of symptom suppression and increased acceptability was greater for own brand than for NPRO EC and Hydro EC.

Conclusions: Under these acute testing conditions, neither of the electronic cigarettes exposed users to measurable levels of nicotine or CO, although both suppressed nicotine/tobacco abstinence symptom ratings.

Impact: This study illustrates how clinical laboratory methods can be used to understand the acute effects of these and other PREPs for tobacco users. The results and methods reported here will likely be relevant to the evaluation and empirically based regulation of electronic cigarettes and similar products. *Cancer Epidemiol Biomarkers Prev; 19(8); OF1–9. ©2010 AACR.*

Introduction

A variety of potential reduced exposure products (PREP) are/were marketed to cigarette smokers with explicit or implied claims that their use is associated with less exposure to lethal smoke constituents (1-3). These PREPs for smokers include products that involve burning specially cured tobacco that contains lower levels of some toxicants, that primarily heat rather than burn tobacco, or smokeless tobacco (4-6). As has been argued many times (1, 7, 8), objective empirical evaluation of these products is critical as a means of determining the extent to which PREP use is associated with reduced toxicant exposure, e.g., to nicotine or carbon monoxide (CO), and suppression of tobacco/nicotine abstinence symptoms. Clinical laboratory work has been very revealing, and sometimes shows reduced toxicant exposure and often shows a failure to suppress aversive abstinence symptoms fully (9, 10). In theory, toxicant exposure reduction may be associated with long-term decreased health risk, but this theoretical decreased risk is very unlikely with a product that is not used because it fails to suppress abstinence symptoms and/or is otherwise unacceptable.

So-called electronic "cigarettes" are one of the newest types of PREPs available, and anecdotal evidence suggests that, at least for some smokers, electronic cigarettes can completely replace tobacco cigarettes (11, 12). Many electronic cigarette brands are available in retail outlets and over the internet. Electronic cigarettes consist of a rechargeable battery, heater, and a cartridge that contains a liquid made of propylene glycol, nicotine, and other chemicals (13). When the battery-powered heater is activated, it heats the solution to produce a vapor that can then be inhaled by the user (14, 15). Electronic cigarettes are

Authors' Affiliation: Virginia Commonwealth University, Richmond, Virginia

Note: The results of this study were presented in poster form at the annual Society for Research on Nicotine and Tobacco meeting held in Baltimore, MD February 24-27, 2010.

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EXHIBIT C

marketed as PREPs for smokers, with manufacturer claims such as "alternative to smoking that will satisfy your nicotine urges and cravings" (16), "helps smokers quit, cut down or smoke healthier" (17), and "gives smokers all the pleasure and satisfaction of traditional smoking without all the health, social and economic problems" (18). To date, however, there are few objective data to substantiate these claims. Indeed, there is little objective information describing electronic cigarette toxicant content and yield or user toxicant exposure and effect.

The little available data suggest that electronic cigarette cartridges and vapors may contain trace amounts of impurities and tobacco-specific nitrosamines (13, 19). Electronic cigarette cartridge nicotine content may be less than the product labeling indicates, and the vapor produced from the cartridge may yield very little nicotine (13, 19). The scant data from human laboratory studies suggest that electronic cigarette use is likely to involve little nicotine exposure and tobacco abstinence symptom suppression that is far less than that produced by a tobacco cigarette (20, 21). Existing clinical models that have been used to evaluate combustible and noncombustible PREPs (10, 22, 23) might be adapted to quickly and efficiently provide necessary information regarding electronic cigarette toxicant exposure and effect.

The purpose of this study was to describe clinical laboratory methods that could be used to characterize electronic cigarette users' nicotine and CO exposure, cardiovascular response, and ratings of tobacco/nicotine abstinence symptom suppression and product acceptability. Accordingly, this within-subject study used these outcomes to compare, in 32 tobacco cigarette smokers, the effect of two marketed electronic cigarette brands with own brand cigarettes and sham smoking (i.e., puffing on an unlit cigarette). Based on preliminary data presented elsewhere (20, 21) we hypothesized that, compared with own brand, electronic cigarettes would deliver less nicotine and no CO and would be less effective at reducing symptoms of tobacco abstinence while producing lower acceptability ratings.

Materials and Methods

Participants

This study was approved by the Institutional Review Board of Virginia Commonwealth University and was conducted in accordance with the Declaration of Helsinki. Sixty-six men and women recruited from the Richmond, Virginia area provided written, informed consent. Prior to participation in any experimental sessions, 18 individuals were disqualified based on health concerns (e.g., high blood pressure) or failure to meet other inclusion/exclusion criteria (see below). In addition, 2 participants withdrew from the study and another 14 were withdrawn due to failure to comply with study procedures ($n = 9$), poor venous access ($n = 3$), or because study enrollment was completed ($n = 2$). The remaining 32 participants (13 women; 18 white) completed the study proper and were included in the analyses. Participants smoked at least 15 cigarettes per day (mean, 22 cigarettes per day; SD, 8.8), were between the ages of 18 to 55 years (mean, 33.6; SD, 12), provided an afternoon screening CO of at least 15 ppm (mean, 23.5; SD, 8.8), and had a urine cotinine result of at least 4 on a 7-point scale (0-6; NicAlert, Nymox Corp.; mean, 5.9; SD, 0.2). Exclusion criteria included self-reported history of any chronic mental or physical health condition, pregnancy or breastfeeding, active menopause, self-reported use of electronic cigarettes, current smoking cessation attempt, current drug use (other than marijuana), and >20 days self-reported marijuana or alcohol use in the past 30 days.

Study design and procedures

This study was conducted on an outpatient basis at the Clinical Behavioral Pharmacology Laboratory at Virginia Commonwealth University. Participants completed four laboratory sessions; each approximately 150 minutes in duration. One of four Latin-square ordered conditions was presented each session (separated by at least 48 hours) that differed by product administered: own brand (i.e., a lit cigarette of the participant's preferred brand), sham (i.e., an unlit cigarette of the participant's preferred brand), "NPRO" electronic cigarettes (NPRO EC; 18-mg cartridge; NJOY), and "Hydro" electronic cigarettes (Hydro EC; 16-mg cartridge; Crown Seven).

Participants were asked to refrain from cigarette smoking for at least 12 hours prior to their scheduled session. Smoking abstinence was verified upon arrival at the laboratory by an expired air CO level ≤10 ppm. At the start of a session, a heparinized catheter was inserted into a forearm vein, physiologic monitoring equipment was attached, and continuous physiologic recording commenced. Thirty minutes after session onset, participants responded to the subjective effect questionnaires, blood (7 mL) was sampled, and product was administered. Product administration consisted of 10 puffs with a 30-second interpuff interval (IPI; puff number and IPI were monitored by study staff): package instructions state that electronic cigarettes should be used similarly to a tobacco cigarette, and 10 puffs with a 30-second IPI approximates *ad libitum* cigarette smoking (24). Five, 15, 30, and 45 minutes after the first of 10 puffs of the initial product administration, participants responded to the subjective effect questionnaires and blood (7 mL) was sampled. Expired air CO was recorded at 15, 30, and 45 minutes. At 60 minutes, participants responded to the subjective effect questionnaires, blood (7 mL) was sampled, and product was administered a second time (again, 10 puffs, 30-second IPI). Five, 15, 30, and 45 minutes after the second product administration, participants responded to the subjective effects questionnaires and blood (7 mL) was sampled. Expired air CO was recorded at 15, 30, and 45 minutes. At session's end, the venous catheter was removed, participants were compensated for their time, and, if necessary, additional sessions were scheduled.

Materials

NPRO EC was purchased from NJOY (25). The NPRO EC resembles a tobacco cigarette in length and diameter and consists of a disposable mouthpiece that houses a cartridge, a small heating element (vaporizer) that is activated when the user draws air through the device, and a rechargeable lithium battery. Cartridges come in a variety of flavors with varying nicotine content (0-18 mg). According to the NJOY website, cartridge ingredients include nicotine, propylene glycol, water, ethanol, glycerol, acetylpyrazine, guaiacol, mysomine, cotinine, and vanillin.

Hydro EC was purchased from Crown Seven (26). Hydro EC is similar in composition to NPRO EC and, according to the manufacturer's website, cartridges also come in a variety of flavors and contain nicotine (0-16 mg), propylene glycol, water, and tobacco flavoring.

For electronic cigarette conditions, a new 16-mg (Hydro EC) or 18-mg (NPRO EC) nicotine cartridge was used and batteries were fully charged before each session. The flavor of each electronic cigarette was matched to the participants' usual brand of cigarettes (regular or menthol). Consistent with product instructions, participants were instructed to puff from the electronic cigarette devices as they would a normal cigarette.

Participants' usual brand of cigarette was used in the own brand and sham conditions. According to the Federal Trade Commission (FTC, 2001), on average, usual brand yield was 1.06 mg nicotine (27), 14.7 mg tar, and 14.6 mg CO (based on available data for 26 participants).

Outcome measures

Physiologic measures. Heart rate was measured every 20 seconds (Model 506, Criticare Systems, fitted with a reusable pulse oximeter sensor). Blood samples were centrifuged and plasma was stored at −70°C. Plasma samples were sent to the Bioanalytical Analysis Core Laboratories of Virginia Commonwealth University's Department of Pharmaceutics and were analyzed for nicotine content using liquid chromatography/tandem mass spectrometry [limit of quantitation (LOQ) = 2.0 ng/mL; see ref. 24 for details]. Expired air CO was assessed using a BreathCO monitor (Vitalograph).

Subjective effect questionnaires. Participants responded to a computerized version of the Tiffany Drobes Questionnaire of Smoking Urges Brief (QSU Brief; ref. 28). The questionnaire consists of 10 items rated from 0 (strongly disagree) to 6 (strongly agree). Items from this scale are loaded onto two previously validated factors; factor 1 (intention to smoke) and factor 2 (anticipation of relief from withdrawal).

Participants responded to three computerized questionnaires containing visual analog scale (VAS) items. Each word or phrase was centered above a horizontal line that represented a scale from 0 to 100 points; the left anchor was "Not at all" and the right anchor was "Extremely". A mouse-controlled cursor produced a vertical mark on the line that could be adjusted by the participant. Scores on visual analog scale items were calculated as the distance between the vertical mark and the left anchor and were expressed as a percentage of line length.

Eleven VAS items were used to assess nicotine/tobacco abstinence symptom suppression (29). The direct effects of nicotine were assessed using 10 VAS items sensitive to nicotine effects (30, 31). Participants also responded to 14 visual analog scale items that assessed the direct effects of tobacco.

Data analyses

Heart rate values were averaged for 5-minute periods prior to each product administration or blood sampling. One heart rate measurement was missing for one participant in one session, and the missing value was replaced with an average of values before and after it. For plasma nicotine, values below the LOQ were replaced by the LOQ as in previous work (10, 32, 33).

We had previously reported the interim findings of this study, in a letter that examined nicotine exposure, heart rate, and craving results (21). The first 16 participants were included in that analysis. Prior to analyzing the data from all 32 participants described here, we first compared results of the first group of 16 participants with those of the second group of 16 participants using a repeated measures ANOVA with two within-subjects factors: condition (4 levels) and time [10 levels for nicotine, subjective, and heart rate (HR) data; 7 for CO data], and one between-subjects factor: study group (first 16 or second 16). No significant main effects or interactions involving the study group factor were observed on any measure. Given this failure to observe any differences across the two groups, all data were combined. Thus, the data from all 32 participants for plasma nicotine, CO, heart rate, and subjective measures were analyzed using repeated measures ANOVA with two factors: condition (4 levels) and time (10 levels for nicotine, HR data, and subjective data; 7 levels for CO). Huynh-Feldt corrections were used to account for violations of sphericity. Tukey's Honestly Significant Difference (HSD) test was used to examine differences between means ($P < 0.05$).

Results

Table 1 presents the main effects and interactions for all measures. The primary results of interest are those for which a significant condition by time interaction were observed, indicating that changes over time observed on that measure depended upon product used in that condition.

Physiologic measures

Plasma nicotine. A significant condition by time interaction was observed for plasma nicotine (Fig. 1A). Mean (SD) plasma nicotine increased from a preadministration level of 2.1 (0.32) ng/mL to a peak of 18.8 (11.8) ng/mL

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Table 1. Results of statistical analyses for all outcome measures

Measure	Condition F (*P*)	Time F (*P*)	Condition × time F (*P*)
Heart rate*	13.5 (>0.001)	62.0 (>0.001)	16.1 (>0.001)
Plasma nicotine*	112.2 (>0.001)	53.0 (>0.001)	45.2 (>0.001)
Carbon monoxide†	105.5 (>0.001)	107.0 (>0.001)	205.5 (>0.001)
Hughes and Hatsukami*			
Anxious	4.8 (0.01)	5.7 (>0.001)	1.8 (0.05)
Craving a cigarette	37.7 (>0.001)	25.7 (>0.001)	10.6 (>0.001)
Depression/feeling blue	0.5 (ns)	1.5 (ns)	1.1 (ns)
Difficulty concentrating	0.5 (ns)	3.4 (0.02)	0.8 (ns)
Drowsy	0.6 (ns)	3.9 (0.007)	1.6 (ns)
Hunger	2.6 (ns)	7.8 (>0.001)	1.8 (ns)
Impatient	4.3 (0.009)	3.7 (0.006)	2.5 (0.005)
Irritability/frustration/anger	5.8 (0.004)	2.3 (ns)	3.3 (0.001)
Restless	1.5 (ns)	2.5 (0.05)	1.9 (0.025)
Desire for sweets	1.7 (ns)	1.7 (ns)	1.7 (ns)
Urge to smoke	40.8 (>0.001)	28.2 (>0.001)	9.7 (>0.001)
QSU*			
Factor 1	40.6 (>0.001)	35.7 (>0.001)	16.9 (>0.001)
Factor 2	19.5 (>0.001)	16.6 (>0.001)	7.6 (>0.001)
Direct effects of nicotine*			
Confused	1.0 (ns)	1.4 (ns)	1.4 (ns)
Dizzy	1.5 (ns)	5.2 (0.002)	4.1 (0.002)
Headache	0.7 (ns)	0.9 (ns)	1.6 (ns)
Heart pounding	0.4 (ns)	2.9 (0.05)	1.9 (ns)
Lightheaded	1.2 (ns)	7.6 (>0.001)	5.8 (>0.001)
Nausea	0.1 (ns)	0.8 (ns)	1.1 (ns)
Nervous	1.0 (ns)	1.0 (ns)	1.2 (ns)
Salivation	0.5 (ns)	0.2 (ns)	1.0 (ns)
Sweaty	0.8 (ns)	0.9 (ns)	1.3 (ns)
Weak	0.1 (ns)	0.8 (ns)	1.1 (ns)
Direct effects of tobacco*			
Satisfying	76.2 (>0.001)	61.6 (>0.001)	17.2 (>0.001)
Pleasant	66.5 (>0.001)	68.5 (>0.001)	17.6 (>0.001)
Taste good	47.7 (>0.001)	66.8 (>0.001)	14.4 (>0.001)
Dizzy	19.2 (>0.001)	17.6 (>0.001)	7.2 (>0.001)
Calm	42.0 (>0.001)	31.1 (>0.001)	10.3 (>0.001)
Concentrate	17.9 (>0.001)	15.8 (>0.001)	5.5 (>0.001)
Awake	27.0 (>0.001)	22.0 (>0.001)	6.6 (>0.001)
Reduce hunger	24.2 (>0.001)	19.4 (>0.001)	5.6 (>0.001)
Sick	3.6 (0.02)	3.6 (0.01)	0.9 (ns)
Taste like own brand	115.5 (>0.001)	60.0 (>0.001)	26.9 (>0.001)
Feel like own brand	65.9 (>0.001)	67.0 (>0.001)	21.6 (>0.001)
Harsh as own brand	64.9 (>0.001)	49.2 (>0.001)	21.3 (>0.001)
Mild as own brand	62.4 (>0.001)	54.0 (>0.001)	20.5 (>0.001)
Smoke another cigarette RIGHT NOW	6.5 (>0.001)	38.3 (>0.001)	4.8 (>0.001)

Abbreviation: ns, nonsignificant.

*$df_{Condition}$, 3,93; df_{Time}, 9,279; $df_{Condxtime}$, 27,837.

†$df_{Condition}$, 3,93; df_{Time}, 6,186; $df_{Condxtime}$, 18,558.

five minutes after the first administration under the own-brand condition. No significant changes in plasma nicotine were observed for the Hydro EC, NPRO EC, or sham conditions.

Heart rate. A significant condition by time interaction was also observed for heart rate (Fig. 1B). Heart rate increased from an average (SD) of 65.7 (10.4) bpm at baseline to a peak of 80.3 (10.9) bpm five minutes after the

first administration under the own-brand condition. No significant changes in heart rate were observed for the Hydro EC, NPRO EC, or sham conditions.

Expired air CO. A significant condition by time interaction was observed for expired air CO levels (Fig. 2). Mean (SD) CO increased from a preadministration level of 5.3 (2.1) ppm to a peak of 16.2 (4.5) ppm 15 minutes after the second administration under the own-brand condition. No significant changes in CO level were observed for the Hydro EC, NPRO EC, or sham conditions.

Subjective effect questionnaires

QSU brief. A significant condition by time interaction was observed for both factors of the QSU brief. Figure 3A shows data for factor 1 (intention to smoke; the QSU factor with the greater condition by time F value). Hydro EC and NPRO EC significantly decreased scores on both factors (relative to sham and/or baseline) at several time points. In contrast, own brand significantly decreased scores (relative to baseline and sham) on both factors at nearly every time point. In addition, the scores observed for own brand after product administration were significantly lower than Hydro EC and NPRO EC at almost every time point. A nearly identical pattern of results was observed for factor 2, although ratings were generally lower than those observed on factor 1.

Nicotine/tobacco abstinence symptom suppression. Significant condition by time interactions were observed on ratings of "anxious," "craving a cigarette/nicotine," "impatient," "irritability/frustration/anger," "restless,"

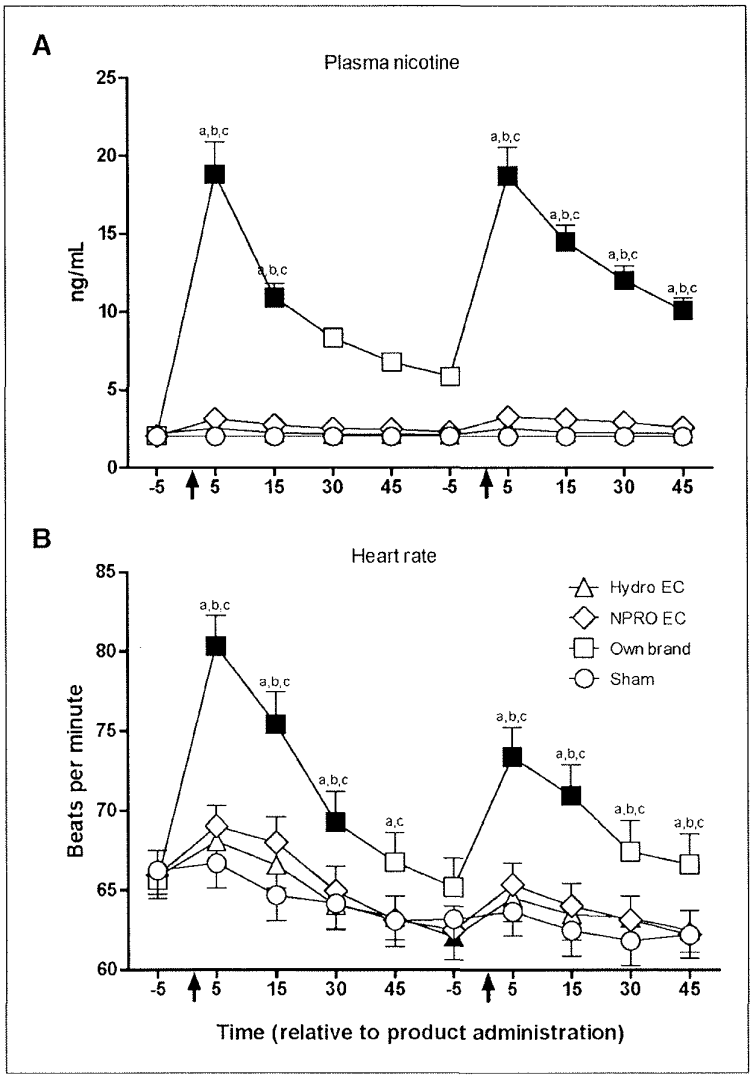

Figure 1. Mean data for nicotine blood plasma (A) and heart rate (B) as a function of condition and time. *X*-axes, time in minutes relative to product administration; arrows, first and second product administrations. *Y*-axes, A, nicotine blood plasma concentration (ng/mL); B, heart rate (beats per minute); filled symbols, significant difference from baseline. An "a," "b," or "c" indicates that own brand was significantly different from sham, Hydro EC, or NPRO EC at that time point. A "d" indicates that Hydro EC was significantly different from sham at that time point. An "e" indicates that NPRO EC was significantly different from sham at that time point (Tukey's HSD, $P < 0.05$). Unidirectional error bars, 1 SE.

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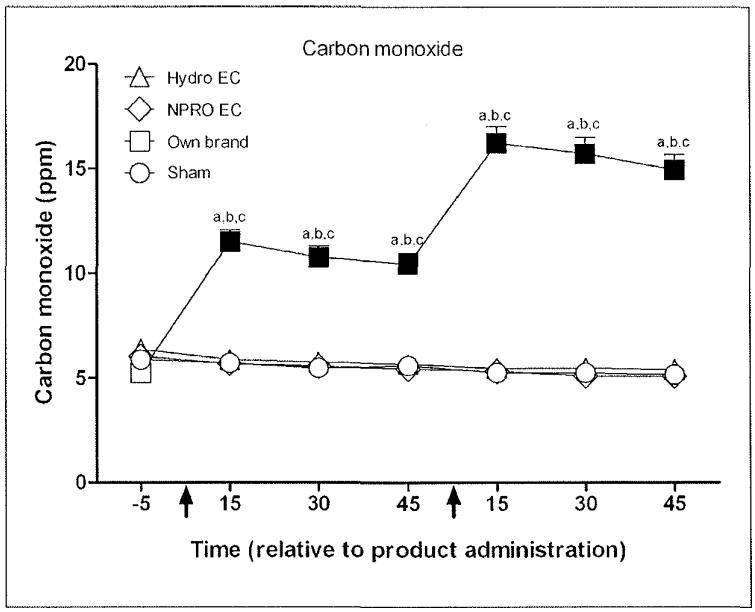

Figure 2. Mean data for carbon monoxide (CO) as a function of condition and time. *X*-axis, time in minutes relative to product administration; arrows, first and second product administrations. *Y*-axis, CO in parts per million (ppm); filled symbols, significant difference from baseline. An "a," "b," or "c" indicates that own brand was significantly different from sham, Hydro EC, or NPRO EC at that time point. A "d" indicates that Hydro EC was significantly different from sham at that time point. An "e" indicates that NPRO EC was significantly different from sham at that time point (Tukey's HSD, $P < 0.05$). Unidirectional error bars, 1 SE.

and "urge to smoke a cigarette." Own brand generally decreased ratings on all of these measures. NPRO EC and Hydro EC produced some abstinence symptom suppression on two measures: "craving a cigarette" and "urge to smoke." Figure 3B depicts data for ratings of "craving a cigarette" (the measure with the largest F-value). Ratings of "urge to smoke" decreased significantly 5 minutes following the first Hydro EC administration, and 5, 15, and 30 minutes following the first and second NPRO EC administrations relative to baseline. Ratings of "urge to smoke" decreased significantly at all time points following the first and second own-brand administrations relative to baseline, and own brand was significantly different from Hydro EC and NPRO EC at several time points. Similar effects of own brand, Hydro EC, and NPRO EC were observed on ratings of "craving a cigarette" (Fig. 3B).

Direct effects of nicotine. Significant condition by time interactions were observed on VAS items assessing "dizzy" and "lightheaded." Own brand significantly increased ratings of "lightheaded" and "dizzy" within the first five minutes following the first administration. NPRO EC, Hydro EC, and sham did not alter ratings significantly on these measures.

Direct effects of tobacco. Significant condition by time interactions were observed for ratings of "satisfying," "pleasant," "taste good," "dizzy," "calm," "concentrate," "awake," "reduce hunger," "taste like own brand," "feel like own brand," "harsh as own brand," "mild as own brand," and "smoke another cigarette right now." Ratings of "calm" and "satisfying" are shown in Fig. 3C and D. Ratings of "satisfying" and "pleasant" increased significantly at all time points under the Hydro EC, NPRO EC, and own-brand conditions (relative to baseline). Own brand increased ratings of "satisfying" and "pleasant" to a significantly greater degree than Hydro EC or NPRO EC. Ratings of "taste good," "calm," "concentrate," "awake," and "reduce hunger" increased significantly at all time points after own brand and at several time points after Hydro EC and NPRO EC (relative to baseline). Ratings of "taste like own brand," "feel like own brand," "harsh as own brand," and "dizzy" increased significantly at all time points under the own-brand condition (relative to baseline and sham). Ratings of "mild as own brand" increased significantly at all time points under the own-brand condition (relative to baseline and sham) and at nearly all time points under the Hydro EC condition (relative to baseline). Ratings of "smoke another cigarette right now" increased significantly relative to baseline at all time points under the Hydro EC and NPRO EC conditions, and 30 and 45 minutes postadministration 1 and 45 minutes postadministration 2 under the own-brand condition.

Discussion

The purpose of this acute study was to describe clinical laboratory methods that could be used to understand electronic cigarettes better by examining users' toxicant exposure, cardiovascular response, and subjective reports. The results of this study show the usefulness of the clinical model and suggest that, unlike puffing from a tobacco cigarette, two 10-puff bouts with the two electronic cigarettes described here expose users to no measurable nicotine or CO and do not increase heart rate. Despite the failure to deliver nicotine, acute use of

the two products tested in this study produced some tobacco abstinence symptom suppression and increased subjective ratings of acceptability. Relative to the effects produced by an own-brand tobacco cigarette, these subjective effects of electronic cigarettes were modest.

With regard to nicotine exposure, the observation that 20 puffs from Hydro EC (16-mg cartridge) and NPRO EC (18-mg cartridges) did not increase plasma nicotine concentration significantly is entirely consistent with our preliminary report regarding these products (21). The plasma nicotine results are also consistent with the heart rate data reported here. That is, heart rate increases are observed when nicotine is administered via pharmaceutical products (34, 35) or tobacco products (32, 33, 36), and we observed increased heart rate when participants in this study smoked their own brand of cigarette (that also delivered nicotine). However, no heart rate increases were observed in either electronic cigarette condition (where no significant increases in plasma nicotine were observed). Finally, the mean peak changes from baseline in plasma nicotine concentration observed for NPRO EC (1.4 ng/mL) and Hydro EC (0.5 ng/mL) during the first product administration were similar in magnitude to the maximum nicotine concentration reported for a third electronic cigarette brand with a 16-mg cartridge (1.3 ng/mL; ref. 20). The consistency of results across participants, measures, and laboratories highlights the reliability of the clinical methods reported here (see also ref. 24), while also calling into question the ability of the three different electronic cigarettes that have been tested to date to approximate the nicotine delivery of a tobacco cigarette under acute conditions.

In spite of delivering no measurable nicotine, both electronic cigarettes tested in this study reduced ratings of "craving a cigarette" and "urge to smoke" and increased subjective ratings of product acceptability (e.g., "satisfying," "taste good," "pleasant"). These results are consistent with anecdotal reports from long-term electronic cigarette users and support the notion that electronic cigarettes may provide an alternative, perhaps a substitute, to cigarette smoking in some cases (11, 12). Interestingly, denicotinized cigarettes have also been shown to suppress tobacco abstinence symptoms for as

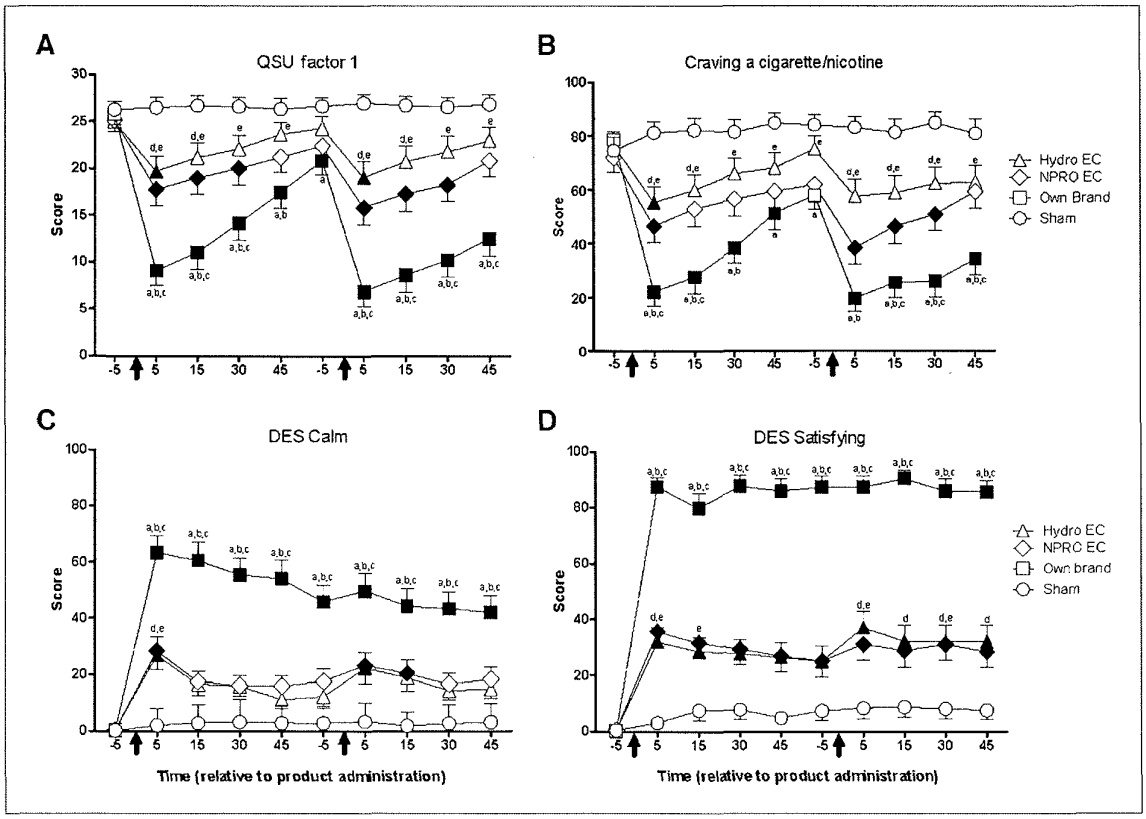

Figure 3. Mean data for QSU factor 1 ratings (A), ratings of "craving a cigarette" (B), ratings of "calm" (C), and ratings of "satisfying" (D) as a function of condition and time. *X*-axes, time in minutes relative to product administration; arrows, first and second product administrations. *Y*-axes, subjective ratings; filled symbols, significant difference from baseline. An "a," "b," or "c" indicates that own brand was significantly different from sham, Hydro EC, or NPRO EC at that time point. A "d" indicates that Hydro EC was significantly different from sham at that time point. An "e" indicates that NPRO EC was significantly different from sham at that time point (Tukey's HSD, $P < 0.05$). Unidirectional error bars, 1 SE. DES, direct effects of smoking.

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long as 96 hours (37). However, under the acute conditions reported here, the two electronic cigarettes did not suppress nicotine/tobacco abstinence symptoms fully, relative to own-brand smoking. Other PREPs that failed to suppress abstinence symptoms fully have been shown to supplement rather than substitute for cigarette smoking (9, 24, 37, 38). Further controlled evaluation is needed to determine the extent to which the effects reported here are sufficient for electronic cigarettes to substitute for tobacco cigarettes, and in what proportion of smokers and under what conditions this substitution effect might occur.

Importantly, neither of the electronic cigarettes tested in this study was associated with any measurable CO exposure. Long-term CO exposure has been linked to cardiovascular disease caused by tobacco cigarette smoking (39). In part for this reason, substituting noncombustible tobacco or nicotine products for cigarettes has been suggested as a potentially effective strategy for reducing the harm of tobacco smoking (40). Following this same logic, and taking into account the trace levels of tobacco-specific nitrosamines found in some electronic cigarette products (13), electronic cigarettes may also warrant careful empirical examination by those interested in harm reduction for smokers. Clinical laboratory methods have an important role to play in this empirical examination, and can reveal carcinogen exposure and abstinence symptoms suppression over several days' PREP use (22, 24, 33, 41). These methods will likely be extremely important to any future regulation of electronic cigarettes either as tobacco products or drug delivery devices in the United States (i.e., by the Food and Drug Administration) and elsewhere.

Methodologic considerations of the current study include the brief electronic cigarette exposure period, rigorous control over some aspects of smoking behavior, use of two brands of electronic cigarette with similar cartridge nicotine content, and inclusion of electronic cigarette–naïve participants who may be representative of cigarette smokers sampling an electronic cigarette for the first time, but not of a more experienced electronic cigarette user population. The results of some outcome measures might be influenced by longer-term use, different puffing profiles, other electronic cigarette models/cartridge strengths, and/or the user's previous experience with electronic cigarettes. In future studies, control conditions other than own brand and sham smoking might be of interest. Indeed, a recently published study compared the subjective and physiologic effects of another brand of electronic cigarette, the Ruyan electronic cigarette, to that of a pharmaceutical nicotine inhalator and found that the two products were associated with similar low levels of nicotine exposure, incomplete withdrawal suppression, and moderate acceptability (20). In addition, behavioral studies that assess the reinforcing/rewarding properties of electronic cigarettes could reveal the extent to which electronic cigarettes might be used or abused (42). Finally, the adverse event profile associated with long-term use of electronic cigarettes is uncertain, and must be explored empirically. Many of these methodologic issues and research questions can be addressed parametrically and conveniently in the clinical laboratory, highlighting the strength of these efficient and reliable evaluation methods (see also ref. 24).

In sum, this study revealed that two electronic cigarette brands do not expose electronic cigarette–naïve users to nicotine or carbon monoxide under the acute testing procedures described here, but do produce some tobacco abstinence symptom suppression and positive ratings of product acceptability. Although these results are necessarily a function of the products tested and procedures used, they suggest that electronic cigarette–naïve individuals may require substantial motivation if they are to learn whatever product/procedure combination maximizes these outcomes for them. Future clinical laboratory evaluation can build on these methods and results to establish the extent to which electronic cigarettes might be expected to substitute for tobacco cigarettes, and help to identify under what conditions this substitution might occur. Parallel studies addressing the abuse liability and long-term adverse event profile of electronic cigarettes are also required to ensure safety and appropriate labeling and marketing of these products.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

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EXHIBIT D

Brief Report

Electronic Cigarettes: Effective Nicotine Delivery After Acute Administration

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Abstract

Introduction: Electronic cigarettes (ECs) are marketed as nicotine delivery devices. Two studies with EC-naïve participants suggest that ECs deliver little or no nicotine. In those studies, standard-sized ECs were used, though experienced EC users often use larger devices that house higher voltage and/or longer lasting batteries. Whether user experience and device characteristics influence EC nicotine delivery is uncertain. The purpose of the present study was to examine the effects of ECs in experienced users who were using their preferred devices.

Methods: Eight EC users (3 women) who had been using ECs for at least 3 months, completed one 5-hr session using devices they provided and the flavor/strength nicotine cartridges they selected. Sessions consisted of 4 phases: baseline, 10 puffs (30-s interpuff interval) from the device, 1-hr ad lib puffing period, and a 2-hr rest period (no puffing). Outcome measures in each phase included plasma nicotine concentration, heart rate, and subjective ratings of nicotine/product effects and abstinence symptoms.

Results: Relative to baseline, plasma nicotine and heart rate increased significantly within 5 min of the first puff and remained elevated throughout the ad lib puffing period. Increases in ratings of direct effects of nicotine and product were observed as well as decreases in abstinence symptoms.

Conclusions: User experience and/or device characteristics likely influence EC nicotine delivery and other effects. Systematic manipulation of these and other variables could elucidate conditions that produce intended effects.

Introduction

Electronic cigarettes (ECs) that consist of a battery, heater, and nicotine-containing liquid are marketed as devices that deliver nicotine to the user. ECs have become increasingly popular, and some reports suggest that they help users quit or reduce cigarette smoking (Ayers, Ribisi, & Brownstein, 2011; Etter, 2010; Etter and Bullen, 2011a; Heavner, Dunworth, Bergen, Nissen, & Phillips, 2009; McQueen, Tower, & Sumner, 2011; Polosa et al., 2011). Results of two clinical laboratory studies, conducted with EC-naïve cigarette smokers, suggest that ECs either deliver nicotine inefficiently or not at all (Bullen, McRobie, Thornley, Glover, & Laugesen, 2010; Vansickel, Cobb, Weaver, & Eissenberg, 2010). Those studies used standard-sized cigarette-like ECs, while experienced EC users ("vapers") often use models that are larger than a cigarette and house higher voltage or longer life batteries (Foulds, Veldheer, & Berg, 2011). Furthermore, EC and tobacco cigarette puffing characteristics may differ, suggesting that inexperienced users may not use ECs in a manner that allows for sufficient nicotine delivery (Trtchounian et al., 2011). Whether user experience and/or device characteristics influence nicotine delivery is unknown. The purpose of the present study was to characterize the nicotine delivery profile, subjective, and cardiovascular effects of ECs in experienced ECs users who were using their preferred devices.

Methods

Eight EC users (3 women; 8 Caucasian) consented to and completed this single-session (5 hr) Institutional Review Board-approved protocol. Participants used their own fully charged EC, and a prefilled cartomizer (heater + liquid) of their chosen flavor/nicotine content was provided. At the start of the session, participants were surveyed regarding health, demographics, and EC use habits. Participants were included in the study if they reported using an EC for at least 3 months, used at least 2–3 ml of nicotine solution or two cartridges per day, used nicotine solution of at least 10 mg/ml nicotine, smoked fewer than five cigarettes per day, and were between the ages of 18 and 55. Participants were excluded if they reported any chronic health or psychiatric conditions, had a history of high or low blood pressure, or were unwilling to use a cartridge or cartomizer during the session.

Participants were required to abstain from all nicotine and tobacco product use, including ECs, for at least 12 hr prior to the session. Abstinence was verified upon arrival at the laboratory by a carbon monoxide level of 10 ppm or less and was further verified later by plasma nicotine levels at or below the limit of quantification (2 ng/ml). At session onset, a venous catheter was inserted into the participant's forearm vein and continuous physiological monitoring commenced. Approximately 55 min

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later, blood was sampled, and 5 min after that, participants were provided with their EC and were instructed to take 10 puffs (30-s interpuff interval [IPI; as in Eissenberg, 2010; Vansickel et al., 2010]). Blood was sampled 5 and 15 min after the start of the 10-puff period. Then, a 60-min ad lib puffing period began, and blood was sampled every 15 min. Participants then entered a 2-hr rest period during which no puffing occurred, and blood was sampled every 30 min. Participants completed subjective questionnaires at baseline and again after the 10-puff, ad lib, and rest periods. At session's end, the venous catheter was removed, physiological monitoring ceased, and participants were compensated.

Physiological outcome measures included heart rate (measured every 20 s) and plasma nicotine concentration (blood centrifuged and plasma stored at −70 °C for analysis of nicotine concentration). Subjective and behavioral outcome measures included the Tiffany–Drobes Questionnaire of Smoking Urges Brief (QSU Brief; Cox, Tiffany, & Christen, 2001), 11 visual analogue scale (VAS) items that assessed nicotine/EC abstinence symptoms (Kleykamp et al., 2008), 10 VAS items that assessed the direct effects of nicotine (Blank, Sams, Weaver, & Eissenberg, 2008), 14 VAS items that assessed the direct effects of the EC (Vansickel et al., 2010) as well as the total number of puffs taken during the ad lib period.

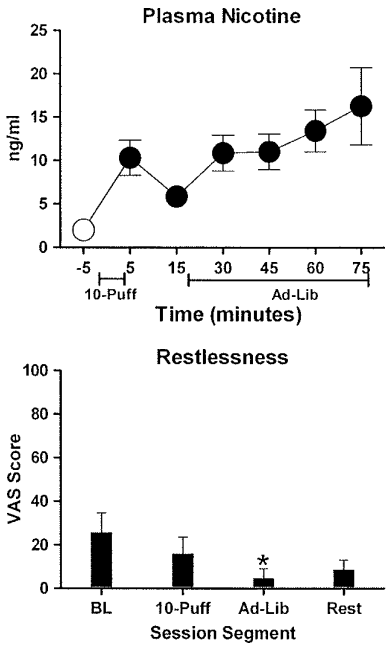

Figure 1. Top panel: *M* (±1 *SEM*) plasma nicotine (assay's limit of quantitation = 2 ng/ml; Breland, Kleykamp, & Eissenberg, 2006) levels at baseline (−5) and during the 10-puff and 1-hr ad lib puffing periods. Filled symbols indicate a significant difference from baseline. Bottom panel: *M* (+1 *SEM*) response to a visual analogue scale item assessing "restlessness" (0–100 scale) at baseline and the end of the 10-puff, ad lib, and rest periods. An asterisk indicates a significant difference from baseline. Data are from eight electronic cigarettes (EC) using participants who abstained from ECs for at least 12 hr before session. Paired *t* tests were used to compare means, $p \leq .05$.

Results

Participants were former smokers who had tried to quit smoking an average (*SD*) of 3.9 (1.8) times in their lifetime, had quit smoking for 11.4 (5.4) months, and had been using ECs for 11.5 (5.4) months. Their average age was 33.4 (8.6) years, and they had completed 15.3 (2) years of education. Seven participants used devices that did not resemble tobacco cigarettes and housed higher voltage and/or longer lasting batteries than in previous work (e.g., Vansickel et al., 2010). Six participants used 18 mg/ml nicotine solution, one used 9, and the other used 24 mg/ml solution.

Plasma nicotine increased significantly from a baseline mean of 2 ng/ml (*SEM* = 0) to a mean of 10.3 ng/ml (*SEM* = 2) within 5 min of the first puff. Plasma nicotine reached a maximum mean concentration (*M* = 16.3 ng/ml, *SEM* = 4.5) by the end of the ad lib period (see Figure 1; relative to baseline all $P < .05$ by paired *t* test). Heart rate increased significantly from a baseline mean of 73.2 (*SEM* = 2.0) beats per minute (bpm) to 78 (*SEM* = 1.9) bpm within 5 min of the first puff and remained elevated during the ad lib period. The number of puffs during the 1-hr ad lib period ranged from 4 to 76 (*M* = 46.6, *N* = 7).

VAS ratings of "Anxious" were elevated at baseline (*M* = 13.9, *SEM* = 4.5), were significantly reduced following the 10-puff (*M* = 2.8, *SEM* = 2.5) and ad lib (*M* = 0.9, *SEM* = 0.6) periods, and returned to baseline levels after the rest period (*M* = 12.4, *SEM* = 4). VAS ratings of "Restlessness" were elevated at baseline (*M* = 26, *SEM* = 9), were significantly reduced following the ad lib period (*M* = 4.8, *SEM* = 4), and increased following the rest period (*M* = 8.8, *SEM* = 4) (see Figure 1). Similarly QSU Factor 1 (intention to smoke) scores were elevated at baseline (*M* = 21, *SEM* = 2.7), were significantly reduced following the ad lib puffing period (*M* = 5.6, *SEM* = 1.9), and returned to baseline levels after the rest period (*M* = 18.3, *SEM* = 2.2). Positive direct effects of EC administration were also observed. VAS ratings of Did the EC help you "Feel awake," "Calm you down," and "Concentrate" as well as Was the EC "Pleasant" and "Satisfying" and Did the EC "Reduce your hunger for food" and "Taste Good" increased significantly following the 10-puff period, peaked following the ad lib period, and decreased after the rest period. For example, ratings of "Satisfying" increased from 0.125 (*SEM* = 0.125) to 83.9 (*SEM* = 7) after the 10-puff bout and further increased to 92.6 (*SEM* = 3.3) following the ad lib period before dropping to 36.9 (*SEM* = 13.5) after the rest period. EC use did not significantly affect ratings on any other measure.

Discussion

Previous reports have described conditions of EC use that support minimal or no nicotine delivery (Bullen et al., 2010; Eissenberg, 2010; Vansickel et al., 2010). In those studies, current cigarette smokers, who were not experienced with ECs, engaged in brief periods of EC use. In addition, the ECs used in those studies were cigarette-sized EC models. In the current study, experienced EC users who provided their preferred ECs loaded with their selected flavor/nicotine concentration completed a 10-puff (30-s IPI) bout and a 1-hr ad lib puffing period. Under these conditions, EC use resulted in reliable nicotine delivery. These results are the first to demonstrate unequivocally that ECs alone are capable of increasing plasma nicotine concentrations to levels seen during cigarette smoking. In support of this conclusion, the results of a recent study in which the saliva cotinine

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concentration of self-reported EC users was measured are also consistent with nicotine exposure that approximated tobacco cigarette use (e.g., Etter & Bullen, 2011b). However, unlike the current laboratory study, results of this previous work may have been influenced by the concurrent use of other nicotine-containing products.

Interestingly, abstinence symptoms were observed prior to EC use, and these symptoms were suppressed after EC use, a potential indicator of nicotine dependence (Carter and Griffiths, 2009). Of course, these participants were former cigarette smokers and thus may have been nicotine dependent prior to initiating EC use. The extent to which EC use leads to the development of nicotine dependence in nicotine-naïve users is unknown.

Some reports suggest that ECs have the potential to be safe and efficacious replacements for tobacco cigarettes due to nicotine's effects (Etter & Bullen, 2011a; Siegel, Tanwar, & Wood, 2011). That potential is undermined by ineffective devices and a requirement that users learn specific but as-yet-undetermined behaviors in order to maximize nicotine delivery. Thus, an important area for future research is the parametric manipulation of device characteristics and user behavior (i.e., puff topography) as well as other factors (e.g., nicotine concentration) that might contribute to safety and efficacy. In addition, the potential deleterious health effects of chronic inhalation of vaporized nicotine solutions are unknown (Etter, Bullen, Fouris, Laugesen, & Eissenberg, 2011). Clinical laboratory evaluation of lung and cardiovascular function, measurement of biomarkers of harm (e.g., inflammatory biomarkers such as C-reactive protein), as well as population level surveillance of adverse events associated with EC use will be necessary for ensuring safety and proper regulation. Taken together, results of the current and previous studies demonstrate considerable variability in EC nicotine delivery, device performance, and/or cartridge and vapor nicotine content (Bullen et al., 2010; Eissenberg, 2010; U.S. Food and Drug Administration, 2009; Vansickel et al., 2010; Williams & Talbot, 2011). One important potential benefit of EC regulation may be more consistent nicotine delivery, device performance, and cartridge and vapor content.

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Declaration of Interests

The authors have no conflicts of interest to declare. The sponsor had no role in the design and conduct of the study; or in the preparation, review, or approval of the manuscript. The authors had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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EXHIBIT E

LOG IN TO MY ESC

ELECTRONIC CIGARETTES DO NOT DAMAGE THE HEART

First-hand smoke, second-hand smoke or electronic cigarettes

25 AUG 2012

Electronic cigarettes have no acute adverse effects on cardiac function, according to research presented today at an ESC Congress 2012 press conference by Dr Konstantinos Farsalinos from Greece.

Topic(s): Prevention;

Smoking is the most preventable risk factor for cardiac and lung disease and is expected to cause 1 billion deaths during the 21st century. Electronic cigarettes have been marketed in recent years as a safer habit for smokers, with several millions of people already using them worldwide.

Electronic cigarettes simulate the effect of smoking by producing an inhaled vapor. The device consists of a battery, a cartridge containing liquid and a heating element which gets warm and evaporates the liquid. Laboratory analyses of the liquids show that they are less toxic than regular cigarettes. Most studies have found no nitrosamines, but even in studies where nitrosamines were found, the levels detected were

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500-1400 times less than the amount present in one tobacco cigarette. This means that electronic cigarettes must be used daily for 4-12 months to get the amount of nitrosamines present in a single tobacco cigarette.

Since heart disease is the main cause of morbidity and mortality in smokers, with 40% of deaths in smokers due to coronary artery disease alone, the research team decided to perform the first clinical study of the acute effects of electronic cigarettes on cardiac function.
They decided to compare their results with the acute effects of regular cigarettes on cardiac function since electronic cigarettes are marketed to smokers only, as an alternative habit.

Previous studies from the research group and several others have shown that acute smoking inhalation produces significant defects in myocardial function. This indicates that subclinical dysfunction is already present in apparently healthy, asymptomatic young people who smoke tobacco cigarettes. The goal was to evaluate whether these signs of preclinical disease appear in a similar population after using electronic cigarettes.

The researchers measured myocardial function in 20 healthy young daily smokers aged 25-45 years before and after smoking one tobacco cigarette and 22 daily electronic cigarette users of similar age before and after using the device for 7 minutes.

Experienced users of electronic cigarettes were studied because they use the device more intensively than first-time users. Although both groups were of equal age, users of electronic cigarettes had a 44% higher lifetime tobacco smoking exposure compared to current smokers.

For the electronic cigarettes, a commercially available liquid with a nicotine concentration of 11mg/ml was used (NOBACCO USA Mix). This was tested by an independent toxicology laboratory and found to contain no nitrosamines or polycyclic aromatic hydrocarbons.

Myocardial function was examined using cardiac ultrasound (echocardiography) and hemodynamic measurements (blood pressure and heart rate).

The researchers found that smoking one tobacco cigarette led

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to significant acute myocardial dysfunction but electronic cigarettes had no acute adverse effects on cardiac function. Smoking a tobacco cigarette had important hemodynamic consequences, with significant increases in systolic and diastolic blood pressure and in heart rate. In contrast, electronic cigarettes produced only a slight elevation in diastolic blood pressure. Dr Farsalinos said: "This is an indication that although nicotine was present in the liquid used (11mg/ml), it is absorbed at a lower rate compared to regular cigarette smoking."

The echocardiography examination focused on the function of the left ventricle, the part of the heart that receives oxygenated blood from the lungs (filling or diastolic phase) and then delivers the blood to the whole body (pumping or systolic phase). The investigators found significant defects in the diastolic phase of left ventricular function after smoking one cigarette, with four echocardiographic parameters indicating worsening function. In contrast, none of the echocardiographic parameters showed any significant worsening in subjects after using the electronic cigarette. "Diastolic dysfunction is very important because it is usually the first defect that is detected before any clinically-evident cardiac disease develops," said Dr Farsalinos.

He added: "It is too early to say whether the electronic cigarette is a revolution in tobacco harm reduction but the potential is there. It is the only available product that deals with both the chemical (nicotine delivery) and psychological (inhaling and exhaling 'smoke', holding it, etc) addiction to smoking, laboratory analyses indicate that it is significantly less toxic and our study has shown no significant defects in cardiac function after acute use."

Dr Farsalinos continued: "More clinical studies need to be done before suggesting that this is a revolutionary product. However, considering the extreme hazards associated with cigarette smoking, currently available data suggest that electronic cigarettes are far less harmful and substituting tobacco with electronic cigarettes may be beneficial to health."

Dr Farsalinos will also present his results during an ESC Congress 2012 scientific session tomorrow.

Abstract

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References

This press release accompanies both a presentation and an ESC press conference at the ESC Congress 2012. The press release has been written by the investigator and edited by the ESC and does not necessarily reflect the opinion of the European Society of Cardiology.

Refers to session: Tobacco: from early damage to late impact

Refers to press conference: First-hand smoke, second-hand smoke or electronic cigarettes

Notes to editor

About the European Society of Cardiology
The European Society of Cardiology (ESC) represents more than 75,000 cardiology professionals across Europe and the Mediterranean. Its mission is to reduce the burden of cardiovascular disease in Europe.

About ESC Congress 2012
ESC Congress 2012 will take place from 25 to 29 August at the Messe München centre in Munich, Germany. Information on the scientific programme is available here. More information on ESC Congress 2012 is available from the ESC Press Office or contact us at press@escardio.org

Electronic Patent Application Fee Transmittal

Application Number:	14925968
Filing Date:	28-Oct-2015
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Filer:	Richard Douglas Shoop/Mary Buggie
Attorney Docket Number:	13211-713.303

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:				
INDEPENDENT CLAIMS IN EXCESS OF 3	2201	1	210	210
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**210**

Electronic Acknowledgement Receipt

EFS ID:	27550000
Application Number:	14925968
International Application Number:	
Confirmation Number:	2707
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Customer Number:	66854
Filer:	Richard Douglas Shoop/Mary Buggie
Filer Authorized By:	Richard Douglas Shoop
Attorney Docket Number:	13211-713.303
Receipt Date:	17-NOV-2016
Filing Date:	28-OCT-2015
Time Stamp:	21:43:37
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$210
RAM confirmation Number	111816INTEFSW00006523504050
Deposit Account	504050
Authorized User	Richard Shoop
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		13211-713-303_Supp_Amendment_Decl_1-132_Exhibits_11-17-2016.pdf	2096665 b6688ec737f482a2708ad66392aa8d79252cec07	yes	31

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Supplemental Response or Supplemental Amendment	1	1
	Claims	2	6
	Applicant Arguments/Remarks Made in an Amendment	7	9
	Affidavit-traversing rejectns or objectns rule 132	10	31

Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30681 493bd4d7eb0a2fc17be23767b61ad788038df03b	no	2
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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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.

PTO/SB/06 (09-11)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/925,968	Filing Date 10/28/2015	☐ To be Mailed

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 $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ 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

AMENDMENT	11/17/2016	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 19	Minus	** 20	= 0	X $40 =	0
	Independent (37 CFR 1.16(h))	* 4	Minus	***3	= 1	X $210 =	210
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	**210**

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	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.

LIE
TARA WASHINGTON

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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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/925,968	10/28/2015	Adam BOWEN	13211-713.303	2707

66854 7590 12/02/2016

SHAY GLENN LLP
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SAN MATEO, CA 94403

EXAMINER	
MAYES, DIONNE WALLS	

ART UNIT	PAPER NUMBER
1747	

NOTIFICATION DATE	DELIVERY MODE
12/02/2016	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):

info@shayglenn.com

PTOL-90A (Rev. 04/07)

Office Action Summary	Application No. 14/925,968	Applicant(s) BOWEN ET AL.	
	Examiner DIONNE W. MAYES	Art Unit 1747	AIA (First Inventor to File) Status Yes

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/17/2016*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-3,6-10,12-18 and 20-23* is/are pending in the application.

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

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-3,6-10,12-18 and 20-23* is/are rejected.

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

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 19, 2016, and also the Supplemental Amendment filed on November 17, 2016, has been entered.

Declaration of Adam Bowen Under 32 CFR 1.132

3. The Declaration of Adam Bowen, under 37 CFR 1.132, filed on November 17, to the extent that it provides additional experimental evidence in support of the heart rate effect of vaporizing nicotine lactate has been accepted and, for the purposes of Examination, the subject matter thereof will be considered to have been incorporated into Applicant's Provisional Application filed on May 6, 2013. This same Declaration, to the extent that it articulates “unexpected results” is insufficient to establish the same. As shown in the following prior art rejection over Sebastian et al, the use of as much as 10% (w/w) nicotine in a equimolar ratio with lactic acid (hence, forming nicotine lactate) in a liquid solution of glycerol by heating the same in an electronic cigarette and being

inhaled by a user is already known, and would provide the claimed increases in heart rate comparable to inhaling a traditional burned cigarette. As such, the results indicated by Applicant, and that which is instantly claimed, are not "unexpected".

Declaration of Gal Cohen Under 32 CFR 1.132

4. The Declaration of Gal Cohen, filed on August 19, 2016, has now been rendered moot due to the subsequent filing of the Supplemental Amendment on November 17, 2016 which substantially changed the scope of the instant claims.

Claim Rejections - 35 USC § 112

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

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

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

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

6. Claims 7-20 and 22-23 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the amendment filed on November 17, 2016, Applicant has amended the claims to recite nicotine lactate concentrations which are "from about 4% (w/w) to about 6.5% (w/w)" (both independent claims 7 and 13), and "about 4.5% (w/w)" (independent claim 23); and, also, that there is an "increase in heart rate that peaks within about 5 minutes from the first puff" (independent claim 13). However, there appears to be no evidence provided in the Declaration of Adam Bowen filed on November 17, 2016 that supports such values. As indicated on Exhibit B "Nicotine Lactate effect on heart rate", concentrations which are reflected on the chart/graph reflect values of "4.0%" and "6.5%", ***only*** - *not* a range between these two concentrations or a concentration of "about 4.5%". Also, the chart/graph reflects that the heart rate peeks at within about 3.5 minutes at a nicotine lactate concentration of 6.5%, and within about 2 minutes at a nicotine lactate concentration of about 4.0% ***only*** - *not* "within ***5*** minutes". Correction is requested.

Claim Rejections - 35 USC § 103

7. 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 of this title, 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.

8. 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.

9. 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.

10. Claims 1-3, 7-10, 13-18 and 21-23 are rejected under 35 U.S.C. 103 as being unpatentable over Sebastian et al (US. Pat. App. Pub. 2014/0000638).

Regarding independent claims 1 and 23, Sebastian et al discloses an electronic smoking article (i.e., electronic cigarette) that provides for delivery of aerosolized components of an aerosol precursor composition to at least one heating element (See abstract. Note: According to Applicant's instant disclosure, the terms "electronic cigarette" and "low temperature vaporization device" are synonymous. See instant published application, para. [0119]) (corresponding to the claimed "deploying a low-temperature vaporizer").

The aerosol precursor composition may include a medicament, such as nicotine, which may comprise up to 10% of the weight of the aerosol precursor (see para.

[0060]). When nicotine is chosen, organic acids can be combined with the nicotine in order to favorably affect the flavor, sensation, or organoleptic properties. Organic acids such as lactic acid may be used, such that the total amount of acid present is equimolar to the total amount of nicotine present in the aerosol precursor (see para. [0059]). The aerosol precursor composition may include glycerol in an amount of up to 98% (see para. [0060]). Since the nicotine and lactic acid can be provided in equimolar ratios, it is presumed that "nicotine lactate" is thereby formed, resulting in the claimed "nicotine formulation that comprises nicotine lactate, and a biologically acceptable liquid carrier...the biologically acceptable liquid carrier comprises glycerol".

Further, Sebastian et al discloses that, as a non-limiting example, an aerosol precursor composition may include nicotine in an amount of about 0.1-5.0%. This would motivate one of ordinary skill to undergo routine experimentation to find the optimal amount of nicotine to add to the precursor composition and, in doing so, selected the high end of this range, i.e. 3-5%, after determining that such nicotine concentration provided for superior flavor, sensation and organoleptic properties for the user (Note: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (corresponding to the claimed "the nicotine lactate concentration is about 4%/4.5% (w/w)".

At least one wick can be used to transport the aerosolized components of the aerosol precursor composition from a reservoir to an aerosolization zone (i.e., at or around a resistive heating element) within the electronic smoking article (para. [0009])

(corresponding to the claimed “operation of the low-temperature vaporizer comprises wicking the nicotine formulation to a heating element and heating at least a portion of the nicotine formulation to generate an inhalable aerosol of nicotine lactate").

Lastly, it follows to reason, that the upon inhalation of the aerosolized vapor resulting from heating the aerosol precursor composition in the modified Sebastian et al electronic smoking article, the user would experience the claimed heart rate increase as, absent any indication to the contrary, such effects would “flow naturally” from use of said article (corresponding to the claimed “wherein inhalation of the aerosol into a user’s lungs increases heart rate comparable to inhaling a traditional burned cigarette in that inhaling 10 puffs of the aerosol over a period of about 3 minutes results in an increase in heart rate that peaks within about 3.5 minutes form the first puff”).

Regarding claim 2, as stated above, Sebastian et al discloses that its aerosol precursor can include nicotine and lactic acid provided in equimolar ratios (see para. [0059]) (corresponding to the claimed “wherein a molar ratio of nicotine to organic acid is between about 1:1 and 1:3”).

Regarding claim 3, Sebastian et al discloses that its aerosol precursor material can be combined with more than one flavorant (see para. [0031]) (corresponding to the claimed “wherein the nicotine formulation further comprises at least one flavorant”).

Regarding independent claims 7 and 13, and claims 10 and 17-18, Sebastian et al discloses an electronic smoking article (i.e., electronic cigarette) that provides for delivery of aerosolized components of an aerosol precursor composition to at least one heating element (See abstract. Note: According to Applicant’s instant disclosure, the

terms “electronic cigarette” and “low temperature vaporization device” are synonymous. See instant published application, para. [0119]) (corresponding to the claimed "deploying a low-temperature vaporizer").

The aerosol precursor composition may include a medicament, such as nicotine, which may comprise up to 10% of the weight of the aerosol precursor (see para. [0060]). When nicotine is chosen, organic acids can be combined with the nicotine in order to favorably affect the flavor, sensation, or organoleptic properties. Organic acids such as lactic acid may be used, such that the total amount of acid present is equimolar to the total amount of nicotine present in the aerosol precursor (see para. [0059]). The aerosol precursor composition may include glycerol in an amount of up to 98% (see para. [0060]). Since the nicotine and lactic acid can be provided in equimolar ratios, it is presumed that "nicotine lactate” is thereby formed, resulting in the claimed “nicotine formulation that comprises nicotine lactate, and a biologically acceptable liquid carrier...the biologically acceptable liquid carrier comprises glycerol”.

Further, Sebastian et al discloses that, as a non-limiting example, an aerosol precursor composition may include nicotine in an amount of about 0.1-5.0%. This would motivate one of ordinary skill to undergo routine experimentation to find the optimal amount of nicotine to add to the precursor composition and, in doing so, selected the high end of this range, i.e. 3-5%, after determining that such nicotine concentration provided for superior flavor, sensation and organoleptic properties for the user (Note: “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re*

Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (corresponding to the claimed “the nicotine lactate concentration is from about 4% (w/w) to about 6.5% (w/w)”; and the “wherein the nicotine concentration is about 4.5%” recitation of claims 10 and 18).

At least one wick can be used to transport the aerosolized components of the aerosol precursor composition from a reservoir to an aerosolization zone (i.e., at or around a resistive heating element) within the electronic smoking article (para. [0009]) (corresponding to the claimed “operation of the low-temperature vaporizer comprises wicking the nicotine formulation to a heating element and heating at least a portion of the nicotine formulation to generate an inhalable aerosol of nicotine lactate"; and the “wherein the vaporizing component comprises a heating element in fluid communication with the nicotine formulation” recitation of claim 17).

Lastly, it follows to reason, that the upon inhalation of the aerosolized vapor resulting from heating the aerosol precursor composition in the modified Sebastian et al electronic smoking article, the user would experience the claimed heart rate increase as, absent any indication to the contrary, such effects would “flow naturally” from use of said article (corresponding to the claimed “wherein inhalation of the aerosol into a user’s lungs increases heart rate comparable to inhaling a traditional burned cigarette in that inhaling 10 puffs of the aerosol over a period of about 3 minutes results in an increase in heart rate that peaks within about 3.5/5 minutes form the first puff”).

Regarding claim 8, as stated above, Sebastian et al discloses that its aerosol precursor can include nicotine and lactic acid provided in equimolar ratios (see para.

[0059]) (corresponding to the claimed “wherein a molar ratio of nicotine to organic acid is between about 1:1 and 1:3”).

Regarding claim 9, Sebastian et al discloses that its aerosol precursor material can be combined with more than one flavorant (see para. [0031]) (corresponding to the claimed “wherein the nicotine formulation further comprises at least one flavorant”).

Regarding claim 12, based on the disclosure of Gonda, as discussed above, that by decreasing the particle size, the aerosolized particles of nicotine will deposit deeper in the lungs, which increases the rate of absorption of the nicotine and leads to an increase in peak nicotine plasma levels, it would have been obvious to one having ordinary skill in the art to have optimized the particle size of its aerosol to fall between 0.1 - 5 microns (Corresponding to the claimed “wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns”).

Regarding claim 14, the electronic smoking article of Sebastian et al may include a battery (40)(see Fig. 1, para. [0078]) (corresponding to the claimed “further comprises a battery configured to provide power to the vaporizing component”).

Regarding claim 15, as stated above, Sebastian et al discloses that its aerosol precursor can include nicotine and lactic acid provided in equimolar ratios (see para. [0059]) (corresponding to the claimed “wherein a molar ratio of nicotine to organic acid is between about 1:1 and 1:3”).

Regarding claim 16, Sebastian et al discloses that its aerosol precursor material can be combined with more than one flavorant (see para. [0031]) (corresponding to the claimed “wherein the nicotine formulation further comprises at least one flavorant”).

Regarding claim 17, as stated above, Griffith, Jr. et al discloses that the aerosol, from an inside cavity, is vaporized by a resistive heating element (50) that heats the nicotine-containing aerosol precursor material located on a substrate (53)(see para. [0137])(corresponding to the claimed "wherein the vaporizing component comprises a heating element in fluid communication with the nicotine formulation").

Regarding claim 18, Griffith, Jr. et al discloses that a specific non-limiting example of the nicotine content in its aerosol precursor may be about 2-3% by weight (see para. [00888]). However, it would have been obvious to one having ordinary skill in the art to have adjusted this amount to be a bit higher - corresponding to the claimed amount - in order to satisfy the particular organoleptic preferences of the user (corresponding to the claimed "wherein the nicotine concentration is about 4.5%").

Regarding claim 20, based on the disclosure of Gonda, as discussed above, that by decreasing the particle size, the aerosolized particles of nicotine will deposit deeper in the lungs, which increases the rate of absorption of the nicotine and leads to an increase in peak nicotine plasma levels, it would have been obvious to one having ordinary skill in the art to have optimized the particle size of its aerosol to fall between 0.1 - 5 microns (Corresponding to the claimed "wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns").

Regarding claims 21-22, Sebastian et al discloses that the aerosol precursor composition can take a variety of conformations, and may comprises up to 95% by weight of a polyol. This total amount can be split in any combination between two or more different polyols, such as glycerol (i.e., vegetable glycerol) and propylene glycol.

This would motivate one of ordinary skill to undergo routine experimentation to find the optimal amount of each polyol to add to the precursor composition and, in doing so, selected the claimed polyol combination (Note: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955))(corresponding to the claimed "wherein the nicotine formulation comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin" recitation of claim21; and the "wherein the nicotine formulation comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin" recitation of claim 22").

11. Claims 6, 12 and 20 are rejected under 35 U.S.C. 103 as being unpatentable over Sebastian et al (US. Pat. App. Pub. 2014/0000638) in view of Gonda (US. Pat. No. 2014/0261474).

Regarding claims 6, 12 and 20, based on the disclosure of Gonda, that by decreasing the particle size, the aerosolized particles of nicotine will deposit deeper in the lungs, which increases the rate of absorption of the nicotine and leads to an increase in peak nicotine plasma levels, it would have been obvious to one having ordinary skill in the art to have optimized the particle size of its aerosol to fall between 0.1 - 5 microns (Corresponding to the claimed "wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns").

Response to Arguments

12. Applicant's arguments with respect to the claims have been considered but are moot in view of the new grounds for rejection, presented above, involving a new

combination of prior art references, which were necessitated because of the amendments made to the claims, filed on November 17, 2016.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIONNE W. MAYES whose telephone number is (571)272-5836. The examiner can normally be reached on Tuesdays and Thursdays, 8:00A - 4:30P.

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.

/DIONNE W MAYES/
Examiner, Art Unit 1747

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	14/925,968	BOWEN ET AL.	
	Examiner	Art Unit	
	DIONNE W. MAYES	1747	

All participants (applicant, applicant's representative, PTO personnel):

(1) *DIONNE W. MAYES*.

(2) *RICHARD SHOOP*.

(3) *ADAM BOWEN*.

(4) *GAL COHEN*.

Date of Interview: *10 November 2016*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☒112 ☐102 ☐103 ☒Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *Those of Record*.

Identification of prior art discussed: *None*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Examiner Mayes, Applicant Adam Bowen, Declarant Gal Cohen and Applicant's Representative, Richard Shoop, discussed the RCE filed on August 19, 2016 - which included claim amendments and a Commercial Success Declaration by Gal Cohen. Examiner Mayes indicated that she felt the amended claim language raised potential 112-1 issues, and support for some of the subject matter of the claims didn't appear to be present in the earliest filed Provisional Application (61/820,128) - whose filing date (May 6, 2013) Applicant desires to use as a prior art date. It was determined that a further Declaration would be filed to provide evidence to support the amended claim language particularly as it pertains to nicotine lactate and heart rate increase resulting from inhaling vaporixed nicotine lactate. Applicants also indicated that the claims would be amended to be commensurate in scope with the newly provided evidence .

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☒ Attachment

/DIONNE W MAYES/ Examiner, Art Unit 1747	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

———

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Notice of References Cited	Application/Control No. 14/925,968	Applicant(s)/Patent Under Reexamination BOWEN ET AL.	
	Examiner DIONNE W. MAYES	Art Unit 1747	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-2014/0000638 A1	01-2014	Sebastian et al	A24F47/008	131/328
	B	US-				
	C	US-				
	D	US-				
	E	US-				
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 2

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

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	595	US- 9,220,302	12/29/2015	DePiano et al.	
	596	US- 9,226,526	1/5/2016	Liu	
	597	US- 9,271,525	3/1/2016	Liu	
	598	US- 9,271,529	3/1/2016	Alima	
	599	US- 9,272,103	3/1/2016	Storz	
	600	US- 9,277,769	3/8/2016	Liu	
	601	US- 9,282,772	3/15/2016	Tucker et al.	
	602	US- 9,282,773	3/15/2016	Greim et al.	
	603	US- 9,289,014	3/22/2016	Tucker et al.	
	604	US- 9,308,336	4/12/2016	Newton	
	605	US- 9,326,547	5/3/2016	Tucker et al.	
	606	US- 9,351,522	5/31/2016	Safari	
	590	US- 2013/0199528	8/8/2013	Goodman et al.	
	591	US- 2014/0144429	5/29/2014	Wensley et al.	
	592	US- 2015/0272220	10/1/2015	Spinka et al.	
	608	US- 2015/0282525	10/8/2015	Plojoux et al.	
	609	US- 2015/0313275	11/5/2015	Andersonet al.	
	611	US- 2015/0351456	12/10/2015	Johnson et al.	
	614	US- 2016/0021931	1/28/2016	Haweset al.	

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	639	WO2015/149647A1(w/ Eng Abs)	10/8/2015	Kimree Hi-Tech Inc.		
	640	WO2015/168828A1(w/ Eng Abs)	11/12/2015	Kimree Hi-Tech Inc.		

Examiner Signature	/Dionne Walls Mayes/	Date Considered	10/27/2016

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Sheet 2 of 2

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

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	607	US- 2016/0058071	3/3/2016	Hearn	
	618	US- 2016/0058072	3/3/2016	Liu	
	621	US- 2016/0081395	3/24/2016	Thorens et al.	
	623	US- 2016/0106154	4/21/2016	Lord	
	624	US- 2016/0106155	4/21/2016	Reevell	
	627	US- 2016/0120218	5/5/2016	Schennum et al.	
	630	US- 2016/0135503	5/19/2016	Liu	
	632	US- 2016/0143359	5/26/2016	Xiang	
	635	US- 2016/0143365	5/26/2016	Liu	
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	666	US- 8,809,261	8/19/2014	Elsohly et al.	
	669	US- 8,881,737	11/11/2014	Collett et al.	
	667	US- 2015/0038567	2/5/2015	Herkenroth et al.	
	580	US- 2016/0174611**	6/23/2016	Monsees et al.	
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	668	EP2152313B1	9/3/2014	McNeil AB		

Examiner Signature	/Dionne Walls Mayes/	Date Considered	10/27/2016

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Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

NON PATENT 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.	T[2]
	587	MONSEES et al.; U.S. Pat. Appl. # 15/165,954 entitled "Devices for vaporization of a substance," filed 5/26/2016	
	588	MONSEES et al.; U.S. Pat. Appl. # 15/166,001 entitled "Electronic vaporization device," filed 5/26/2016	
	589	MONSEES et al.; U.S. Pat. Appl. # 15/165,972 entitled "Portable devices for generating an inhalable vapor," filed 5/26/2016	
	665	BOWEN et al.; U.S. Pat Appl. # 15/101,303 entitled "Nicotine liquid formulations for aerosol devices and methods thereof," filed 6/2/2016	

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Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

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	585	JP10-501999A(w/EngEquiv)	2/24/1998	Boehringer Ingelheim		

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	718	US- 6,603,924	8/5/2003	Brown et al.	
	719	US- 2013/0298905	11/14/2013	Levin et al.	
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	721	FARSALINOS et al.; Electronic cigarettes do not damage the heart; European Society of Cardiology; 4 pages; retrieved from the internet (http://www.escardio.org/The-ESC/Press-Office/Press-releases/Electronic-cigarettes-do-not-damage-the-heart); August 25, 2012	
	720	VANSICKEL et al.; Electronic cigarettes: effective nicotine delivery after acute administration; Nicotine & Tobacco Research; 15(1); pp. 267-270; January 2013	

Examiner Signature	/Dionne Walls Mayes/	Date Considered	11/28/2016

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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	581	US- 2015/0128967	5/14/2015	Robinson et al.	
		US-			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature	/Dionne Walls Mayes/	Date Considered	07/12/2016

*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. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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U. S. PATENT DOCUMENTS

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	714	US- 2014/0190501	7/10/2014	Liu	
	713	US- 2015/0157054	6/11/2015	Liu	
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	712	EP3024343A2(WO2015/013327)	1/29/2015	Altria Client Serv. Inc.		
	716	WO 03/103387A2	12/18/2003	S.C. Johnson & Son Inc.		
	715	WO2014/159982A1	10/2/2014	R.J. Reynolds Tobacco Co.		

Examiner Signature	/Dionne Walls Mayes/	Date Considered	10/27/2016

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Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

NON PATENT 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.	T[2]
	703	MONSEES et al.; U.S. Pat. Appl. # 15/257,748 entitled "Cartridge for use with a vaporizer device," filed 9/6/2016	
	704	MONSEES et al.; U.S. Pat. Appl. # 15/257,760 entitled "Vaporizer apparatus," filed 9/6/2016	
	705	MONSEES et al.; U.S. Pat. Appl. # 15/257,768 entitled "Vaporizer apparatus," filed 9/6/2016	
	706	MONSEES et al.; U.S. Pat. Appl. # 15/261,823 entitled "Low temperature electronic vaporization device and methods," filed 9/9/2016	

Examiner Signature	/Dionne Walls Mayes/	Date Considered	10/27/2016

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U. S. PATENT DOCUMENTS

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	684	US- 5,031,646	7/16/1991	Lippiello et al.	
	685	US- 5,133,368	7/28/1992	Neumann et al.	
	488	US- 8,511,318	8/20/2013	Hon	
	680	US- 5,240,012	8/31/1993	Ehrman et al.	
		US-			
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	687	EP0283672B1	9/22/1993	R J Reynolds Tobacco		
	688	EP2319934B1	9/2/2015	Stichting Dienst		
	689	WO2007/078273A1	7/12/2007	Augite Inc.		
	690	WO2015/009862A2	1/22/2015	Altria Client Services		

Examiner Signature	/Dionne Walls Mayes/	Date Considered	10/27/2016

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NON PATENT LITERATURE DOCUMENTS

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	683	BURCH et al.; Effect of pH on nicotine absorption and side effects produced by aerosolized nicotine; Journal of Aerosol Medicine: Deposition, Clearance, and Effects in the Lung; 6(1); pp. 45-52; 1993	

Examiner Signature	/Dionne Walls Mayes/	Date Considered	10/27/2016

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14925968	BOWEN ET AL.
	Examiner	Art Unit
	DIONNE W MAYES	1747

CPC- SEARCHED		
Symbol	Date	Examiner
a24f47/00; a24f47/008	4/27/2016	DWM

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Search conducted (see attached search strategy)	12/10/2015	DWM
Inventor search conducted	12/10/2015	DWM
EAST Search conducted (see attached search strategy)	4/27/2016	DWM
Inventor search updated	4/27/2016	DWM
EAST Search conducted (see attached search strategy)	11/28/2016	DWM

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	3	(("20060195518") or ("20120256567") or ("20080241255")).PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 11:41
S2	3	(("20060195518") or ("20120255567") or ("20080241255")).PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 11:41
S3	2	(("20120255567") or ("20080241255")).PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 11:42
S4	0	("2006").pn. and (hon).in.	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 11:42
S5	42	(hon).in. and cigarette	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 11:44
S6	25	("131"/$ or "128"/$).ccls. and electronic cigarette and nicotine and plasma	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:06
S7	6	("131"/$ or "128"/$).ccls. and (fuisz).in. and nicotine and plasma	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:06
S8	91	("131"/$ or "128"/$).ccls. and inhal$5 near15 nicotine and plasma	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:15
S9	25	("131"/$ or "128"/$).ccls. and inhal$5 near15 nicotine and plasma and ((max or maxim$3) near25 time)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:16
S10	23	("131"/$ or "128"/$).ccls. and inhal$5 near15 nicotine and (plasma near25 (peak or max or maxim$3) near25 time)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:25
S11	9	("131"/$ or "128"/$).ccls. and inhal$5 same (nicotine same (plasma near25 (peak or max or maxim$3) near25 time))	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:25
S12	9	("131"/$ or "128"/$).ccls. and inhal$5 same (nicotine same (plasma near25 (peak or max or maxim$3) near25 time))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:26
S13	32	("131"/$ or "128"/$).ccls. and inhal$5 and (nicotine same (plasma near25 (peak or max or maxim$3) same time))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:28
S14	2	("131"/$ or "128"/$).ccls. and nicotine benzoate	US-PGPUB; USPAT; USOCR; FPRS;	ADJ	ON	2015/01/20 15:51

			EPO; JPO; DERWENT; IBM_TDB			
S15	2	(vaporiz$3 or electronic cigarette) and nicotine benzoate	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:52
S16	346	("131"/$ or "128"/$).ccls. and (salt near5 nicotine)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:53
S17	230	("131"/$ or "128"/$).ccls. and (salt near5 nicotine) same (acid)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:54
S18	210	("131"/$ or "128"/$).ccls. and (salt near5 nicotine) near35 (acid)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:55
S19	17	("131"/$ or "128"/$).ccls. and (salt near5 nicotine) near35 (carboxylic or citric)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 16:08
S20	1	("2356185").PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 16:32
S21	1	("2356185").PN.	USOCR	OR	OFF	2015/01/20 16:33
S22	4	nicotine benzoate	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 16:38
S23	1	("20010029959").PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 16:43
S24	0	electronic cigarette and inhal$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 16:47
S25	1	nicotine and inhal$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 16:48
S26	1	nicotine and inhal$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR;	ADJ	ON	2015/01/20 16:59

			FPRS; EPO; JPO; DERWENT; IBM_TDB			
S27	53	inhal$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 17:33
S28	222	puff$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 17:37
S29	207	("131"/$ or "128"/$ or cigarette) and puff$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 17:40
S30	179	("131"/$ or "128"/$) and puff$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 17:40
S31	28	(("20070163610") or ("20090293895") or ("20130186416") or ("7832410") or ("8,156,944") or ("8,511,318") or ("20140345631") or ("20140345635") or ("20040191322") or ("20060018840") or ("20060196518") or ("20080241255") or ("20090004249") or ("20100242976") or ("20110268809") or ("20120255567") or ("4,830,028") or ("4,836,224") or ("6,102,036") or ("6,234,169") or ("6,799,576") or ("6,874,507") or ("7,767,698") or ("8,079,371") or ("8,322,350") or ("8,375,957") or ("8,381,739") or ("8,741,348")).PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 20:10
S32	1	(14/512311).APP.	US-PGPUB; USPAT	OR	OFF	2015/03/23 22:03
S33	1	(14/512311).APP.	US-PGPUB; USPAT	OR	OFF	2015/05/14 15:25
S34	1605	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:07
S35	237	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:08
S36	221	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5 or mouth or oral$4)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:08

S37	191	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5 or mouth or oral$4) and (plasma or blood)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:08
S38	163	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5 or mouth or oral$4) and (plasma or blood) and ph	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:09
S39	108	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5 or mouth or oral$4) and (plasma or blood) and ph and ((drop$4 or vapor$4 or aerosol$4 or particle) near25 size)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:10
S40	87	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5 or mouth or oral$4) and (plasma or blood) and ph and ((drop$4 or vapor$4 or aerosol$4 or particle) near25 size) and heat$4	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:11
S41	77	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5) and (plasma or blood) and ph and ((drop$4 or vapor$4 or aerosol$4 or particle) near25 size) and heat$4	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:12
S42	4	("2004076289").PN.	FPRS; EPO; JPO	OR	OFF	2015/05/14 18:13
S43	15	ANDERSSON near3 SVEN-BORJE	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:15
S44	13	ANDERSSON near3 SVEN-BORJE and nicotine	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:15
S45	71	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5) and (plasma or blood) and ph and ((drop$4 or vapor$4 or aerosol$4 or particle) near25 size) and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:26
S46	21	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5) and (plasma or blood) and (ph near5 "7") and ((drop$4 or vapor$4 or aerosol$4 or particle) near25 size) and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:27
S47	26	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5) and (plasma or blood) and (ph near5 "7") and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:28
S48	38	("128"/$ or "131"/$ or "424"/$ or "514"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5) and	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:31

		(plasma or blood) and (ph near5 "7") and heat$4 and lung				
S49	1	("20060196518").PN.	US-PGPUB; USPAT	OR	OFF	2015/05/14 19:32
S50	34	("128"/$ or "131"/$ or "424"/$ or "514"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and (salicylic or sorbic or lauric or levulinic or citric or benzoic or pyruvic) and (inhal$5) and ((plasma or blood or peek or peak) near10 concentration) and (ph near5 "7") and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 08:30
S51	1	("8831739").PN.	US-PGPUB; USPAT	OR	OFF	2015/05/15 08:43
S52	1	("8381739").PN.	US-PGPUB; USPAT	OR	OFF	2015/05/15 08:43
S53	14	(igor near3 gonda) and nicotine and ng/ml	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 10:42
S54	13	(igor near3 gonda) and nicotine near50 concentration near50 ng/ml	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 10:42
S55	0	(igor near3 gonda) and nicotine near50 concentration near50 ng/ml near50 salt	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 10:43
S56	64	(igor near3 gonda) and ((blood or plasma or nicotine) near50 concentration)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 10:46
S57	13	(igor near3 gonda) and ((blood or plasma or nicotine) near50 concentration) same nicotine	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 10:46
S58	1	("20030136404").PN.	US-PGPUB; USPAT	OR	OFF	2015/05/17 15:16
S59	1	(14/512311).APP.	US-PGPUB; USPAT	OR	OFF	2015/07/14 09:12
S60	1	("20140261474").PN.	US-PGPUB; USPAT	OR	OFF	2015/07/14 10:27
S61	1	(14/512311).APP.	US-PGPUB; USPAT	OR	OFF	2015/09/17 14:40
S62	934	(A24F47/008).cpc.	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/09/17 14:46
S63	78	("128"/$ or "131"/$ or "424"/$ or "514"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and acid and (inhal$5) and (plasma or blood) and (ph near5 "7") and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/09/17 14:46
S64	367	("128"/$ or "131"/$ or "424"/$ or "514"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and acid and (inhal$5) and (plasma or blood) and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/09/17 14:47
S65	283	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and (levulinic or pyruvic or salicylic or sorbic or lauric or benzoic) and (inhal$5 or mouth or oral$4) and	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/09/17 14:48

		(plasma or blood)				
S69	2	(("20060196518") or ("20140261474")).PN.	US-PGPUB; USPAT	OR	OFF	2015/12/10 16:09
S70	1	("9215895").PN.	US-PGPUB; USPAT	OR	OFF	2016/03/30 20:38
S71	0	(14/925958).APP.	US-PGPUB; USPAT	OR	OFF	2016/04/24 10:41
S72	1	(14/925968).APP.	US-PGPUB; USPAT	OR	OFF	2016/04/24 10:41
S73	2	(12/236439).APP.	US-PGPUB; USPAT	OR	OFF	2016/04/24 10:56
S74	120	(A24F47/008).cpc. and temperature near25 ("100" or "200" or "300")	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 12:53
S75	34	(A24F47/008).cpc. and temperature near25 ("100" or "200" or "300") near25 degrees	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 12:56
S76	35	(A24F47/008 or A24F47/00 or A24F47/002).cpc. and temperature near25 ("100" or "200" or "300") near25 degrees	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 12:57
S77	0	((128/$ or 131/$).ccls. or (A24F47/008 or A24F47/00 or A24F47/002).cpc.) and low tempereture and ("100" or "200" or "300") near25 degrees	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 13:27
S78	1787	((128/$ or 131/$).ccls. or (A24F47/008 or A24F47/00 or A24F47/002).cpc.) and low temperature	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 13:28
S79	118	((128/$ or 131/$).ccls. or (A24F47/008 or A24F47/00 or A24F47/002).cpc.) and low temperature and ("100" or "200" or "300") near25 degrees	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 13:28
S80	29	((128/$ or 131/$).ccls. or (A24F47/008 or A24F47/00 or A24F47/002).cpc.) and low temperature and ("100" or "200" or "300") near25 degrees and nicotine	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 13:29
S81	2	(12/336439).APP.	US-PGPUB; USPAT	OR	OFF	2016/04/25 13:38
S82	1	("5,544,646").PN.	US-PGPUB; USPAT	OR	OFF	2016/04/25 19:16
S83	10	(rose).in. and pyruvic and nicotine	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 19:18
S84	1	(12/481908).APP.	US-PGPUB; USPAT	OR	OFF	2016/04/25 21:20
S85	389	nicotine near50 (lactic or lactate)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/27 09:16
S86	440	nicotine near50 (lactic or lactate)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/04/27 09:16
S87	65	((a24f47/00)".cpc" or (131/$.ccls.) or (128/$).ccls.) and nicotine near50 (lactic	US-PGPUB; USPAT;	ADJ	ON	2016/04/27 09:20

		or lactate)	USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			
S88	70	((a24f47/00).cpc. or (131/$.ccls.) or (128/$).ccls.) and nicotine near50 (lactic or lactate)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/04/27 09:20
S89	73	((a24f47/00 or a24f47/008).cpc. or (131/$.ccls.) or (128/$).ccls.) and nicotine near50 (lactic or lactate)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/04/27 09:20
S90	1	("9,215,895").PN.	US-PGPUB; USPAT	OR	OFF	2016/04/27 11:18
S91	6717	(a24f47/00 or a24f47/008).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/04/27 18:29
S92	754	glycerol near50 ((veggie or vegetable) near2 glycerol)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/05/05 09:10
S93	719	glycerol near5 ((veggie or vegetable) near2 glycerol)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/05/05 09:10
S94	48	glycerol near5 (veggie glycerol or vegetable glycerol)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/05/05 09:14
S95	3	glycerin near5 (veggie glycerol or vegetable glycerol)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/05/05 09:15
S96	3	glycerin near25 (veggie glycerol or vegetable glycerol)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/05/05 09:15
S97	3	(a24f47/00 or a24f47/008).cpc. and (veggie glycerol or vegetable glycerol)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/05/05 09:17
S99	1	("20130255702").PN.	US-PGPUB; USPAT	OR	OFF	2016/06/09 12:43
S100	1	(14/925968).APP.	US-PGPUB; USPAT	OR	OFF	2016/06/09 12:44
S101	7	((han near3 li) or (lik near3 hon)).in. and wick$4	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/06/09 12:50
S102	16	a24f47/$2.cpc. and wick$3	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/06/09 12:53
S103	1	("20150128967").PN.	US-PGPUB; USPAT	OR	OFF	2016/07/12 08:38

S104	1	(14/213108).APP.	US-PGPUB; USPAT	OR	OFF	2016/07/12 11:29
S105	2	(("4,793,365") or ("5,101,839")).PN.	US-PGPUB; USPAT	OR	OFF	2016/07/12 12:51
S106	686	(131/$.ccls. or a24f47/$.cpc.) and lactic	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/07/12 15:04
S107	252	(131/$.ccls. or a24f47/$.cpc.) and lactic and nicotine	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/07/12 15:04
S108	219	(131/$.ccls. or a24f47/$.cpc.) and lactic and nicotine and (glycer$$ or glycol)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/07/12 15:05
S109	218	(131/$.ccls. or a24f47/$.cpc.) and lactic and nicotine and (glycer$4 or glycol)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/07/12 15:05
S110	76	(a24f47/$.cpc.) and lactic and nicotine and (glycer$4 or glycol)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/07/12 15:06
S111	72	(a24f47/$.cpc.) and lactic and nicotine and (glycer$4 or glycol) and temperature	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/07/12 15:42
S112	73	(a24f47/$.cpc.) and lactic and nicotine and (glycer$4 or glycol) and heat$4	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/07/12 15:44
S113	57	(a24f47/$.cpc.) and lactic and nicotine and (glycer$4 and glycol) and heat$4	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/07/12 15:45
S114	57	(a24f47/$.cpc.) and lactic and nicotine and (glycer$4 and glycol) and heat$4 and temperature	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/07/12 15:45
S115	52	(a24f47/$.cpc.) and lactic and nicotine and (glycer$4 and glycol) and (heat$4 near50 temperature)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/07/12 15:45
S116	38	(a24f47/$.cpc.) and lactic and nicotine and (glycer$4 and glycol) and (heat$4 near50 temperature) and wick$4	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/07/12 15:46
S117	1	("20060196518").PN.	US-PGPUB; USPAT	OR	OFF	2016/10/23 19:49
S118	195	((han or hon) near3 (lik or li)).in. and temperature	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/10/23 19:52
S119	48	((han or hon) near3 (lik or li)).in. and temperature near5 (low)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/10/23 19:53
S120	0	((han or hon) near3 (lik or li)).in. and low-temperature and cigarette	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/10/23 19:54
S121	12	((han or hon) near3 (lik or li)).in. and low near10 temperature and cigarette	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/10/23 19:54
S122	19	((han or hon) near3 (lik or li)).in. and citric and glycerol	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/10/23 20:32
S123	6	(adam near3 bowen).in. and "C.sub.max"	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/10/23 20:55

S124	1	(14/925968).APP.	US-PGPUB; USPAT	OR	OFF	2016/10/23 20:55
S125	23	(adam near3 bowen).in. and nicotine	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/10/23 20:58
S126	6	(adam near3 bowen).in. and (plasma or blood) near15 (peak or max or maxim$3)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/10/23 20:59
S127	102	a24f47/$.cpc. and (plasma or blood) near15 (peak or max or maxim$3)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/10/23 21:00
S128	82	a24f47/$.cpc. and (plasma or blood) near15 (peak or max or maxim$3) and acid and nicotine	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/10/23 21:01
S129	61	a24f47/$.cpc. and (plasma or blood) near15 (peak or max or maxim$3) and ((organic or citric) near30 acid) and nicotine	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/10/23 21:02
S130	1	(14/925968).APP.	US-PGPUB; USPAT	OR	OFF	2016/11/09 13:58
S131	2	(14/512311).APP.	US-PGPUB; USPAT	OR	OFF	2016/11/10 09:32
S132	1	(14/271071).APP.	US-PGPUB; USPAT	OR	OFF	2016/11/10 09:33
S133	22	131/$.ccls. and nicotine and levulinate	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/11/14 20:23
S134	153	131/$.ccls. and nicotine and levul$5	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/11/14 21:59
S135	140	131/$.ccls. and nicotine and (levul$5 near50 acid)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/11/14 21:59
S136	47	131/$.ccls. and (nicotin$3 near50 (levul$5 near50 acid))	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/11/14 22:00
S137	70	131/$.ccls. and (nicotin$3 near50 ((lactic near50 acid) or lactate))	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/11/27 12:30
S138	70	(131/$.ccls. or a24f47/$.cpc) and (nicotin$3 near50 ((lactic near50 acid) or lactate))	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/11/27 12:30
S139	0	(a24f47/$.cpc) and (nicotin$3 near50 ((lactic near50 acid) or lactate))	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/11/27 12:31
S140	94	(131/$.ccls. or a24f47/$.cpc.) and (nicotin$3 near50 ((lactic near50 acid) or lactate))	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/11/27 12:31
S141	103	(131/$.ccls. or a24f47/$.cpc.) and (nicotin$3 near50 ((lactic near50 acid) or lactate))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/11/27 12:31
S142	49	(131/$.ccls. or a24f47/$.cpc.) and (nicotin$3 near50 ((lactic near50 acid) or	US-PGPUB; USPAT;	ADJ	ON	2016/11/27 14:14

		lactate)) and wick$4	USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			
S143	1	(14/925968).APP.	US-PGPUB; USPAT	OR	OFF	2016/11/27 14:31
S144	1	("9,215,895").PN.	US-PGPUB; USPAT	OR	OFF	2016/11/27 21:05
S145	30	(131/$.ccls. or a24f47/$.cpc.) and (nicotin$3 near50 ((lactic near50 acid) or lactate)) and particle size	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/11/27 23:17

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S66	723	(A24F47/008).cpc.	US-PGPUB	ADJ	ON	2015/09/17 14:46
S67	246	("128"/$ or "131"/$ or "424"/$ or "514"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and acid and (inhal$5) and (plasma or blood) and heat$4 and lung	US-PGPUB	ADJ	ON	2015/09/17 14:47
S68	196	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and (levulinic or pyruvic or salicylic or sorbic or lauric or benzoic) and (inhal$5 or mouth or oral$4) and (plasma or blood)	US-PGPUB	ADJ	ON	2015/09/17 14:49

11/28/2016 10:22:39 AM
C:\Users\dmayes\Documents\EAST\Workspaces\14925968.wsp

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 6

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	694	US- 3,271,719	9/6/1966	Ovshinsky	
	670	US- 3,443,827	5/13/1969	Acker et al.	
	671	US- 5,497,791	3/12/1996	Bowen et al.	
	672	US- 5,529,078	6/25/1996	Rehder et al.	
	117	US- 6,089,857	7/18/2000	Matsuura et al.	
	673	US- 6,196,232	3/6/2001	Chkadua	
	150	US- 7,015,796	3/21/2006	Snyder	
	675	US- 7,801,573	9/21/2010	Yazdi et al.	
	173	US- 8,820,330	9/2/2014	Bellinger et al.	
	174	US- 8,851,081	10/7/2014	Fernando et al.	
	178	US- 9,095,175	8/4/2015	Terry et al.	
	722	US- D725310	3/24/2015	Eksouzian	
	695	US- 2004/0050382	3/18/2004	Goodchild	
	696	US- 2007/0277816	12/6/2007	Morrison et al.	
	674	US- 2009/0111287	4/30/2009	Lindberg et al.	
	263	US- 2010/0200008	8/12/2010	Taieb	
	676	US- 2011/0240047	10/6/2011	Adamic	
	297	US- 2012/0285475	11/15/2012	Liu	
	310	US- 2013/0319440	12/5/2013	Capuano	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	387	EP2856893A1	4/8/2015	Fontem Holdings		
	388	EP2908675A1(asWO2014/060268)	8/26/2015	Nicoventures Holdings Ltd		
	389	EP2915443A1	9/9/2015	Fontem Holdings		
	757	EP3062646A1 (WO2015/66136)	9/7/2016	Rai Strategic Holdings Inc		
	758	EP3065581A2 (WO2015/68044)	9/14/2016	SIS Resources Ltd		
	759	EP3068244A1 (WO2015/73975)	9/21/2016	VMR Products LLC		

Examiner Signature		Date Considered	

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(Use as many sheets as necessary)

Sheet 2 of 6

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	312	US- 2013/0340775	12/26/2013	Juster et al.	
	723	US- 2014/0007891	1/9/2014	Liu	
	314	US- 2014/0014126	1/16/2014	Peleg et al.	
	316	US- 2014/0053856	2/27/2014	Liu	
	318	US- 2014/0060556	3/6/2014	Liu	
	319	US- 2014/0096782	4/10/2014	Ampolini et al.	
	320	US- 2014/0109921	4/24/2014	Chen	
	321	US- 2014/0116455	5/1/2014	Youn	
	322	US- 2014/0123990	5/8/2014	Timmermans	
	323	US- 2014/0150810	6/5/2014	Hon	
	324	US- 2014/0174459	6/26/2014	Burstyn	
	327	US- 2014/0196735	7/17/2014	Liu	
	328	US- 2014/0216450	8/7/2014	Liu	
	329	US- 2014/0230835	8/21/2014	Saliman	
	331	US- 2014/0270727	9/18/2014	Ampolini et al.	
	332	US- 2014/0301721	10/9/2014	Ruscio et al.	
	333	US- 2014/0305450	10/16/2014	Xiang	
	336	US- 2014/0355969	12/4/2014	Stern	
	340	US- 2015/0020825	1/22/2015	Galloway et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	416	WO2004/080216A1(EngAbs)	9/23/2004	Hon, Lik		
	420	WO2008/077271A1(EngAbs)	7/3/2008	Maas, Bernard		
	427	WO2012/120487A2	9/13/2012	Chong Corp		
	430	WO2013/089551A1	6/20/2013	Foo, Kit Seng		
	433	WO2014/040915A1(EngAbs)	3/20/2014	Snoke Gmbh & Co		
	435	WO2014/101734A1	7/3/2014	Shenzhen Smoore Tech		

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 6

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	341	US- 2015/0020831	1/22/2015	Weigensberg et al.	
	343	US- 2015/0027472	1/29/2015	Amir	
	344	US- 2015/0034103	2/5/2015	Hon	
	724	US- 2015/0034104	2/5/2015	Zhou	
	345	US- 2015/0040929	2/12/2015	Hon	
	346	US- 2015/0101625	4/16/2015	Newton et al.	
	347	US- 2015/0122252	5/7/2015	Frija	
	348	US- 2015/0122274	5/7/2015	Cohen et al.	
	349	US- 2015/0128965	5/14/2015	Lord	
	351	US- 2015/0136153	5/21/2015	Lord	
	697	US- 2015/0136158	5/21/2015	Stevens et al.	
	352	US- 2015/0142387	5/21/2015	Alarcon et al.	
	355	US- 2015/0164141	6/18/2015	Newton	
	356	US- 2015/0164144	6/18/2015	Liu	
	698	US- 2015/0164147	6/18/2015	Verleur et al.	
	357	US- 2015/0181928	7/2/2015	Liu	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	439	WO2014/150704A2	9/25/2014	Altria Client Svs Inc.		
	442	WO2014/205263A1	12/24/2014	Loec Inc.		
	444	WO2015/028815A1	3/5/2015	British American Tobacco		
	446	WO2015/058387A1(EngAbs)	4/30/2015	Kimree Hi-Tech Inc.		
	447	WO2015/063126A1	5/7/2015	Choukroun, B.		
	450	WO2015/089711A1(EngAbs)	6/25/2015	Kimree Hi-Tech Inc.		

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Sheet 4 of 6

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

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	361	US- 2015/0208731	7/30/2015	Malamud et al.	
	700	US- 2015/0216237	8/6/2015	Wensley et al.	
	362	US- 2015/0223521	8/13/2015	Menting et al.	
	363	US- 2015/0224268	8/13/2015	Henry et al.	
	364	US- 2015/0237917	8/27/2015	Lord	
	365	US- 2015/0237918	8/27/2015	Liu	
	366	US- 2015/0245654	9/3/2015	Memari et al.	
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	369	US- 2015/0258289	9/17/2015	Henry Jr. et al.	
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	701	US- 2015/0305409	10/29/2015	Verleur et al.	
	702	US- 2016/0021933	1/28/2016	Thorens et al.	
	750	US- 2016/0242466	8/25/2016	Lord et al.	
	751	US- 2016/0249680	9/1/2016	Liu	
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	717	US- 2016/0309784	10/27/2016	Silvestrini et al.	
	726	US- 2016/0324215	11/10/2016	Mironov et al.	

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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	452	WO2015/109616A1(EngAbs)	7/30/2015	Kimree Hi-Tech Inc.		

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Sheet 5 of 6

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

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	735	US- 2016/0331033	11/17/2016	Hopps et al.	
	737	US- 2016/0331038	11/17/2016	Farine et al.	
	738	US- 2016/0331040	11/17/2016	Nakano et al.	
	745	US- 2016/0338410	11/24/2016	Batista et al.	
	746	US- 2016/0338411	11/24/2016	Liu	
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Sheet 6 of 6

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Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

NON PATENT 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.	T[2]
	481	BRADLEY et al.; Electronic cigarette aerosol particle size distribution measurements; Inhal. Toxicol.; 24(14); pp. 976-984; Dec. 2012	
	482	BULLEN et al.; Effect of an electronic nicotine delivery device (e cigarette) on desire to smoke and withdrawal, user preferences and nicotine delivery: randomised cross-over trial; Tobacco Control; 19(2); pp. 98-103; Apr. 2010	
	678	CAPPONNETTO et al.; Successful smoking cessation with cigarettes in smokers with a documented history of recurring relapses: a case series; Journal of Medical Case Reports; 5(1); 6 pages; (year of pub. sufficiently earlier than effective US filing date and any foreign priority date); 2011	
	677	HURT et al.; Treating tobacco dependence in a medical setting; CA: A Cancer Journal for Clinicians; 59(5); pp. 314-326; Sept. 2009	

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Electronic Patent Application Fee Transmittal

Application Number:	14925968
Filing Date:	28-Oct-2015
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Filer:	Richard Douglas Shoop/Brian Flick
Attorney Docket Number:	13211-713.303

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($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	90	90
		Total in USD ($)		**90**

Electronic Acknowledgement Receipt

EFS ID:	27809803
Application Number:	14925968
International Application Number:	
Confirmation Number:	2707
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Customer Number:	66854
Filer:	Richard Douglas Shoop/Brian Flick
Filer Authorized By:	Richard Douglas Shoop
Attorney Docket Number:	13211-713.303
Receipt Date:	15-DEC-2016
Filing Date:	28-OCT-2015
Time Stamp:	16:32:36
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$90
RAM confirmation Number	121616INTEFSW00003636504050
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		13211-713-303_IDS_Filing_SupplIDS_12-15-2016.pdf	766418 3354ebaab33df0a21adf53dd03ed50c1d5fcf7dd	yes	9
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Transmittal Letter		1	3	
	Information Disclosure Statement (IDS) Form (SB08)		4	9	
Warnings:					
Information:					
2	Foreign Reference	EP2856893A1.pdf	3797855 9e9e535e97febc0832fb271b2d51ddddc5024ca6	no	17
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3	Foreign Reference	EP2908675A1.pdf	2851612 18617c20f28d55beeb6be340e76a7896f5f4abb3	no	26
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4	Foreign Reference	EP2915443A1.pdf	3131188 edc6785026730a393e33a42f16b2c43177494d5d	no	11
Warnings:					
Information:					
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6	Foreign Reference	EP3065581-WO2015068044.pdf	729371 db68ce2ef9dae6813f00c055614d9cb7896df474	no	15
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9	Foreign Reference	WO2008077271A1.pdf	827852 05b9db2349cb9260c6d037bf6a571ccf0e41be68	no	21
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Information:					
10	Foreign Reference	WO2012120487A2.pdf	3158287 ede9fa584af52f2d97df4cbbdaa0708545f1ef31	no	79
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Information:					
11	Foreign Reference	WO2013089551A1.pdf	1094113 33c2a25276d66ea2bff596b18c46f1f606c609d6	no	36
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12	Foreign Reference	WO2014040915A1.pdf	781426 b4fca67d78087fa18028b2fd3d734bee21816da5	no	20
Warnings:					
Information:					

13	Foreign Reference	WO2014101734A1.pdf	728234 c1d700ac238628f508823ccef0ecb737fb652c26	no	18
Warnings:					
Information:					
14	Foreign Reference	WO2014150704A2.pdf	828026 394f7aaf1d89f7d22a7e415029137a7bba8cf56a	no	19
Warnings:					
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15	Foreign Reference	WO2014205263A1.pdf	1056949 6db12fe466b36da318f6c948f7acc69fe1c2edae	no	35
Warnings:					
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16	Foreign Reference	WO2015028815A1.pdf	1594036 9d638f363ab8782b303dc2a82e54d0bdec971717	no	33
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17	Foreign Reference	WO2015058387A1.pdf	931263 341e193f14ba9602ebfd6abe761969c79c44fc8b	no	23
Warnings:					
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18	Foreign Reference	WO2015063126A1.pdf	1411710 e0ef616442510431ce0ffff8802d5ad5f81cb1c2	no	39
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19	Foreign Reference	WO2015089711A1.pdf	1209458 7e7365e68bb5bc9fe94eafda5fccd512f93a6dcb	no	27
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20	Foreign Reference	WO2015109616A1.pdf	667054 d3aafca22d01992c54b1a974c2f1d23659d14517	no	18
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21	Non Patent Literature	Bradley_et_al_ElectronicCigaretteAerosol_2012.pdf	5098764 f8b6e76ddde2d5e4306ba1de5d0ec91180c45a66	no	10
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22	Non Patent Literature	Bullen_EffectElectronicNicotine_2010.pdf	3656275 dcda601d833bb249ef0884fa3718b17416ec42a0	no	7
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23	Non Patent Literature	Caponnetto_et_al_SuccessfulSmokingCessation_2011.pdf	2503183 756b138489ce9750e025de03abdef56f0d476156	no	6
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24	Non Patent Literature	Hurt_et_al_TreatingTobaccoDependence_2009.pdf	13685927 a8e5b848e6aac6a987c0fc18291c770e1fd3bc6d	no	13
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25	Fee Worksheet (SB06)	fee-info.pdf	30628 316c0c00a5de8d691a58bf77fc97786538e512fc	no	2
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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.

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on December 15, 2016.

/Brian Flick/
Brian Flick

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 14/925,968	Confirmation No.: 2707
First Named Inventor	: Adam Bowen	
Filed	: October 28, 2015	
Art Unit	: 1747	
Examiner	: Mayes, Dionne Walls	
Title	: NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF	
Customer No.	: 66854	

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☐ **37 CFR §1.97(b)**
This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:
- ☐ **1).** Within 3 months of the application filing date, or
- ☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or
- ☐ **3).** Before the mail date of a first Office Action on the merits, or
  - ☐ **3a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below
- ☐ **4).** With or after the filing of a request for continued examination (RCE) under § 1.114 but before the mailing date of a first Office Action (after RCE).
  - ☐ **4a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below

☒ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☒ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☒ **A).** A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

or

☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under §1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☒ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☒ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☐ **3).** Items identified by a double asterisk (**) on the SB08A are *commonly-owned U.S. patents and U.S. patent application publications.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), *Commonly-owned, unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s), and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **3).** A copy of each application specification is not submitted because the application is stored in the IFW. Cite no(s):

Applicant(s) assume the Examiner has access to the file histories of these items. However, if the Examiner would like to receive copies of Office Actions in any of the commonly-owned applications, publications and/or patents identified on the attached SB08, please inform the undersigned and copies will be provided.

☒ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☒ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☒ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and 609.04(a)III, Foreign patent(s) or other foreign documents not in English cited. Either:**

☒ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☒ **2a).** An English language abstract or an English language copy of a foreign search report or other action by a foreign patent office is provided herewith to fulfill the requirement for a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language: Cite no(s): 416, 420, 433, 446, 450, and 452

--AND/OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached: Cite no(s):

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. Cite no(s):

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement. Cite no(s):

STATEMENT UNDER 37 CFR § 1.704(d)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $90.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: December 15, 2016

By: /Richard D. Shoop/
Richard D. Shoop, Reg. No. 45,763

Shay Glenn LLP
2755 Campus Drive, Suite 210
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I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on April 3, 2017.

MINTZ LEVIN COHN FERRIS GLOVSKY AND POPEO pc

By: /Teri Barnett /

PATENT
Attorney Docket No.: 52210-501C02US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Adam Bowen et al.

Application No.: 14/925,968 | Confirmation No.: 2707

Filed: October 28, 2015 | Art Unit: 1747

For: NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF | Examiner: Dionne W. MAYES

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

AMENDMENT IN RESPONSE TO THE NON-FINAL OFFICE ACTION

In response to the Non-Final Office Action dated December 2, 2016, please amend the above-identified U.S. patent application as follows:

Amendments to the Claims begin on page **2** of this paper.

Remarks begin on page 6 of this paper.

Electronic Patent Application Fee Transmittal

Application Number:	14925968
Filing Date:	28-Oct-2015
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Filer:	Fred C. Hernandez/Teri Barnett
Attorney Docket Number:	13211-713.303

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 - 1 month with $0 paid	2251	1	100	100
Miscellaneous:				
			Total in USD ($)	**100**

Electronic Acknowledgement Receipt

EFS ID:	28819869
Application Number:	14925968
International Application Number:	
Confirmation Number:	2707
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Customer Number:	66854
Filer:	Fred C. Hernandez/Teri Barnett
Filer Authorized By:	Fred C. Hernandez
Attorney Docket Number:	13211-713.303
Receipt Date:	03-APR-2017
Filing Date:	28-OCT-2015
Time Stamp:	18:05:42
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$100
RAM confirmation Number	040417INTEFSW00005266500311
Deposit Account	500311
Authorized User	Teri Barnett
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.19 (Document supply fees) 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		52210_501C02US_Amendment.pdf	190358 babe53480cf31c735b3422504db974b2089e6b84	yes	10

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Applicant Arguments/Remarks Made in an Amendment	6	10
	Claims	2	5
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1

Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30658 f9cb468177bbbadc5dfbe4a6ec82b27e76b885b4	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	221016		

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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.

REMARKS

Claim Status

Claims 1, 7, 13 and 23 are amended. Support for the amendments may be found throughout the application as filed, for example at paragraph [0070]. Therefore, no new matter has been added. With entry of this amendment, claims 1-3, 6-10, 12-18 and 20-23 will be pending and under examination.

Claim Rejections

35 U.S.C. § 112(a)

The Office states that claims 7-20 and 22-23 are rejected under 35 U.S.C. § 112(a) first paragraph, as failing to comply with the written description requirement. Applicants note that claims 1-3, 7-10, 13-18 and 21-23 are pending and, therefore, have interpreted the rejection as applying to pending claims 7-10, 13-18 and 21-23.

The Office asserts that recitation of heart rate increases within the time periods recited in the previously pending claims are not supported by the evidence provided in Declaration of Adam Bowen. Applicants respectfully disagree.

In an effort to expedite prosecution, however, Applicants have amended the claims by removing the recitations at issue thereby rendering the rejection moot. Therefore, Applicants respectfully request withdrawal of the rejection.

35 U.S.C. § 103

Claims 1-3, 7-10, 13-18 and 21-23 are rejected under 35 U.S.C. § 103 as being unpatentable over Sebastian et al. (U.S. Patent Publication No. 2014/0000638) hereinafter "Sebastian". Claims 6, 12 and 20 are rejected under 35 U.S.C. § 103 as being unpatentable over Sebastian in view of Gonda (U.S. Patent Publication No. 2014/0261474) hereinafter "Gonda". Applicants respectfully disagree.

Nonetheless, in an effort to expedite prosecution, Applicants have amended the claims to specify that the recited aerosol includes protonated nicotine in an amount effective to increase the heart rate of a user.

None of the art cited by the Office teaches or suggests ***an aerosol containing a protonated nicotine*** as set forth in the pending claims as amended. For example, Sebastian merely teaches that certain organic acids may be included as a component of a composition ***prior to aerosolization*** for the purpose of ***altering flavor***. Sebastian lists several organic acids as flavoring agents, including levulinic acid, lactic acid and pyruvic acid, in addition to other flavoring agents such as vanillin, tea, coffee, fruit, cocoa, and many others. *See* Sebastian at paragraph [0059].

Nothing in Sebastian indicates that the suggested use of organic acids in a composition prior to aerosolization for the purpose of altering flavor would somehow result in protonated nicotine in the resulting aerosol, much less a sufficient amount of protonated nicotine to increase the heart rate of the user, as set forth in Applicants' amended claims.

Indeed, Sebastian teaches that lactic acid and other flavoring agents can be delivered to the heating element ***separately*** from other components, such as nicotine. *See* Sebastian at paragraph [0059]. In fact, the entire purpose of Sebastian is to provide ***separate delivery of two or more components*** of an aerosol precursor composition to one or more heaters so as ***to separately control the rate of delivery or heating*** of the separate components of the various portions of the aerosol precursor composition. *See e.g.* Sebastian at Abstract and Title. There is no disclosure in Sebastian indicating that separately supplying nicotine and lactic acid to one or more heaters so as to separately control their respective rate of delivery or heating would somehow result in protonated nicotine in the aerosol as set forth in Applicants' amended claims.

Moreover, Sebastian teaches that flavorants "can be provided ***on a substrate*** positioned within the aerosolization zone so as ***to be stored separate*** from the further components of the aerosol precursor composition." *See* Sebastian at paragraph [0059]. There is no disclosure in Sebastian indicating that the inclusion of lactic acid on a substrate within the aerosolization zone would somehow result in protonated nicotine in the aerosol, much less produce a sufficient amount of protonated nicotine to increase the heart rate of the user as set forth in Applicants' amended claims.

Nothing in Sebastian indicates that sufficient amounts of acid are combined with nicotine ***in a single nicotine formulation***, as presently claimed, in order to achieve formation of an aerosol containing protonated nicotine. Moreover, nothing in Sebastian indicates that sufficient amounts of acid are combined with nicotine ***with glycerol and propylene glycol in a single***

nicotine formulation, as presently claimed, in order to achieve formation of an aerosol containing protonated nicotine.

In fact, similar to the separate delivery of nicotine and organic acid flavorants, Sebastian further teaches that glycerol and propylene glycol can be delivered separately:

> In one embodiment, ***first reservoir layer 201 can include a polyol, such as glycerol, and a further component, such as nicotine, and second reservoir 202 can include a different polyol, such as propylene glycol.*** The first reservoir layer 201 is in fluid connection with a first transport element 301 (a wick in this embodiment), and the second reservoir layer 202 is in fluid connection with a second trans port element 302 (a wick in this embodiment). The first wick 301 and the second wick 302 separately transport the components of the aerosol precursor composition stored in the respective reservoir layers via capillary action to the aerosolization zone 400 of the cartridge 90. As illustrated, the first wick 301 and the second wick 302 essentially merge in the aerosolization zone 400 to form a single wick that this in direct contact with the resistive heating element 50 that is in the form of a metal wire coil in this embodiment.

See Sebastian at paragraph [0108]. There is no disclosure in Sebastian indicating that the separate delivery of glycerol and propylene glycol at different rates or to different heaters would somehow produce a composition that would allow protonated nicotine to form in the aerosol. And there is certainly no indication in Sebastian that a sufficient amount of protonated nicotine would be produced to increase the heart rate of the user as set forth in Applicants' amended claims.

Because Sebastian fails to teach or suggest protonated nicotine in the aerosol, much less any benefits of having protonated nicotine in the aerosol, a person having ordinary skill in the art would have ***no reason*** to modify the teachings of Sebastian to provide an aerosol having protonated nicotine. Even if the cited art did provide some reason to form an aerosol with protonated nicotine, nothing in the cited art indicates that a person having ordinary skill in the art would have ***reasonably expected*** to successfully increase the heart rate of the user.

As set forth in the previously submitted Declaration of Adam Bowen submitted, prior to Applicants' invention, "those of skill in the art believed that vaporized nicotine did not result in an effect on heart rate comparable to that seen with a traditional cigarette." *See* the Declaration of Adam Bowen previously submitted on December 12, 2016 at paragraph (7). It was Applicants' invention that protonated nicotine, for example in the form or nicotine lactate, resulted in a significant increase in heart rate. Prior to this discovery, a person having ordinary

skill in the art would have had ***no reason*** to form an aerosol with protonated nicotine and certainly ***no reasonable expectation*** of successfully doing so.

With regard to the rejection of claims 6, 12, 17, 18 and 20, Applicants respectfully submit that Griffith, Jr. and Gonda fail to cure the defects of Sebastian. Like Sebastian, nothing in Griffith, Jr. or Gonda teaches or suggests ***an aerosol containing a protonated nicotine*** as set forth in the pending claims as amended, much less a sufficient amount of protonated nicotine to increase the heart rate of the user as set forth in Applicants' amended claims.

For at least the reasons recited above, Applicants respectfully request withdrawal of the obviousness rejection.

CONCLUSION

In view of the foregoing amendments and remarks, reconsideration is respectfully requested. This application should now be in condition for allowance; a notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

Except for the issue fees payable under 37 C.F.R. § 1.18, the Commissioner is authorized to charge any fees that may be due in connection with the filing of this paper, or to credit any overpayment thereof, to Deposit Account No. 50-0311 referencing the above-identified attorney docket number.

Respectfully submitted,

/Ken Jenkins /
Kenneth E. Jenkins, Ph.D.
Registration No. 51,846

MINTZ LEVIN COHN FERRIS GLOVSKY AND POPEO, P.C.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings in the above-referenced patent application. The foregoing amendments are without prejudice and do not constitute an admission regarding the patentability of the amended subject matter and should not so be construed.

1. (Currently Amended) A method of delivering nicotine to a user comprising:

deploying a low-temperature vaporizer comprising a nicotine formulation that comprises nicotine, lactate, and a biologically acceptable liquid carrier, wherein:

a. the nicotine ~~**lactate**~~ concentration is about 4% (w/w);

b. the biologically acceptable liquid carrier comprises glycerol **and propylene glycol**; and

c. operation of the low-temperature vaporizer comprises wicking the nicotine formulation to a heating element and heating at least a portion of the nicotine formulation to generate an inhalable aerosol ~~**of**~~ **comprising an amount of protonated nicotine effective to increase the heart rate of said user**[[;]]

~~**wherein inhalation of the aerosol into a user's lungs increases heart rate comparable to inhaling a traditional burned cigarette in that inhaling 10 puffs of the aerosol over a period of about 3 minutes results in an increase in heart rate that peaks within about 3.5 minutes from the first puff**~~.

2. (Previously presented) The method of claim 1, wherein a molar ratio of nicotine to lactic acid is between about 1:1 and 1:3.

3. (Original) The method of claim 1, wherein the nicotine formulation further comprises at least one flavorant.

4. (Cancelled)

5. (Cancelled)

6. (Original) The method of claim 1, wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns.

7. (Currently Amended) A method of delivering nicotine to a user comprising:

deploying a low-temperature vaporizer comprising a nicotine formulation that comprises nicotine, lactate, and a biologically acceptable liquid carrier, wherein:

a. the nicotine ~~**lactate**~~ concentration is from about 4% (w/w) to about 6.5% (w/w);

b. the biologically acceptable liquid carrier comprises glycerol **and propylene glycol propylene diol**; and

c. operation of the low-temperature vaporizer comprises wicking the nicotine formulation to the heating element and heating at least a portion of the nicotine formulation to generate an inhalable aerosol **comprising an amount of protonated nicotine effective to increase the heart rate of said user**[[;]]

~~**wherein inhalation of the aerosol into a user's lungs increases heart rate comparable to inhaling a traditional burned cigarette in that inhaling 10 puffs of the aerosol over a period of about 3 minutes results in an increase in heart rate that peaks within about 3.5 minutes from the first puff**~~.

8. (Previously presented) The method of claim 7, wherein a molar ratio of nicotine to lactic acid is between 1:1 and 1:3.

9. (Original) The method of claim 7, wherein the nicotine formulation further comprises at least one flavorant.

10. (Original) The method of claim 7, wherein the nicotine concentration is about 4.5%.

11. (Cancelled)

12. (Original) The method of claim 7, wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns.

13. (Currently Amended) A low-temperature vaporizer, comprising:

a liquid reservoir;

a nicotine formulation within the liquid reservoir, the nicotine formulation comprising:

nicotine ~~**lactate**~~;

propylene glycol; and

glycerol;

wherein a concentration of the nicotine ~~**lactate**~~ in the nicotine formulation is about 4% (w/w) to about 6.5% (w/w);

a vaporizing component configured to produce an aerosol from the nicotine formulation by heating at least a portion of the nicotine formulation**, wherein the aerosol comprises an amount of protonated nicotine effective to increase the heart rate of a user of said low-temperature vaporizer**,

wherein the liquid reservoir is connected to the vaporizing component by a wick; and

a mouthpiece configured to connect to the reservoir for inhalation of the aerosol[[;]]

~~**wherein inhalation of the aerosol into the user's lungs increases heart rate comparable to inhaling a traditional burned cigarette in that inhaling 10 puffs of the aerosol over a period of about 3 minutes results in an increase in heart rate that peaks within about 5 minutes from the first puff**~~.

14. (Original) The electronic cigarette of claim 13, further comprises a battery configured to provide power to the vaporizing component.

15. (Previously presented) The electronic cigarette of claim 13, wherein a molar ratio of nicotine to lactic acid is between 1:1 and 1:3.

16. (Original) The electronic cigarette of claim 13, wherein the nicotine formulation further comprises at least one flavorant.

17. (Original) The electronic cigarette of claim 13, wherein the vaporizing component comprises a heating element in fluid communication with the nicotine formulation.

18. (Original) The electronic cigarette of claim 13, wherein the nicotine concentration is about 4.5%.

19. (Cancelled)

20. (Original) The electronic cigarette of claim 13, wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns.

21. (Previously presented) The method of claim 1, wherein the nicotine formulation comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

22. (Previously presented) The method of claim 7, wherein the nicotine formulation comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

23. (Currently Amended) A method of delivering nicotine to a user comprising:

deploying a low-temperature vaporizer comprising a nicotine formulation that comprises nicotine ~~**lactate**~~, and a biologically acceptable liquid carrier, wherein:

a. the nicotine ~~**lactate**~~ concentration is about 4.5% (w/w);

b. the biologically acceptable liquid carrier comprises glycerol **and propylene glycol**; and

c. operation of the low-temperature vaporizer comprises wicking the nicotine formulation to a heating element and heating at least a portion of the nicotine formulation to generate an inhalable aerosol ~~**of nicotine lactate,**~~ **wherein the inhalable aerosol comprises an amount of protonated nicotine effective to increase the heart rate of the user**[[;]]

~~**wherein inhalation of the aerosol into a user's lungs increases heart rate comparable to inhaling a traditional burned cigarette in that inhaling 10 puffs of the aerosol over a period of about 3 minutes results in an increase in heart rate that peaks within about 3.5 minutes from the first puff**~~.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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 14/925,968	Filing Date 10/28/2015	☐ To be Mailed

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 $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ 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

AMENDMENT	04/03/2017	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 18	Minus	** 20	= 0	X $40 =	0
	Independent (37 CFR 1.16(h))	* 4	Minus	***4	= 0	X $210 =	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		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	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.

SLIE
ALA HUNTER

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.

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82A (07-13)
Approved for use through 11/30/2014. OMB 0651-0051
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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.

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Title	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
Art Unit	1747
Examiner Name	D. W. Mayes
Attorney Docket Number	52210-501C02US

SIGNATURE of Applicant or Patent Practitioner

Signature	/Ken Jenkins/	Date (Optional)	April 25, 2017
Name	Kenneth E. Jenkins, Ph.D.	Registration Number	51,846
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ *Total of 1 forms are submitted.

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
Approved for use through 11/30/2014. OMB 0651-0051
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

[X] I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 64046

OR

[ ] I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

[X] The address associated with the above-mentioned Customer Number

OR

[ ] The address associated with Customer Number:

OR

Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

PAX Labs, Inc.

[ ] Inventor or Joint Inventor (title not required below)

[ ] Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

[X] Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

[ ] Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	4/5/17
Name	Ashley C. Gould		
Title	General Counsel, Chief Regulatory and Communications Officer		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

[ ] Total of 1 forms are submitted.

Electronic Acknowledgement Receipt

EFS ID:	29025220
Application Number:	14925968
International Application Number:	
Confirmation Number:	2707
Title of Invention:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF
First Named Inventor/Applicant Name:	Adam BOWEN
Customer Number:	66854
Filer:	Kenneth Edwin Jenkins/Teri Barnett
Filer Authorized By:	Kenneth Edwin Jenkins
Attorney Docket Number:	13211-713.303
Receipt Date:	25-APR-2017
Filing Date:	28-OCT-2015
Time Stamp:	17:00:03
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	52210_501C02US_POA.pdf	80168 48740028d7916dac6c441d3da6bdc56395536bd5	no	2

Warnings:

Information:	
Total Files Size (in bytes):	80168

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.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/925,968	10/28/2015	Adam BOWEN	13211-713.303

CONFIRMATION NO. 2707

66854
SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

POWER OF ATTORNEY NOTICE

OC000000090948909

Date Mailed: 04/28/2017

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 04/25/2017.

- The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/sleutchit/

UNITED STATES PATENT AND TRADEMARK OFFICE

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Alexandria, Virginia 22313-1450
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/925,968	10/28/2015	Adam BOWEN	13211-713.303

CONFIRMATION NO. 2707

64046
Mintz Levin/San Diego Office
One Financial Center
Boston, MA 02111

POA ACCEPTANCE LETTER

OC000000090948928

Date Mailed: 04/28/2017

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 04/25/2017.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/sleutchit/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	PATENT NUMBER	GROUP ART UNIT	REQUEST ID
14/925,968		1747	40380

PAIR Correspondence Address/Fee Address Change

The following fields have been changed to Customer Number 148514 on 05/23/2017 via Private PAIR in view of the certification copied below that authorized the change.

- Correspondence Address

The address for Customer Number 148514 is:
148514
Mintz Levin/PAX
One Financial Center
Boston, MA 02111

I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

An attorney or Agent of Record registered to practice before the Patent and Trademark Office who has been given power of attorney in this application

Signature:	/Ken Jenkins/
Name:	Kenneth E. Jenkins
Registration Number:	51846

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/925,968	10/28/2015	Adam BOWEN	52210-501C02US /713.303	2707

148514 7590 06/02/2017

Mintz Levin/PAX
One Financial Center
Boston, MA 02111

EXAMINER	
MAYES, DIONNE WALLS	

ART UNIT	PAPER NUMBER
1747	

NOTIFICATION DATE	DELIVERY MODE
06/02/2017	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):

IPDocketingBOS@mintz.com
IPFileroombos@mintz.com

Office Action Summary	Application No. 14/925,968	Applicant(s) BOWEN ET AL.	
	Examiner DIONNE W. MAYES	Art Unit 1747	AIA (First Inventor to File) Status Yes

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/3/2017*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-3,7-10,13-18 and 21-23* is/are pending in the application.

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

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-3,7-10,13-18 and 21-23* is/are rejected.

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

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Notice of 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.

Claim Rejections - 35 USC § 112

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

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

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

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

3. Claims 1-3, 6-10, 12-18 and 20-23 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, because the specification, while being enabling for "a method of delivering nicotine to a user" and "a low temperature vaporizer" comprising nicotine lactate and a biologically acceptable liquid carrier (as previously recited), does not reasonably provide enablement for "a method of delivering nicotine to a user" and "a low temperature vaporizer" comprising "nicotine**,** lactate, and a biologically acceptable liquid carrier…to generate an inhalable aerosol comprising an amount of protonated nicotine" or "nicotine; propylene glycol; and glycerol…[to] produce an aerosol from the nicotine formulation…wherein the aerosol comprises an amount of

protonated nicotine" (which is presently claimed). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

On October 28, 2015, Applicant filed the instant application which included recitation in independent claim 1 which claimed, in part, "method of delivering nicotine to a user comprising: deploying an electronic cigarette comprising a nicotine formulation that comprises nicotine, an organic acid, and a biologically acceptable liquid carrier" and independent claim 13 which claimed, in part, "An electronic cigarette, comprising…a nicotine formulation comprising: nicotine lactate; propylene glycol; and glycerol". This recitation accurately reflects the disclosure of the instant specification. The newly amended recitation of the independent claims, filed on April 3, 2017, however, reflect embodiments wherein nicotine/lactic acid (or an organic acid) or nicotine lactate is not required - resulting in the claims being open to be "read upon" by a reference in which an aerosolizable formulation may include nicotine with *any* lactate or no lactate at all - which is not commensurate in scope with that which is enabled by the instant disclosure. For purposes of Examination, the Examiner will interpret independent claims 1, 7 and 23 as if they were recited, in part, as follows: "nicotine formulation that comprises **nicotine lactate** and a biologically acceptable liquid carrier", and independent claim 13 will be interpreted as if it were recited, in part, "nicotine formulation comprising **nicotine lactate**, propylene glycol and glycerol". Correction is requested.

4. Claims 1-3, 6-10, 12-18 and 20-23 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed, had possession of the claimed invention.

As stated above, the now-presented claimed invention, reflected by the newly amended recitation of the independent claims (filed on April 3, 2017), reflect embodiments wherein nicotine is provided, in a liquid carrier, with (any) lactate or where nicotine is not provided with an organic acid. These embodiments do not appear to be disclosed in the instant specification at all and, as such, is certainly not disclosed in such a way as to reasonably convey to one skill in art that the inventor had possession of the claimed invention at the time the application was filed. Correction is requested.

5. 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.

6. Claims 1-3, 6-10, 12-18 and 20-23 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

In all of the independent claims, Applicant has amended the claims to recite that a portion of the nicotine formulation generates an inhalable aerosol comprising an amount of "protonated nicotine"; however, it is not clear how protonated nicotine would result from a nicotine formulation having no proton-donor source (i.e., organic acid). As stated above, for examination purposes, the Examiner will interpret the claims as requiring "nicotine lactate" which was provided in previously-filed claim sets.

Further, independent claim 7 includes the recitation, "the biologically acceptable liquid carrier comprises glycerol and propylene glycol propylene diol"; however, is it not clear what "propylene glycol propylene diol" is, as this particular "substance" is not disclosed in the instant specification. The Examiner presumes that this recitation is a typo, and for purposes of Examination will interpret this portion of the claim to recite: "the biologically acceptable liquid carrier comprises glycerol and propylene glycol" as is similarly recited in independent claims 1, 13 and 23.

Claim Rejections - 35 USC § 103

7. 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.

8. 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.

9. 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.

10. Claims 1-3, 7-10, 13-18 and 21-23 are rejected under 35 U.S.C. 103 as being unpatentable over Sebastian et al (US. Pat. App. Pub. 2014/0000638).

Regarding independent claims 1 and 23, Sebastian et al discloses an electronic smoking article (i.e., electronic cigarette) that provides for delivery of aerosolized components of an aerosol precursor composition to at least one heating element (See abstract. Note: According to Applicant's instant disclosure, the terms "electronic cigarette" and "low temperature vaporization device" are synonymous. See instant published application, para. [0119]) (corresponding to the claimed "deploying a low-temperature vaporizer").

The aerosol precursor composition may include a medicament, such as nicotine, which may comprise up to 10% of the weight of the aerosol precursor (see para. [0060]). When nicotine is chosen, organic acids can be combined with the nicotine in

order to favorably affect the flavor, sensation, or organoleptic properties. Organic acids such as lactic acid may be used, such that the total amount of acid present is equimolar to the total amount of nicotine present in the aerosol precursor (see para. [0059]). The aerosol precursor composition may also include a polyol. Specifically, in one embodiment, the composition may include a polyol in the form of glycerol (in an amount of about 70%), and propylene glycol (in an amount ranging from about 1% to about 10%)(see para. [0060]-[0061]). Since the nicotine and lactic acid can be provided in equimolar ratios, it is presumed that "nicotine lactate" is thereby formed, resulting in the claimed "nicotine formulation that comprises nicotine lactate, and a biologically acceptable liquid carrier...the biologically acceptable liquid carrier comprises glycerol and propylene glycol".

Further, Sebastian et al discloses that, as a non-limiting example, an aerosol precursor composition may include nicotine in an amount of about 0.1-5.0%. This would motivate one of ordinary skill to undergo routine experimentation to find the optimal amount of nicotine to add to the precursor composition and, in doing so, selected the high end of this range, i.e. 3-5%, after determining that such nicotine concentration provided for superior flavor, sensation and organoleptic properties for the user (Note: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (corresponding to the claimed "the nicotine concentration is about 4%/4.5% (w/w)".

At least one wick can be used to transport the aerosolized components of the aerosol precursor composition from a reservoir to an aerosolization zone (i.e., at or around a resistive heating element) within the electronic smoking article (para. [0009]) (corresponding to the claimed “operation of the low-temperature vaporizer comprises wicking the nicotine formulation to a heating element and heating at least a portion of the nicotine formulation to generate an inhalable aerosol of nicotine lactate").

Lastly, it follows to reason, that the upon inhalation of the aerosolized vapor resulting from heating the aerosol precursor nicotine composition in the modified Sebastian et al electronic smoking article, the user would experience heart rate increase as, absent any indication to the contrary, such effects would “flow naturally” from use of said apparatus which contains the nicotine formulation since Applicant has already indicated, in the instant specification, that “nicotine is a chemical stimulant and increases heart rate...when provided to an individual" (para. [0110] of published application) (corresponding to the claimed “an inhalable aerosol comprising an amount of protonated nicotine effective to increase the heart rate of said user”).

Regarding claim 2, as stated above, Sebastian et al discloses that its aerosol precursor can include nicotine and lactic acid provided in equimolar ratios (see para. [0059]) (corresponding to the claimed “wherein a molar ratio of nicotine to organic acid is between about 1:1 and 1:3”).

Regarding claim 3, Sebastian et al discloses that its aerosol precursor material can be combined with more than one flavorant (see para. [0031]) (corresponding to the claimed “wherein the nicotine formulation further comprises at least one flavorant”).

Regarding independent claims 7 and 13, and claims 10 and 17-18, Sebastian et al discloses an electronic smoking article (i.e., electronic cigarette) that provides for delivery of aerosolized components of an aerosol precursor composition to at least one heating element (See abstract. Note: According to Applicant's instant disclosure, the terms "electronic cigarette" and "low temperature vaporization device" are synonymous. See instant published application, para. [0119]) (corresponding to the claimed "deploying a low-temperature vaporizer").

The aerosol precursor composition may include a medicament, such as nicotine, which may comprise up to 10% of the weight of the aerosol precursor (see para. [0060]). When nicotine is chosen, organic acids can be combined with the nicotine in order to favorably affect the flavor, sensation, or organoleptic properties. Organic acids such as lactic acid may be used, such that the total amount of acid present is equimolar to the total amount of nicotine present in the aerosol precursor (see para. [0059]). The aerosol precursor composition may also include a polyol. Specifically, in one embodiment, the composition may include a polyol in the form of glycerol (in an amount of about 70%), and propylene glycol (in an amount ranging from about 1% to about 10%)(see para. [0060]-[0061]). Since the nicotine and lactic acid can be provided in equimolar ratios, it is presumed that "nicotine lactate" is thereby formed, resulting in the claimed "nicotine formulation that comprises nicotine lactate, and a biologically acceptable liquid carrier...the biologically acceptable liquid carrier comprises glycerol and propylene glycol".

Further, Sebastian et al discloses that, as a non-limiting example, an aerosol precursor composition may include nicotine in an amount of about 0.1-5.0%. This would motivate one of ordinary skill to undergo routine experimentation to find the optimal amount of nicotine to add to the precursor composition and, in doing so, selected the high end of this range, i.e. 3-5%, after determining that such nicotine concentration provided for superior flavor, sensation and organoleptic properties for the user (Note: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (corresponding to the claimed "the nicotine lactate concentration is from about 4% (w/w) to about 6.5% (w/w)"; and the "wherein the nicotine concentration is about 4.5%" recitation of claims 10 and 18).

At least one wick can be used to transport the aerosolized components of the aerosol precursor composition from a reservoir to an aerosolization zone (i.e., at or around a resistive heating element) within the electronic smoking article (para. [0009]) (corresponding to the claimed "operation of the low-temperature vaporizer comprises wicking the nicotine formulation to a heating element and heating at least a portion of the nicotine formulation to generate an inhalable aerosol of nicotine lactate"; and the "wherein the vaporizing component comprises a heating element in fluid communication with the nicotine formulation" recitation of claim 17).

Lastly, it follows to reason, that the upon inhalation of the aerosolized vapor resulting from heating the aerosol precursor nicotine composition in the modified

Sebastian et al electronic smoking article, the user would experience the claimed heart rate increase as, absent any indication to the contrary, such effects would “flow naturally” from use of said apparatus which contains the nicotine formulation since Applicant has already indicated, in the instant specification, that “nicotine is a chemical stimulant and increases heart rate...when provided to an individual" (para. [0110] of published application)(corresponding to the claimed “an inhalable aerosol comprising an amount of protonated nicotine effective to increase the heart rate of said user”).

Regarding claim 8, as stated above, Sebastian et al discloses that its aerosol precursor can include nicotine and lactic acid provided in equimolar ratios (see para. [0059]) (corresponding to the claimed “wherein a molar ratio of nicotine to organic acid is between about 1:1 and 1:3”).

Regarding claim 9, Sebastian et al discloses that its aerosol precursor material can be combined with more than one flavorant (see para. [0031]) (corresponding to the claimed “wherein the nicotine formulation further comprises at least one flavorant”).

Regarding claim 14, the electronic smoking article of Sebastian et al may include a battery (40)(see Fig. 1, para. [0078]) (corresponding to the claimed “further comprises a battery configured to provide power to the vaporizing component”).

Regarding claim 15, as stated above, Sebastian et al discloses that its aerosol precursor can include nicotine and lactic acid provided in equimolar ratios (see para. [0059]) (corresponding to the claimed “wherein a molar ratio of nicotine to organic acid is between about 1:1 and 1:3”).

Regarding claim 16, Sebastian et al discloses that its aerosol precursor material can be combined with more than one flavorant (see para. [0031]) (corresponding to the claimed “wherein the nicotine formulation further comprises at least one flavorant”).

Regarding claim 17, as stated above, Griffith, Jr. et al discloses that the aerosol, from an inside cavity, is vaporized by a resistive heating element (50) that heats the nicotine-containing aerosol precursor material located on a substrate (53)(see para. [0137])(corresponding to the claimed “wherein the vaporizing component comprises a heating element in fluid communication with the nicotine formulation”).

Regarding claim 18, Griffith, Jr. et al discloses that a specific non-limiting example of the nicotine content in its aerosol precursor may be about 2-3% by weight (see para. [00888]). However, it would have been obvious to one having ordinary skill in the art to have adjusted this amount to be a bit higher - corresponding to the claimed amount - in order to satisfy the particular organoleptic preferences of the user (corresponding to the claimed “wherein the nicotine concentration is about 4.5%”).

Regarding claims 21-22, Sebastian et al discloses that the aerosol precursor composition can take a variety of conformations, and may comprises up to 95% by weight of a polyol. This total amount can be split in any combination between two or more different polyols, such as glycerol (i.e., vegetable glycerol) and propylene glycol. This would motivate one of ordinary skill to undergo routine experimentation to find the optimal amount of each polyol to add to the precursor composition and, in doing so, selected the claimed polyol combination (Note: “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or

workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955))(corresponding to the claimed "wherein the nicotine formulation comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin" recitation of claim21; and the "wherein the nicotine formulation comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin" recitation of claim 22").

11. Claims 6, 12 and 20 are rejected under 35 U.S.C. 103 as being unpatentable over Sebastian et al (US. Pat. App. Pub. 2014/0000638) in view of Gonda (US. Pat. No. 2014/0261474).

Regarding claims 6, 12 and 20, based on the disclosure of Gonda, that by decreasing the particle size, the aerosolized particles of nicotine will deposit deeper in the lungs, which increases the rate of absorption of the nicotine and leads to an increase in peak nicotine plasma levels, it would have been obvious to one having ordinary skill in the art to have optimized the particle size of its aerosol to fall between 0.1 - 5 microns (Corresponding to the claimed "wherein the inhalable aerosol has a particle size from about 0.1 microns to about 5 microns").

Response to Arguments

12. Applicant's arguments filed April 3, 2017 have been fully considered but they are not persuasive.

-Applicant argues that the prior art fails to teach or reasonably suggest the claimed "aerosol containing a protonated nicotine". Specifically, Applicant submits, nothing in the Sebastian reference indicates that the suggested use of organic acids in a composition (prior to aerosolization) for the purpose of altering flavor would somehow

result in protonated nicotine in the resulting aerosol, much less a sufficient amount of protonated nicotine to increase the heart rate of the user. The Examiner, however, disagrees. First, it is true that Sebastian lists several acids (lactic acid, included) to be included in the nicotine composition for the purpose of altering flavor ("flavoring agents")(see Sebastian para. [0060]); however, regarding the instant invention, it is to be noted that Applicant has also articulated that organic acids (including lactic acid) coupled with nicotine to produce nicotine lactate can be used to provide flavor (see instant published application para. [0131]). Second, because Sebastian teaches an equimolar ratio of nicotine to organic acid, as stated above, it is more than reasonable to presume that "nicotine lactate" is thereby formed, resulting in the claimed "nicotine formulation that comprises nicotine lactate" which, in turn, would produce an "inhalable aerosol comprising an amount of protonated nicotine". Lastly, Applicant points out that Sebastian states that lactic acid can be delivered to the heating element separately from other components, such as nicotine and/or the liquid carrier, and separately supplying the components to one or more heaters. Applicant further seems to suggest that, in such an arrangement, the formation of protonated nicotine is doubtful or uncertain. The Examiner submits that while Sebastian may disclose the separate delivery of the various components of the nicotine formulation, the Examiner wishes to point out that this appears to be one of many different ways in which the formulation of Sebastian can be delivered to the heater. Note the use of the words "can be" (see para. [0059]) of Sebastian. As disclosed above, the Examiner has also provided evidence in Sebastian that it envisions a formulation that includes a homogeneous mixture of nicotine, lactic

acid (hence, forming nicotine lactate) in a liquid carrier. Further, Sebastian even clearly articulates the same in para, [0058] where it states that “components [of the aerosol precursor composition] can be separately or simultaneously delivered to the resistive heating element for aerosolization in an air stream to be inhaled by a user".

Conclusion

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

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIONNE W. MAYES whose telephone number is (571)272-5836. The examiner can normally be reached on Tuesdays and Thursdays, 8:00A - 4:30P.

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.

/DIONNE W MAYES/
Examiner, Art Unit 1747

/MICHAEL H WILSON/
Supervisory Patent Examiner, Art Unit 1747

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	3	(("20060195518") or ("20120256567") or ("20080241255")).PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 11:41
S2	3	(("20060195518") or ("20120255567") or ("20080241255")).PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 11:41
S3	2	(("20120255567") or ("20080241255")).PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 11:42
S4	0	("2006").pn. and (hon).in.	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 11:42
S5	42	(hon).in. and cigarette	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 11:44
S6	25	("131"/$ or "128"/$).ccls. and electronic cigarette and nicotine and plasma	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:06
S7	6	("131"/$ or "128"/$).ccls. and (fuisz).in. and nicotine and plasma	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:06
S8	91	("131"/$ or "128"/$).ccls. and inhal$5 near15 nicotine and plasma	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:15
S9	25	("131"/$ or "128"/$).ccls. and inhal$5 near15 nicotine and plasma and ((max or maxim$3) near25 time)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:16
S10	23	("131"/$ or "128"/$).ccls. and inhal$5 near15 nicotine and (plasma near25 (peak or max or maxim$3) near25 time)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:25
S11	9	("131"/$ or "128"/$).ccls. and inhal$5 same (nicotine same (plasma near25 (peak or max or maxim$3) near25 time))	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 15:25
S12	9	("131"/$ or "128"/$).ccls. and inhal$5 same (nicotine same (plasma near25 (peak or max or maxim$3) near25 time))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:26
S13	32	("131"/$ or "128"/$).ccls. and inhal$5 and (nicotine same (plasma near25 (peak or max or maxim$3) same time))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:28
S14	2	("131"/$ or "128"/$).ccls. and nicotine benzoate	US-PGPUB; USPAT; USOCR; FPRS;	ADJ	ON	2015/01/20 15:51

			EPO; JPO; DERWENT; IBM_TDB			
S15	2	(vaporiz$3 or electronic cigarette) and nicotine benzoate	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:52
S16	346	("131"/$ or "128"/$).ccls. and (salt near5 nicotine)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:53
S17	230	("131"/$ or "128"/$).ccls. and (salt near5 nicotine) same (acid)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:54
S18	210	("131"/$ or "128"/$).ccls. and (salt near5 nicotine) near35 (acid)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 15:55
S19	17	("131"/$ or "128"/$).ccls. and (salt near5 nicotine) near35 (carboxylic or citric)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 16:08
S20	1	("2356185").PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 16:32
S21	1	("2356185").PN.	USOCR	OR	OFF	2015/01/20 16:33
S22	4	nicotine benzoate	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 16:38
S23	1	("20010029959").PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 16:43
S24	0	electronic cigarette and inhal$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 16:47
S25	1	nicotine and inhal$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/01/20 16:48
S26	1	nicotine and inhal$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR;	ADJ	ON	2015/01/20 16:59

			FPRS; EPO; JPO; DERWENT; IBM_TDB			
S27	53	inhal$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 17:33
S28	222	puff$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 17:37
S29	207	("131"/$ or "128"/$ or cigarette) and puff$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 17:40
S30	179	("131"/$ or "128"/$) and puff$4 near25 every near15 (seconds or secs)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/01/20 17:40
S31	28	(("20070163610") or ("20090293895") or ("20130186416") or ("7832410") or ("8,156,944") or ("8,511,318") or ("20140345631") or ("20140345635") or ("20040191322") or ("20060018840") or ("20060196518") or ("20080241255") or ("20090004249") or ("20100242976") or ("20110268809") or ("20120255567") or ("4,830,028") or ("4,836,224") or ("6,102,036") or ("6,234,169") or ("6,799,576") or ("6,874,507") or ("7,767,698") or ("8,079,371") or ("8,322,350") or ("8,375,957") or ("8,381,739") or ("8,741,348")).PN.	US-PGPUB; USPAT	OR	OFF	2015/01/20 20:10
S32	1	(14/512311).APP.	US-PGPUB; USPAT	OR	OFF	2015/03/23 22:03
S33	1	(14/512311).APP.	US-PGPUB; USPAT	OR	OFF	2015/05/14 15:25
S34	1605	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:07
S35	237	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:08
S36	221	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5 or mouth or oral$4)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:08

S37	191	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5 or mouth or oral$4) and (plasma or blood)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:08
S38	163	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5 or mouth or oral$4) and (plasma or blood) and ph	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:09
S39	108	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5 or mouth or oral$4) and (plasma or blood) and ph and ((drop$4 or vapor$4 or aerosol$4 or particle) near25 size)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:10
S40	87	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5 or mouth or oral$4) and (plasma or blood) and ph and ((drop$4 or vapor$4 or aerosol$4 or particle) near25 size) and heat$4	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:11
S41	77	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5) and (plasma or blood) and ph and ((drop$4 or vapor$4 or aerosol$4 or particle) near25 size) and heat$4	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 16:12
S42	4	("2004076289").PN.	FPRS; EPO; JPO	OR	OFF	2015/05/14 18:13
S43	15	ANDERSSON near3 SVEN-BORJE	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:15
S44	13	ANDERSSON near3 SVEN-BORJE and nicotine	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:15
S45	71	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5) and (plasma or blood) and ph and ((drop$4 or vapor$4 or aerosol$4 or particle) near25 size) and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:26
S46	21	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5) and (plasma or blood) and (ph near5 "7") and ((drop$4 or vapor$4 or aerosol$4 or particle) near25 size) and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:27
S47	26	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5) and (plasma or blood) and (ph near5 "7") and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:28
S48	38	("128"/$ or "131"/$ or "424"/$ or "514"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and benzoic and (inhal$5) and	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/14 18:31

		(plasma or blood) and (ph near5 "7") and heat$4 and lung				
S49	1	("20060196518").PN.	US-PGPUB; USPAT	OR	OFF	2015/05/14 19:32
S50	34	("128"/$ or "131"/$ or "424"/$ or "514"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and (salicylic or sorbic or lauric or levulinic or citric or benzoic or pyruvic) and (inhal$5) and ((plasma or blood or peek or peak) near10 concentration) and (ph near5 "7") and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 08:30
S51	1	("8831739").PN.	US-PGPUB; USPAT	OR	OFF	2015/05/15 08:43
S52	1	("8381739").PN.	US-PGPUB; USPAT	OR	OFF	2015/05/15 08:43
S53	14	(igor near3 gonda) and nicotine and ng/ml	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 10:42
S54	13	(igor near3 gonda) and nicotine near50 concentration near50 ng/ml	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 10:42
S55	0	(igor near3 gonda) and nicotine near50 concentration near50 ng/ml near50 salt	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 10:43
S56	64	(igor near3 gonda) and ((blood or plasma or nicotine) near50 concentration)	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 10:46
S57	13	(igor near3 gonda) and ((blood or plasma or nicotine) near50 concentration) same nicotine	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/05/15 10:46
S58	1	("20030136404").PN.	US-PGPUB; USPAT	OR	OFF	2015/05/17 15:16
S59	1	(14/512311).APP.	US-PGPUB; USPAT	OR	OFF	2015/07/14 09:12
S60	1	("20140261474").PN.	US-PGPUB; USPAT	OR	OFF	2015/07/14 10:27
S61	1	(14/512311).APP.	US-PGPUB; USPAT	OR	OFF	2015/09/17 14:40
S62	934	(A24F47/008).cpc.	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/09/17 14:46
S63	78	("128"/$ or "131"/$ or "424"/$ or "514"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and acid and (inhal$5) and (plasma or blood) and (ph near5 "7") and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/09/17 14:46
S64	367	("128"/$ or "131"/$ or "424"/$ or "514"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and acid and (inhal$5) and (plasma or blood) and heat$4 and lung	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/09/17 14:47
S65	283	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and (levulinic or pyruvic or salicylic or sorbic or lauric or benzoic) and (inhal$5 or mouth or oral$4) and	US-PGPUB; USPAT; USOCR	ADJ	ON	2015/09/17 14:48

		(plasma or blood)				
S69	2	(("20060196518") or ("20140261474")).PN.	US-PGPUB; USPAT	OR	OFF	2015/12/10 16:09
S70	1	("9215895").PN.	US-PGPUB; USPAT	OR	OFF	2016/03/30 20:38
S71	0	(14/925958).APP.	US-PGPUB; USPAT	OR	OFF	2016/04/24 10:41
S72	1	(14/925968).APP.	US-PGPUB; USPAT	OR	OFF	2016/04/24 10:41
S73	2	(12/236439).APP.	US-PGPUB; USPAT	OR	OFF	2016/04/24 10:56
S74	120	(A24F47/008).cpc. and temperature near25 ("100" or "200" or "300")	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 12:53
S75	34	(A24F47/008).cpc. and temperature near25 ("100" or "200" or "300") near25 degrees	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 12:56
S76	35	(A24F47/008 or A24F47/00 or A24F47/002).cpc. and temperature near25 ("100" or "200" or "300") near25 degrees	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 12:57
S77	0	((128/$ or 131/$).ccls. or (A24F47/008 or A24F47/00 or A24F47/002).cpc.) and low tempereture and ("100" or "200" or "300") near25 degrees	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 13:27
S78	1787	((128/$ or 131/$).ccls. or (A24F47/008 or A24F47/00 or A24F47/002).cpc.) and low temperature	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 13:28
S79	118	((128/$ or 131/$).ccls. or (A24F47/008 or A24F47/00 or A24F47/002).cpc.) and low temperature and ("100" or "200" or "300") near25 degrees	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 13:28
S80	29	((128/$ or 131/$).ccls. or (A24F47/008 or A24F47/00 or A24F47/002).cpc.) and low temperature and ("100" or "200" or "300") near25 degrees and nicotine	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 13:29
S81	2	(12/336439).APP.	US-PGPUB; USPAT	OR	OFF	2016/04/25 13:38
S82	1	("5,544,646").PN.	US-PGPUB; USPAT	OR	OFF	2016/04/25 19:16
S83	10	(rose).in. and pyruvic and nicotine	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/25 19:18
S84	1	(12/481908).APP.	US-PGPUB; USPAT	OR	OFF	2016/04/25 21:20
S85	389	nicotine near50 (lactic or lactate)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/04/27 09:16
S86	440	nicotine near50 (lactic or lactate)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/04/27 09:16
S87	65	((a24f47/00)".cpc" or (131/$.ccls.) or (128/$).ccls.) and nicotine near50 (lactic	US-PGPUB; USPAT;	ADJ	ON	2016/04/27 09:20

		or lactate)	USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			
S88	70	((a24f47/00).cpc. or (131/$.ccls.) or (128/$).ccls.) and nicotine near50 (lactic or lactate)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/04/27 09:20
S89	73	((a24f47/00 or a24f47/008).cpc. or (131/$.ccls.) or (128/$).ccls.) and nicotine near50 (lactic or lactate)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/04/27 09:20
S90	1	("9,215,895").PN.	US-PGPUB; USPAT	OR	OFF	2016/04/27 11:18
S91	6717	(a24f47/00 or a24f47/008).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/04/27 18:29
S92	754	glycerol near50 ((veggie or vegetable) near2 glycerol)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/05/05 09:10
S93	719	glycerol near5 ((veggie or vegetable) near2 glycerol)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/05/05 09:10
S94	48	glycerol near5 (veggie glycerol or vegetable glycerol)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/05/05 09:14
S95	3	glycerin near5 (veggie glycerol or vegetable glycerol)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/05/05 09:15
S96	3	glycerin near25 (veggie glycerol or vegetable glycerol)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/05/05 09:15
S97	3	(a24f47/00 or a24f47/008).cpc. and (veggie glycerol or vegetable glycerol)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/05/05 09:17
S99	1	("20130255702").PN.	US-PGPUB; USPAT	OR	OFF	2016/06/09 12:43
S100	1	(14/925968).APP.	US-PGPUB; USPAT	OR	OFF	2016/06/09 12:44
S101	7	((han near3 li) or (lik near3 hon)).in. and wick$4	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/06/09 12:50
S102	16	a24f47/$2.cpc. and wick$3	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/06/09 12:53
S103	1	("20150128967").PN.	US-PGPUB; USPAT	OR	OFF	2016/07/12 08:38

S104	1	(14/213108).APP.	US-PGPUB; USPAT	OR	OFF	2016/07/12 11:29
S105	2	(("4,793,365") or ("5,101,839")).PN.	US-PGPUB; USPAT	OR	OFF	2016/07/12 12:51
S106	686	(131/$.ccls. or a24f47/$.cpc.) and lactic	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/07/12 15:04
S107	252	(131/$.ccls. or a24f47/$.cpc.) and lactic and nicotine	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/07/12 15:04
S108	219	(131/$.ccls. or a24f47/$.cpc.) and lactic and nicotine and (glycer$$ or glycol)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/07/12 15:05
S109	218	(131/$.ccls. or a24f47/$.cpc.) and lactic and nicotine and (glycer$4 or glycol)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/07/12 15:05
S110	76	(a24f47/$.cpc.) and lactic and nicotine and (glycer$4 or glycol)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/07/12 15:06
S111	72	(a24f47/$.cpc.) and lactic and nicotine and (glycer$4 or glycol) and temperature	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/07/12 15:42
S112	73	(a24f47/$.cpc.) and lactic and nicotine and (glycer$4 or glycol) and heat$4	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/07/12 15:44
S113	57	(a24f47/$.cpc.) and lactic and nicotine and (glycer$4 and glycol) and heat$4	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/07/12 15:45
S114	57	(a24f47/$.cpc.) and lactic and nicotine and (glycer$4 and glycol) and heat$4 and temperature	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/07/12 15:45
S115	52	(a24f47/$.cpc.) and lactic and nicotine and (glycer$4 and glycol) and (heat$4 near50 temperature)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/07/12 15:45
S116	38	(a24f47/$.cpc.) and lactic and nicotine and (glycer$4 and glycol) and (heat$4 near50 temperature) and wick$4	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/07/12 15:46
S117	1	("20060196518").PN.	US-PGPUB; USPAT	OR	OFF	2016/10/23 19:49
S118	195	((han or hon) near3 (lik or li)).in. and temperature	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/10/23 19:52
S119	48	((han or hon) near3 (lik or li)).in. and temperature near5 (low)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/10/23 19:53
S120	0	((han or hon) near3 (lik or li)).in. and low-temperature and cigarette	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/10/23 19:54
S121	12	((han or hon) near3 (lik or li)).in. and low near10 temperature and cigarette	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/10/23 19:54
S122	19	((han or hon) near3 (lik or li)).in. and citric and glycerol	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/10/23 20:32
S123	6	(adam near3 bowen).in. and "C.sub.max"	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/10/23 20:55

S124	1	(14/925968).APP.	US-PGPUB; USPAT	OR	OFF	2016/10/23 20:55
S125	23	(adam near3 bowen).in. and nicotine	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/10/23 20:58
S126	6	(adam near3 bowen).in. and (plasma or blood) near15 (peak or max or maxim$3)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/10/23 20:59
S127	102	a24f47/$.cpc. and (plasma or blood) near15 (peak or max or maxim$3)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/10/23 21:00
S128	82	a24f47/$.cpc. and (plasma or blood) near15 (peak or max or maxim$3) and acid and nicotine	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/10/23 21:01
S129	61	a24f47/$.cpc. and (plasma or blood) near15 (peak or max or maxim$3) and ((organic or citric) near30 acid) and nicotine	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/10/23 21:02
S130	1	(14/925968).APP.	US-PGPUB; USPAT	OR	OFF	2016/11/09 13:58
S131	2	(14/512311).APP.	US-PGPUB; USPAT	OR	OFF	2016/11/10 09:32
S132	1	(14/271071).APP.	US-PGPUB; USPAT	OR	OFF	2016/11/10 09:33
S133	22	131/$.ccls. and nicotine and levulinate	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/11/14 20:23
S134	153	131/$.ccls. and nicotine and levul$5	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/11/14 21:59
S135	140	131/$.ccls. and nicotine and (levul$5 near50 acid)	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/11/14 21:59
S136	47	131/$.ccls. and (nicotin$3 near50 (levul$5 near50 acid))	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/11/14 22:00
S137	70	131/$.ccls. and (nicotin$3 near50 ((lactic near50 acid) or lactate))	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/11/27 12:30
S138	70	(131/$.ccls. or a24f47/$.cpc) and (nicotin$3 near50 ((lactic near50 acid) or lactate))	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/11/27 12:30
S139	0	(a24f47/$.cpc) and (nicotin$3 near50 ((lactic near50 acid) or lactate))	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/11/27 12:31
S140	94	(131/$.ccls. or a24f47/$.cpc.) and (nicotin$3 near50 ((lactic near50 acid) or lactate))	US-PGPUB; USPAT; USOCR	ADJ	ON	2016/11/27 12:31
S141	103	(131/$.ccls. or a24f47/$.cpc.) and (nicotin$3 near50 ((lactic near50 acid) or lactate))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/11/27 12:31
S142	49	(131/$.ccls. or a24f47/$.cpc.) and (nicotin$3 near50 ((lactic near50 acid) or	US-PGPUB; USPAT;	ADJ	ON	2016/11/27 14:14

		lactate)) and wick$4	USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			
S143	1	(14/925968).APP.	US-PGPUB; USPAT	OR	OFF	2016/11/27 14:31
S144	1	("9,215,895").PN.	US-PGPUB; USPAT	OR	OFF	2016/11/27 21:05
S145	30	(131/$.ccls. or a24f47/$.cpc.) and (nicotin$3 near50 ((lactic near50 acid) or lactate)) and particle size	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/11/27 23:17
S146	1	(14/925961).APP.	US-PGPUB; USPAT	OR	OFF	2017/05/22 13:03
S147	0	(2016/0037825).CCLS.	US-PGPUB; USPAT	OR	OFF	2017/05/22 21:50
S148	1	("20160037825").PN.	US-PGPUB; USPAT	OR	OFF	2017/05/22 21:51
S149	1	(14/960122).APP.	US-PGPUB; USPAT	OR	OFF	2017/05/22 21:52

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S66	723	(A24F47/008).cpc.	US-PGPUB	ADJ	ON	2015/09/17 14:46
S67	246	("128"/$ or "131"/$ or "424"/$ or "514"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and acid and (inhal$5) and (plasma or blood) and heat$4 and lung	US-PGPUB	ADJ	ON	2015/09/17 14:47
S68	196	("128"/$ or "131"/$ or "424"/$).ccls. and nicotine near25 (formulation or solution or liquid or solvent) and (levulinic or pyruvic or salicylic or sorbic or lauric or benzoic) and (inhal$5 or mouth or oral$4) and (plasma or blood)	US-PGPUB	ADJ	ON	2015/09/17 14:49

5/23/2017 9:09:13 AM
C:\Users\dmayes\Documents\EAST\Workspaces\14925968.wsp

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 6

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

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	694	US- 3,271,719	9/6/1966	Ovshinsky	
	670	US- 3,443,827	5/13/1969	Acker et al.	
	671	US- 5,497,791	3/12/1996	Bowen et al.	
	672	US- 5,529,078	6/25/1996	Rehder et al.	
	117	US- 6,089,857	7/18/2000	Matsuura et al.	
	673	US- 6,196,232	3/6/2001	Chkadua	
	150	US- 7,015,796	3/21/2006	Snyder	
	675	US- 7,801,573	9/21/2010	Yazdi et al.	
	173	US- 8,820,330	9/2/2014	Bellinger et al.	
	174	US- 8,851,081	10/7/2014	Fernando et al.	
	178	US- 9,095,175	8/4/2015	Terry et al.	
	722	US- D725310	3/24/2015	Eksouzian	
	695	US- 2004/0050382	3/18/2004	Goodchild	
	696	US- 2007/0277816	12/6/2007	Morrison et al.	
	674	US- 2009/0111287	4/30/2009	Lindberg et al.	
	263	US- 2010/0200008	8/12/2010	Taieb	
	676	US- 2011/0240047	10/6/2011	Adamic	
	297	US- 2012/0285475	11/15/2012	Liu	
	310	US- 2013/0319440	12/5/2013	Capuano	

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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	387	EP2856893A1	4/8/2015	Fontem Holdings		
	388	EP2908675A1(asWO2014/060268)	8/26/2015	Nicoventures Holdings Ltd		
	389	EP2915443A1	9/9/2015	Fontem Holdings		
	757	EP3062646A1 (WO2015/66136)	9/7/2016	Rai Strategic Holdings Inc		
	758	EP3065581A2 (WO2015/68044)	9/14/2016	SIS Resources Ltd		
	759	EP3068244A1 (WO2015/73975)	9/21/2016	VMR Products LLC		

Examiner Signature	/DIONNE W. MAYES/	Date Considered	05/24/2017

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Sheet 2 of 6

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Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

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	312	US- 2013/0340775	12/26/2013	Juster et al.	
	723	US- 2014/0007891	1/9/2014	Liu	
	314	US- 2014/0014126	1/16/2014	Peleg et al.	
	316	US- 2014/0053856	2/27/2014	Liu	
	318	US- 2014/0060556	3/6/2014	Liu	
	319	US- 2014/0096782	4/10/2014	Ampolini et al.	
	320	US- 2014/0109921	4/24/2014	Chen	
	321	US- 2014/0116455	5/1/2014	Youn	
	322	US- 2014/0123990	5/8/2014	Timmermans	
	323	US- 2014/0150810	6/5/2014	Hon	
	324	US- 2014/0174459	6/26/2014	Burstyn	
	327	US- 2014/0196735	7/17/2014	Liu	
	328	US- 2014/0216450	8/7/2014	Liu	
	329	US- 2014/0230835	8/21/2014	Saliman	
	331	US- 2014/0270727	9/18/2014	Ampolini et al.	
	332	US- 2014/0301721	10/9/2014	Ruscio et al.	
	333	US- 2014/0305450	10/16/2014	Xiang	
	336	US- 2014/0355969	12/4/2014	Stern	
	340	US- 2015/0020825	1/22/2015	Galloway et al.	

FOREIGN PATENT DOCUMENTS

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	416	WO2004/080216A1(EngAbs)	9/23/2004	Hon, Lik		
	420	WO2008/077271A1(EngAbs)	7/3/2008	Maas, Bernard		
	427	WO2012/120487A2	9/13/2012	Chong Corp		
	430	WO2013/089551A1	6/20/2013	Foo, Kit Seng		
	433	WO2014/040915A1(EngAbs)	3/20/2014	Snoke Gmbh & Co		
	435	WO2014/101734A1	7/3/2014	Shenzhen Smoore Tech		

Examiner Signature	/DIONNE W. MAYES/	Date Considered	05/24/2017

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Attorney Docket Number	13211-713.303

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	341	US- 2015/0020831	1/22/2015	Weigensberg et al.	
	343	US- 2015/0027472	1/29/2015	Amir	
	344	US- 2015/0034103	2/5/2015	Hon	
	724	US- 2015/0034104	2/5/2015	Zhou	
	345	US- 2015/0040929	2/12/2015	Hon	
	346	US- 2015/0101625	4/16/2015	Newton et al.	
	347	US- 2015/0122252	5/7/2015	Frija	
	348	US- 2015/0122274	5/7/2015	Cohen et al.	
	349	US- 2015/0128965	5/14/2015	Lord	
	351	US- 2015/0136153	5/21/2015	Lord	
	697	US- 2015/0136158	5/21/2015	Stevens et al.	
	352	US- 2015/0142387	5/21/2015	Alarcon et al.	
	355	US- 2015/0164141	6/18/2015	Newton	
	356	US- 2015/0164144	6/18/2015	Liu	
	698	US- 2015/0164147	6/18/2015	Verleur et al.	
	357	US- 2015/0181928	7/2/2015	Liu	
	358	US- 2015/0189695	7/2/2015	Xiang	
	359	US- 2015/0196059	7/16/2015	Liu	
	699	US- 2015/0196060	7/16/2015	Wensley et al.	

FOREIGN PATENT DOCUMENTS

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	439	WO2014/150704A2	9/25/2014	Altria Client Svs Inc.		
	442	WO2014/205263A1	12/24/2014	Loec Inc.		
	444	WO2015/028815A1	3/5/2015	British American Tobacco		
	446	WO2015/058387A1(EngAbs)	4/30/2015	Kimree Hi-Tech Inc.		
	447	WO2015/063126A1	5/7/2015	Choukroun, B.		
	450	WO2015/089711A1(EngAbs)	6/25/2015	Kimree Hi-Tech Inc.		

Examiner Signature	/DIONNE W. MAYES/	Date Considered	05/24/2017

*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. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 4 of 6

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	361	US- 2015/0208731	7/30/2015	Malamud et al.	
	700	US- 2015/0216237	8/6/2015	Wensley et al.	
	362	US- 2015/0223521	8/13/2015	Menting et al.	
	363	US- 2015/0224268	8/13/2015	Henry et al.	
	364	US- 2015/0237917	8/27/2015	Lord	
	365	US- 2015/0237918	8/27/2015	Liu	
	366	US- 2015/0245654	9/3/2015	Memari et al.	
	367	US- 2015/0245660	9/3/2015	Lord	
	368	US- 2015/0257445	9/17/2015	Henry Jr. et al.	
	369	US- 2015/0258289	9/17/2015	Henry Jr. et al.	
	370	US- 2015/0282527	10/8/2015	Henry Jr.	
	701	US- 2015/0305409	10/29/2015	Verleur et al.	
	702	US- 2016/0021933	1/28/2016	Thorens et al.	
	750	US- 2016/0242466	8/25/2016	Lord et al.	
	751	US- 2016/0249680	9/1/2016	Liu	
	753	US- 2016/0295924	10/13/2016	Liu	
	754	US- 2016/0302483	10/20/2016	Liu	
	717	US- 2016/0309784	10/27/2016	Silvestrini et al.	
	726	US- 2016/0324215	11/10/2016	Mironov et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	452	WO2015/109616A1(EngAbs)	7/30/2015	Kimree Hi-Tech Inc.		

Examiner Signature	/DIONNE W. MAYES/	Date Considered	05/24/2017

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PTO/SB/08A (04-07)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 5 of 6

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	735	US- 2016/0331033	11/17/2016	Hopps et al.	
	737	US- 2016/0331038	11/17/2016	Farine et al.	
	738	US- 2016/0331040	11/17/2016	Nakano et al.	
	745	US- 2016/0338410	11/24/2016	Batista et al.	
	746	US- 2016/0338411	11/24/2016	Liu	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature	/DIONNE W. MAYES/	Date Considered	05/24/2017

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PTO/SB/08b (07-09)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 6 of 6

Complete if Known	
Application Number	14/925,968
Filing Date	October 28, 2015
First Named Inventor	Adam Bowen
Art Unit	1747
Examiner Name	Mayes, Dionne Walls
Attorney Docket Number	13211-713.303

NON PATENT 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.	T[2]
	481	BRADLEY et al.; Electronic cigarette aerosol particle size distribution measurements; Inhal. Toxicol.; 24(14); pp. 976-984; Dec. 2012	
	482	BULLEN et al.; Effect of an electronic nicotine delivery device (e cigarette) on desire to smoke and withdrawal, user preferences and nicotine delivery: randomised cross-over trial; Tobacco Control; 19(2); pp. 98-103; Apr. 2010	
	678	CAPPONNETTO et al.; Successful smoking cessation with cigarettes in smokers with a documented history of recurring relapses: a case series; Journal of Medical Case Reports; 5(1); 6 pages; (year of pub. sufficiently earlier than effective US filing date and any foreign priority date); 2011	
	677	HURT et al.; Treating tobacco dependence in a medical setting; CA: A Cancer Journal for Clinicians; 59(5); pp. 314-326; Sept. 2009	

Examiner Signature	/DIONNE W. MAYES/	Date Considered	05/24/2017

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1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14925968	BOWEN ET AL.
	Examiner	Art Unit
	DIONNE W MAYES	1747

CPC- SEARCHED		
Symbol	Date	Examiner
a24f47/00; a24f47/008	4/27/2016	DWM

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Search conducted (see attached search strategy)	12/10/2015	DWM
Inventor search conducted	12/10/2015	DWM
EAST Search conducted (see attached search strategy)	4/27/2016	DWM
Inventor search updated	4/27/2016	DWM
EAST Search conducted (see attached search strategy)	11/28/2016	DWM
EAST Search conducted (see attached search strategy)	5/23/2017	DWM

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

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APPLICATION NUMBER	PATENT NUMBER	GROUP ART UNIT	REQUEST ID
14/925,968		1747	45212

PAIR Correspondence Address/Fee Address Change

The following fields have been changed to Customer Number 148514 on 08/14/2017 via Private PAIR in view of the certification copied below that authorized the change.

- Correspondence Address

The address for Customer Number 148514 is:
148514
Mintz/JUUL/PAX
One Financial Center
Boston, MA 02111

I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

An attorney or Agent of Record registered to practice before the Patent and Trademark Office who has been given power of attorney in this application

Signature:	/npm/
Name:	Nicholas Mouton
Registration Number:	75306

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Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/925,968	10/28/2015	Adam BOWEN	52210-501C02US/713.303	2707

148514 7590 01/10/2018

Mintz/JUUL/PAX
One Financial Center
Boston, MA 02111

EXAMINER
MAYES, DIONNE WALLS

ART UNIT	PAPER NUMBER
1747	

NOTIFICATION DATE	DELIVERY MODE
01/10/2018	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):

IPDocketingBOS@mintz.com
IPFileroombos@mintz.com

Notice of Abandonment	Application No.	Applicant(s)
	14/925,968	BOWEN ET AL.
	Examiner	Art Unit
	DIONNE W. MAYES	1747

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

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on *02 June 2017*.
   (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
   (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 to the final rejection.
   (A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) if this is utility or plant application, a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. Note that RCEs are not permitted in design applications.)
   (c) ☐ A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
   (d) ☒ No reply has been received.

2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
   (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
   (b) ☐ The submitted fee of $_____ is insufficient. A balance of $_____ is due.
   The issue fee required by 37 CFR 1.18 is $_____. The publication fee, if required by 37 CFR 1.18(d), is $_____.
   (c) ☐ The issue fee and publication fee, if applicable, has not been received.

3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
   (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
   (b) ☐ No corrected drawings have been received.

4. ☐ The letter of express abandonment which is signed by the attorney or agent of record or other party authorized under 37 CFR 1.33(b). See 37 CFR 1.138(b).

5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34) upon the filing of a continuing application.

6. ☐ The decision by the Patent Trial and Appeal Board rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.

7. ☐ The reason(s) below:

/MICHAEL H WILSON/ Supervisory Patent Examiner, Art Unit 1747	/DIONNE W MAYES/ Examiner, Art Unit 1747

Petitions to revive under 37 CFR 1.137, or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.