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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/394,340	08/04/2021	Gregory Ellis	1001-US2

CONFIRMATION NO. 7359

PUBLICATION NOTICE



OC000000131580845

173064
Gregory Ellis
PO Box 86924
Portland, OR 97286

Title:Delivery System For Ayahuasca-Like Substances

Publication No.US-2022-0031966-A1

Publication Date:02/03/2022

NOTICE OF PUBLICATION OF APPLICATION

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.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently <https://portal.uspto.gov/pair/PublicPair>. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101



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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/394,340	02/01/2022	11235110	1001-US2	7359

173064 7590 01/12/2022
Gregory Ellis
PO Box 86924
Portland, OR 97286

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

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

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

INVENTOR(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional inventors):

Gregory Ellis, Portland, OR;

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Change(s) applied to document, /C.H.J./ 12/20/2021	Application Number		17394340
	Filing Date		2021-08-04
	First Named Inventor	Ellis, Gregory	
	Art Unit	na	
	Examiner Name	Raymond J. Henley III	
Attorney Docket Number		1001-US2	

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
/R.J.H./	1	20180070647		2018-04-24	Juul Labs	

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T ⁵
/R.J.H./	1	WO2017122196	WO		07/2017	SYQE Medical Ltd		☐
/R.J.H./	2	WO2016001926	WO		01/2016	SYQE Medical Ltd		☐

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NON-PATENT LITERATURE DOCUMENTS

/RAYMOND J HENLEY III/ (11/16/2021)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		
	Filing Date		2021-08-04
	First Named Inventor	Ellis, Gregory	
	Art Unit		
	Examiner Name	Not Yet Assigned	
	Attorney Docket Number		1001-US2

Change(s) applied to document, /A.C./ 12/22/2021	17	20160120220		2016-05-05	~~Philip Morris~~ Malgat et al.	
	18	20180289905		~~2018-03-24~~ 10/2018	~~Philip Morris~~ Hogwood et al.	
	19	20200360239		2020-11-19	Eric Campos	

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1							☐

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NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	BLACK, LESTER, New on the Black Market: Vape Pens Full of DMT, The Stranger, August 15, 2018. United States.	☐
	2	VAPOR VANITY STAFF, DMT Vape Pens: What You Need to Know, Vapor Vanity, May 12, 2019.	☐

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

EXAMINER SIGNATURE

Examiner Signature	/RAYMOND J HENLEY III/ (11/16/2021)	Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		
Filing Date		2021-08-04
First Named Inventor	Ellis, Gregory	
Art Unit		
Examiner Name	Not Yet Assigned	
Attorney Docket Number		1001-US2

Change(s) applied to document, /A.C./ 12/22/2021	6	20200178616		2020-06-11	~~KOY Technologies~~ Yu	
	7	20170095624		2017-04-06	~~SYQE Medical~~ Davidson et al.	
	8	20170106153		2017-04-20	~~SYQE Medical~~ Davidson et al.	
	9	20170119979		2017-05-04	~~SYQE Medical~~ Davidson et al.	
	10	20170119981		2017-05-04	~~SYQE Medical~~ Davidson et al.	
	11	20170127727		2017-05-11	~~SYQE Medical~~ Davidson et al.	
	12	20170157343		2017-06-08	~~SYQE Medical~~ Davidson et al.	
	13	20170203058		2017-07-20	~~SYQE Medical~~ Davidson et al.	
	14	20180042305		2018-02-15	~~Phillip Morris~~ Hogwood et al.	
	15	20160081395		2016-03-24	~~Phillip Morris~~ Thorens et al.	
	16	20180042304		2018-02-15	~~Phillip Morris~~ Hogwood et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		17/394,340
	Filing Date		2021-08-04
	First Named Inventor	Ellis, Gregory	
	Art Unit	1629	
	Examiner Name	Not Yet Assigned	
	Attorney Docket Number	1001-US2	

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					
If you wish to add additional U.S. Patent citation information please click the Add button.						
U.S.PATENT APPLICATION PUBLICATIONS						
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
Change(s) applied to document, /A.C./ 12/22/2021	1	20190290862		2019-09-26	~~SYQE Medical~~ Davidson et al.	
	2	20190001087		2019-01-03	~~SYQE Medical~~ Davidson et al.	
	3	20190009039		2019-01-10	~~SYQE Medical~~ Davidson et al.	
	4	20180318529		2018-11-08	~~SYQE Medical~~ Davidson et al.	
	5	20180104425		2018-04-18	~~Philip Morris~~ Hogwood et al.	

/RAYMOND J HENLEY III/ (11/16/2021)

PART B – FEE(S) TRANSMITTAL

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

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

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

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

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

Gregory Ellis
 PO Box 86924
 Portland, OR 97286

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

Certificate of Mailing or Transmission

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

Gregory Ellis	(Typed or printed name)
/Gregory Ellis/	(Signature)
2021-12-21	(Date)

APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
17/394,340	2021-08-04	Gregory Ellis	1001-US2	7359

TITLE OF INVENTION:

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
Nonprovisional	Micro	\$300	\$0	\$0	\$300	2021-03-21

EXAMINER	ART UNIT	CLASS-SUBCLASS
Henley III, Raymond J.	1629	128-200140

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363) ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. Use of a Customer Number is required.	2. For printing on the patent front page, list (1) The names of up to 3 registered patent attorneys or agents OR, alternatively, 1. (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2. 3.
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3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

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

(A) NAME OF ASSIGNEE

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

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government4a. Fees Submitted: ☒ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

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

☒ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

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

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29. NOTE: Absent a valid Certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ☐ 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 as a notification of loss of entitlement to micro entity status.
- ☐ Applicant changing to regular undiscounted fee status. NOTE: Checking this box will be taken as a notification of loss of entitlement to small or micro entity status, as applicable.

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

Authorized Signature /Gregory Ellis/

Date 2021-12-21

Typed or printed name Gregory Ellis

Registration No. 56186

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

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

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

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

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

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

Electronic Patent Application Fee Transmittal				
Application Number:		17394340		
Filing Date:		04-Aug-2021		
Title of Invention:		Delivery System For Ayahuasca-Like Substances		
First Named Inventor/Applicant Name:		Gregory Ellis		
Filer:		Gregory Ellis		
Attorney Docket Number:		1001-US2		
Filed as Micro 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:				
UTILITY ISSUE FEE	3501	1	300	300

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				300

Electronic Acknowledgement Receipt

EFS ID:	44561264
Application Number:	17394340
International Application Number:	
Confirmation Number:	7359
Title of Invention:	Delivery System For Ayahuasca-Like Substances
First Named Inventor/Applicant Name:	Gregory Ellis
Customer Number:	173064
Filer:	Gregory Ellis
Filer Authorized By:	
Attorney Docket Number:	1001-US2
Receipt Date:	20-DEC-2021
Filing Date:	04-AUG-2021
Time Stamp:	13:35:08
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$ 300
RAM confirmation Number	E2021BJD36323835
Deposit Account	
Authorized User	

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

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	1001-US2_issue.pdf	283651	no	2
			4211759705a5f10d66865e226e94b69f2f5c4664		
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	37251	no	2
			3d1905c6691be9396b574248e3ac389668d8015f		
Warnings:					
Information:					
Total Files Size (in bytes):			320902		
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. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					



UNITED STATES PATENT AND TRADEMARK OFFICE

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NOTICE OF ALLOWANCE AND FEE(S) DUE

173064 7590 12/20/2021
Gregory Ellis
PO Box 86924
Portland, OR 97286

EXAMINER	
HENLEY III, RAYMOND J	
ART UNIT	PAPER NUMBER
1629	

DATE MAILED: 12/20/2021

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/394,340	08/04/2021	Gregory Ellis	1001-US2	7359

TITLE OF INVENTION: Delivery System For Ayahuasca-Like Substances

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	MICRO	\$300	\$0.00	\$0.00	\$300	03/21/2022

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

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

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

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

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

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

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

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

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

PART B - FEE(S) TRANSMITTAL

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

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
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By fax, send to: (571)-273-2885

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

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

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

173064 7590 12/20/2021
Gregory Ellis
PO Box 86924
Portland, OR 97286

Certificate of Mailing or Transmission

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/394,340	08/04/2021	Gregory Ellis	1001-US2	7359

TITLE OF INVENTION: Delivery System For Ayahuasca-Like Substances

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	MICRO	\$300	\$0.00	\$0.00	\$300	03/21/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
HENLEY III, RAYMOND J	1629	128-200140

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

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

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

2 _____

3 _____

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

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

(A) NAME OF ASSIGNEE

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

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

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

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

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

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

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

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

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

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

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

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

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/394,340	08/04/2021	Gregory Ellis	1001-US2	7359
173064	7590	12/20/2021	EXAMINER	
Gregory Ellis PO Box 86924 Portland, OR 97286			HENLEY III, RAYMOND J	
			ART UNIT	PAPER NUMBER
			1629	
DATE MAILED: 12/20/2021				

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

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

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

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

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

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

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

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

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

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

Notice of Allowability	Application No. 17/394,340	Applicant(s) Ellis, Gregory	
	Examiner RAYMOND J HENLEY III	Art Unit 1629	AIA (FITF) Status Yes

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

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

1. ☒ This communication is responsive to Applicant's amendment/remarks filed December 03, 2021.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 1-20. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. ____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

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

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

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

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

Attachment(s)

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

/RAYMOND J HENLEY III/ Primary Examiner, Art Unit 1629	The drawings filed August 04, 2021 are accepted.
---	--

<i>Search Notes</i> 	Application/Control No. 17/394,340	Applicant(s)/Patent Under Reexamination Ellis, Gregory
	Examiner RAYMOND J HENLEY III	Art Unit 1629

CPC - Searched*		
Symbol	Date	Examiner
A61M 11/00; A61K 31/40	11/16/2021	RJH
updated	12/13/2021	RJH

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner
128	200.14	11/16/2021	RJH
514	415	11/16/2021	RJH
	updated	12/13/2021	RJH

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

Search Notes		
Search Notes	Date	Examiner
EAST/PALM Applicant/Inventor search	11/16/2021	RJH
STN art search, (summary in file)	11/16/2021	RJH
updated	12/13/2021	RJH

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	See STN search noted above	12/13/2021	RJH

/RAYMOND J HENLEY III/ Primary Examiner, Art Unit 1629	
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Issue Classification 	Application/Control No. 17/394,340	Applicant(s)/Patent Under Reexamination Ellis, Gregory
	Examiner RAYMOND J HENLEY III	Art Unit 1629

CPC						
Symbol					Type	Version
A61M	/	11	/	042	F	2014-02-04
A61K	/	31	/	4045	I	2013-01-01
A61K	/	47	/	10	I	2013-01-01
C07B	/	2200	/	05	A	2013-01-01
A61M	/	2205	/	8206	A	2013-01-01

CPC Combination Sets					
Symbol				Type	Version
	/		/		

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	20	
/RAYMOND J HENLEY III/ Primary Examiner, Art Unit 1629	13 December 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

Issue Classification 	Application/Control No. 17/394,340	Applicant(s)/Patent Under Reexamination Ellis, Gregory
	Examiner RAYMOND J HENLEY III	Art Unit 1629

INTERNATIONAL CLASSIFICATION			
CLAIMED			
A61M	/	11	/ 00
A61K	/	31	/ 40

NON-CLAIMED			
	/		/

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS
128	200.14

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					
514	415					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	20	
/RAYMOND J HENLEY III/ Primary Examiner, Art Unit 1629	13 December 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

Issue Classification 	Application/Control No. 17/394,340	Applicant(s)/Patent Under Reexamination Ellis, Gregory
	Examiner RAYMOND J HENLEY III	Art Unit 1629

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47															
CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 20	
/RAYMOND J HENLEY III/ Primary Examiner, Art Unit 1629 (Primary Examiner) _____ (Date) 13 December 2021		O.G. Print Claim(s) 1	O.G. Print Figure NONE

<i>Index of Claims</i> 	Application/Control No. 17/394,340	Applicant(s)/Patent Under Reexamination Ellis, Gregory
	Examiner RAYMOND J HENLEY III	Art Unit 1629

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS										
☒ Claims renumbered in the same order as presented by applicant					☐ CPA		☐ T.D.		☐ R.1.47	
CLAIM		DATE								
Final	Original	11/16/2021	12/13/2021							
	1	✓	=							
	2	✓	=							
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<i>Index of Claims</i> 	Application/Control No. 17/394,340	Applicant(s)/Patent Under Reexamination Ellis, Gregory
	Examiner RAYMOND J HENLEY III	Art Unit 1629

CLAIM		DATE								
Final	Original	11/16/2021	12/13/2021							
	43	-	-							
	44	-	-							
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	88	-	-							
	89	-	-							

Bibliographic Data

Application No: 17/394,340

Foreign Priority claimed: ☐ Yes ☒ No

35 USC 119 (a-d) conditions met: ☐ Yes ☒ No ☐ Met After Allowance

Verified and Acknowledged: /RAYMOND J HENLEY III/

Examiner's Signature

Initials

Title: Delivery System For Ayahuasca-Like Substances

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
08/04/2021	128	1629	1001-US2
RULE			

APPLICANTS

INVENTORS

Gregory Ellis, Portland, OR, UNITED STATES

CONTINUING DATA

This application is a CON of PCT/US21/42123 07/18/2021

PCT/US21/42123 has PRO of 63144923 02/02/2021

PCT/US21/42123 has PRO of 63058444 07/29/2020

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

08/17/2021

**** MICRO ENTITY ****

STATE OR COUNTRY

UNITED STATES

ADDRESS

Gregory Ellis

PO Box 86924

Portland, OR 97286

UNITED STATES

FILING FEE RECEIVED

\$1,540

(FILE 'HOME' ENTERED AT 13:01:34 ON 16 NOV 2021)

D CLUSTER
D CLUSTER .PHARM .PHARMACEUTICAL
D SET

FILE 'CAPLUS' ENTERED AT 13:01:44 ON 16 NOV 2021

L1 28034 SEA SPE=ON ABB=ON PLU=ON INHALER? OR VAPORIZER? OR NEBULIZER
?
L2 489 SEA SPE=ON ABB=ON PLU=ON MOUTH (W) PIECE
L3 4028 SEA SPE=ON ABB=ON PLU=ON MOUTHPIECE
L4 4442 SEA SPE=ON ABB=ON PLU=ON L3 OR L2
L5 720 SEA SPE=ON ABB=ON PLU=ON L1 AND L4
L6 111959 SEA SPE=ON ABB=ON PLU=ON APERTURE?
L7 31 SEA SPE=ON ABB=ON PLU=ON L5 AND L6
L8 5980988 SEA SPE=ON ABB=ON PLU=ON ELECTRIC? OR POWER? OR (POWER (W)
(UNIT OR SOURCE))
L9 144 SEA SPE=ON ABB=ON PLU=ON L5 AND L8
L10 134406 SEA SPE=ON ABB=ON PLU=ON CHAMBERS
L11 1 SEA SPE=ON ABB=ON PLU=ON L9 AND L10
L12 1753 SEA SPE=ON ABB=ON PLU=ON (AYAHUASCA OR DIMETHYLTRYPTAMINE
OR "5-METHOXY-N,N-DIMETHYLTRYPTAMINE" OR "2-5-DIMETHOXY-4-BROMO
PHENETHYLAMINE")
L13 0 SEA SPE=ON ABB=ON PLU=ON L5 AND L12

FILE 'USPATFULL' ENTERED AT 13:08:38 ON 16 NOV 2021

L14 6338 SEA SPE=ON ABB=ON PLU=ON L1 (P) L4
L15 21 SEA SPE=ON ABB=ON PLU=ON L14 AND L12
L16 3958 SEA SPE=ON ABB=ON PLU=ON L14 AND L8
L17 450 SEA SPE=ON ABB=ON PLU=ON (((INHALER?/TI,AB,CLM OR VAPORIZER?
/TI,AB,CLM OR NEBULIZER?/TI,AB,CLM) (P) ((MOUTHPIECE/TI,AB,CLM)
OR (MOUTH/TI,AB,CLM (W) PIECE/TI,AB,CLM))) AND (ELECTRIC?/TI,A
B,CLM OR POWER?/TI,AB,CLM OR (POWER/TI,AB,CLM (W) (UNIT/TI,AB,C
LM OR SOURCE/TI,AB,CLM))))
L18 1 SEA SPE=ON ABB=ON PLU=ON L17 AND L12
L19 325 SEA SPE=ON ABB=ON PLU=ON L17 AND CHAMBER?
L20 569840 SEA SPE=ON ABB=ON PLU=ON CHAMBER?/TI,AB,CLM
L21 193 SEA SPE=ON ABB=ON PLU=ON L19 AND L20
L22 39 SEA SPE=ON ABB=ON PLU=ON L21 AND PHARMACEUTICAL?

Electronic Acknowledgement Receipt

EFS ID:	44435084
Application Number:	17394340
International Application Number:	
Confirmation Number:	7359
Title of Invention:	Delivery System For Ayahuasca-Like Substances
First Named Inventor/Applicant Name:	Gregory Ellis
Customer Number:	173064
Filer:	Gregory Ellis
Filer Authorized By:	
Attorney Docket Number:	1001-US2
Receipt Date:	03-DEC-2021
Filing Date:	04-AUG-2021
Time Stamp:	20:33:38
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment/Req. Reconsideration-After Non-Final Reject	1001-US2_resNFOA.pdf	170410	no	9
			3ca79f8b354fc4210ae4ade13a2bc33367905d54		

Warnings:

Information:	
Total Files Size (in bytes):	170410
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. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.	

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Ellis, Gregory

Confirmation No.: 7359

Application No.: 17/394,340

Art Unit: 1629

Filed: 08/04/2021

Examiner: Henley III, Raymond

For: Delivery System for Ayahuasca-
Like Substances

Amendment and Response to NFOA

Mail Stop Amendment
Commission for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

This paper is being submitted in response to the Non-Final Office Action mailed November 19, 2021, and is timely filed on or before February 19, 2022.

Amendment to the Specification begins on page 2 of this paper.

Amendments to the Claims begin on page 3 of this paper.

Remarks begin on page 6 of this paper.

AMENDMENTS TO THE SPECIFICATION

Please replace paragraph [0086] with the following:

[0086] A skilled artisan will appreciate that other methods of making the ayahuasca-like substances of the present invention are possible, including but not limited to the extraction and/or purification from plants and other natural substances. Dimethyltryptamine is found in many naturally occurring substances, including but not limited to, *Mimosa hostilis*, *Mimosa tenuiflora*, ~~*Banisteriopsis caapi*~~, *Phalaris arundinacea*, *Phalaris aquatica*, *Diplopterys cabrerana*, *Psychotria viridis*, *Acacia confusa*, *Anadenanthera peregrina*, and *Anadenanthera colubrina*. Methods of extracting dimethyltryptamine from natural substances are well known in the art, and may include the non-limiting methods incorporating the use of a non-polar hydrocarbon solvent and a subsequent alkaline purification, or an acid-base extraction.

AMENDMENTS TO THE CLAIMS

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

Listing of Claims:

Claim 1. (Currently amended) A device for the delivery of ~~an ayahuasca-like~~ a substance[[,]] comprising: a chamber comprising at least one vaporizable formulation wherein the vaporizable formulation comprises the ~~ayahuasca-like~~ substance and wherein the substance comprises one or more of dimethyltryptamine, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine.

Claim 2. (Original) The device of claim 1 wherein the chamber comprises a top portion adapted for coupling to a mouthpiece wherein the top portion of the chamber comprises at least one aperture adapted to permit flow of air, liquid, solids, or vapor between the top portion of the chamber and the mouthpiece.

Claim 3. (Original) The device of claim 2 additionally comprising a mouthpiece coupled to the top portion of the chamber wherein the mouthpiece comprises a top aperture, a central open bore, a bottom portion comprising an aperture, and wherein the bottom portion of the mouthpiece is coupled to the top portion of the chamber.

Claim 4. (Original) The device of claim 3 additionally comprising at least one seal situated between the bottom portion of the mouthpiece comprising an aperture and the top portion of the chamber.

Claim 5. (Original) The device of claim 2 wherein the mouthpiece is releasably coupled to the top portion of the chamber.

Claim 6. (Original) The device of claim 2 wherein the mouthpiece is lockably coupled to the top portion of the chamber.

Claim 7. (Original) The device of claim 1 wherein the chamber comprises a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the vaporizable formulation.

Claim 8. (Original) The device of claim 7 wherein the chamber is coupled to the power unit capable of providing power to vaporize the vaporizable formulation.

Claim 9. (Original) The device of claim 8 wherein the chamber is releasably coupled to the power unit.

Claim 10. (Original) The device of claim 8 wherein the chamber is lockably coupled to the power unit.

Claim 11. (Original) The device of claim 1 wherein the chamber comprises one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector.

Claim 12. (Original) The device of claim 11 wherein the chamber comprises a 510 connector.

Claim 13. (Original) The device of claim 1 wherein the chamber is transparent to permit visualization of levels of the vaporizable formulation.

Claim 14. (Original) The device of claim 1 wherein the chamber is refillable.

Claim 15. (Currently amended) The device of claim 1 wherein the ~~ayahuasca-like substance~~ or vaporizable formulation further comprises ~~one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine.~~

Claim 16. (Currently amended) The device of claim ~~1~~ 45 wherein the ~~ayahuasca-like substance comprises~~ is dimethyltryptamine.

Claim 17. (Currently amended) The device of claim ~~1~~ 45 wherein the ~~ayahuasca-like substance comprises an isotopomer or isotopologue of~~ one or more of dimethyltryptamine, a

~~monoamine oxidase inhibitor~~, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine comprises an isotopomer or isotopologue of the one or more of dimethyltryptamine, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine.

Claim 18. (Original) The device of claim 17 wherein the isotopomer or isotopologue comprises deuterium.

Claim 19. (Currently amended) The device of claim 17 wherein the isotopomer or isotopologue of the one or more of dimethyltryptamine, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine ~~ayahuasca-like substance~~ is dimethyltryptamine comprising deuterium.

Claim 20. (Original) The device of claim 1 wherein the vaporizable formulation comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG).

Claims 21-89 (Canceled)

REMARKS**Status of the Claims**

Claims 1-20 are pending. Claims 1, 15-17, and 19 are currently amended.

Amendments to the Specification

Paragraph [0086] is amended to remove *Banisteriopsis caapi* as a plant containing dimethyltryptamine because as described in detail below, *Banisteriopsis caapi* provides the MAOI component of ayahuasca, but itself does not produce or contain dimethyltryptamine.

Amendments to the Claims

Claim 1 is amended to recite that the delivery device comprises a substance wherein the substance comprises one or more of dimethyltryptamine, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. Support for this amendment can be found throughout the specification, e.g., in paragraphs [0007], [0082], and [0083] of the specification; and in original claim 15 as filed.

Claim 15 is amended for clarity to recite that the vaporizable formulation further comprises a monoamine oxidase inhibitor. Support for this amendment can be found throughout the specification, e.g., in paragraphs [0007], [0009], and [0076] of the specification; and in original claim 15 as filed.

Claim 16 is amended for clarity and to perfect antecedence.

Claim 17 is amended for clarity to recite that the substance comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. Support for this amendment can be found throughout the specification, e.g., in paragraphs [0007] and [0083] of the specification; and in original claim 17 as filed.

Claim 19 is amended for clarity and to perfect antecedence.

Applicant submits that no new matter has been added resulting from the amendments made herein.

Rejection under 35 USC § 102 - Novelty

Claims 1-20 stand rejected under 35 USC § 102(a)(1) as being anticipated by SYQE Medical Ltd., (WO2017/122196) ("SYQE"). In particular, the Action alleges that "SYQE discloses a device for the delivery of any ayahuasca-like substance, comprising: a chamber comprising at least one vaporizable formulation wherein the vaporizable formulation comprises the ayahuasca-like substance (p. 6 line 8, p. 28 lines 13-14)" (Action, page 2, last paragraph).

A claim is anticipated if each and every element as set forth in the claim is found in a single prior art reference. MPEP 2131. A claimed element is inherently present if that element is a necessary feature or result of a prior art embodiment. MPEP 2112. "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Oelrich*, 666 F.2d 578, 581-82 (CCPA 1981; emphasis in original); see *also* MPEP 2112 IV. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990; emphasis in original). See MPEP 2112.

The amended claims recite a device for the delivery of a substance wherein the substance comprises one or more of dimethyltryptamine, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. SYQE does not describe any of these substances explicitly or inherently.

SYQE describes a delivery device having source material "comprising at least one plant material..." (SYQE, page 27, line 6) wherein "Ayahuasca (*Banisteriopsis caapi*)" is a member of the described plant material Markush group (SYQE, page 28, lines 13-14). Ayahuasca is not plant material, but instead is colloquial nomenclature describing a mixture comprising two components: dimethyltryptamine and a monoamine oxidase inhibitor (MAOI) (see, e.g., Lopes Santos *et al.*¹; Pic-Taylor *et al.*²; or Morales-Garcia *et al.*³). Accordingly, the plant material described in SYQE is *Banisteriopsis caapi*, not ayahuasca.

¹ <https://www.mdpi.com/2223-7747/9/7/870>

² <https://pubmed.ncbi.nlm.nih.gov/26049017/>

³ <https://www.nature.com/articles/s41598-017-05407-9>

However, *Banisteriopsis caapi* does not contain or produce any of dimethyltryptamine, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. Instead, *Banisteriopsis caapi* contains and provides the MAOI component of ayahuasca (see, e.g., Lopes Santos *et al.*; Pic-Taylor *et al.*; or Morales-Garcia *et al.*).

Thus, SYQE does not describe each of the elements recited in the amended claims because nowhere in SYQE is any of dimethyltryptamine, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine described. Furthermore, because SQYE describes *Banisteriopsis caapi*, which does not produce the substances presently recited in the amended claims, SQYE further does not inherently describe each of the elements recited in the pending claims.

Applicant thus submits that the claims as amended are not anticipated by SYQE, and respectfully requests that this rejection be withdrawn.

CONCLUSION

All stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding objections and rejections, and respectfully requests that they be withdrawn.

Applicant submits that a full and complete reply has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

Respectfully submitted

/Gregory Ellis/

Gregory Ellis
Applicant
December 03, 2021

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 17/394,340		Filing Date 08/04/2021		☐ 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 \$25 =				
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 =	*			x \$ 120 =				
☐ 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	12/03/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)			
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	x \$ 25 =	0			
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0	x \$ 120 =	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 \$ 0 =				
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x \$ 0 =				
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE				
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.						LIE				
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".						/MARSHA R RICHARDS/				
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".										
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.										

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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



UNITED STATES PATENT AND TRADEMARK OFFICE

USPTO Automated Interview Request (AIR)

Nov 24 2021

This paper requesting to schedule and/or conduct an interview is appropriate because:

I am concurrently submitting an authorization to communicate via the internet.
See form SB/0439.

Name(s) :
Gregory Ellis

S-signature:
/Gregory Ellis/

Registration Number:
56186

U.S. Application Number:
17394340

Confirmation Number:
7359

E-mail Address:
ellisgreg503@gmail.com

Phone Number:
+1 9713737677

Proposed Time of Interview:
12-3-2021 1:00 PM ET

Alternative Proposed Time(s) of Interview:
12-6-2021 1:00 PM ET

Alternative Proposed Time(s) of Interview:
12-8-2021 1:00 PM ET

Preferred Interview Type:
Video Conference

I am the applicant or applicant's representative for this application.

Topic for Discussion:
Discussion of possible claim amendments to overcome novelty rejection.

Doc Description: Internet Communications Authorized/Internet Communications Authorization Withdrawn

AUTHORIZATION FOR INTERNET COMMUNICATIONS IN A PATENT APPLICATION OR REQUEST TO WITHDRAW AUTHORIZATION FOR INTERNET COMMUNICATIONS

Application No.	17/394,340
Filing Date	2021-08-04
First Named Inventor	Ellis, Gregory
Art Unit	1629
Examiner Name	Henley III, Raymond
Practitioner Docket No.	1001-US2

I. To authorize permission for Internet Communications.

II. To withdraw authorization for Internet Communications.

I am the

☒ applicant.

 attorney or agent of record. Registration number _____

 attorney or agent acting under 37 CFR 1.34. Registration number _____

/Gregory C. Ellis/
Signature

2021-11-23
Date

Gregory C. Ellis
Typed or printed name

971.373.7677
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 1 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:	44359437
Application Number:	17394340
International Application Number:	
Confirmation Number:	7359
Title of Invention:	Delivery System For Ayahuasca-Like Substances
First Named Inventor/Applicant Name:	Gregory Ellis
Customer Number:	173064
Filer:	Gregory Ellis
Filer Authorized By:	
Attorney Docket Number:	1001-US2
Receipt Date:	23-NOV-2021
Filing Date:	04-AUG-2021
Time Stamp:	20:38:45
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Internet Communications Authorized	1001-US2_IA.pdf	96123	no	2
			b65f55e49e4c7133840b7fd58d0f3671d5d ac184		

Warnings:

Information:	
Total Files Size (in bytes):	96123
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. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.	



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/394,340	08/04/2021	Gregory Ellis	1001-US2

173064
Gregory Ellis
PO Box 86924
Portland, OR 97286

CONFIRMATION NO. 7359
POA ACCEPTANCE LETTER



Date Mailed: 11/23/2021

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 11/17/2021.

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.

/ytdemisse/



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/394,340	08/04/2021	Gregory Ellis	1001-US2	7359
173064	7590	11/19/2021	EXAMINER	
Gregory Ellis			HENLEY III, RAYMOND J	
PO Box 86924				
Portland, OR 97286				
			ART UNIT	PAPER NUMBER
			1629	
			NOTIFICATION DATE	DELIVERY MODE
			11/19/2021	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):

ellisgreg503@gmail.com

CLAIMS 1-20 ARE PRESENTED FOR EXAMINATION

Notice of Pre-AIA or AIA Status

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

Applicant's Preliminary Amendment filed August 04, 2021 and Information Disclosure Statements filed August 04, 2021 and November 03, 2021 have been received and entered into the application. Accordingly, the application papers have been amended as directed. Also, as reflected by the attached, completed copies of form PTO/SB/08, the cited references have been considered by the Examiner.

Claim Rejection - 35 USC § 102

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

A person shall be entitled to a patent unless –

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claims 1-20 are rejected under 35 U.S.C. 102(a)(1) as being anticipated by SYQE Medical Ltd., (“SYQE”), (WO 2017/122196, cited by Applicant).

SYQE discloses a device for the delivery of an ayahuasca-like substance, comprising: a chamber comprising at least one vaporizable formulation wherein the vaporizable formulation comprises the ayahuasca-like substance (p. 6 line 8, p. 28 lines 13-14). It further discloses a method for delivering an ayahuasca-like substance (p. 28 line 13), wherein the method comprises heating a vaporizable formulation comprising the ayahuasca-like substance to vaporize at least a portion of the vaporizable formulation (p. 6 line 8).

The features of dependent claim 2, concerning a top portion of the chamber, are known from SYQE (claim 26, fig. 5, ref. sign 510). The feature of dependent claims 3, concerning the presence of a mouthpiece, is known from SYQE (claim 18). The feature of dependent claim 4, concerning the presence of at least one seal, are known from SYQE (fig. 21A-C). The feature of dependent claim 5, concerning that the mouthpiece is releasably coupled, is known from SYQE (p. 67 lines 5-15). The feature of dependent claim 6, concerning that the mouthpiece is lockably coupled, is known from SYQE (fig. 21A-C).

Further, the feature of dependent claim 7, concerning a bottom portion of the chamber, are known from SYQE (fig. 10B, ref. sign 1006). The feature of dependent claim 8, concerning that the chamber is coupled to the power unit, is known from SYQE (fig. 10B). The feature of dependent claim 9, concerning that the chamber is releasably coupled to the power unit, is known from SYQE (claim 22). The feature of dependent claims 10, concerning that the chamber is lockably coupled to the power unit, is known from SYQE, (claim 22). The features of dependent claims 11 and 12, concerning that the chamber comprises one or several connectors, are known from SYQE (p. 40 lines 7-23). The features of dependent claim 13, concerning that the chamber is transparent, is known from SYQE (p. 46 line 23). The feature of dependent claim 14, concerning that the chamber is refillable, is known from SYQE (p. 10 lines 12-15). The features of dependent claims 15-20, concerning the substance, propylene glycol (PG) and/or vegetable glycerin (VG) or the vaporizable formulation, are also known from SYQE (p. 27 line 5 — p. 28 line 29 and p. 43 lines 29-30).

Accordingly, for the above reasons, the claims are deemed properly rejected and none of the claims are currently in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RAYMOND J HENLEY III whose telephone number is (571)272-0575. The examiner can normally be reached M-F 6-2:30pm EST.

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

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey S Lundgren can be reached on 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/RAYMOND J HENLEY III/
Primary Examiner, Art Unit 1629
November 16, 2021

<i>Index of Claims</i> 	Application/Control No. 17/394,340	Applicant(s)/Patent Under Reexamination Ellis, Gregory
	Examiner RAYMOND J HENLEY III	Art Unit 1629

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS										
☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47										
CLAIM		DATE								
Final	Original	11/16/2021								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	✓								
	6	✓								
	7	✓								
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<i>Index of Claims</i> 	Application/Control No. 17/394,340	Applicant(s)/Patent Under Reexamination Ellis, Gregory
	Examiner RAYMOND J HENLEY III	Art Unit 1629

CLAIM		DATE								
Final	Original	11/16/2021								
	43	-								
	44	-								
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<i>Search Notes</i> 	Application/Control No. 17/394,340	Applicant(s)/Patent Under Reexamination Ellis, Gregory
	Examiner RAYMOND J HENLEY III	Art Unit 1629

CPC - Searched*		
Symbol	Date	Examiner
A61M 11/00; A61K 31/40	11/16/2021	RJH

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner
128	200.14	11/16/2021	RJH
514	415	11/16/2021	RJH

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

Search Notes		
Search Notes	Date	Examiner
EAST/PALM Applicant/Inventor search	11/16/2021	RJH
STN art search, (summary in file)	11/16/2021	RJH

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

/RAYMOND J HENLEY III/ Primary Examiner, Art Unit 1629	
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(FILE 'HOME' ENTERED AT 13:01:34 ON 16 NOV 2021)

D CLUSTER
D CLUSTER .PHARM .PHARMACEUTICAL
D SET

FILE 'CAPLUS' ENTERED AT 13:01:44 ON 16 NOV 2021

L1 28034 SEA SPE=ON ABB=ON PLU=ON INHALER? OR VAPORIZER? OR NEBULIZER
?
L2 489 SEA SPE=ON ABB=ON PLU=ON MOUTH (W) PIECE
L3 4028 SEA SPE=ON ABB=ON PLU=ON MOUTHPIECE
L4 4442 SEA SPE=ON ABB=ON PLU=ON L3 OR L2
L5 720 SEA SPE=ON ABB=ON PLU=ON L1 AND L4
L6 111959 SEA SPE=ON ABB=ON PLU=ON APERTURE?
L7 31 SEA SPE=ON ABB=ON PLU=ON L5 AND L6
L8 5980988 SEA SPE=ON ABB=ON PLU=ON ELECTRIC? OR POWER? OR (POWER (W)
(UNIT OR SOURCE))
L9 144 SEA SPE=ON ABB=ON PLU=ON L5 AND L8
L10 134406 SEA SPE=ON ABB=ON PLU=ON CHAMBERS
L11 1 SEA SPE=ON ABB=ON PLU=ON L9 AND L10
L12 1753 SEA SPE=ON ABB=ON PLU=ON (AYAHUASCA OR DIMETHYLTRYPTAMINE
OR "5-METHOXY-N,N-DIMETHYLTRYPTAMINE" OR "2-5-DIMETHOXY-4-BROMO
PHENETHYLAMINE")
L13 0 SEA SPE=ON ABB=ON PLU=ON L5 AND L12

FILE 'USPATFULL' ENTERED AT 13:08:38 ON 16 NOV 2021

L14 6338 SEA SPE=ON ABB=ON PLU=ON L1 (P) L4
L15 21 SEA SPE=ON ABB=ON PLU=ON L14 AND L12
L16 3958 SEA SPE=ON ABB=ON PLU=ON L14 AND L8
L17 450 SEA SPE=ON ABB=ON PLU=ON (((INHALER?/TI,AB,CLM OR VAPORIZER?
/TI,AB,CLM OR NEBULIZER?/TI,AB,CLM) (P) ((MOUTHPIECE/TI,AB,CLM)
OR (MOUTH/TI,AB,CLM (W) PIECE/TI,AB,CLM))) AND (ELECTRIC?/TI,A
B,CLM OR POWER?/TI,AB,CLM OR (POWER/TI,AB,CLM (W) (UNIT/TI,AB,C
LM OR SOURCE/TI,AB,CLM))))
L18 1 SEA SPE=ON ABB=ON PLU=ON L17 AND L12
L19 325 SEA SPE=ON ABB=ON PLU=ON L17 AND CHAMBER?
L20 569840 SEA SPE=ON ABB=ON PLU=ON CHAMBER?/TI,AB,CLM
L21 193 SEA SPE=ON ABB=ON PLU=ON L19 AND L20
L22 39 SEA SPE=ON ABB=ON PLU=ON L21 AND PHARMACEUTICAL?

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17/394,340
Filing Date	2021-08-04
First Named Inventor	Ellis, Gregory
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	1001-US2

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20190290862		2019-09-26	SYQE Medical	
	2	20190001087		2019-01-03	SYQE Medical	
	3	20190009039		2019-01-10	SYQE Medical	
	4	20180318529		2018-11-08	SYQE Medical	
	5	20180104425		2018-04-18	Phillip Morris	

/RAYMOND J HENLEY III/ (11/16/2021)

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		
Filing Date		2021-08-04
First Named Inventor	Ellis, Gregory	
Art Unit		
Examiner Name	Not Yet Assigned	
Attorney Docket Number		1001-US2

6	20200178616		2020-06-11	KSY Technologies	
7	20170095624		2017-04-06	SYQE Medical	
8	20170106153		2017-04-20	SYQE Medical	
9	20170119979		2017-05-04	SYQE Medical	
10	20170119981		2017-05-04	SYQE Medical	
11	20170127727		2017-05-11	SYQE Medical	
12	20170157343		2017-06-08	SYQE Medical	
13	20170203058		2017-07-20	SYQE Medical	
14	20180042305		2018-02-15	Phillip Morris	
15	20160081395		2016-03-24	Phillip Morris	
16	20180042304		2018-02-15	Phillip Morris	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number			
	Filing Date		2021-08-04	
	First Named Inventor	Ellis, Gregory		
	Art Unit			
	Examiner Name	Not Yet Assigned		
	Attorney Docket Number		1001-US2	

	17	20160120220		2016-05-05	Phillip Morris	
	18	20180289905		2016-03-24	Phillip Morris	
	19	20200360239		2020-11-19	Eric Campos	

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	BLACK, LESTER, New on the Black Market: Vape Pens Full of DMT, The Stranger, August 15, 2018. United States.	☐
	2	VAPOR VANITY STAFF, DMT Vape Pens: What You Need to Know, Vapor Vanity, May 12, 2019.	☐

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

EXAMINER SIGNATURE

Examiner Signature	/RAYMOND J HENLEY III/ (11/16/2021)	Date Considered	
--------------------	-------------------------------------	-----------------	--

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

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		
Filing Date		2021-08-04
First Named Inventor	Ellis, Gregory	
Art Unit		
Examiner Name	Not Yet Assigned	
Attorney Docket Number		1001-US2

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

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2021-08-04
First Named Inventor	Ellis, Gregory
Art Unit	
Examiner Name	Not Yet Assigned
Attorney Docket Number	1001-US2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

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

OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Gregory Ellis	Date (YYYY-MM-DD)	2021-08-04
Name/Print	Gregory Ellis	Registration Number	56,186

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

Bibliographic Data

Application No: 17/394,340

Foreign Priority claimed: ☐ Yes ☒ No

35 USC 119 (a-d) conditions met: ☐ Yes ☒ No ☐ Met After Allowance

Verified and Acknowledged: /RAYMOND J HENLEY III/

Examiner's Signature

Initials

Title: Delivery System For Ayahuasca-Like Substances

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
08/04/2021	128	1629	1001-US2
RULE			

APPLICANTS

INVENTORS

Gregory Ellis, Portland, OR, UNITED STATES

CONTINUING DATA

This application is a CON of PCT/US21/42123 07/18/2021

PCT/US21/42123 has PRO of 63144923 02/02/2021

PCT/US21/42123 has PRO of 63058444 07/29/2020

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

08/17/2021

**** MICRO ENTITY ****

STATE OR COUNTRY

UNITED STATES

ADDRESS

Gregory Ellis

PO Box 86924

Portland, OR 97286

UNITED STATES

FILING FEE RECEIVED

\$1,540

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		17394340
	Filing Date		2021-08-04
	First Named Inventor	Ellis, Gregory	
	Art Unit	na	
	Examiner Name	Raymond J. Henley III	
	Attorney Docket Number	1001-US2	

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS						
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
/R.J.H/	1	20180070647		2018-04-24	Juul Labs	

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS								
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T ⁵
/R.J.H/	1	WO2017122196	WO			SYQE Medical Ltd		☐
/R.J.H/	2	WO2016001926	WO			SYQE Medical Ltd		☐

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS								
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/RAYMOND J HENLEY III/ (11/16/2021)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		17394340
	Filing Date		2021-08-04
	First Named Inventor	Ellis, Gregory	
	Art Unit	na	
	Examiner Name	na	
	Attorney Docket Number	1001-US2	

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
/R. J. H/	1	PALHANO-FONTES, FERNANDA et al, Rapid antidepressant effects of the psychedelic ayahuasca in treatment-resistant depression: a randomized placebo-controlled trial, Psychological Medicine 49, 655-, 24 April 2018, https://doi.org/10.1017/S0033291718001356	☐
/R. J. H/	2	PCT Search Report for International application No. PCT/US2021/042123	☐

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

EXAMINER SIGNATURE

Examiner Signature	/RAYMOND J HENLEY III/ (11/16/2021)	Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17394340
Filing Date	2021-08-04
First Named Inventor	Ellis, Gregory
Art Unit	na
Examiner Name	na
Attorney Docket Number	1001-US2

CERTIFICATION STATEMENT

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

OR

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

☐ See attached certification statement.

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

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Gregory Ellis/	Date (YYYY-MM-DD)	2021-11-03
Name/Print	Gregory Ellis	Registration Number	56,186

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

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
17/394,340	2021-08-04

(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:

173064

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):

- ☒ 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

/Gregory C. Ellis/

Date (Optional)

2021-11-17

Name

Gregory C. Ellis

Title

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 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.**

Electronic Acknowledgement Receipt

EFS ID:	44311445
Application Number:	17394340
International Application Number:	
Confirmation Number:	7359
Title of Invention:	Delivery System For Ayahuasca-Like Substances
First Named Inventor/Applicant Name:	Gregory Ellis
Customer Number:	173064
Filer:	Gregory Ellis
Filer Authorized By:	
Attorney Docket Number:	1001-US2
Receipt Date:	17-NOV-2021
Filing Date:	04-AUG-2021
Time Stamp:	22:55:06
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	1001-US2_POA.pdf	232796	no	1
			d637cac6b7e14a6293884d5ae2f67e4b6de f7334		

Warnings:

Information:	
Total Files Size (in bytes):	232796
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. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.	

Electronic Acknowledgement Receipt

EFS ID:	44201595
Application Number:	17394340
International Application Number:	
Confirmation Number:	7359
Title of Invention:	Delivery System For Ayahuasca-Like Substances
First Named Inventor/Applicant Name:	Gregory Ellis
Customer Number:	173064
Filer:	Gregory Ellis
Filer Authorized By:	
Attorney Docket Number:	1001-US2
Receipt Date:	04-NOV-2021
Filing Date:	04-AUG-2021
Time Stamp:	10:48:40
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	Vapor_Vanity.pdf	490930	no	9
			f079879871fa28b8a50738f541e928c60ce3095a		

Warnings:

Information:					
2	Non Patent Literature	Stranger.pdf	421053	no	14
			df73ac36f70b4cfd6e0de10a5cbd53c43f9a5019		
Warnings:					
Information:					
			Total Files Size (in bytes):	911983	
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. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		17394340
	Filing Date		2021-08-04
	First Named Inventor	Ellis, Gregory	
	Art Unit	na	
	Examiner Name	na	
	Attorney Docket Number	1001-US2	

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS						
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20180070647		2018-04-24	Juul Labs	

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS								
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1	WO2017122196	WO			SYQE Medical Ltd		☐
	2	WO2016001926	WO			SYQE Medical Ltd		☐

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS								
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		17394340
	Filing Date		2021-08-04
	First Named Inventor	Ellis, Gregory	
	Art Unit	na	
	Examiner Name	na	
	Attorney Docket Number	1001-US2	

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	PALHANO-FONTES, FERNANDA et al, Rapid antidepressant effects of the psychedelic ayahuasca in treatment-resistant depression: a randomized placebo-controlled trial, Psychological Medicine 49, 655-, 24 April 2018, https://doi.org/10.1017/S0033291718001356	☐
	2	PCT Search Report for International application No. PCT/US2021/042123	☐

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

EXAMINER SIGNATURE

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

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

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

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17394340
Filing Date	2021-08-04
First Named Inventor	Ellis, Gregory
Art Unit	na
Examiner Name	na
Attorney Docket Number	1001-US2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

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

OR

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

☐ See attached certification statement.

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

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Gregory Ellis/	Date (YYYY-MM-DD)	2021-11-03
Name/Print	Gregory Ellis	Registration Number	56,186

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

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 1001-WO1	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 2021/042123	International filing date (<i>day/month/year</i>) 18 July 2021 (18.07.2021)	(Earliest) Priority Date (<i>day/month/year</i>) 29 July 2020 (29.07.2020)
Applicant ELLIS, Gregory		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the drawings to be published with the abstract is Figure No. 3

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 2021/042123

A. CLASSIFICATION OF SUBJECT MATTER		
<i>A61M 15/06 (2006.01)</i> <i>A24F 40/00 (2020.01)</i> <i>A61K 31/4045 (2006.01)</i> <i>A61P 25/18 (2006.01)</i> According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
A61M 15/00, 15/06, 11/04, A24F 40/00, 47/00, A61K 31/4045, A61P 25/18		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
PatSearch (RUPTO Internal), USPTO, PAJ, Espacenet, Information Retrieval System of FIPS		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2017/122196 A1 (SYQE MEDICAL LTD) 20.07.2017, claims 1, 5, 18, 22, 23, 26, page 6, line 8, page 10, lines 12-15, page 18, lines 26-29, page 27, line 5-page 28, line 29, page 40, lines 7-23, page 43, lines 29-30, page 67, lines 5-15, figures 5, 10B, 21A-C	1-71, 73-89
Y		72
Y	PALHANO-FONTES Fernanda et al. Rapid antidepressant effects of the psychedelic ayahuasca in treatment-resistant depression: a randomized placebo-controlled trial. Psychological Medicine 49, 655–, 24 April 2018, https://doi.org/10.1017/S0033291718001356	72
A	US 2018/0070647 A1 (JUUL LABS, INC) 15.03.2018	1-89
A	WO 2016/001926 A1 (SYQE MEDICAL, LTD) 07.01.2016	1-89
☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.		
* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "A" document defining the general state of the art which is not considered to be of particular relevance "D" document cited by the applicant in the international application "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family	
Date of the actual completion of the international search	Date of mailing of the international search report	
23 August 2021 (23.08.2021)	23 September 2021 (23.09.2021)	
Name and mailing address of the ISA/RU: Federal Institute of Industrial Property, Berezhkovskaya nab., 30-1, Moscow, G-59, GSP-3, Russia, 125993 Facsimile No: (8-495) 531-63-18, (8-499) 243-33-37	Authorized officer N. Khapsirokov Telephone No. 8(495)531-64-81	

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:

ELLIS, Gregory
PO Box 86924
Portland, OR 97286
United States of America

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 1001-WO1		Date of mailing (<i>day/month/year</i>) 23 September 2021 (23.09.2021)
FOR FURTHER ACTION See paragraph 2 below		
International application No. PCT/US 2021/042123	International filing date (<i>day/month/year</i>) 18 July 2021 (18.07.2021)	Priority date (<i>day/month/year</i>) 29 July 2020 (29.07.2020)
International Patent Classification (IPC) or both national classification and IPC A61M 15/06 (2006.01) A24F 40/00 (2020.01) A61K 31/4045 (2006.01) A61P 25/18 (2006.01)		
Applicant ELLIS, Gregory		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/RU: Federal Institute of Industrial Property, Berezhkovskaya nab., 30-1, Moscow, G-59, GSP-3, Russia, 125993 Facsimile No: +7 (495) 531-63-18, +7 (499) 243-33-37	Date of completion of this opinion 23 August 2021 (23.08.2021)	Authorized officer N. Khapsirokov Telephone No. 8(495)531-64-81
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Form PCT/ISA/237 (cover sheet) (revised January 2019)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 2021/042123

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(b)).
3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:
 - a. ☐ forming part of the international application as filed:
 - ☐ in the form of an Annex C/ST.25 text file.
 - ☐ on paper or in the form of an image file.
 - b. ☐ furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. ☐ furnished subsequent to the international filing date for the purposes of international search only:
 - ☐ in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).
 - ☐ on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US 2021/042123

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	72	YES
	Claims	1-71, 73-89	NO
Inventive step (IS)	Claims		YES
	Claims	1-89	NO
Industrial applicability (IA)	Claims	1-89	YES
	Claims		NO

2. Citations and explanations:

D1: WO 2017/122196 A1

D2: Palhano-Fontes F. et al (2019). Rapid antidepressant effects of the psychedelic ayahuasca in treatment-resistant depression: a randomized placebo-controlled trial. *Psychological Medicine* 49, 655–663. <<https://doi.org/10.1017/S0033291718001356>>

D1 discloses a device for the delivery of an ayahuasca-like substance, comprising: a chamber comprising at least one vaporizable formulation (claim 23) wherein the vaporizable formulation comprises the ayahuasca-like substance (p. 6 line 8, p. 28 lines 13-14).

D1 discloses a method for delivering an ayahuasca-like substance (p. 28 line 13), wherein the method comprises heating a vaporizable formulation (claim 5) comprising the ayahuasca-like substance to vaporize at least a portion of the vaporizable formulation (p. 6 line 8).

D1 also discloses a method of treating a psychological disorder (p. 18 lines 26-29) comprising administering to a patient an effective amount of an ayahuasca-like substance (p. 6 line 8), wherein the method comprises heating a vaporizable formulation comprising the ayahuasca-like substance to vaporize at least a portion of the vaporizable formulation (p. 6 line 8).

D1 discloses a kit comprising a chamber (claim 1) comprising at least one vaporizable formulation (claim 23) wherein the vaporizable formulation comprises an ayahuasca-like substance (p. 28 lines 13-14).

Therefore, the independent claims 1, 21, 43, 50 and 73 are not novel.

The features of dependent claims 2, 22, 51, concerning a top portion of the chamber, are known from D1 (claim 26, fig. 5, ref. sign 510).

The features of dependent claims 3, 23, 52, 74, concerning the presence of a mouthpiece, are known from D1 (claim 18).

The features of dependent claims 4, 24, 53, concerning the presence of at least one seal, are known from D1 (fig. 21A-C).

The features of dependent claims 5, 25, 54, 75, concerning that the mouthpiece is releasably coupled, are known from D1 (p. 67 lines 5-15).

The features of dependent claims 6, 26, 55, 76, concerning that the mouthpiece is lockably coupled, are known from D1 (fig. 21A-C).

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of V:

The features of dependent claims 7, 27, 56, concerning a bottom portion of the chamber, are known from D1 (fig. 10B, ref. sign 1006).

The features of dependent claims 8, 28, 57, 77, concerning that the chamber is coupled to the power unit, are known from D1 (fig. 10B).

The features of dependent claims 9, 29, 58, 78, concerning that the chamber is releasably coupled to the power unit, are known from D1 (claim 22).

The features of dependent claims 10, 30, 59, 79, concerning that the chamber is lockably coupled to the power unit, are known from D1 (claim 22).

The features of dependent claims 11, 12, 31-33, 60-62, 80-81, concerning that the chamber comprises one or several connectors, are known from D1 (p. 40 lines 7-23).

The features of dependent claims 13, 36, 65, 82, concerning that the chamber is transparent, are known from D1 (p. 46 line 23).

The features of dependent claims 14, 34, 63, 83, concerning that the chamber is refillable, are known from D1 (p. 10 lines 12-15).

The features of dependent claims 15-20, 37-41, 44-49, 66-70, 84-89, concerning the substance or the vaporizable formulation, are known from D1 (p. 27 line 5 – p. 28 line 29).

The features of dependent claims 35 and 64, concerning that the chamber is single-use, are known from D1 (p. 41 line 8).

The features of dependent claims 42 and 71, concerning that the vaporizable formulation comprises propylene glycol (PG) and/or vegetable glycerin (VG), are known from D1 (p. 43 lines 29-30).

Therefore, the dependent claims 2-20, 22-42, 44-49, 51-71, 74-89 are not novel.

D2 (abstract) discloses information about rapid antidepressant effects of the ayahuasca in treatment-resistant depression.

Thus, the dependent claim 72 does not involve an inventive step.

The claims 1-89 are industrially applicable.

Electronic Acknowledgement Receipt

EFS ID:	44199559
Application Number:	17394340
International Application Number:	
Confirmation Number:	7359
Title of Invention:	Delivery System For Ayahuasca-Like Substances
First Named Inventor/Applicant Name:	Gregory Ellis
Customer Number:	173064
Filer:	Gregory Ellis
Filer Authorized By:	
Attorney Docket Number:	1001-US2
Receipt Date:	03-NOV-2021
Filing Date:	04-AUG-2021
Time Stamp:	21:39:39
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	1001-US2_IDS_Nov21.pdf	92398	no	2
			dadd8412e5c61b8b7158eebbd97ce03f03c186cc		

Warnings:

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	1001-US2_IDS_PCT.pdf	478391 6889781341f00d419b73651b1657afce061 7136d	no	3
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Other Reference-Patent/App/Search documents	ISR.pdf	86260 46fa68e508c2fbffc06304c833070b51f6ecd 92a	no	6
Warnings:					
Information:					
4	Non Patent Literature	Palhano.pdf	388152 c464fa9429ca12c249d04e0d58562f93f2f6a 56e	no	9
Warnings:					
Information:					
Total Files Size (in bytes):			1045201		
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. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Ellis, Gregory

Confirmation No.: 7359

Application No.: 17/394,340

Art Unit: Not Yet Assigned

Filed: August 04, 2021

Examiner: Not Yet Assigned

For: Delivery System for Ayahuasca-
Like Substances

Information Disclosure Statement

Mail Stop Amendment
Commission for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

The references cited on attached form PTO/SB/08A are being called to the attention of the Examiner. In accordance with the provisions of 37 CFR §1.98(a)(2), copies of any cited U.S. Patents and U.S. Patent Application Publications are not provided. Copies of the remaining cited references, if any, are provided.

It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR §1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information. This Information Disclosure Statement is being filed before the mailing date of the first Office Action on the merits.

Applicant believes that no fee is required for submission of this statement.

Respectfully submitted

/Gregory Ellis/
Gregory Ellis
Registration No: 56,186
November 03, 2021



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/394,340	08/04/2021	Gregory Ellis	1001-US2	7359
173064	7590	11/01/2021	EXAMINER	
Gregory Ellis			CENTRAL, DOCKET	
PO Box 86924			ART UNIT	PAPER NUMBER
Portland, OR 97286			OPAP	
			NOTIFICATION DATE	DELIVERY MODE
			11/01/2021	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):

ellisgreg503@gmail.com

<i>Decision Granting Request for Prioritized Examination (Track I)</i>	Application No. 17/394,340	Applicant(s) Ellis, Gregory	
	Examiner ANGELA E WALKER	Art Unit OPET	AIA (FITF) Status Yes
1. THE REQUEST FILED <u>04 August 2021</u> 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 <u>petition for extension of time</u> to extend the time period for filing a reply; B. filing an <u>amendment to amend the application to contain more than four independent claims, more than thirty total claims</u>, or a multiple dependent claim; C. filing a <u>request for continued examination</u> ; 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 ANGELA WALKER at (571) 272-1058. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.			
/IRVIN DINGLE/ Lead Paralegal Specialist, OPET			



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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
17/394,340	08/04/2021		455	1001-US2	20	1

173064
Gregory Ellis
PO Box 86924
Portland, OR 97286

CONFIRMATION NO. 7359
UPDATED FILING RECEIPT



Date Mailed: 08/24/2021

Receipt is acknowledged of this non-provisional utility 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 FIRST INVENTOR, 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 corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction 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 provided that the request is grantable.

Inventor(s)

Gregory Ellis, Portland, OR;

Applicant(s)

Gregory Ellis, Portland, OR;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of PCT/US21/42123 07/18/2021
which claims benefit of 63/144,923 02/02/2021
and claims benefit of 63/058,444 07/29/2020

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: Yes

Permission to Access Search Results: Yes

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: 08/17/2021

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/394,340**

Projected Publication Date: 02/03/2022

Non-Publication Request: No

Early Publication Request: No

**** MICRO ENTITY ****

Title

Delivery System For Ayahuasca-Like Substances

Preliminary Class

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 Assets Control, 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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The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit <http://www.SelectUSA.gov> or call +1-202-482-6800.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 17/394,340				
APPLICATION AS FILED - PART I										
(Column 1)		(Column 2)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY				
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)			
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	80			
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A	175			
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	200			
TOTAL CLAIMS (37 CFR 1.16(j))	20	minus 20 = *				x 25 =	0.00			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1	minus 3 = *				x 120 =	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			
				TOTAL		TOTAL	455			
* If the difference in column 1 is less than zero, enter "0" in column 2.										
APPLICATION AS AMENDED - PART II										
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY		
AMENDMENT A		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x	=		x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=		x	=
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE			TOTAL ADD'L FEE	
AMENDMENT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x	=		x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=		x	=
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE			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.										



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/394,340	08/04/2021	Gregory Ellis	1001-US2

173064
Gregory Ellis
PO Box 86924
Portland, OR 97286

CONFIRMATION NO. 7359
FORMALITIES LETTER



Date Mailed: 08/18/2021

NOTICE OF OMITTED ITEM(S) IN A NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

A filing date has been accorded to the above-identified nonprovisional application papers; however, the following item(s) appear to have been omitted from the application:

- Figure(s) 2 described in the specification.

Applicant must reply to this notice within the time period set forth in this notice to avoid abandonment of this application. Applicant must select one of the three following options and the reply must comply with the requirements set forth in the selected option and any other requirements set forth in this notice. **The reply should also indicate which option applicant has selected.**

I. Petition for date of deposit: Should applicant contend that the above-noted omitted item(s) was in fact deposited in the U.S. Patent and Trademark Office (USPTO) with the nonprovisional application papers, a copy of this Notice and a petition (and the petition fee set forth in 37 CFR 1.17(f) with evidence of such deposit must be filed within **TWO MONTHS** of the date of this Notice. The petition fee will be refunded if it is determined that the item(s) was received by the USPTO. THIS TWO MONTH PERIOD IS EXTENDABLE UNDER 37 CFR 1.136(a) or (b).

Applicant should review their application file and determine whether their file differs from USPTO's records. In some situations there may be a mislabeling of the drawings and/or a failure to describe in the brief description each of the figures as labeled. See 37 CFR 1.74, 1.77(b)(9), and 1.84(u)(1).

The brief description of the drawings in the specification must correspond with the figures and the figures must be labeled in accordance with 37 CFR 1.84(u)(1). For example, if the brief description describes Figure 1 and Figure 2 only, but the drawings show Fig. 1 and Fig. 2A and Fig. 2B, then the specification must be amended to refer to Figure 2A and Figure 2B and delete the reference to Figure 2 and a substitute specification in compliance with 37 CFR 1.52, 1.121(b)(3), and 1.125, is required. As another example, if a drawing is labeled Figure 2, but there are actually multiple figures within the labeled Figure 2 having labels A, B, and C, then the drawings must be relabeled in accordance with 37 CFR 1.84(u)(1) (e.g., Fig. 2A, Fig. 2B, and Fig. 2C). If the specification does not refer to the figures as relabeled, then the specification must be amended to refer to the relabeled figures (e.g., Fig. 2A, Fig. 2B, and Fig. 2C) and a substitute specification in compliance with 37 CFR 1.52, 1.121(b)(3), and 1.125, is required. A petition for date of deposit under option I should NOT be filed in either situation or in similar situations where there is simply a mislabeling of the drawings and/or a failure to describe in the brief description each of the figures. Instead, applicant should file a reply under option III.A below (including replacement drawing sheets and/or a substitute specification as required in III.A.2).

A petition for date of deposit under option I should NOT be filed in situations where there is simply a mislabeling of the drawings and/or a failure to describe in the brief description each of the figures. Instead, applicant should file a reply under option III(A) below (including replacement drawing sheets and/or a substitute specification as described).

II. Petition for later filing date: Should applicant desire to supply the omitted item(s) and accept the date that such omitted item(s) was filed in the USPTO as the filing date of the above-identified application, a copy of this Notice, the omitted item(s), and a petition under 37 CFR 1.182 with the petition fee set forth in 37 CFR 1.17(f) requesting the later filing date must be filed within **TWO MONTHS** of the date of this Notice. THIS TWO MONTH PERIOD IS EXTENDABLE UNDER 37 CFR 1.136(a) or (b).

Applicant is advised that generally the filing fee required for an application is the filing fee in effect on the filing date accorded the application and that payment of the requisite basic filing fee on a date later than the filing date of the application requires payment of a surcharge (37 CFR 1.16(f)). To avoid processing delays and payment of a surcharge, applicant should submit any balance due for the requisite filing fee based on the later filing date being requested when submitting the omitted item(s) and the petition (and petition fee) requesting the later filing date.

III. Acceptance of application as deposited: Applicant may accept the application as deposited in the USPTO by filing an appropriate amendment as set forth in either (A) or (B) below within **TWO MONTHS** of the date of this Notice. THIS TWO MONTH PERIOD IS EXTENDABLE UNDER 37 CFR 1.136(a) or (b). The application will maintain a filing date as of the date of deposit of the application papers in the USPTO, and original application papers (i.e., the original disclosure of the invention) will include only those application papers present in the USPTO on the date of deposit. A petition is not required for this option.

(A) If applicant wants to accept the application as deposited without adding the subject matter that was in the omitted item, applicant is required to submit one or more of the following items without adding any new matter (see 35 U.S.C. 132(a)):

To remove a missing figure of the drawings or to correct the figure labeling,

- replacement drawing sheets in compliance with 37 CFR 1.121(d) to renumber the drawing figures consecutively (if necessary), and/or
- a substitute specification excluding claims in compliance with 37 CFR 1.121(b)(3) and 1.125 that amends the specification to cancel any references to any omitted drawing(s) and corrects the references in the specification to the drawing figures to correspond with any relabeled drawing figures,

A proper substitute specification in compliance with 37 CFR 1.121(b)(3) and 1.125 consists of:

- A copy of the previously-submitted specification, with deletions shown with strikethrough or brackets and insertions shown with underlining (marked-up version) unless it is indicated above that a marked-up version is not required for each of the correction(s).
- A copy of the amended specification without markings (clean version).
- A statement that the substitute specification contains no new matter, in compliance with 37 CFR 1.121(b)(3) and 1.125.

(B) Alternatively, if applicant wants to accept the application as deposited but wishes to add the subject matter in the omitted item by relying on an incorporation by reference under 37 CFR 1.57 or other portions of the original disclosure, applicant is required to submit the following without adding any new matter (see 35 U.S.C. 132(a)):

To add a missing figure of the drawings, new and replacement drawing sheets in compliance with 37 CFR 1.121(d);

If applicant is relying on an incorporation by reference under 37 CFR 1.57 to add the omitted subject matter, then applicant must also comply with the requirements of 37 CFR 1.57.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

Replies must be received in the USPTO within the set time period or must include a proper Certificate of Mailing or Transmission under 37 CFR 1.8 with a mailing or transmission date within the set time period. For more information and a suggested format, see Form PTO/SB/92 and MPEP 512.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web, including a copy of this Notice and selecting the document description "Applicant response to Pre-Exam Formalities Notice".
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

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**.

/dtdinh/

DELIVERY SYSTEM FOR AYAHUASCA-LIKE SUBSTANCES

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation under 35 USC 365(c) of International Application No. PCT/US21/42123, filed July 18, 2021, which claims priority benefit to U.S. Provisional Application No. 63/058,444, filed July 29, 2020, and U.S. Provisional Application No. 63/144,923, filed February 02, 2021, the entire contents of each of which are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

[0002] In certain jurisdictions, ayahuasca-like substances and other psychedelic medicines are being legalized or decriminalized, hence allowing for breakthrough alternative medicines and/or recreational experiences. Psychedelic research is still in its infancy, which in part is a consequence of legal barriers to such research that has existed for decades. Yet preliminary reports are encouraging. For example, it was recently reported that dimethyltryptamine, which is the active ingredient in ayahuasca, can promote the proliferation of neural stem cells and subsequent neurogenesis, thus leading to improvements in memory. Such results have significant implications for neurodegenerative disorders such as Alzheimer's, Parkinson's, and dementia (Morales-Garcia *et al.*, *Translational Psychiatry*, 10:331 (2020)).

[0003] However, the ability to distribute reliably consistent amounts and types of ayahuasca-like substances having a particular level of therapeutic or recreational quality is limited. Safety concerns may also arise when ayahuasca-like substances are obtained in a manner where the exact composition is unknown due to risks of contamination, tampering, misrepresentation, etc.

[0004] The ability to store and seal a dose-specific vaporizable formulation comprising an ayahuasca-like substance in a controlled environment with a labelled package that is easily portable provides a tremendous benefit to patients and other consumers. When

an ayahuasca-like substance comes pre-processed and stored in a dry, secure, contamination-free environment, a patient or other consumer is provided with a level of confidence and convenience that has not previously been available. The devices and methods of the present invention thus solve problems associated with both ease of use and safety, and further provide a greater degree of legitimacy so that a patient or consumer can be confident that the contents of the packaged product is in fact what is listed by the labelling.

[0005] The invention described herein provides a device, formulation, methods of use, methods of treatment of psychological disorders, and kits for the delivery of ayahuasca-like substances, which has significant commercial and medicinal potential in jurisdictions that have legalized or decriminalized psychedelic substances.

SUMMARY OF THE INVENTION

[0006] The present teachings relate to a system for the delivery of a vaporizable formulation comprising an ayahuasca-like substance.

[0007] In an embodiment, a device for the delivery of an ayahuasca-like substance is provided. The device comprises a chamber comprising at least one vaporizable formulation wherein the vaporizable formulation comprises the ayahuasca-like substance. In an embodiment, the chamber of the device comprises a top portion adapted for coupling to a mouthpiece wherein the top portion of the chamber comprises at least one aperture adapted to permit flow of air, liquid, solids, or vapor between the top portion of the chamber and the mouthpiece. In an embodiment, a mouthpiece of the device coupled to the top portion of the chamber is provided wherein the mouthpiece comprises a top aperture, a central open bore, a bottom portion comprising an aperture, and wherein the bottom portion of the mouthpiece is coupled to the top portion of the chamber. In an embodiment, at least one seal situated between the bottom portion of the mouthpiece of the device comprising an aperture and the top portion of the chamber is provided. In an embodiment, the mouthpiece of the device is releasably coupled to the top portion of the chamber. In an embodiment, the mouthpiece of the device is lockably coupled to the top portion of the chamber. In an embodiment, the chamber of

the device comprises a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the vaporizable formulation. In an embodiment, the chamber of the device is coupled to the power unit capable of providing power to vaporize the vaporizable formulation. In an embodiment, the chamber of the device is releasably coupled to the power unit. In an embodiment, the chamber of the device is lockably coupled to the power unit. In an embodiment, the chamber of the device comprises one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector. In an embodiment, the chamber of the device comprises a 510 connector. In an embodiment, the chamber of the device is transparent to permit visualization of levels of the vaporizable formulation. In an embodiment, the chamber of the device is refillable. In an embodiment, the ayahuasca-like substance or vaporizable formulation of the device comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the device comprises dimethyltryptamine. In an embodiment, the ayahuasca-like substance of the device comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the device is dimethyltryptamine comprising deuterium. In an embodiment, the vaporizable formulation of the device comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG).

[0008] In another embodiment, a method for delivering an ayahuasca-like substance is provided. In this embodiment the method comprises heating a vaporizable formulation comprising the ayahuasca-like substance to vaporize at least a portion of the vaporizable formulation. In an embodiment, the vaporizable formulation of the method is housed in a chamber comprising a top portion adapted for coupling to a mouthpiece wherein the top portion of the chamber comprises at least one aperture adapted to permit flow of air, liquid, solids, or vapor between the top portion of the chamber and the mouthpiece. In an embodiment, the chamber of the method comprises a mouthpiece coupled to the top portion of the chamber wherein the mouthpiece comprises a top aperture, a central open bore, a bottom portion comprising an aperture, and wherein the

bottom portion of the mouthpiece is coupled to the top portion of the chamber. In an embodiment, the chamber of the method comprises at least one seal situated between the bottom portion of the mouthpiece comprising an aperture and the top portion of the chamber. In an embodiment, the mouthpiece of the method is releasably coupled to the top portion of the chamber. In an embodiment, the mouthpiece of the method is lockably coupled to the top portion of the chamber. In an embodiment, the chamber of the method comprises a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the vaporizable formulation. In an embodiment, the chamber of the method is coupled to the power unit capable of providing power to vaporize the vaporizable formulation. In an embodiment, the chamber of the method is releasably coupled to the power unit. In an embodiment, the chamber of the method is lockably coupled to the power unit. In an embodiment, the chamber of the method comprises one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector. In an embodiment, the chamber of the method comprises an eGo connector. In an embodiment, the chamber of the method comprises a 510 connector. In an embodiment, the chamber of the method is refillable. In an embodiment, the chamber of the method is single-use. In an embodiment, the chamber of the method is transparent to permit visualization of levels of the vaporizable formulation. In an embodiment, the ayahuasca-like substance or vaporizable formulation of the method comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the method comprises dimethyltryptamine. In an embodiment, the ayahuasca-like substance of the method comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the method is dimethyltryptamine comprising deuterium. In an embodiment, the vaporizable formulation of the method comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG).

[0009] In another embodiment, a vaporizable formulation is provided. In this embodiment the vaporizable formulation comprises an ayahuasca-like substance. In an

embodiment, the ayahuasca-like substance or vaporizable formulation comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the vaporizable formulation comprises dimethyltryptamine. In an embodiment, the ayahuasca-like substance of the vaporizable formulation comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the vaporizable formulation is dimethyltryptamine comprising deuterium. In an embodiment, the vaporizable formulation comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG).

[0010] In another embodiment, a method of treating a psychological disorder is provided. In this embodiment the method comprises administering to a patient an effective amount of an ayahuasca-like substance, wherein the method comprises heating a vaporizable formulation comprising the ayahuasca-like substance to vaporize at least a portion of the vaporizable formulation. In an embodiment, the vaporizable formulation of the method of treatment is housed in a chamber comprising a top portion adapted for coupling to a mouthpiece wherein the top portion of the chamber comprises at least one aperture adapted to permit flow of air, liquid, solids, or vapor between the top portion of the chamber and the mouthpiece. In an embodiment, the chamber of the method of treatment comprises a mouthpiece coupled to the top portion of the chamber wherein the mouthpiece comprises a top aperture, a central open bore, a bottom portion comprising an aperture, and wherein the bottom portion of the mouthpiece is coupled to the top portion of the chamber. In an embodiment, the chamber of the method of treatment comprises at least one seal situated between the bottom portion of the mouthpiece comprising an aperture and the top portion of the chamber. In an embodiment, the mouthpiece of the method of treatment is releasably coupled to the top portion of the chamber. In an embodiment, the mouthpiece of the method of treatment is lockably coupled to the top portion of the chamber. In an embodiment, the chamber of the method of treatment comprises a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the vaporizable formulation. In an

embodiment, the chamber of the method of treatment is coupled to the power unit capable of providing power to vaporize the vaporizable formulation. In an embodiment, the chamber of the method of treatment is releasably coupled to the power unit. In an embodiment, the chamber of the method of treatment is lockably coupled to the power unit. In an embodiment, the chamber of the method of treatment comprises one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector. In an embodiment, the chamber of the method of treatment comprises an eGo connector. In an embodiment, the chamber of the method of treatment comprises a 510 connector. In an embodiment, the chamber of the method of treatment is refillable. In an embodiment, the chamber of the method of treatment is single-use. In an embodiment, the chamber of the method of treatment is transparent to permit visualization of levels of the vaporizable formulation. In an embodiment, the ayahuasca-like substance or vaporizable formulation of the method of treatment comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the method of treatment comprises dimethyltryptamine. In an embodiment, the ayahuasca-like substance of the method of treatment comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the method of treatment is dimethyltryptamine comprising deuterium. In an embodiment, the vaporizable formulation of the method of treatment comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG). In an embodiment, the psychological disorder of the method of treatment comprises one or more of obsessive compulsive disorder, nicotine addiction, alcoholism, narcotic addiction, depression and anxiety related to diagnosis of a life-threatening or terminal illness, major depressive disorder, depression, bipolar disorder, dysthymic disorder, panic attacks, schizophrenia, attention deficit disorder, attention deficit hyperactivity disorder, general anxiety disorder, impulse disorders, delusional disorders, cluster headaches, migraines, personality disorders, gambling disorders, eating disorder, body dysmorphic disorder, or post traumatic stress disorder.

[0011] In another embodiment, a kit is provided. The kit comprises a chamber comprising at least one vaporizable formulation wherein the vaporizable formulation comprises an ayahuasca-like substance. In an embodiment, the chamber of the kit comprises a mouthpiece coupled to the top portion of the chamber wherein the mouthpiece comprises a top aperture, a central open bore, a bottom portion comprising an aperture, and wherein the bottom portion of the mouthpiece is coupled to the top portion of the chamber. In an embodiment, the mouthpiece of the kit is releasably coupled to the top portion of the chamber. In an embodiment, the mouthpiece of the kit is lockably coupled to the top portion of the chamber. In an embodiment, the chamber of the kit is coupled to the power unit capable of providing power to vaporize the vaporizable formulation. In an embodiment, the chamber of the kit is releasably coupled to the power unit. In an embodiment, the chamber of the kit is lockably coupled to the power unit. In an embodiment, the chamber of the kit comprises one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector. In an embodiment, the chamber of the kit comprises a 510 connector. In an embodiment, the chamber of the kit is transparent to permit visualization of levels of the vaporizable formulation. In an embodiment, the chamber of the kit is refillable. In an embodiment, the ayahuasca-like substance or vaporizable formulation of the kit comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the kit comprises dimethyltryptamine. In an embodiment, the ayahuasca-like substance of the kit comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the kit is dimethyltryptamine comprising deuterium. In an embodiment, the vaporizable formulation of the kit comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG).

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] A skilled artisan will understand that the drawings, described below, are for illustrative purposes only. The drawings are not intended to limit the scope of the present teachings in any way.

[0013] FIG. 1 illustrates an exemplary chamber of the present invention. The chamber comprises a mouthpiece (101) coupled to the top portion of the chamber, a transparent wall (102) to permit visualization of a vaporizable formulation that may be present within the hollow section of the chamber, and a threaded 510 connector (103).

[0014] ~~FIG. 2 illustrates an exemplary chamber of the present invention using an adaptable “eGo” threaded connector.~~ Figure 2A illustrates an exemplary chamber of the present invention using an adaptable “eGo” threaded connector with a “closed” chamber [[with]] and a 510 connector. Figure 2B illustrates an adaptable “eGo” threaded connector with an “open” chamber exposing “eGo” threads.

[0015] FIG. 3 illustrates an exemplary chamber of the present invention having a threaded 510 connector and containing a vaporizable formulation (301) comprising dimethyltryptamine.

[0016] FIG. 4 illustrates an optional embodiment of the present invention wherein a chamber comprising a vaporizable formulation comprising dimethyltryptamine (401) is connected via a 510 threaded connector to a commercially available power unit capable of connecting to 510 threaded connectors (402).

DETAILED DESCRIPTION OF THE INVENTION

[0017] The present teachings relate generally to a delivery device that provides users with the ability to safely, reliably, and conveniently obtain a high-quality, therapeutic, and vaporizable formulation comprising an ayahuasca-like substance, such as dimethyltryptamine.

[0018] Devices used to vaporize substances are known in the art, and are commonly referred to in the art as vaporizers, atomizers (e.g., rebuildable atomizers, rebuildable dripping atomizers, rebuildable tank atomizers, clearomizers, or cartomizers), mods (including but not limited to squonk mods, sub ohm mods, box mods, tube modes,

temperature control mods, regulated mods, and mechanical mods), E-cigs, vape pens, etc.

[0019] During use, power may be generated by a power unit through the application of voltage generated by the power unit, which is then passed through to threads of a chamber, thus permitting a heating element that may be positioned within the chamber to generate heat. The heat may then vaporize a vaporizable formulation in the chamber adjacent to the heating element present in the chamber. The vaporizable formulation comprising the ayahuasca-like substance may then be inhaled by the user of the chamber. These and other features of the present teachings will become more apparent from the description herein. While the present teachings are described in conjunction with various embodiments, it is not intended that the present teachings be limited to such embodiments. On the contrary, the present teachings encompass various alternatives, modifications, and equivalents, as will be appreciated by those of skill in the art.

[0020] The terminology used in the disclosure herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the disclosure. As used in the description of the embodiments of the disclosure and the appended claims, the singular forms of “a,” “an,” and “the” are intended to include the plural forms as well, unless the context clearly indicates otherwise. Also, as used herein, “and/or” refers to and encompasses any and all possible combinations of one or more of the associated listed items. Furthermore, the term “about,” as used herein when referring to a measurable value such as an amount of a compound, amount, dose, time, temperature of the specified amount. It will be further understood that the terms “comprises” and/or “comprising,” when used in this specification, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components, and/or groups thereof. Unless otherwise defined, all terms, including technical and scientific terms used in the description, have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosure belongs.

Definitions

[0021] As used herein, an “aperture” refers to an opening, e.g. within a mouthpiece, chamber, or power unit, that permits the flow of air, liquids, solids, or vapor between components of the invention as described herein.

[0022] As used herein, an “ayahuasca-like substance” refers to a substance having any amount or sort of psychological or psychedelic effect, which can include, but is not limited to, dimethyltryptamine (also known as *N,N*-dimethyltryptamine, or DMT), a monoamine oxidase inhibitor, 5-methoxy-*N,N*-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. Ayahuasca-like substances may include isotopomer or isotopologue variations thereof, including but not limited to deuterium-containing substances. In some embodiments the ayahuasca-like substance is dimethyltryptamine. The ayahuasca-like substances of the present invention can be mixed with additional substances in the vaporizable formulation, e.g., monoamine oxidase inhibitors.

[0023] As used herein, a “chamber” refers to a device that holds a vaporizable formulation comprising an ayahuasca-like substance. A chamber is analogous to a “vape cartridge” well known in the art that may include a top portion connected to a mouthpiece, and a bottom portion connected to a battery or power supply that provides power to a heating element that may be present in the chamber that functions to heat the vaporizable formulation to produce vapor.

[0024] As used herein, a “connector” or “connection” refers to the type of connection between the chamber and the power unit. A connector may include a tenon (or “male” component) to connect the chamber to a mortise (or “female” component) configured within the power unit. In most embodiments the chamber will have the tenon and the power unit will have the mortise. The type of connectors described herein are usually referred to by the thread type, which can include, but is not limited to, 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo thread. By way of example, a “510 connector” is a connector having a 510 thread as is commonly referred to in the art. In preferred embodiments a “510 connector” means the chamber is adapted with a 510 threaded tenon and the power unit has a 510 mortise able to accept a 510 threaded

tenon, as is commonly referred to in the art. An eGo thread can have any diameter, but in most cases as used herein refers to an approximately 14mm diameter. An eGo thread is usually larger than other threads used in the art, such that a smaller thread, e.g., a 510 thread, can be adapted to function with an eGo connector.

[0025] As used here, “delivery” or “delivering” refers to the delivery of an ayahuasca-like substance present within a vaporizable formulation-produced vapor generated by power supplied to the chamber of the present invention.

[0026] As used herein, “lockably coupled” refers to components that are not intended to be removed by an end-using consumer. For illustrative purposes, a mouthpiece that is lockably coupled to a chamber is not intended to be removed. Lockably coupled chambers are intended for single-use and are meant to be discarded following vaporization of all the vaporizable formulation present in a chamber. As used herein, “releasably coupled” refers to components that may be removed by an end-using consumer. For illustrative purposes, a mouthpiece that is releasably coupled to a chamber may be removed so that a user may reuse and refill a chamber with additional vaporizable formulation.

[0027] As used herein, “monoamine oxidase inhibitor” or “MAO inhibitor” refers to a compound that acts by inhibiting the activity of monoamine oxidase.

[0028] As used herein, a “mouthpiece” refers to a component that permits a user to easily inhale vapor produced within the chamber. Mouthpieces may be many different sizes and shapes, for example, flat, round, oval, square, rectangular, etc. The mouthpiece may be made of any suitable material, including but not limited to, plastic, glass, ceramic, silicon, or wood.

[0029] As used herein, the terms “propylene glycol (PG),” “vegetable glycerin (VG),” and “polyethylene glycol (PEG)” refer to components of vaporizable formulations that are substances commonly used as food additives, and have other medical applications, and which are commonly used substances known in the field of vaporizing. The components can be an molecular weight variation, for example but not limited to, PEG 200, PEG 400, and the like.

[0030] As used herein, “refillable” refers to a chamber that may be refilled and reused. This is opposed to a “single-use” chamber, which is not meant to be refillable.

[0031] As used herein, “power” refers to energy capable of generating heat within a heating element capable of producing vapor as described herein.

[0032] As used herein, a “power unit” refers to a device meant to provide power, e.g., voltage, to vaporize a vaporizable formulation comprising an ayahuasca-like substance within the chamber of the present invention.

[0033] As used herein, a “psychological disorder” refers to any disorder that may be treated by the methods and devices of the present invention. Non-limiting examples of psychological disorders may include, but are not limited to, obsessive compulsive disorder, nicotine addiction, alcoholism, narcotic addiction, depression and anxiety related to diagnosis of a life-threatening or terminal illness, major depressive disorder, depression, bipolar disorder, dysthymic disorder, panic attacks, schizophrenia, attention deficit disorder, attention deficit hyperactivity disorder, general anxiety disorder, impulse disorders, delusional disorders, cluster headaches, personality disorders, gambling disorders, eating disorder, body dysmorphic disorder, or post traumatic stress disorder.

[0034] As used herein, a “seal” refers to an item that is situated between two components of the device of the present invention, and may function to provide a more efficient and/or stronger connection between the components. A seal may also function to prevent tampering of the devices described herein. The seal can be made of any material known in the art, including but not limited to, PTFE, nitrile, neoprene, silicone, EDPM rubber, fluorocarbon, etc.

[0035] As used herein, “treating” or “treatment” or “therapy” refers to ameliorating, preventing, or improving at least one psychological disorder.

[0036] As used herein, “vapor” refers to both a substance in the gaseous state and a suspension of finely divided solid particles or liquid droplets in a gas, including aerosols and mists, which functions to deliver the ayahuasca-like substances of the present

invention to an end-using consumer. The term “vaporize” refers to the process to producing vapor, e.g., from a vaporizable formulation.

[0037] As used herein, a “vaporizable formulation” refers to a liquid (e.g., an oil) and/or solid (e.g., a wax) solution that may be contained within the chamber of the present invention, and which produces a mist or vapour when heated by a heating element that functions to provide a vaporizable carrier for the ayahuasca-like substances described herein.

Delivery Device Chambers

[0038] The present invention provides a chamber filled with a vaporizable formulation comprising an ayahuasca-like substance. Non-limiting exemplary chambers are illustrated in Figure 1 and Figure 2. An exemplary chamber comprising an ayahuasca-like substance (301) is illustrated in Figure 3. In some embodiments the chamber is coupled to a power unit capable of providing power to vaporize the formulation (Figure 4). The heat generated within the chamber via a heating element may vaporize the vaporizable formulation in the chamber adjacent to the heating element present in the chamber. Following vaporization, the vaporizable formulation comprising the ayahuasca-like substance may then mix with air and subsequently be inhaled by the user, which in some embodiments is through a mouthpiece of the chamber that results in an aerosol that is delivered to the user.

[0039] A user may desire to have a pre-loaded or manually loaded vaporizable formulation comprising a therapeutic ayahuasca-like substance in the chamber to permit an efficient vaporization of the vaporizable formulation for inhalation and delivery of the substance to the user without having to measure, weigh, touch, or risk spilling the vaporizable formulation to be vaporized and consumed. A pre-loaded chamber further reduces the risk of contact of the vaporizable formulation during many aspects of the supply chain, thus reducing the potential for improper dosing or contamination. Alternatively, a user may desire to have the ability to load the chamber themselves. The chamber may be either refillable or single-use, pre-loaded or loaded prior to use. Numerous delivery device chambers known in the art can be used to practice the

present invention, including but not limited to portable or desktop vaporizable cartridges or tanks.

[0040] In an embodiment the chamber comprises a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the vaporizable formulation. In an embodiment the chamber is coupled to the power unit capable of providing power to vaporize the vaporizable formulation. Any manner of coupling the power unit to the chamber is sufficient. The chamber may be locked to the power unit. In such embodiments the power unit may be locked as a single use device, or maybe locked to a reusable chamber. In some embodiments the power unit may be releasable from the chamber, which a user may find useful for recharging the power unit.

[0041] In an embodiment a connector (103) is provided to connect the chamber to the power unit to permit a heating element that may be integrated within the chamber to provide heat for vaporization of the vaporizable formulation. Such connections are well known in the art. For example, the connector may include a tenon (or “male” component) to connect the chamber to a mortise (or “female” component) configured within the power unit. In most embodiments the chamber will have the tenon and the power unit will have the mortise.

[0042] In an embodiment, the tenon may include threads complementary to the threads of the power unit in a standard connection known in the art as a “510 connection,” or a “510 connector,” or as having “510 threads,” or any colloquial variation thereof. By way of example, a “510 connector” is a connector having a 510 thread as commonly referred to in the art. In preferred embodiments a “510 connector” means the chamber is adapted with a 510 threaded tenon and the power unit has a 510 compatible mortise able to accept a 510 threaded tenon, as is commonly referred to in the art. In another embodiment the threads of the power unit may utilize an “eGo connection,” or an “eGo connector,” or have “eGo threads.”

[0043] In other embodiments the chamber may utilize a “401 connection,” or a “401 connector,” or have “401 threads.” In an embodiment the chamber unit may utilize a “601 connection,” or a “601 connector,” or have “601 threads.” In an embodiment the

chamber may utilize a “610 connection,” or a “610 connector,” or have “610 threads.” In an embodiment the chamber may utilize a “710 connection,” or an “710 connector,” or have “710 threads.” In an embodiment the chamber may utilize an “808 connection,” or an “808 connector,” or have “808 threads.” In an embodiment the chamber may utilize a “901 connection,” or a “901 connector,” or have “901 threads.” In an embodiment the chamber may utilize a “4081 connection,” or a “4081 connector,” or have “4081 threads.” In an embodiment the chamber may utilize a “CE-4 connection,” or a “CE-4 connector,” or have “CE-4 threads.” In an embodiment the chamber may utilize an “E9 connection,” or an “E9 connector,” or have “601 threads.” In an embodiment the chamber may utilize a “CE-5 connection,” or a “CE-5 connector,” or have “CE-5 threads.” Any other suitable connections for providing an electrical connection to the chamber from the power unit as is known in the art may be used.

[0044] In some embodiments the chamber may include more than one, or multiple types of thread connections that are easily adaptable to create numerous permutations of thread types for adaptability between connection types. In an embodiment, both 510 and eGo threads are configured to the same chamber such that a 510 thread connector is adapted to be used with an eGo thread connector to permit connection versatility (Figure 2). In an embodiment, both 401 and eGo threads are configured to the same chamber such that a 401 thread connector is adapted to be used with an eGo thread connector to permit connection versatility. In an embodiment, both 601 and eGo threads are configured to the same chamber such that a 601 thread connector is adapted to be used with an eGo thread connector to permit connection versatility. In an embodiment, both 610 and eGo threads are configured to the same chamber such that a 610 thread connector is adapted to be used with an eGo thread connector to permit connection versatility. In an embodiment, both 710 and eGo threads are configured to the same chamber such that a 710 thread connector is adapted to be used with an eGo thread connector to permit connection versatility. In an embodiment, both 808 and eGo threads are configured to the same chamber such that an 808 thread connector is adapted to be used with an eGo thread connector to permit connection versatility. In an embodiment, both 901 and eGo threads are configured to the same chamber such that

a 901 thread connector is adapted to be used with an eGo thread connector to permit connection versatility.

[0045] In some embodiments the chamber comprises a top portion adapted for coupling to a mouthpiece (101) wherein the top portion of the chamber comprises at least one air aperture adapted to permit the flow of air, liquid, or vapor between the top portion of the chamber and the mouthpiece.

[0046] The mouthpiece may be many different sizes and shapes, for example, flat, round, oval, square, rectangular, etc. The mouthpiece may be made of any suitable material, including but not limited to, plastic, glass, ceramic, silicon, stainless steel, or wood. In some embodiments the mouthpiece is coupled to the top portion of the chamber and the mouthpiece has a bottom portion comprising an aperture to permit liquids, solids, vapor, or air to flow from the chamber to the mouthpiece. In some embodiments the mouthpiece has a central open bore to permit liquids, solids, vapor, or air to flow through the mouthpiece; and in some embodiments, the mouthpiece has a top aperture to permit liquids, solids, vapor, or air to exit the mouthpiece in order to be inhaled or utilized by a user.

[0047] In an embodiment, the chamber includes a seal that is situated between the bottom opening of the mouthpiece and the top portion of the chamber. The seal can be made of any material known in the art, including but not limited to, PTFE, nitrile, neoprene, silicone, EDPM rubber, fluorocarbon, etc. In an embodiment, the mouthpiece is releasably coupled to the top portion of the chamber. Releasably coupled mouthpieces may be useful for refilling and multiple uses of chambers. Any mechanism known in the art can be used to permit the mouthpiece to be releasable from the top portion of the chamber, including but not limited to tenon and mortises with or without threads. In an embodiment, the mouthpiece is lockably coupled to the top portion of the chamber. Locked configurations are useful to prevent tampering with the chamber and/or vaporizable formulation.

[0048] The chamber may include a heating element to provide heat that will vaporize the vaporizable formulation comprising the ayahuasca-like substance present within the

chamber. During use, power may be supplied to a heating element positioned within the chamber through the application of voltage generated by the power unit to the threads of the tenon, as described herein, which is then transferred to the heating element positioned within the chamber.

[0049] Many different types of heating elements may be used. The heating element may include a coil and wick, many of which are well known in the art. Exemplary coils are the kanthal ceramic coil, kanthal (FeCrAl) derivatives, nichrome, aluminum, stainless steel, nickel, and titanium. Many different grades of stainless steel wire may be used. The most popular gauges for the wire are 32, 30, 28, 26, 24, and 22. The type of wicking material can vary and preferably includes the organic cotton for the use with botanical extracts, but in some cases, Japanese cotton pads, ekowool, silica, and rayon fiber may be used. The heating element may also be wickless, as is sometimes used in the art.

[0050] The chamber of the present invention will be hollow to some respects such that the vaporizable formulation may be held within the chamber (102). The chamber thus may further include a wall that provides a structural element that further defines an internal volume for containing the vaporizable formulation. The chamber wall can be transparent to permit a user to visualize the amount of vaporizable formulation present within the chamber. An exemplary embodiment of a chamber having a transparent chamber wall permitting visualization of vaporizable formulation is shown in Figure 3 and Figure 4. A transparent chamber wall can be glass or plastic. The chamber wall may also include materials that are opaque, or non-light transmitting. For example the chamber may prevent light from entering into the internal volume. As a result, while stored within the chamber, the vaporizable formulation may be free from exposure to light, thus, reducing degradative effects that may arise due to the light.

[0051] The chamber may include a lid may provide a seal for the chamber so that the vaporizable formulation located within the internal volume is isolated from the external environment and, for example, is kept from degrading. The sealed chamber may further provide quality control for the vaporizable formulation, which may be pre-processed and packaged therein, providing consistency and reliability of its contents. The chamber may

also provide an appropriate environment (e.g., dark, low in relative humidity, inert, etc.) to provide the vaporizable formulation with a relatively long shelf-life. Thus, the chamber in accordance with the present disclosure may be kept for long periods of time without suffering degradation of the contents therein and, for example, may be easily transported, sold in stores, used in vending dispense machines, etc.

[0052] The chamber may further include readable information, for example, given by clear labelling (e.g., markings) on an exterior surface of the chamber, for providing to a user and/or system information regarding its contents. Such information may ultimately be relevant in subjecting the vaporizable formulation to conditions that predictably result in a preferred vapor, with consistency in effects/experience, quality, taste and/or smell.

[0053] The chamber may include a filtering mechanism, such as one or more filters located on either side of the vaporizable formulation, for removing undesirable particulates and/or other contaminants from the vaporizable formulation as it travels away from the internal volume of the chamber.

[0054] The chamber may also include a support member to hold the vaporizable formulation within the internal volume of the chamber during vaporization. The support member may suspend or otherwise distribute the vaporizable formulation within the internal volume during exposure to vaporization heat.

[0055] It can be appreciated that a number of different types, shapes, sizes of chambers may be possible, for use with a variety of different power units. The chamber of the present invention can be commonly used cartridges having 0.25 ml, 0.50 ml, and 1.0 ml capacities. The chamber of the present invention can be commonly used tanks or sub ohm tanks having non-limiting capacities of 2 ml, 3 ml, 4 ml, 5 ml or greater.

[0056] The chamber wall may have a cylindrical shape, a conical shape, a domed shape and/or a tapered construction. In some cases, the particular shape or structure of the chamber may allow it to be suitably placed within a complementary receptacle of a power unit. The shape/structure of the chamber may also provide for a suitable funneling or Venturi effect of the vapor. For instance, an upper end of the chamber may be tapered or dome-shaped such that vapor arising from the chamber is funneled

upward toward an opening and into a collection area (e.g., bag, canister, mouthpiece, flow tube, etc.) where the vapor may be stored or otherwise contained for subsequent consumption.

[0057] In some embodiments it may be preferable to provide a chamber that holds a number of different vaporizable formulations (e.g., having varying types/blends) inside. And it may be further preferable for these different vaporizable formulations to be kept separate during storage. The chamber can include a dividing wall that partitions the internal volume of the chamber into multiple sub-chambers or compartments. For example, the chamber and the power unit may be arranged such that only one of the different types/blends of vaporizable formulations comprising an ayahuasca-like substance is vaporized at a time. Or, vaporization may occur in succession, where the process of vaporization/extraction occurs for each of the vaporizable formulations comprising an ayahuasca-like substance during offset time periods. In some cases, it may be preferable for the power unit to have multiple lines through which separate parts of the chamber may be subject to vaporization and extraction. That is, different compartments of the chamber may be individually heated and subject to separate air flows, allowing for more customized vapors to be produced, with blending of the ingredients at different times during the vaporization process. In various embodiments, the chamber may include materials that exhibit high temperature tolerance that are able to withstand relatively high heat temperatures.

[0058] The chamber further provides dose-specific and consistent amounts of vaporizable formulations and ayahuasca-like substance concentrations for ease of use applications.. Doses can be measured and pre-packaged, and heated precisely to a temperature that produces a therapeutically-active concentration of ayahuasca-like substances. Such dose-specific efficiency increases the present invention's commercial and medicinal value. The chamber may also be configured to permit control over the airflow to the heating element or through the mouthpiece so that the user may adjust the amount of vapor being released.

[0059] The chamber may also be configured to have inlet holes to regulate flow of the vaporizable formulation from the chamber to the external environment for inhalation,

which may be desirable for vaporizable formulations having different viscosities.

Commonly used sizes in the art, for example, may inlet holes can have non-limiting diameters of less than or equal to 1.2mm, 1.4mm, 1.6mm, 1.8mm, 2.0mm, or greater.

[0060] The internal volume of the chamber within which the vaporizable formulation is stored may be substantially removed of oxidizing or otherwise deleterious substances. For instance, prolonged exposure of the vaporizable formulation to oxygen may have negative consequences and may reduce the overall quality of the vapor produced therefrom. For example, exposure to oxygen may result in the occurrence of undesirable oxidation or other reaction(s), which may remove a number of desirable qualities from the vaporizable formulation comprising the ayahuasca-like substance. To remove oxygen, an inert air (e.g., nitrogen gas, noble gas, etc.) may be flushed through the chamber. Accordingly, when suitably packaged, the vaporizable formulation may be stored in a relatively inert environment substantially devoid of oxygen. When appropriately packaged, the internal volume of the chamber may also be maintained at a suitable level of relative humidity, as measured according to methods known in the art. It may be preferable for the vaporizable formulation to be stored within a relatively dry environment to reduce opportunities for degradation.

[0061] The chamber may further include a filtering system. For instance, the filter(s) may be constructed to trap unwanted particles that may arise during vaporization of the vaporizable formulation comprising the ayahuasca-like substance. However, in some instances, it may be preferable for the filter(s) to be constructed such that the vaporizable formulation, or derivatives therefrom (e.g., oils, residue, vapor, etc.), does not clog the filter(s). In some embodiments, the filter(s) may include a fine mesh that allows vapor produced from the vaporizable formulation to pass freely therethrough, for example, without an undesirable amount of condensation or accumulation of debris.

Power Units

[0062] An optional embodiment of the present invention is a chamber connected to a power unit, as illustrated in Figure 4. Power units (also sometimes referred to in the art as batteries) are devices used to provide power to vaporize a vaporizable formulation

comprising an ayahuasca-like substance within the chamber of the present invention, for the purpose of inhalation. During use, the application of voltage is generated by a power source within the power unit, which is then passed through to the threads of the chamber. This permits a heating element positioned within the chamber to generate heat in order to vaporize the vaporizable formulation in the chamber adjacent to a heating element present in the chamber.

[0063] Numerous types and examples of power units, both portable and “desktop,” are well known in the art, any one of which may be sufficient to practice the present invention. The power unit may generate heat using many methods well known in the art, and may be configured to heat the vaporizable formulation through a wide range of incremental heats based on the preferences of the user.

[0064] The power unit may be charged by any method well known in the art to provide power to the heating unit, including but not limited to the use of rechargeable batteries. Rechargeable batteries can be recharged using many methods known in the art, for example, via a USB recharging system.

[0065] In some embodiments, a power unit may be equipped with a controller that is configured to obtain information regarding the contents of the vaporizable formulation comprising an ayahuasca-like substance based on the readable information. For instance, the power unit may have an information reader, such as a digital code reader (e.g., for barcodes, QR codes, etc.) for reading the readable information on the surface of the chamber and/or user interface, for providing input to the controller of the information about the vaporizable formulation comprising an ayahuasca-like substance. Based on this input, the power unit may process the vaporizable formulation comprising an ayahuasca-like substance within the chamber according to a specific vaporization recipe, to produce a vapor having particularly desirable characteristics. For example, the power unit may flow air through the chamber as well as provide a temperature profile within the chamber for extracting a suitable combination of chemical compounds according to a specified protocol. In some embodiments, this temperature profile may include a number of timed temperature adjustments that occur during the period of vaporization when extraction of the vaporization formulation comprising an ayahuasca-

like substance occurs. In some cases, the power unit may provide this temperature profile as part of an automated process of vaporization and extraction, or a user may input such a profile into the power unit. Vapor generated from the vaporizable formulation comprising an ayahuasca-like substance is then passed from the internal volume of the chamber externally, or alternatively, to a bag, canister and/or other collection region, for consumption by a user.

[0066] The power unit may include sensors to provide a user with an appropriate notification (e.g., audio/visual/tactile signal(s)) as the production of vapor is ongoing, or completed. In some embodiments, a sensor coupled with the power unit that tracks the progress of vapor production may be employed so as to present the user with a real-time status report of the vapor being generated, or even if the vapor is being generated at all. For example, such a report may be an indicator for how full the chamber is, the particular concentration of one or more ayahuasca-like substances within the vapor, whether the vaporization cycle has been completed, the existence of vapor produced, etc. Hence, at an appropriate time (e.g., when the chamber is full of vapor, when the user wants to stop the cycle, etc.), the chamber may be removed from the power unit and the user may sip and/or breathe the vapor through a suitable mouthpiece.

[0067] The power unit may be configured to process the chamber and its contents so as to extract the ayahuasca-like substances as fully as possible therefrom. Accordingly, the power may control the overall dosage of vapor and extraction by varying a number of parameters during certain steps such as cycle time, start/stop times, temperature settings, rate of air flow therethrough, relative humidity, amongst others, the combination of which may play a substantial role in producing a desirable amount of substance and flavor.

[0068] The power unit may also be configured as a smart machine that learns the preferences of a user. For example, a user may input a number of parameters and/or the power unit may track the particular conditions for vaporizing the contents of the chamber. The user may determine that a certain set of conditions may be especially effective in producing a vapor that achieves a favorable experience. The vaporizer may also track specific combinations of chamber and vaporization conditions that correspond

to favorable user experiences, and may communicate such combinations to the user for later use, as suitably desired.

[0069] In an embodiment a power unit may be made available in combination with the chamber, and may be releasably coupled to the chamber. In an embodiment a power unit may be made available in combination with the chamber, and may be lockably coupled to the chamber. In embodiments where the power unit is lockably coupled to the chamber, the purpose may be for a “all in one” single use application. However, power units may be lockably coupled to a refillable chamber as described herein, if desired by a consumer.

Vaporizable Formulations

[0070] Included in the present invention are vaporizable formulations, sometimes referred to in the art as “vape juice,” or “e-liquid,” or “e-juice,” and which refers to a liquid (e.g., an oil) and/or solid (e.g., a wax) solution that may be contained within the chamber of the present invention, and which produces a mist or vapour when heated by a heating element that functions to provide a vaporizable carrier for the ayahuasca-like substances described herein.

[0071] The vapor may include a mist, aerosol and/or nebulized composition that includes fine solid and/or liquid particles suspended in a gas or, in some cases, the vapor may be substantially formed as a gas. The vapor may also include a gaseous substance having small droplets of oil, water and/or other chemical compounds suspended therein. In some cases, a vapor includes liquid (e.g., water, oil, etc.) particles mixed with hot ambient air, which is cooled down so as to condense into a fine cloud of visible airborne droplets. Accordingly, the vaporizable formulation may be breathed or otherwise administered as medication and/or as therapy in a vaporized form.

[0072] In an embodiment, the vaporizable formulation is a mix of propylene glycol (PG) and vegetable glycerin (VG). The vaporizable formulation of the present invention may contain any ratio of PG/VG based on user preference, for example, between 0:100 PG:VG and 10:90 PG:VG, between 10:90 PG:VG and 20:80 PG:VG, between 20:80

PG:VG and 30:70 PG:VG, between 30:70 PG:VG and 40:60 PG:VG, between 40:60 PG:VG and 50:50 PG:VG, between 50:50 PG:VG and 60:40 PG:VG, between 60:40 PG:VG and 70:30 PG:VG, between 70:30 PG:VG and 80:20 PG:VG, between 80:20 PG:VG and 90:10 PG:VG, or between 90:10 PG:VG and 100:0 PG:VG.

[0073] The vaporizable formulation may also include water, terpene, and/or polyethylene glycol (PEG) as the vaporizable formulation, and in combination with any ratio of PG and VG. The PEG can be of any molecular weight, including but not limited to, PEG200 and PEG 400. The vaporizable formulation of the present invention may contain any ratio of PEG/VG based on user preference, for example, between 0:100 PEG:VG and 10:90 PEG:VG, between 10:90 PEG:VG and 20:80 PEG:VG, between 20:80 PEG:VG and 30:70 PEG:VG, between 30:70 PEG:VG and 40:60 PEG:VG, between 40:60 PEG:VG and 50:50 PEG:VG, between 50:50 PEG:VG and 60:40 PEG:VG, between 60:40 PEG:VG and 70:30 PEG:VG, between 70:30 PEG:VG and 80:20 PEG:VG, between 80:20 PEG:VG and 90:10 PEG:VG, or between 90:10 PEG:VG and 100:0 PEG:VG. The vaporizable formulation of the present invention may contain any ratio of PG/PEG based on user preference, for example, between 0:100 PG:PEG and 10:90 PG:PEG, between 10:90 PG:PEG and 20:80 PG:PEG, between 20:80 PG:PEG and 30:70 PG:PEG, between 30:70 PG:PEG and 40:60 PG:PEG, between 40:60 PG:PEG and 50:50 PG:PEG, between 50:50 PG:PEG and 60:40 PG:PEG, between 60:40 PG:PEG and 70:30 PG:PEG between 70:30 PG:PEG and 80:20 PG:PEG, between 80:20 PG:PEG and 90:10 PG:PEG, or between 90:10 PG:PEG and 100:0 PG:PEG.

[0074] The present invention should not be limited by variability in the purity, kinds and concentrations of chemicals used in liquids, and significant variability between labeled content and concentration and actual content and concentration.

[0075] A skilled artisan will be familiar with a substantial range of vaporizable formulations that can be used with the present invention, and any substance that is vaporizable and capable of acting as a carrier for the ayahuasca-like substance will suffice. Numerous naturally extracted e-liquids may be used as the vaporizable

formulation for the present invention, for example, the e-liquids described in United States Patent Application No. 20160309775.

[0076] Traditional ayahuasca preparations include monoamine oxidase inhibitors (MAOIs). Thus the vaporizable formulation of the present invention can further include one or more MAOIs, which are well known in the art, and can include, but not be limited to, Clorgyline, Minaprine, and the reversible MAO-A inhibitors Befloxatone, Brofaromine, Cimoxatone, Harmaline, Moclobemide, Pirlindole and Toloxatone. Examples of MAO-B inhibitors include, but are not limited to, Rasagiline, Selegiline and Pargyline. Examples of unselective MAO-A and MAO-B inhibitors include, but are not limited to, Iproclozide (Sursum), Iproniazid (Marsilid, Iprozid, Ipronid, Rivivol, Propilniazida), Isocarboxazid (Marplan), Mebanazine (Actomol), Metfendrazine (H.M.-11), Nialamide (Niamid), Phenelzine (Nardil), Pheniprazine (Caton), Phenoxypropazine (Drazine), Pivalylbenzhydrazine (Tersavid, Neomarsilid), Safrazine (Safra) and Tranylcypromine (Parnate). See, for example, Remington: The Science and Practice of Pharmacy, 21st Edition, (2005, Lippincott Williams & Wilkins), pages 1517-1523, and Physicians' Desk Reference, Edition 60 (2006, Thomson PDR) page 1499 (each of which is incorporated herein by reference).

[0077] The vaporizable formulation may further include additional components so that users may choose to modify or boost their flavor or concentration of the ayahuasca-like substance with various offerings, including flavorings (non-limiting examples known in art such terpenes, flavonoids, mint, ginger, cinnamon, vanilla, pepper jack cheese, chocolate and peanut butter, Pennsylvania fruit cake, chamomile, ginko, Izzy treats, mango, etc.), and other additives or ingredients, as suitably desired.

[0078] Other compositions may also be included in the vaporizable formulation to complement the ayahuasca-like substance. For example, the vaporizable formulation may also include flavonoids, terpenoids, amino acids, proteins, sugars, enzymes, fatty acids, esters and/or other compounds, including but not limited to cannabinoid extracts from cannabis, THC, THCV, ketorolac, morphine, testosterone, ibuprofen, codeine, nicotine, Vitamin A, Vitamin E acetate, Vitamin E, nitroglycerin, pilocarpine, mescaline, testosterone enanthate, menthol, phencaramide, methsuximide, eptastigmine,

promethazine, procaine, retinol, lidocaine, trimeprazine, isosorbide dinitrate, timolol, methypylon, etamiphyllin, propoxyphene, salmetrol, vitamin E succinate, methadone, oxprenolol, isoproterenol bitartrate, etaqualone, Vitamin D3, ethambutol, ritodrine, omoconazole, lomustine, ketamine, ketoprofen, cilazaprol, propranolol, sufentanil, metaproterenol, pentoxapylline, captopril, loxapine, cyproheptidine, carvediol, trihexylphenadine, alprostadiol, melatonin, testosterone propionate, valproic acid, acebutolol, terbutaline, diazepam, topiramate, pentobarbital, alfentanil HCl, papaverine, nicergoline, fluconazole, zafirlukast, testosterone acetate, droperidol, atenolol, metoclopramide, enalapril, albuterol, ketotifen, isoproterenol, amiodarone HCl, zileuton, midazolam, oxycodone, cilostazol, propofol, nabilone, gabapentin, famotidine, lorezepam, naltrexone, acetaminophen, sumatriptan, bitolterol, nifedipine, phenobarbital, phentolamine, 13-cis retinoic acid, droprenilamine HCl, amlodipine, caffeine, zopiclone, tramadol HCl, pirbuterol, naloxone, meperidine HCl, trimethobenzamide, nalmeferene, scopolamine, sildenafil, carbamazepine, procaterol HCl, methysergide, glutathione, olanzapine, zolpidem, levorphanol, buspirone, and mixtures thereof.

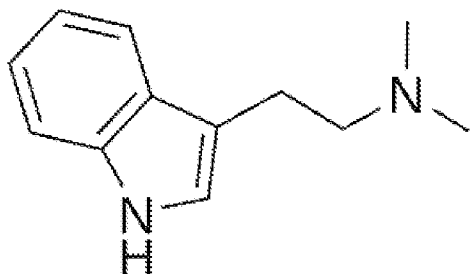
[0079] The vaporizable formulations of the present invention need not be limited to oils, and may also include other liquids or waxes. In some embodiments the vaporizable formulation can be adapted for dry vaporization, or be adapted for wax vaporization. In some embodiments, the vaporizable formulation can be adapted for a combination of one or more oil, dry, or wax vaporizable formulations

[0080] The present invention may be practiced using a variety of different embodiments, including pre-filled chambers that are single use, or refillable. In another embodiment, a vaporizable substance is provided comprising an ayahuasca-like substance, which can be made available separately from the other components of the devices described herein, such that an end-using consumer can refill their chamber after the initial chamber prefilled with the vaporizable formulation is depleted. In another embodiment, the vaporizable formulation can be made available separate from the chamber such that a consumer can adapt their own chamber to be configured with the vaporizable formulations.

Ayahuasca-like Substances

[0081] In some embodiments the vaporizable formulations as described herein comprise an ayahuasca-like substance that is provided for medicinal, therapeutic and/or recreational purposes. The substance may include matter derived from a plant, used for consumption, such as for medicinal, therapeutic, aromatic and/or culinary purposes.

[0082] In an embodiment, ayahuasca-like substance may be dimethyltryptamine (also referred to as *N,N*-dimethyltryptamine, or DMT):



[0083] The ayahuasca-like substance does not need to be limited to substances commonly found in ayahuasca, and can include other substances as well, by way of example and not meant to be limiting, 5-methoxy-*N,N*-dimethyltryptamine or 2-5-dimethoxy-4-bromophenethylamine. The ayahuasca-like substance can further include isotopomer and isotopologue variations, for example, a DMT isotopomer or isotopologue comprising deuterium or tritium.

[0084] Ayahuasca-like substances are often combined with MAOIs, many of which are included in the vaporizable formulation and described elsewhere herein.

[0085] The ayahuasca-like substances of the present invention can be synthesized by a variety of methods known to one of skill in the art (see Comprehensive Organic Transformations Richard C. Larock, 1989) or by an appropriate combination of generally well known synthetic methods. Dimethyltryptamine can be synthesized through several possible pathways from different starting materials. A common method skilled artisans use to synthesize dimethyltryptamine is through reaction of indole with oxalyl chloride followed by reaction with dimethylamine and reduction of the carbonyl functionalities with lithium aluminum hydride. Another method commonly known for the synthesis of

dimethyltryptamine is through the n,n-dimethylation of tryptamine using formaldehyde followed by reduction with sodium cyanoborohydride or sodium triacetoxyborohydride. Techniques useful in synthesizing the ayahuasca-like substances of the present invention are both readily apparent and accessible to those of skill in the relevant art.

[0086] A skilled artisan will appreciate that other methods of making the ayahuasca-like substances of the present invention are possible, including but not limited to the extraction and/or purification from plants and other natural substances.

Dimethyltryptamine is found in many naturally occurring substances, including but not limited to, *Mimosa hostilis*, *Mimosa tenuiflora*, *Banisteriopsis caapi*, *Phalaris arundinacea*, *Phalaris aquatica*, *Diplopterys cabrerana*, *Psychotria viridis*, *Acacia confusa*, *Anadenanthera peregrina*, and *Anadenanthera colubrina*. Methods of extracting dimethyltryptamine from natural substances are well known in the art, and may include the non-limiting methods incorporating the use of a non-polar hydrocarbon solvent and a subsequent alkaline purification, or an acid-base extraction.

[0087] It should be stressed that dimethyltryptamine can be synthesized or extracted using a variety of different well known methodologies, and need not be limited to any specific synthesis and/or extraction method specifically described herein.

[0088] Most ayahuasca-like substances are readily available and need not be synthesized or extracted. For example, dimethyltryptamine, which was first synthesized in 1931, is readily available in decriminalized jurisdictions.

[0089] The present invention is not intended to be limited to any specific weight per volume concentration of the ayahuasca-like substance dissolved in the vaporizable formulation, and may comprise a weight per volume content of greater than 0.1 w/v %, greater than 1.0 w/v %, greater than 10.0 w/v %, greater than 20.0 w/v %, greater than 30.0 w/v %, greater than 40.0 w/v %, greater than 50.0 w/v %, greater than 60.0 w/v %, greater than 70.0 w/v %, greater than 80.0 w/v %, greater than 90.0 w/v %, greater than 100.0 w/v %, greater than 125.0 w/v %, greater than 150.0 w/v %, greater than 200.0 w/v %; or less than 200.0 w/v %, less than 150.0 w/v %, less than 125.0 w/v %, less than 100.0 w/v %, less than 90.0 w/v %, less than 80.0 w/v %, less than 70.0 w/v %, less than 60.0 w/v %, less than 50.0 w/v %, less than 40.0 w/v %, less than 30.0 w/v %, less than 20.0 w/v %, less than 10.0 w/v %, less than 1.0 w/v %, or less than 0.1 w/v %.

less than 60.0 w/v %, less than 50.0 w/v %, less than 40.0 w/v %, less than 30.0 w/v %, less than 20.0 w/v %, less than 10.0 w/v %, less than 1.0 w/v %, or less than 0.1 w/v %. Combinations of the above-noted ranges, or values outside of these ranges, may be possible for the ayahuasca-like substance content levels of the vaporizable formulation based on user preference or for medicinal optimization.

Methods of Use

[0090] In some embodiments, the present invention describes methods of using the chambers described herein. Such methods are particularly useful for refillable chambers or for end users who wish to load chambers with the vaporizable formulations comprising the anahuasca-like substances themselves.

[0091] In an embodiment, a method for delivering an ayahuasca-like substance as described herein is provided wherein the method of use comprises heating a vaporizable formulation comprising the ayahuasca-like substance as described herein to vaporize at least a portion of the vaporizable formulation.

[0092] In some embodiments the vaporizable formulation of the methods of use of the present invention may be housed in a chamber comprising a top portion adapted for coupling to a mouthpiece and wherein the top portion comprises at least one air aperture adapted to permit flow of air, liquid, or vapor between the chamber and the mouthpiece as described herein. In some embodiments the mouthpiece used by the method of use may comprise a top aperture, a central open bore, and a bottom portion comprising an aperture and coupled to the chamber as described herein. In some embodiments the chamber used by the method of use may comprise at least one seal situated between the bottom opening of the mouthpiece and the top portion of the chamber as described herein. In some embodiments the mouthpiece used in the method of use may be releasably coupled to the top portion of the chamber as described herein. In some embodiments, the mouthpiece used in the method of use may be lockably coupled to the top portion of the chamber as described herein. In some embodiments the chamber used in the method of use may comprise a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the

vaporizable formulation as described herein. In some embodiments the chamber used in the method of use may be transparent to permit visualization of levels of the vaporizable formulation.

[0093] In some embodiments the chamber used by the methods of use of the present invention may be coupled to the power unit capable of providing power to vaporize the vaporizable formulation as described herein; in some embodiments the chamber used by the method is releasably coupled to the power unit as described herein. In some embodiments the chamber used by the methods of use of the present invention may be lockably coupled to the power unit as described herein; in some embodiments the chamber used by the method may comprise one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector to couple the chamber to the power unit as described herein; in an embodiment the chamber used by the methods of use of the present invention comprises a 510 connector as described herein.

[0094] In some embodiments the chamber used in the methods of use of the present invention is refillable as described herein, although it should be noted that the methods of the present invention should not be limited to refillable chambers, and users may choose to practice the methods of use of the present invention using single use applications.

[0095] In some embodiments the ayahuasca-like substance used in the methods of use of the present invention may comprise one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine as described herein. In an embodiment the ayahuasca-like substance used by the methods of use of the present invention comprises dimethyltryptamine as described herein. In an embodiment, the ayahuasca-like substance of the methods of use of the present invention comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the methods of use of the present invention is dimethyltryptamine comprising deuterium.

[0096] In some embodiments the vaporizable formulation used in the methods of the present invention may comprise one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG), or any other compound as described herein.

Methods of Treatment

[0097] Therapeutic benefits of psychedelic drugs, such as dimethyltryptamine, lysergic acid diethylamide and psilocybin, are being actively researched in humans. Studies in healthy volunteers have shown long-term increases in trait optimism (Carhart-Harris et al., *Psychological Medicine* 2016, 46:1379-1390), well-being (Id. and Griffiths et al., *Psychopharmacology* 2011, 218:649-665), and openness (Carhart-Harris et al., *Psychological Medicine* 2016, 46:1379-1390; MacLean et al., *Journal of Psychopharmacology* 2011, 25:1453-1461), neurodegenerative disorders (Morales-Garcia et al, *Translational Psychiatry*, 10:331 (2020)), and studies in patients have found long-term improvements in obsessive compulsive disorder (Moreno et al., *Journal of Clinical Psychiatry* 2006, 67:1735-1740), nicotine addiction (Garcia-Romeu et al., *Current Drug Abuse Reviews* 2014, 7:157-164), alcoholism (Krebs and Johansen, *Psychopharmacology* 2012, 26.7:994-1002; Bogenschutz et al., *Journal of Psychopharmacology* 2015, 29.3:289-299), narcotic addiction (Savage and McCabe, *Psychiatry* 1973, 28.6:808-814), depression and anxiety related to diagnosis of a life-threatening or terminal illness (Grob et al., *Archives of General Psychiatry* 2011, 68:71-78; Griffiths et al., *Journal of Psychopharmacology* 2016, 30(12):1181-1197; Ross et al., *Journal of Psychopharmacology* 2016, 30(12):1165-1180), and depression (Carhart-Harris et al., *The Lancet Psychiatry* 2016; Sanches et al., *Journal of Clinical Psychopharmacology* 2016, 36:77-81) after treatment with psychedelics. Other psychological disorders can include, but are not limited to general anxiety, major depressive disorder, dysthymic disorder, bipolar disorder, panic attacks, schizophrenia, attention deficit disorder, attention deficit hyperactivity disorder, impulse disorders, delusional disorders, cluster headaches, migraines, personality disorders, gambling disorders, eating disorder, body dysmorphic disorder, and other psychological disorders described in the "Diagnostic and Statistical Manual, Version IV." These long-term

positive effects can endure for several months, if not years, even after the compound has been metabolized and has been excreted from the body.

[0098] In some embodiments, the present invention includes methods of treating a psychological disorder comprising administering to a patient an effective amount of an ayahuasca-like substance, wherein the method comprises heating a vaporizable formulation comprising the ayahuasca-like substance to vaporize at least a portion of the vaporizable formulation.

[0099] In some embodiments the vaporizable formulation of the methods of treatment of the present invention may be housed in a chamber comprising a top portion adapted for coupling to a mouthpiece and wherein the top portion comprises at least one air aperture adapted to permit flow of air, liquid, or vapor between the chamber and the mouthpiece as described herein. In some embodiments the mouthpiece used by the methods of treatment may comprise a top aperture, a central open bore, and a bottom portion comprising an aperture that is coupled to the chamber as described herein. In some embodiments the chamber used by the methods of treatment may comprise at least one seal situated between the bottom opening of the mouthpiece and the top portion of the chamber as described herein. In some embodiments the mouthpiece used in the methods of treatment may be releasably coupled to the top portion of the chamber as described herein. In some embodiments, the mouthpiece used in the methods of treatment may be lockably coupled to the top portion of the chamber as described herein. In some embodiments the chamber used in the methods of treatment may comprise a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the vaporizable formulation as described herein. In some embodiments the chamber used in the methods of treatment may be transparent to permit visualization of levels of the vaporizable formulation.

[0100] In some embodiments the chamber used by the methods of treatment of the present invention may be coupled to the power unit capable of providing power to vaporize the vaporizable formulation as described herein. In some embodiments the chamber used by the methods of treatment is releasably coupled to the power unit as described herein. In some embodiments the chamber used by the methods of treatment

of the present invention may be lockably coupled to the power unit as described herein. In some embodiments the chamber used by the methods of treatment may comprise one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector to couple the chamber to the power unit as described herein. In an embodiment the chamber used by the methods of treatment of the present invention comprises a 510 connector as described herein.

[0101] In some embodiments the chamber used in the methods of treatment of the present invention is refillable as described herein, although it should be noted that the methods of treatment of the present invention should not be limited to refillable chambers, and users may choose to practice the methods of the present invention using single use applications.

[0102] In some embodiments the ayahuasca-like substance used in the methods of treatment of the present invention may comprise one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine as described herein. In an embodiment the ayahuasca-like substance used by the methods of treatment of the present invention comprises dimethyltryptamine as described herein. In an embodiment, the ayahuasca-like substance used in the methods of treatment of the present invention comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance used in the methods of treatment is dimethyltryptamine comprising deuterium.

[0103] In some embodiments the vaporizable formulation used in the methods of treatment of the present invention may comprise one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG), or any other compound as described herein.

[0104] The methods of treatment as described herein may be administered by an individual qualified to administer the vaporizable formulations of the present invention in

accordance with local jurisdictional laws, which may include, but is not limited to, a psychiatrist, psychologist, therapist, shaman, or any other qualified individual.

Kits

[0105] In other embodiments the present invention provides components packaged together in the form of a kit for performing any of the methods described herein.

[0106] In some embodiments, the kit comprises a chamber comprising at least one vaporizable formulation wherein the vaporizable formulation comprises an ayahuasca-like substance. In some embodiments, the chamber that is part of the kit comprises a mouthpiece coupled to a top portion of the chamber. In some embodiments the mouthpiece comprises a top aperture, a central open bore, a bottom portion comprising an aperture, and wherein the bottom portion of the mouthpiece is coupled to the top portion of the chamber. In some embodiments, the mouthpiece that is part of the kit is releasably coupled to the top portion of the chamber. In some embodiments, the mouthpiece that is part of the kit is lockably coupled to the top portion of the chamber. In some embodiments, the chamber that is part of the kit is coupled to the power unit capable of providing power to vaporize the vaporizable formulation. In some embodiments, the chamber that is part of the kit is releasably coupled to the power unit. In some embodiments, the chamber that is part of the kit is lockably coupled to the power unit. In some embodiments, the chamber that is part of the kit comprises one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector to couple the chamber to the power unit. In some embodiments, the chamber that is part of the kit comprises a 510 connector. In some embodiments, the chamber that is part of the kit is transparent to permit visualization of levels of the vaporizable formulation. In some embodiments, the chamber that is part of the kit is refillable. In some embodiments, the ayahuasca-like substance that is part of the kit comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In some embodiments, the ayahuasca-like substance that is part of the kit comprises dimethyltryptamine. In an embodiment, the ayahuasca-like substance that is part of the kit comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase

inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance that is part of the kit is dimethyltryptamine comprising deuterium. In some embodiments, the vaporizable formulation that is part of the kit comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG).

EXAMPLE

[0107] Aspects of the present teachings can be further understood in light of the following example, which should not be construed as limiting the scope of the present teachings in any way.

[0108] The following example was performed in a jurisdiction where each substance described has been decriminalized.

Step 1: Dimethyltryptamine

[0109] Pure dimethyltryptamine was acquired through readily available channels. Melting point analyses were taken from two samples to confirm the chemical makeup. The two samples each melted at approximately 46 degrees celsius, confirming that the chemical makeup was dimethyltryptamine.

Step 2: Formulating a vaporizable formulation

[0110] The dimethyltryptamine (i.e., the ayahuasca-like substance) derived from Step 1 was mixed into a formulation comprising propylene glycol (PG) and vegetable glycerin (VG) to formulate a vaporizable formulation comprising the ayahuasca-like substance. The dimethyltryptamine (i.e., the ayahuasca-like substance) derived from Step 1 was also mixed into a formulation comprising polyethylene glycol (PEG) and vegetable glycerin (VG) to formulate a vaporizable formulation comprising the ayahuasca-like substance. Finally, the dimethyltryptamine (i.e., the ayahuasca-like substance) derived from Step 1 was mixed into a formulation comprising propylene glycol (PG) and polyethylene glycol (PEG) to formulate a vaporizable formulation comprising the ayahuasca-like substance.

[0111] Dimethyltryptamine was mixed at different concentrations varying from 250mg/ml to 1g/ml. Optional formulation ratios are described in Table 1.

PG:VG	0:100	PEG:VG	0:100	PG:PEG	0:100
PG:VG	10:90	PEG:VG	10:90	PG:PEG	10:90
PG:VG	20:80	PEG:VG	20:80	PG:PEG	20:80
PG:VG	30:70	PEG:VG	30:70	PG:PEG	30:70
PG:VG	40:60	PEG:VG	40:60	PG:PEG	40:60
PG:VG	50:50	PEG:VG	50:50	PG:PEG	50:50
PG:VG	60:40	PEG:VG	60:40	PG:PEG	60:40
PG:VG	70:30	PEG:VG	70:30	PG:PEG	70:30
PG:VG	80:20	PEG:VG	80:20	PG:PEG	80:20
PG:VG	90:10	PEG:VG	90:10	PG:PEG	90:10
PG:VG	100:0	PEG:VG	100:0	PG:PEG	100:0

Table 1.

Step 3: Production of delivery device

[0112] Step 3 describes an embodiment of the invention wherein a chamber as described herein is combined with an ayahuasca-like substance. The vaporizable formulation of Step 2 comprising the ayahuasca-like substance derived from Step 1 was placed into the hollow portion of a chamber comprising a 510 threaded connector as described herein and illustrated in Figure 3.

[0113] The vaporizable formulation of Step 2 comprising the ayahuasca-like substance derived from Step 1 was also placed into the hollow portion of a chamber comprising an eGo threaded connector as described herein.

Step 4: Attachment to a power unit

[0114] An optional embodiment of the present invention includes a power unit. The delivery device comprising the chamber of Step 3 comprising the vaporizable

formulation of Step 2 comprising the ayahuasca-like substance derived from Step 1 was affixed to a commercially available power unit as shown in Figure 4.

[0115] All publications and patent applications cited in this specification are herein incorporated by reference as if each individual publication or patent application were specifically and individually indicated to be incorporated by reference.

[0116] Although the foregoing invention has been described in some detail by way of illustration and example for purposes of clarity of understanding, it will be readily apparent to one of ordinary skill in the art in light of the teachings of this invention that certain changes and modifications may be made thereto without departing from the spirit or scope of the invention as defined in the appended claims.

DELIVERY SYSTEM FOR AYAHUASCA-LIKE SUBSTANCES

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation under 35 USC 365(c) of International Application No. PCT/US21/42123, filed July 18, 2021, which claims priority benefit to U.S. Provisional Application No. 63/058,444, filed July 29, 2020, and U.S. Provisional Application No. 63/144,923, filed February 02, 2021, the entire contents of each of which are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

[0002] In certain jurisdictions, ayahuasca-like substances and other psychedelic medicines are being legalized or decriminalized, hence allowing for breakthrough alternative medicines and/or recreational experiences. Psychedelic research is still in its infancy, which in part is a consequence of legal barriers to such research that has existed for decades. Yet preliminary reports are encouraging. For example, it was recently reported that dimethyltryptamine, which is the active ingredient in ayahuasca, can promote the proliferation of neural stem cells and subsequent neurogenesis, thus leading to improvements in memory. Such results have significant implications for neurodegenerative disorders such as Alzheimer's, Parkinson's, and dementia (Morales-Garcia *et al.*, *Translational Psychiatry*, 10:331 (2020)).

[0003] However, the ability to distribute reliably consistent amounts and types of ayahuasca-like substances having a particular level of therapeutic or recreational quality is limited. Safety concerns may also arise when ayahuasca-like substances are obtained in a manner where the exact composition is unknown due to risks of contamination, tampering, misrepresentation, etc.

[0004] The ability to store and seal a dose-specific vaporizable formulation comprising an ayahuasca-like substance in a controlled environment with a labelled package that is easily portable provides a tremendous benefit to patients and other consumers. When

an ayahuasca-like substance comes pre-processed and stored in a dry, secure, contamination-free environment, a patient or other consumer is provided with a level of confidence and convenience that has not previously been available. The devices and methods of the present invention thus solve problems associated with both ease of use and safety, and further provide a greater degree of legitimacy so that a patient or consumer can be confident that the contents of the packaged product is in fact what is listed by the labelling.

[0005] The invention described herein provides a device, formulation, methods of use, methods of treatment of psychological disorders, and kits for the delivery of ayahuasca-like substances, which has significant commercial and medicinal potential in jurisdictions that have legalized or decriminalized psychedelic substances.

SUMMARY OF THE INVENTION

[0006] The present teachings relate to a system for the delivery of a vaporizable formulation comprising an ayahuasca-like substance.

[0007] In an embodiment, a device for the delivery of an ayahuasca-like substance is provided. The device comprises a chamber comprising at least one vaporizable formulation wherein the vaporizable formulation comprises the ayahuasca-like substance. In an embodiment, the chamber of the device comprises a top portion adapted for coupling to a mouthpiece wherein the top portion of the chamber comprises at least one aperture adapted to permit flow of air, liquid, solids, or vapor between the top portion of the chamber and the mouthpiece. In an embodiment, a mouthpiece of the device coupled to the top portion of the chamber is provided wherein the mouthpiece comprises a top aperture, a central open bore, a bottom portion comprising an aperture, and wherein the bottom portion of the mouthpiece is coupled to the top portion of the chamber. In an embodiment, at least one seal situated between the bottom portion of the mouthpiece of the device comprising an aperture and the top portion of the chamber is provided. In an embodiment, the mouthpiece of the device is releasably coupled to the top portion of the chamber. In an embodiment, the mouthpiece of the device is lockably coupled to the top portion of the chamber. In an embodiment, the chamber of

the device comprises a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the vaporizable formulation. In an embodiment, the chamber of the device is coupled to the power unit capable of providing power to vaporize the vaporizable formulation. In an embodiment, the chamber of the device is releasably coupled to the power unit. In an embodiment, the chamber of the device is lockably coupled to the power unit. In an embodiment, the chamber of the device comprises one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector. In an embodiment, the chamber of the device comprises a 510 connector. In an embodiment, the chamber of the device is transparent to permit visualization of levels of the vaporizable formulation. In an embodiment, the chamber of the device is refillable. In an embodiment, the ayahuasca-like substance or vaporizable formulation of the device comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the device comprises dimethyltryptamine. In an embodiment, the ayahuasca-like substance of the device comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the device is dimethyltryptamine comprising deuterium. In an embodiment, the vaporizable formulation of the device comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG).

[0008] In another embodiment, a method for delivering an ayahuasca-like substance is provided. In this embodiment the method comprises heating a vaporizable formulation comprising the ayahuasca-like substance to vaporize at least a portion of the vaporizable formulation. In an embodiment, the vaporizable formulation of the method is housed in a chamber comprising a top portion adapted for coupling to a mouthpiece wherein the top portion of the chamber comprises at least one aperture adapted to permit flow of air, liquid, solids, or vapor between the top portion of the chamber and the mouthpiece. In an embodiment, the chamber of the method comprises a mouthpiece coupled to the top portion of the chamber wherein the mouthpiece comprises a top aperture, a central open bore, a bottom portion comprising an aperture, and wherein the

bottom portion of the mouthpiece is coupled to the top portion of the chamber. In an embodiment, the chamber of the method comprises at least one seal situated between the bottom portion of the mouthpiece comprising an aperture and the top portion of the chamber. In an embodiment, the mouthpiece of the method is releasably coupled to the top portion of the chamber. In an embodiment, the mouthpiece of the method is lockably coupled to the top portion of the chamber. In an embodiment, the chamber of the method comprises a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the vaporizable formulation. In an embodiment, the chamber of the method is coupled to the power unit capable of providing power to vaporize the vaporizable formulation. In an embodiment, the chamber of the method is releasably coupled to the power unit. In an embodiment, the chamber of the method is lockably coupled to the power unit. In an embodiment, the chamber of the method comprises one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector. In an embodiment, the chamber of the method comprises an eGo connector. In an embodiment, the chamber of the method comprises a 510 connector. In an embodiment, the chamber of the method is refillable. In an embodiment, the chamber of the method is single-use. In an embodiment, the chamber of the method is transparent to permit visualization of levels of the vaporizable formulation. In an embodiment, the ayahuasca-like substance or vaporizable formulation of the method comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the method comprises dimethyltryptamine. In an embodiment, the ayahuasca-like substance of the method comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the method is dimethyltryptamine comprising deuterium. In an embodiment, the vaporizable formulation of the method comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG).

[0009] In another embodiment, a vaporizable formulation is provided. In this embodiment the vaporizable formulation comprises an ayahuasca-like substance. In an

embodiment, the ayahuasca-like substance or vaporizable formulation comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the vaporizable formulation comprises dimethyltryptamine. In an embodiment, the ayahuasca-like substance of the vaporizable formulation comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the vaporizable formulation is dimethyltryptamine comprising deuterium. In an embodiment, the vaporizable formulation comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG).

[0010] In another embodiment, a method of treating a psychological disorder is provided. In this embodiment the method comprises administering to a patient an effective amount of an ayahuasca-like substance, wherein the method comprises heating a vaporizable formulation comprising the ayahuasca-like substance to vaporize at least a portion of the vaporizable formulation. In an embodiment, the vaporizable formulation of the method of treatment is housed in a chamber comprising a top portion adapted for coupling to a mouthpiece wherein the top portion of the chamber comprises at least one aperture adapted to permit flow of air, liquid, solids, or vapor between the top portion of the chamber and the mouthpiece. In an embodiment, the chamber of the method of treatment comprises a mouthpiece coupled to the top portion of the chamber wherein the mouthpiece comprises a top aperture, a central open bore, a bottom portion comprising an aperture, and wherein the bottom portion of the mouthpiece is coupled to the top portion of the chamber. In an embodiment, the chamber of the method of treatment comprises at least one seal situated between the bottom portion of the mouthpiece comprising an aperture and the top portion of the chamber. In an embodiment, the mouthpiece of the method of treatment is releasably coupled to the top portion of the chamber. In an embodiment, the mouthpiece of the method of treatment is lockably coupled to the top portion of the chamber. In an embodiment, the chamber of the method of treatment comprises a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the vaporizable formulation. In an

embodiment, the chamber of the method of treatment is coupled to the power unit capable of providing power to vaporize the vaporizable formulation. In an embodiment, the chamber of the method of treatment is releasably coupled to the power unit. In an embodiment, the chamber of the method of treatment is lockably coupled to the power unit. In an embodiment, the chamber of the method of treatment comprises one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector. In an embodiment, the chamber of the method of treatment comprises an eGo connector. In an embodiment, the chamber of the method of treatment comprises a 510 connector. In an embodiment, the chamber of the method of treatment is refillable. In an embodiment, the chamber of the method of treatment is single-use. In an embodiment, the chamber of the method of treatment is transparent to permit visualization of levels of the vaporizable formulation. In an embodiment, the ayahuasca-like substance or vaporizable formulation of the method of treatment comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the method of treatment comprises dimethyltryptamine. In an embodiment, the ayahuasca-like substance of the method of treatment comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the method of treatment is dimethyltryptamine comprising deuterium. In an embodiment, the vaporizable formulation of the method of treatment comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG). In an embodiment, the psychological disorder of the method of treatment comprises one or more of obsessive compulsive disorder, nicotine addiction, alcoholism, narcotic addiction, depression and anxiety related to diagnosis of a life-threatening or terminal illness, major depressive disorder, depression, bipolar disorder, dysthymic disorder, panic attacks, schizophrenia, attention deficit disorder, attention deficit hyperactivity disorder, general anxiety disorder, impulse disorders, delusional disorders, cluster headaches, migraines, personality disorders, gambling disorders, eating disorder, body dysmorphic disorder, or post traumatic stress disorder.

[0011] In another embodiment, a kit is provided. The kit comprises a chamber comprising at least one vaporizable formulation wherein the vaporizable formulation comprises an ayahuasca-like substance. In an embodiment, the chamber of the kit comprises a mouthpiece coupled to the top portion of the chamber wherein the mouthpiece comprises a top aperture, a central open bore, a bottom portion comprising an aperture, and wherein the bottom portion of the mouthpiece is coupled to the top portion of the chamber. In an embodiment, the mouthpiece of the kit is releasably coupled to the top portion of the chamber. In an embodiment, the mouthpiece of the kit is lockably coupled to the top portion of the chamber. In an embodiment, the chamber of the kit is coupled to the power unit capable of providing power to vaporize the vaporizable formulation. In an embodiment, the chamber of the kit is releasably coupled to the power unit. In an embodiment, the chamber of the kit is lockably coupled to the power unit. In an embodiment, the chamber of the kit comprises one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector. In an embodiment, the chamber of the kit comprises a 510 connector. In an embodiment, the chamber of the kit is transparent to permit visualization of levels of the vaporizable formulation. In an embodiment, the chamber of the kit is refillable. In an embodiment, the ayahuasca-like substance or vaporizable formulation of the kit comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the kit comprises dimethyltryptamine. In an embodiment, the ayahuasca-like substance of the kit comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the kit is dimethyltryptamine comprising deuterium. In an embodiment, the vaporizable formulation of the kit comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG).

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] A skilled artisan will understand that the drawings, described below, are for illustrative purposes only. The drawings are not intended to limit the scope of the present teachings in any way.

[0013] FIG. 1 illustrates an exemplary chamber of the present invention. The chamber comprises a mouthpiece (101) coupled to the top portion of the chamber, a transparent wall (102) to permit visualization of a vaporizable formulation that may be present within the hollow section of the chamber, and a threaded 510 connector (103).

[0014] Figure 2A illustrates an exemplary chamber of the present invention using an adaptable “eGo” threaded connector with a “closed” chamber and a 510 connector. Figure 2B illustrates an adaptable “eGo” threaded connector with an “open” chamber exposing “eGo” threads.

[0015] FIG. 3 illustrates an exemplary chamber of the present invention having a threaded 510 connector and containing a vaporizable formulation (301) comprising dimethyltryptamine.

[0016] FIG. 4 illustrates an optional embodiment of the present invention wherein a chamber comprising a vaporizable formulation comprising dimethyltryptamine (401) is connected via a 510 threaded connector to a commercially available power unit capable of connecting to 510 threaded connectors (402).

DETAILED DESCRIPTION OF THE INVENTION

[0017] The present teachings relate generally to a delivery device that provides users with the ability to safely, reliably, and conveniently obtain a high-quality, therapeutic, and vaporizable formulation comprising an ayahuasca-like substance, such as dimethyltryptamine.

[0018] Devices used to vaporize substances are known in the art, and are commonly referred to in the art as vaporizers, atomizers (e.g., rebuildable atomizers, rebuildable dripping atomizers, rebuildable tank atomizers, clearomizers, or cartomizers), mods (including but not limited to squonk mods, sub ohm mods, box mods, tube modes,

temperature control mods, regulated mods, and mechanical mods), E-cigs, vape pens, etc.

[0019] During use, power may be generated by a power unit through the application of voltage generated by the power unit, which is then passed through to threads of a chamber, thus permitting a heating element that may be positioned within the chamber to generate heat. The heat may then vaporize a vaporizable formulation in the chamber adjacent to the heating element present in the chamber. The vaporizable formulation comprising the ayahuasca-like substance may then be inhaled by the user of the chamber. These and other features of the present teachings will become more apparent from the description herein. While the present teachings are described in conjunction with various embodiments, it is not intended that the present teachings be limited to such embodiments. On the contrary, the present teachings encompass various alternatives, modifications, and equivalents, as will be appreciated by those of skill in the art.

[0020] The terminology used in the disclosure herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the disclosure. As used in the description of the embodiments of the disclosure and the appended claims, the singular forms of “a,” “an,” and “the” are intended to include the plural forms as well, unless the context clearly indicates otherwise. Also, as used herein, “and/or” refers to and encompasses any and all possible combinations of one or more of the associated listed items. Furthermore, the term “about,” as used herein when referring to a measurable value such as an amount of a compound, amount, dose, time, temperature of the specified amount. It will be further understood that the terms “comprises” and/or “comprising,” when used in this specification, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components, and/or groups thereof. Unless otherwise defined, all terms, including technical and scientific terms used in the description, have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosure belongs.

Definitions

[0021] As used herein, an “aperture” refers to an opening, e.g. within a mouthpiece, chamber, or power unit, that permits the flow of air, liquids, solids, or vapor between components of the invention as described herein.

[0022] As used herein, an “ayahuasca-like substance” refers to a substance having any amount or sort of psychological or psychedelic effect, which can include, but is not limited to, dimethyltryptamine (also known as *N,N*-dimethyltryptamine, or DMT), a monoamine oxidase inhibitor, 5-methoxy-*N,N*-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. Ayahuasca-like substances may include isotopomer or isotopologue variations thereof, including but not limited to deuterium-containing substances. In some embodiments the ayahuasca-like substance is dimethyltryptamine. The ayahuasca-like substances of the present invention can be mixed with additional substances in the vaporizable formulation, e.g., monoamine oxidase inhibitors.

[0023] As used herein, a “chamber” refers to a device that holds a vaporizable formulation comprising an ayahuasca-like substance. A chamber is analogous to a “vape cartridge” well known in the art that may include a top portion connected to a mouthpiece, and a bottom portion connected to a battery or power supply that provides power to a heating element that may be present in the chamber that functions to heat the vaporizable formulation to produce vapor.

[0024] As used herein, a “connector” or “connection” refers to the type of connection between the chamber and the power unit. A connector may include a tenon (or “male” component) to connect the chamber to a mortise (or “female” component) configured within the power unit. In most embodiments the chamber will have the tenon and the power unit will have the mortise. The type of connectors described herein are usually referred to by the thread type, which can include, but is not limited to, 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo thread. By way of example, a “510 connector” is a connector having a 510 thread as is commonly referred to in the art. In preferred embodiments a “510 connector” means the chamber is adapted with a 510 threaded tenon and the power unit has a 510 mortise able to accept a 510 threaded

tenon, as is commonly referred to in the art. An eGo thread can have any diameter, but in most cases as used herein refers to an approximately 14mm diameter. An eGo thread is usually larger than other threads used in the art, such that a smaller thread, e.g., a 510 thread, can be adapted to function with an eGo connector.

[0025] As used here, “delivery” or “delivering” refers to the delivery of an ayahuasca-like substance present within a vaporizable formulation-produced vapor generated by power supplied to the chamber of the present invention.

[0026] As used herein, “lockably coupled” refers to components that are not intended to be removed by an end-using consumer. For illustrative purposes, a mouthpiece that is lockably coupled to a chamber is not intended to be removed. Lockably coupled chambers are intended for single-use and are meant to be discarded following vaporization of all the vaporizable formulation present in a chamber. As used herein, “releasably coupled” refers to components that may be removed by an end-using consumer. For illustrative purposes, a mouthpiece that is releasably coupled to a chamber may be removed so that a user may reuse and refill a chamber with additional vaporizable formulation.

[0027] As used herein, “monoamine oxidase inhibitor” or “MAO inhibitor” refers to a compound that acts by inhibiting the activity of monoamine oxidase.

[0028] As used herein, a “mouthpiece” refers to a component that permits a user to easily inhale vapor produced within the chamber. Mouthpieces may be many different sizes and shapes, for example, flat, round, oval, square, rectangular, etc. The mouthpiece may be made of any suitable material, including but not limited to, plastic, glass, ceramic, silicon, or wood.

[0029] As used herein, the terms “propylene glycol (PG),” “vegetable glycerin (VG),” and “polyethylene glycol (PEG)” refer to components of vaporizable formulations that are substances commonly used as food additives, and have other medical applications, and which are commonly used substances known in the field of vaporizing. The components can be an molecular weight variation, for example but not limited to, PEG 200, PEG 400, and the like.

[0030] As used herein, “refillable” refers to a chamber that may be refilled and reused. This is opposed to a “single-use” chamber, which is not meant to be refillable.

[0031] As used herein, “power” refers to energy capable of generating heat within a heating element capable of producing vapor as described herein.

[0032] As used herein, a “power unit” refers to a device meant to provide power, e.g., voltage, to vaporize a vaporizable formulation comprising an ayahuasca-like substance within the chamber of the present invention.

[0033] As used herein, a “psychological disorder” refers to any disorder that may be treated by the methods and devices of the present invention. Non-limiting examples of psychological disorders may include, but are not limited to, obsessive compulsive disorder, nicotine addiction, alcoholism, narcotic addiction, depression and anxiety related to diagnosis of a life-threatening or terminal illness, major depressive disorder, depression, bipolar disorder, dysthymic disorder, panic attacks, schizophrenia, attention deficit disorder, attention deficit hyperactivity disorder, general anxiety disorder, impulse disorders, delusional disorders, cluster headaches, personality disorders, gambling disorders, eating disorder, body dysmorphic disorder, or post traumatic stress disorder.

[0034] As used herein, a “seal” refers to an item that is situated between two components of the device of the present invention, and may function to provide a more efficient and/or stronger connection between the components. A seal may also function to prevent tampering of the devices described herein. The seal can be made of any material known in the art, including but not limited to, PTFE, nitrile, neoprene, silicone, EDPM rubber, fluorocarbon, etc.

[0035] As used herein, “treating” or “treatment” or “therapy” refers to ameliorating, preventing, or improving at least one psychological disorder.

[0036] As used herein, “vapor” refers to both a substance in the gaseous state and a suspension of finely divided solid particles or liquid droplets in a gas, including aerosols and mists, which functions to deliver the ayahuasca-like substances of the present

invention to an end-using consumer. The term “vaporize” refers to the process to producing vapor, e.g., from a vaporizable formulation.

[0037] As used herein, a “vaporizable formulation” refers to a liquid (e.g., an oil) and/or solid (e.g., a wax) solution that may be contained within the chamber of the present invention, and which produces a mist or vapour when heated by a heating element that functions to provide a vaporizable carrier for the ayahuasca-like substances described herein.

Delivery Device Chambers

[0038] The present invention provides a chamber filled with a vaporizable formulation comprising an ayahuasca-like substance. Non-limiting exemplary chambers are illustrated in Figure 1 and Figure 2. An exemplary chamber comprising an ayahuasca-like substance (301) is illustrated in Figure 3. In some embodiments the chamber is coupled to a power unit capable of providing power to vaporize the formulation (Figure 4). The heat generated within the chamber via a heating element may vaporize the vaporizable formulation in the chamber adjacent to the heating element present in the chamber. Following vaporization, the vaporizable formulation comprising the ayahuasca-like substance may then mix with air and subsequently be inhaled by the user, which in some embodiments is through a mouthpiece of the chamber that results in an aerosol that is delivered to the user.

[0039] A user may desire to have a pre-loaded or manually loaded vaporizable formulation comprising a therapeutic ayahuasca-like substance in the chamber to permit an efficient vaporization of the vaporizable formulation for inhalation and delivery of the substance to the user without having to measure, weigh, touch, or risk spilling the vaporizable formulation to be vaporized and consumed. A pre-loaded chamber further reduces the risk of contact of the vaporizable formulation during many aspects of the supply chain, thus reducing the potential for improper dosing or contamination. Alternatively, a user may desire to have the ability to load the chamber themselves. The chamber may be either refillable or single-use, pre-loaded or loaded prior to use. Numerous delivery device chambers known in the art can be used to practice the

present invention, including but not limited to portable or desktop vaporizable cartridges or tanks.

[0040] In an embodiment the chamber comprises a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the vaporizable formulation. In an embodiment the chamber is coupled to the power unit capable of providing power to vaporize the vaporizable formulation. Any manner of coupling the power unit to the chamber is sufficient. The chamber may be locked to the power unit. In such embodiments the power unit may be locked as a single use device, or maybe locked to a reusable chamber. In some embodiments the power unit may be releasable from the chamber, which a user may find useful for recharging the power unit.

[0041] In an embodiment a connector (103) is provided to connect the chamber to the power unit to permit a heating element that may be integrated within the chamber to provide heat for vaporization of the vaporizable formulation. Such connections are well known in the art. For example, the connector may include a tenon (or “male” component) to connect the chamber to a mortise (or “female” component) configured within the power unit. In most embodiments the chamber will have the tenon and the power unit will have the mortise.

[0042] In an embodiment, the tenon may include threads complementary to the threads of the power unit in a standard connection known in the art as a “510 connection,” or a “510 connector,” or as having “510 threads,” or any colloquial variation thereof. By way of example, a “510 connector” is a connector having a 510 thread as commonly referred to in the art. In preferred embodiments a “510 connector” means the chamber is adapted with a 510 threaded tenon and the power unit has a 510 compatible mortise able to accept a 510 threaded tenon, as is commonly referred to in the art. In another embodiment the threads of the power unit may utilize an “eGo connection,” or an “eGo connector,” or have “eGo threads.”

[0043] In other embodiments the chamber may utilize a “401 connection,” or a “401 connector,” or have “401 threads.” In an embodiment the chamber unit may utilize a “601 connection,” or a “601 connector,” or have “601 threads.” In an embodiment the

chamber may utilize a “610 connection,” or a “610 connector,” or have “610 threads.” In an embodiment the chamber may utilize a “710 connection,” or an “710 connector,” or have “710 threads.” In an embodiment the chamber may utilize an “808 connection,” or an “808 connector,” or have “808 threads.” In an embodiment the chamber may utilize a “901 connection,” or a “901 connector,” or have “901 threads.” In an embodiment the chamber may utilize a “4081 connection,” or a “4081 connector,” or have “4081 threads.” In an embodiment the chamber may utilize a “CE-4 connection,” or a “CE-4 connector,” or have “CE-4 threads.” In an embodiment the chamber may utilize an “E9 connection,” or an “E9 connector,” or have “601 threads.” In an embodiment the chamber may utilize a “CE-5 connection,” or a “CE-5 connector,” or have “CE-5 threads.” Any other suitable connections for providing an electrical connection to the chamber from the power unit as is known in the art may be used.

[0044] In some embodiments the chamber may include more than one, or multiple types of thread connections that are easily adaptable to create numerous permutations of thread types for adaptability between connection types. In an embodiment, both 510 and eGo threads are configured to the same chamber such that a 510 thread connector is adapted to be used with an eGo thread connector to permit connection versatility (Figure 2). In an embodiment, both 401 and eGo threads are configured to the same chamber such that a 401 thread connector is adapted to be used with an eGo thread connector to permit connection versatility. In an embodiment, both 601 and eGo threads are configured to the same chamber such that a 601 thread connector is adapted to be used with an eGo thread connector to permit connection versatility. In an embodiment, both 610 and eGo threads are configured to the same chamber such that a 610 thread connector is adapted to be used with an eGo thread connector to permit connection versatility. In an embodiment, both 710 and eGo threads are configured to the same chamber such that a 710 thread connector is adapted to be used with an eGo thread connector to permit connection versatility. In an embodiment, both 808 and eGo threads are configured to the same chamber such that an 808 thread connector is adapted to be used with an eGo thread connector to permit connection versatility. In an embodiment, both 901 and eGo threads are configured to the same chamber such that

a 901 thread connector is adapted to be used with an eGo thread connector to permit connection versatility.

[0045] In some embodiments the chamber comprises a top portion adapted for coupling to a mouthpiece (101) wherein the top portion of the chamber comprises at least one air aperture adapted to permit the flow of air, liquid, or vapor between the top portion of the chamber and the mouthpiece.

[0046] The mouthpiece may be many different sizes and shapes, for example, flat, round, oval, square, rectangular, etc. The mouthpiece may be made of any suitable material, including but not limited to, plastic, glass, ceramic, silicon, stainless steel, or wood. In some embodiments the mouthpiece is coupled to the top portion of the chamber and the mouthpiece has a bottom portion comprising an aperture to permit liquids, solids, vapor, or air to flow from the chamber to the mouthpiece. In some embodiments the mouthpiece has a central open bore to permit liquids, solids, vapor, or air to flow through the mouthpiece; and in some embodiments, the mouthpiece has a top aperture to permit liquids, solids, vapor, or air to exit the mouthpiece in order to be inhaled or utilized by a user.

[0047] In an embodiment, the chamber includes a seal that is situated between the bottom opening of the mouthpiece and the top portion of the chamber. The seal can be made of any material known in the art, including but not limited to, PTFE, nitrile, neoprene, silicone, EDPM rubber, fluorocarbon, etc. In an embodiment, the mouthpiece is releasably coupled to the top portion of the chamber. Releasably coupled mouthpieces may be useful for refilling and multiple uses of chambers. Any mechanism known in the art can be used to permit the mouthpiece to be releasable from the top portion of the chamber, including but not limited to tenon and mortises with or without threads. In an embodiment, the mouthpiece is lockably coupled to the top portion of the chamber. Locked configurations are useful to prevent tampering with the chamber and/or vaporizable formulation.

[0048] The chamber may include a heating element to provide heat that will vaporize the vaporizable formulation comprising the ayahuasca-like substance present within the

chamber. During use, power may be supplied to a heating element positioned within the chamber through the application of voltage generated by the power unit to the threads of the tenon, as described herein, which is then transferred to the heating element positioned within the chamber.

[0049] Many different types of heating elements may be used. The heating element may include a coil and wick, many of which are well known in the art. Exemplary coils are the kanthal ceramic coil, kanthal (FeCrAl) derivatives, nichrome, aluminum, stainless steel, nickel, and titanium. Many different grades of stainless steel wire may be used. The most popular gauges for the wire are 32, 30, 28, 26, 24, and 22. The type of wicking material can vary and preferably includes the organic cotton for the use with botanical extracts, but in some cases, Japanese cotton pads, ekowool, silica, and rayon fiber may be used. The heating element may also be wickless, as is sometimes used in the art.

[0050] The chamber of the present invention will be hollow to some respects such that the vaporizable formulation may be held within the chamber (102). The chamber thus may further include a wall that provides a structural element that further defines an internal volume for containing the vaporizable formulation. The chamber wall can be transparent to permit a user to visualize the amount of vaporizable formulation present within the chamber. An exemplary embodiment of a chamber having a transparent chamber wall permitting visualization of vaporizable formulation is shown in Figure 3 and Figure 4. A transparent chamber wall can be glass or plastic. The chamber wall may also include materials that are opaque, or non-light transmitting. For example the chamber may prevent light from entering into the internal volume. As a result, while stored within the chamber, the vaporizable formulation may be free from exposure to light, thus, reducing degradative effects that may arise due to the light.

[0051] The chamber may include a lid may provide a seal for the chamber so that the vaporizable formulation located within the internal volume is isolated from the external environment and, for example, is kept from degrading. The sealed chamber may further provide quality control for the vaporizable formulation, which may be pre-processed and packaged therein, providing consistency and reliability of its contents. The chamber may

also provide an appropriate environment (e.g., dark, low in relative humidity, inert, etc.) to provide the vaporizable formulation with a relatively long shelf-life. Thus, the chamber in accordance with the present disclosure may be kept for long periods of time without suffering degradation of the contents therein and, for example, may be easily transported, sold in stores, used in vending dispense machines, etc.

[0052] The chamber may further include readable information, for example, given by clear labelling (e.g., markings) on an exterior surface of the chamber, for providing to a user and/or system information regarding its contents. Such information may ultimately be relevant in subjecting the vaporizable formulation to conditions that predictably result in a preferred vapor, with consistency in effects/experience, quality, taste and/or smell.

[0053] The chamber may include a filtering mechanism, such as one or more filters located on either side of the vaporizable formulation, for removing undesirable particulates and/or other contaminants from the vaporizable formulation as it travels away from the internal volume of the chamber.

[0054] The chamber may also include a support member to hold the vaporizable formulation within the internal volume of the chamber during vaporization. The support member may suspend or otherwise distribute the vaporizable formulation within the internal volume during exposure to vaporization heat.

[0055] It can be appreciated that a number of different types, shapes, sizes of chambers may be possible, for use with a variety of different power units. The chamber of the present invention can be commonly used cartridges having 0.25 ml, 0.50 ml, and 1.0 ml capacities. The chamber of the present invention can be commonly used tanks or sub ohm tanks having non-limiting capacities of 2 ml, 3 ml, 4 ml, 5 ml or greater.

[0056] The chamber wall may have a cylindrical shape, a conical shape, a domed shape and/or a tapered construction. In some cases, the particular shape or structure of the chamber may allow it to be suitably placed within a complementary receptacle of a power unit. The shape/structure of the chamber may also provide for a suitable funneling or Venturi effect of the vapor. For instance, an upper end of the chamber may be tapered or dome-shaped such that vapor arising from the chamber is funneled

upward toward an opening and into a collection area (e.g., bag, canister, mouthpiece, flow tube, etc.) where the vapor may be stored or otherwise contained for subsequent consumption.

[0057] In some embodiments it may be preferable to provide a chamber that holds a number of different vaporizable formulations (e.g., having varying types/blends) inside. And it may be further preferable for these different vaporizable formulations to be kept separate during storage. The chamber can include a dividing wall that partitions the internal volume of the chamber into multiple sub-chambers or compartments. For example, the chamber and the power unit may be arranged such that only one of the different types/blends of vaporizable formulations comprising an ayahuasca-like substance is vaporized at a time. Or, vaporization may occur in succession, where the process of vaporization/extraction occurs for each of the vaporizable formulations comprising an ayahuasca-like substance during offset time periods. In some cases, it may be preferable for the power unit to have multiple lines through which separate parts of the chamber may be subject to vaporization and extraction. That is, different compartments of the chamber may be individually heated and subject to separate air flows, allowing for more customized vapors to be produced, with blending of the ingredients at different times during the vaporization process. In various embodiments, the chamber may include materials that exhibit high temperature tolerance that are able to withstand relatively high heat temperatures.

[0058] The chamber further provides dose-specific and consistent amounts of vaporizable formulations and ayahuasca-like substance concentrations for ease of use applications.. Doses can be measured and pre-packaged, and heated precisely to a temperature that produces a therapeutically-active concentration of ayahuasca-like substances. Such dose-specific efficiency increases the present invention's commercial and medicinal value. The chamber may also be configured to permit control over the airflow to the heating element or through the mouthpiece so that the user may adjust the amount of vapor being released.

[0059] The chamber may also be configured to have inlet holes to regulate flow of the vaporizable formulation from the chamber to the external environment for inhalation,

which may be desirable for vaporizable formulations having different viscosities. Commonly used sizes in the art, for example, may inlet holes can have non-limiting diameters of less than or equal to 1.2mm, 1.4mm, 1.6mm, 1.8mm, 2.0mm, or greater.

[0060] The internal volume of the chamber within which the vaporizable formulation is stored may be substantially removed of oxidizing or otherwise deleterious substances. For instance, prolonged exposure of the vaporizable formulation to oxygen may have negative consequences and may reduce the overall quality of the vapor produced therefrom. For example, exposure to oxygen may result in the occurrence of undesirable oxidation or other reaction(s), which may remove a number of desirable qualities from the vaporizable formulation comprising the ayahuasca-like substance. To remove oxygen, an inert air (e.g., nitrogen gas, noble gas, etc.) may be flushed through the chamber. Accordingly, when suitably packaged, the vaporizable formulation may be stored in a relatively inert environment substantially devoid of oxygen. When appropriately packaged, the internal volume of the chamber may also be maintained at a suitable level of relative humidity, as measured according to methods known in the art. It may be preferable for the vaporizable formulation to be stored within a relatively dry environment to reduce opportunities for degradation.

[0061] The chamber may further include a filtering system. For instance, the filter(s) may be constructed to trap unwanted particles that may arise during vaporization of the vaporizable formulation comprising the ayahuasca-like substance. However, in some instances, it may be preferable for the filter(s) to be constructed such that the vaporizable formulation, or derivatives therefrom (e.g., oils, residue, vapor, etc.), does not clog the filter(s). In some embodiments, the filter(s) may include a fine mesh that allows vapor produced from the vaporizable formulation to pass freely therethrough, for example, without an undesirable amount of condensation or accumulation of debris.

Power Units

[0062] An optional embodiment of the present invention is a chamber connected to a power unit, as illustrated in Figure 4. Power units (also sometimes referred to in the art as batteries) are devices used to provide power to vaporize a vaporizable formulation

comprising an ayahuasca-like substance within the chamber of the present invention, for the purpose of inhalation. During use, the application of voltage is generated by a power source within the power unit, which is then passed through to the threads of the chamber. This permits a heating element positioned within the chamber to generate heat in order to vaporize the vaporizable formulation in the chamber adjacent to a heating element present in the chamber.

[0063] Numerous types and examples of power units, both portable and “desktop,” are well known in the art, any one of which may be sufficient to practice the present invention. The power unit may generate heat using many methods well known in the art, and may be configured to heat the vaporizable formulation through a wide range of incremental heats based on the preferences of the user.

[0064] The power unit may be charged by any method well known in the art to provide power to the heating unit, including but not limited to the use of rechargeable batteries. Rechargeable batteries can be recharged using many methods known in the art, for example, via a USB recharging system.

[0065] In some embodiments, a power unit may be equipped with a controller that is configured to obtain information regarding the contents of the vaporizable formulation comprising an ayahuasca-like substance based on the readable information. For instance, the power unit may have an information reader, such as a digital code reader (e.g., for barcodes, QR codes, etc.) for reading the readable information on the surface of the chamber and/or user interface, for providing input to the controller of the information about the vaporizable formulation comprising an ayahuasca-like substance. Based on this input, the power unit may process the vaporizable formulation comprising an ayahuasca-like substance within the chamber according to a specific vaporization recipe, to produce a vapor having particularly desirable characteristics. For example, the power unit may flow air through the chamber as well as provide a temperature profile within the chamber for extracting a suitable combination of chemical compounds according to a specified protocol. In some embodiments, this temperature profile may include a number of timed temperature adjustments that occur during the period of vaporization when extraction of the vaporization formulation comprising an ayahuasca-

like substance occurs. In some cases, the power unit may provide this temperature profile as part of an automated process of vaporization and extraction, or a user may input such a profile into the power unit. Vapor generated from the vaporizable formulation comprising an ayahuasca-like substance is then passed from the internal volume of the chamber externally, or alternatively, to a bag, canister and/or other collection region, for consumption by a user.

[0066] The power unit may include sensors to provide a user with an appropriate notification (e.g., audio/visual/tactile signal(s)) as the production of vapor is ongoing, or completed. In some embodiments, a sensor coupled with the power unit that tracks the progress of vapor production may be employed so as to present the user with a real-time status report of the vapor being generated, or even if the vapor is being generated at all. For example, such a report may be an indicator for how full the chamber is, the particular concentration of one or more ayahuasca-like substances within the vapor, whether the vaporization cycle has been completed, the existence of vapor produced, etc. Hence, at an appropriate time (e.g., when the chamber is full of vapor, when the user wants to stop the cycle, etc.), the chamber may be removed from the power unit and the user may sip and/or breathe the vapor through a suitable mouthpiece.

[0067] The power unit may be configured to process the chamber and its contents so as to extract the ayahuasca-like substances as fully as possible therefrom. Accordingly, the power may control the overall dosage of vapor and extraction by varying a number of parameters during certain steps such as cycle time, start/stop times, temperature settings, rate of air flow therethrough, relative humidity, amongst others, the combination of which may play a substantial role in producing a desirable amount of substance and flavor.

[0068] The power unit may also be configured as a smart machine that learns the preferences of a user. For example, a user may input a number of parameters and/or the power unit may track the particular conditions for vaporizing the contents of the chamber. The user may determine that a certain set of conditions may be especially effective in producing a vapor that achieves a favorable experience. The vaporizer may also track specific combinations of chamber and vaporization conditions that correspond

to favorable user experiences, and may communicate such combinations to the user for later use, as suitably desired.

[0069] In an embodiment a power unit may be made available in combination with the chamber, and may be releasably coupled to the chamber. In an embodiment a power unit may be made available in combination with the chamber, and may be lockably coupled to the chamber. In embodiments where the power unit is lockably coupled to the chamber, the purpose may be for a “all in one” single use application. However, power units may be lockably coupled to a refillable chamber as described herein, if desired by a consumer.

Vaporizable Formulations

[0070] Included in the present invention are vaporizable formulations, sometimes referred to in the art as “vape juice,” or “e-liquid,” or “e-juice,” and which refers to a liquid (e.g., an oil) and/or solid (e.g., a wax) solution that may be contained within the chamber of the present invention, and which produces a mist or vapour when heated by a heating element that functions to provide a vaporizable carrier for the ayahuasca-like substances described herein.

[0071] The vapor may include a mist, aerosol and/or nebulized composition that includes fine solid and/or liquid particles suspended in a gas or, in some cases, the vapor may be substantially formed as a gas. The vapor may also include a gaseous substance having small droplets of oil, water and/or other chemical compounds suspended therein. In some cases, a vapor includes liquid (e.g., water, oil, etc.) particles mixed with hot ambient air, which is cooled down so as to condense into a fine cloud of visible airborne droplets. Accordingly, the vaporizable formulation may be breathed or otherwise administered as medication and/or as therapy in a vaporized form.

[0072] In an embodiment, the vaporizable formulation is a mix of propylene glycol (PG) and vegetable glycerin (VG). The vaporizable formulation of the present invention may contain any ratio of PG/VG based on user preference, for example, between 0:100 PG:VG and 10:90 PG:VG, between 10:90 PG:VG and 20:80 PG:VG, between 20:80

PG:VG and 30:70 PG:VG, between 30:70 PG:VG and 40:60 PG:VG, between 40:60 PG:VG and 50:50 PG:VG, between 50:50 PG:VG and 60:40 PG:VG, between 60:40 PG:VG and 70:30 PG:VG, between 70:30 PG:VG and 80:20 PG:VG, between 80:20 PG:VG and 90:10 PG:VG, or between 90:10 PG:VG and 100:0 PG:VG.

[0073] The vaporizable formulation may also include water, terpene, and/or polyethylene glycol (PEG) as the vaporizable formulation, and in combination with any ratio of PG and VG. The PEG can be of any molecular weight, including but not limited to, PEG200 and PEG 400. The vaporizable formulation of the present invention may contain any ratio of PEG/VG based on user preference, for example, between 0:100 PEG:VG and 10:90 PEG:VG, between 10:90 PEG:VG and 20:80 PEG:VG, between 20:80 PEG:VG and 30:70 PEG:VG, between 30:70 PEG:VG and 40:60 PEG:VG, between 40:60 PEG:VG and 50:50 PEG:VG, between 50:50 PEG:VG and 60:40 PEG:VG, between 60:40 PEG:VG and 70:30 PEG:VG, between 70:30 PEG:VG and 80:20 PEG:VG, between 80:20 PEG:VG and 90:10 PEG:VG, or between 90:10 PEG:VG and 100:0 PEG:VG. The vaporizable formulation of the present invention may contain any ratio of PG/PEG based on user preference, for example, between 0:100 PG:PEG and 10:90 PG:PEG, between 10:90 PG:PEG and 20:80 PG:PEG, between 20:80 PG:PEG and 30:70 PG:PEG, between 30:70 PG:PEG and 40:60 PG:PEG, between 40:60 PG:PEG and 50:50 PG:PEG, between 50:50 PG:PEG and 60:40 PG:PEG, between 60:40 PG:PEG and 70:30 PG:PEG between 70:30 PG:PEG and 80:20 PG:PEG, between 80:20 PG:PEG and 90:10 PG:PEG, or between 90:10 PG:PEG and 100:0 PG:PEG.

[0074] The present invention should not be limited by variability in the purity, kinds and concentrations of chemicals used in liquids, and significant variability between labeled content and concentration and actual content and concentration.

[0075] A skilled artisan will be familiar with a substantial range of vaporizable formulations that can be used with the present invention, and any substance that is vaporizable and capable of acting as a carrier for the ayahuasca-like substance will suffice. Numerous naturally extracted e-liquids may be used as the vaporizable

formulation for the present invention, for example, the e-liquids described in United States Patent Application No. 20160309775.

[0076] Traditional ayahuasca preparations include monoamine oxidase inhibitors (MAOIs). Thus the vaporizable formulation of the present invention can further include one or more MAOIs, which are well known in the art, and can include, but not be limited to, Clorgyline, Minaprine, and the reversible MAO-A inhibitors Befloxatone, Brofaromine, Cimoxatone, Harmaline, Moclobemide, Pirlindole and Toloxatone. Examples of MAO-B inhibitors include, but are not limited to, Rasagiline, Selegiline and Pargyline. Examples of unselective MAO-A and MAO-B inhibitors include, but are not limited to, Iproclozide (Sursum), Iproniazid (Marsilid, Iprozid, Ipronid, Rivivol, Propilniazida), Isocarboxazid (Marplan), Mebanazine (Actomol), Metfendrazine (H.M.-11), Nialamide (Niamid), Phenelzine (Nardil), Pheniprazine (Caton), Phenoxypropazine (Drazine), Pivalylbenzhydrazine (Tersavid, Neomarsilid), Safrazine (Safra) and Tranylcypromine (Parnate). See, for example, Remington: The Science and Practice of Pharmacy, 21st Edition, (2005, Lippincott Williams & Wilkins), pages 1517-1523, and Physicians' Desk Reference, Edition 60 (2006, Thomson PDR) page 1499 (each of which is incorporated herein by reference).

[0077] The vaporizable formulation may further include additional components so that users may choose to modify or boost their flavor or concentration of the ayahuasca-like substance with various offerings, including flavorings (non-limiting examples known in art such terpenes, flavonoids, mint, ginger, cinnamon, vanilla, pepper jack cheese, chocolate and peanut butter, Pennsylvania fruit cake, chamomile, ginko, Izzy treats, mango, etc.), and other additives or ingredients, as suitably desired.

[0078] Other compositions may also be included in the vaporizable formulation to complement the ayahuasca-like substance. For example, the vaporizable formulation may also include flavonoids, terpenoids, amino acids, proteins, sugars, enzymes, fatty acids, esters and/or other compounds, including but not limited to cannabinoid extracts from cannabis, THC, THCV, ketorolac, morphine, testosterone, ibuprofen, codeine, nicotine, Vitamin A, Vitamin E acetate, Vitamin E, nitroglycerin, pilocarpine, mescaline, testosterone enanthate, menthol, phencaramide, methsuximide, eptastigmine,

promethazine, procaine, retinol, lidocaine, trimeprazine, isosorbide dinitrate, timolol, methypylon, etamiphyllin, propoxyphene, salmetrol, vitamin E succinate, methadone, oxprenolol, isoproterenol bitartrate, etaqualone, Vitamin D3, ethambutol, ritodrine, omoconazole, lomustine, ketamine, ketoprofen, cilazaprol, propranolol, sufentanil, metaproterenol, pentoxapylline, captopril, loxapine, cyproheptidine, carvediol, trihexylphenadine, alprostadiol, melatonin, testosterone propionate, valproic acid, acebutolol, terbutaline, diazepam, topiramate, pentobarbital, alfentanil HCl, papaverine, nicergoline, fluconazole, zafirlukast, testosterone acetate, droperidol, atenolol, metoclopramide, enalapril, albuterol, ketotifen, isoproterenol, amiodarone HCl, zileuton, midazolam, oxycodone, cilostazol, propofol, nabilone, gabapentin, famotidine, lorezepam, naltrexone, acetaminophen, sumatriptan, bitolterol, nifedipine, phenobarbital, phentolamine, 13-cis retinoic acid, droprenilamine HCl, amlodipine, caffeine, zopiclone, tramadol HCl, pirbuterol, naloxone, meperidine HCl, trimethobenzamide, nalmeferene, scopolamine, sildenafil, carbamazepine, procaterol HCl, methysergide, glutathione, olanzapine, zolpidem, levorphanol, buspirone, and mixtures thereof.

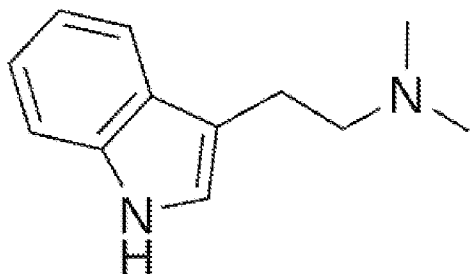
[0079] The vaporizable formulations of the present invention need not be limited to oils, and may also include other liquids or waxes. In some embodiments the vaporizable formulation can be adapted for dry vaporization, or be adapted for wax vaporization. In some embodiments, the vaporizable formulation can be adapted for a combination of one or more oil, dry, or wax vaporizable formulations

[0080] The present invention may be practiced using a variety of different embodiments, including pre-filled chambers that are single use, or refillable. In another embodiment, a vaporizable substance is provided comprising an ayahuasca-like substance, which can be made available separately from the other components of the devices described herein, such that an end-using consumer can refill their chamber after the initial chamber prefilled with the vaporizable formulation is depleted. In another embodiment, the vaporizable formulation can be made available separate from the chamber such that a consumer can adapt their own chamber to be configured with the vaporizable formulations.

Ayahuasca-like Substances

[0081] In some embodiments the vaporizable formulations as described herein comprise an ayahuasca-like substance that is provided for medicinal, therapeutic and/or recreational purposes. The substance may include matter derived from a plant, used for consumption, such as for medicinal, therapeutic, aromatic and/or culinary purposes.

[0082] In an embodiment, ayahuasca-like substance may be dimethyltryptamine (also referred to as *N,N*-dimethyltryptamine, or DMT):



[0083] The ayahuasca-like substance does not need to be limited to substances commonly found in ayahuasca, and can include other substances as well, by way of example and not meant to be limiting, 5-methoxy-*N,N*-dimethyltryptamine or 2-5-dimethoxy-4-bromophenethylamine. The ayahuasca-like substance can further include isotopomer and isotopologue variations, for example, a DMT isotopomer or isotopologue comprising deuterium or tritium.

[0084] Ayahuasca-like substances are often combined with MAOIs, many of which are included in the vaporizable formulation and described elsewhere herein.

[0085] The ayahuasca-like substances of the present invention can be synthesized by a variety of methods known to one of skill in the art (see Comprehensive Organic Transformations Richard C. Larock, 1989) or by an appropriate combination of generally well known synthetic methods. Dimethyltryptamine can be synthesized through several possible pathways from different starting materials. A common method skilled artisans use to synthesize dimethyltryptamine is through reaction of indole with oxalyl chloride followed by reaction with dimethylamine and reduction of the carbonyl functionalities with lithium aluminum hydride. Another method commonly known for the synthesis of

dimethyltryptamine is through the n,n-dimethylation of tryptamine using formaldehyde followed by reduction with sodium cyanoborohydride or sodium triacetoxyborohydride. Techniques useful in synthesizing the ayahuasca-like substances of the present invention are both readily apparent and accessible to those of skill in the relevant art.

[0086] A skilled artisan will appreciate that other methods of making the ayahuasca-like substances of the present invention are possible, including but not limited to the extraction and/or purification from plants and other natural substances.

Dimethyltryptamine is found in many naturally occurring substances, including but not limited to, *Mimosa hostilis*, *Mimosa tenuiflora*, *Banisteriopsis caapi*, *Phalaris arundinacea*, *Phalaris aquatica*, *Diplopterys cabrerana*, *Psychotria viridis*, *Acacia confusa*, *Anadenanthera peregrina*, and *Anadenanthera colubrina*. Methods of extracting dimethyltryptamine from natural substances are well known in the art, and may include the non-limiting methods incorporating the use of a non-polar hydrocarbon solvent and a subsequent alkaline purification, or an acid-base extraction.

[0087] It should be stressed that dimethyltryptamine can be synthesized or extracted using a variety of different well known methodologies, and need not be limited to any specific synthesis and/or extraction method specifically described herein.

[0088] Most ayahuasca-like substances are readily available and need not be synthesized or extracted. For example, dimethyltryptamine, which was first synthesized in 1931, is readily available in decriminalized jurisdictions.

[0089] The present invention is not intended to be limited to any specific weight per volume concentration of the ayahuasca-like substance dissolved in the vaporizable formulation, and may comprise a weight per volume content of greater than 0.1 w/v %, greater than 1.0 w/v %, greater than 10.0 w/v %, greater than 20.0 w/v %, greater than 30.0 w/v %, greater than 40.0 w/v %, greater than 50.0 w/v %, greater than 60.0 w/v %, greater than 70.0 w/v %, greater than 80.0 w/v %, greater than 90.0 w/v %, greater than 100.0 w/v %, greater than 125.0 w/v %, greater than 150.0 w/v %, greater than 200.0 w/v %; or less than 200.0 w/v %, less than 150.0 w/v %, less than 125.0 w/v %, less than 100.0 w/v %, less than 90.0 w/v %, less than 80.0 w/v %, less than 70.0 w/v %, less than 60.0 w/v %, less than 50.0 w/v %, less than 40.0 w/v %, less than 30.0 w/v %, less than 20.0 w/v %, less than 10.0 w/v %, less than 1.0 w/v %, or less than 0.1 w/v %.

less than 60.0 w/v %, less than 50.0 w/v %, less than 40.0 w/v %, less than 30.0 w/v %, less than 20.0 w/v %, less than 10.0 w/v %, less than 1.0 w/v %, or less than 0.1 w/v %. Combinations of the above-noted ranges, or values outside of these ranges, may be possible for the ayahuasca-like substance content levels of the vaporizable formulation based on user preference or for medicinal optimization.

Methods of Use

[0090] In some embodiments, the present invention describes methods of using the chambers described herein. Such methods are particularly useful for refillable chambers or for end users who wish to load chambers with the vaporizable formulations comprising the anahuasca-like substances themselves.

[0091] In an embodiment, a method for delivering an ayahuasca-like substance as described herein is provided wherein the method of use comprises heating a vaporizable formulation comprising the ayahuasca-like substance as described herein to vaporize at least a portion of the vaporizable formulation.

[0092] In some embodiments the vaporizable formulation of the methods of use of the present invention may be housed in a chamber comprising a top portion adapted for coupling to a mouthpiece and wherein the top portion comprises at least one air aperture adapted to permit flow of air, liquid, or vapor between the chamber and the mouthpiece as described herein. In some embodiments the mouthpiece used by the method of use may comprise a top aperture, a central open bore, and a bottom portion comprising an aperture and coupled to the chamber as described herein. In some embodiments the chamber used by the method of use may comprise at least one seal situated between the bottom opening of the mouthpiece and the top portion of the chamber as described herein. In some embodiments the mouthpiece used in the method of use may be releasably coupled to the top portion of the chamber as described herein. In some embodiments, the mouthpiece used in the method of use may be lockably coupled to the top portion of the chamber as described herein. In some embodiments the chamber used in the method of use may comprise a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the

vaporizable formulation as described herein. In some embodiments the chamber used in the method of use may be transparent to permit visualization of levels of the vaporizable formulation.

[0093] In some embodiments the chamber used by the methods of use of the present invention may be coupled to the power unit capable of providing power to vaporize the vaporizable formulation as described herein; in some embodiments the chamber used by the method is releasably coupled to the power unit as described herein. In some embodiments the chamber used by the methods of use of the present invention may be lockably coupled to the power unit as described herein; in some embodiments the chamber used by the method may comprise one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector to couple the chamber to the power unit as described herein; in an embodiment the chamber used by the methods of use of the present invention comprises a 510 connector as described herein.

[0094] In some embodiments the chamber used in the methods of use of the present invention is refillable as described herein, although it should be noted that the methods of the present invention should not be limited to refillable chambers, and users may choose to practice the methods of use of the present invention using single use applications.

[0095] In some embodiments the ayahuasca-like substance used in the methods of use of the present invention may comprise one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine as described herein. In an embodiment the ayahuasca-like substance used by the methods of use of the present invention comprises dimethyltryptamine as described herein. In an embodiment, the ayahuasca-like substance of the methods of use of the present invention comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the methods of use of the present invention is dimethyltryptamine comprising deuterium.

[0096] In some embodiments the vaporizable formulation used in the methods of the present invention may comprise one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG), or any other compound as described herein.

Methods of Treatment

[0097] Therapeutic benefits of psychedelic drugs, such as dimethyltryptamine, lysergic acid diethylamide and psilocybin, are being actively researched in humans. Studies in healthy volunteers have shown long-term increases in trait optimism (Carhart-Harris et al., *Psychological Medicine* 2016, 46:1379-1390), well-being (Id. and Griffiths et al., *Psychopharmacology* 2011, 218:649-665), and openness (Carhart-Harris et al., *Psychological Medicine* 2016, 46:1379-1390; MacLean et al., *Journal of Psychopharmacology* 2011, 25:1453-1461), neurodegenerative disorders (Morales-Garcia et al, *Translational Psychiatry*, 10:331 (2020)), and studies in patients have found long-term improvements in obsessive compulsive disorder (Moreno et al., *Journal of Clinical Psychiatry* 2006, 67:1735-1740), nicotine addiction (Garcia-Romeu et al., *Current Drug Abuse Reviews* 2014, 7:157-164), alcoholism (Krebs and Johansen, *Psychopharmacology* 2012, 26.7:994-1002; Bogenschutz et al., *Journal of Psychopharmacology* 2015, 29.3:289-299), narcotic addiction (Savage and McCabe, *Psychiatry* 1973, 28.6:808-814), depression and anxiety related to diagnosis of a life-threatening or terminal illness (Grob et al., *Archives of General Psychiatry* 2011, 68:71-78; Griffiths et al., *Journal of Psychopharmacology* 2016, 30(12):1181-1197; Ross et al., *Journal of Psychopharmacology* 2016, 30(12):1165-1180), and depression (Carhart-Harris et al., *The Lancet Psychiatry* 2016; Sanches et al., *Journal of Clinical Psychopharmacology* 2016, 36:77-81) after treatment with psychedelics. Other psychological disorders can include, but are not limited to general anxiety, major depressive disorder, dysthymic disorder, bipolar disorder, panic attacks, schizophrenia, attention deficit disorder, attention deficit hyperactivity disorder, impulse disorders, delusional disorders, cluster headaches, migraines, personality disorders, gambling disorders, eating disorder, body dysmorphic disorder, and other psychological disorders described in the "Diagnostic and Statistical Manual, Version IV." These long-term

positive effects can endure for several months, if not years, even after the compound has been metabolized and has been excreted from the body.

[0098] In some embodiments, the present invention includes methods of treating a psychological disorder comprising administering to a patient an effective amount of an ayahuasca-like substance, wherein the method comprises heating a vaporizable formulation comprising the ayahuasca-like substance to vaporize at least a portion of the vaporizable formulation.

[0099] In some embodiments the vaporizable formulation of the methods of treatment of the present invention may be housed in a chamber comprising a top portion adapted for coupling to a mouthpiece and wherein the top portion comprises at least one air aperture adapted to permit flow of air, liquid, or vapor between the chamber and the mouthpiece as described herein. In some embodiments the mouthpiece used by the methods of treatment may comprise a top aperture, a central open bore, and a bottom portion comprising an aperture that is coupled to the chamber as described herein. In some embodiments the chamber used by the methods of treatment may comprise at least one seal situated between the bottom opening of the mouthpiece and the top portion of the chamber as described herein. In some embodiments the mouthpiece used in the methods of treatment may be releasably coupled to the top portion of the chamber as described herein. In some embodiments, the mouthpiece used in the methods of treatment may be lockably coupled to the top portion of the chamber as described herein. In some embodiments the chamber used in the methods of treatment may comprise a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the vaporizable formulation as described herein. In some embodiments the chamber used in the methods of treatment may be transparent to permit visualization of levels of the vaporizable formulation.

[0100] In some embodiments the chamber used by the methods of treatment of the present invention may be coupled to the power unit capable of providing power to vaporize the vaporizable formulation as described herein. In some embodiments the chamber used by the methods of treatment is releasably coupled to the power unit as described herein. In some embodiments the chamber used by the methods of treatment

of the present invention may be lockably coupled to the power unit as described herein. In some embodiments the chamber used by the methods of treatment may comprise one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector to couple the chamber to the power unit as described herein. In an embodiment the chamber used by the methods of treatment of the present invention comprises a 510 connector as described herein.

[0101] In some embodiments the chamber used in the methods of treatment of the present invention is refillable as described herein, although it should be noted that the methods of treatment of the present invention should not be limited to refillable chambers, and users may choose to practice the methods of the present invention using single use applications.

[0102] In some embodiments the ayahuasca-like substance used in the methods of treatment of the present invention may comprise one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine as described herein. In an embodiment the ayahuasca-like substance used by the methods of treatment of the present invention comprises dimethyltryptamine as described herein. In an embodiment, the ayahuasca-like substance used in the methods of treatment of the present invention comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance used in the methods of treatment is dimethyltryptamine comprising deuterium.

[0103] In some embodiments the vaporizable formulation used in the methods of treatment of the present invention may comprise one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG), or any other compound as described herein.

[0104] The methods of treatment as described herein may be administered by an individual qualified to administer the vaporizable formulations of the present invention in

accordance with local jurisdictional laws, which may include, but is not limited to, a psychiatrist, psychologist, therapist, shaman, or any other qualified individual.

Kits

[0105] In other embodiments the present invention provides components packaged together in the form of a kit for performing any of the methods described herein.

[0106] In some embodiments, the kit comprises a chamber comprising at least one vaporizable formulation wherein the vaporizable formulation comprises an ayahuasca-like substance. In some embodiments, the chamber that is part of the kit comprises a mouthpiece coupled to a top portion of the chamber. In some embodiments the mouthpiece comprises a top aperture, a central open bore, a bottom portion comprising an aperture, and wherein the bottom portion of the mouthpiece is coupled to the top portion of the chamber. In some embodiments, the mouthpiece that is part of the kit is releasably coupled to the top portion of the chamber. In some embodiments, the mouthpiece that is part of the kit is lockably coupled to the top portion of the chamber. In some embodiments, the chamber that is part of the kit is coupled to the power unit capable of providing power to vaporize the vaporizable formulation. In some embodiments, the chamber that is part of the kit is releasably coupled to the power unit. In some embodiments, the chamber that is part of the kit is lockably coupled to the power unit. In some embodiments, the chamber that is part of the kit comprises one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector to couple the chamber to the power unit. In some embodiments, the chamber that is part of the kit comprises a 510 connector. In some embodiments, the chamber that is part of the kit is transparent to permit visualization of levels of the vaporizable formulation. In some embodiments, the chamber that is part of the kit is refillable. In some embodiments, the ayahuasca-like substance that is part of the kit comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In some embodiments, the ayahuasca-like substance that is part of the kit comprises dimethyltryptamine. In an embodiment, the ayahuasca-like substance that is part of the kit comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase

inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance that is part of the kit is dimethyltryptamine comprising deuterium. In some embodiments, the vaporizable formulation that is part of the kit comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG).

EXAMPLE

[0107] Aspects of the present teachings can be further understood in light of the following example, which should not be construed as limiting the scope of the present teachings in any way.

[0108] The following example was performed in a jurisdiction where each substance described has been decriminalized.

Step 1: Dimethyltryptamine

[0109] Pure dimethyltryptamine was acquired through readily available channels. Melting point analyses were taken from two samples to confirm the chemical makeup. The two samples each melted at approximately 46 degrees celsius, confirming that the chemical makeup was dimethyltryptamine.

Step 2: Formulating a vaporizable formulation

[0110] The dimethyltryptamine (i.e., the ayahuasca-like substance) derived from Step 1 was mixed into a formulation comprising propylene glycol (PG) and vegetable glycerin (VG) to formulate a vaporizable formulation comprising the ayahuasca-like substance. The dimethyltryptamine (i.e., the ayahuasca-like substance) derived from Step 1 was also mixed into a formulation comprising polyethylene glycol (PEG) and vegetable glycerin (VG) to formulate a vaporizable formulation comprising the ayahuasca-like substance. Finally, the dimethyltryptamine (i.e., the ayahuasca-like substance) derived from Step 1 was mixed into a formulation comprising propylene glycol (PG) and polyethylene glycol (PEG) to formulate a vaporizable formulation comprising the ayahuasca-like substance.

[0111] Dimethyltryptamine was mixed at different concentrations varying from 250mg/ml to 1g/ml. Optional formulation ratios are described in Table 1.

PG:VG	0:100	PEG:VG	0:100	PG:PEG	0:100
PG:VG	10:90	PEG:VG	10:90	PG:PEG	10:90
PG:VG	20:80	PEG:VG	20:80	PG:PEG	20:80
PG:VG	30:70	PEG:VG	30:70	PG:PEG	30:70
PG:VG	40:60	PEG:VG	40:60	PG:PEG	40:60
PG:VG	50:50	PEG:VG	50:50	PG:PEG	50:50
PG:VG	60:40	PEG:VG	60:40	PG:PEG	60:40
PG:VG	70:30	PEG:VG	70:30	PG:PEG	70:30
PG:VG	80:20	PEG:VG	80:20	PG:PEG	80:20
PG:VG	90:10	PEG:VG	90:10	PG:PEG	90:10
PG:VG	100:0	PEG:VG	100:0	PG:PEG	100:0

Table 1.

Step 3: Production of delivery device

[0112] Step 3 describes an embodiment of the invention wherein a chamber as described herein is combined with an ayahuasca-like substance. The vaporizable formulation of Step 2 comprising the ayahuasca-like substance derived from Step 1 was placed into the hollow portion of a chamber comprising a 510 threaded connector as described herein and illustrated in Figure 3.

[0113] The vaporizable formulation of Step 2 comprising the ayahuasca-like substance derived from Step 1 was also placed into the hollow portion of a chamber comprising an eGo threaded connector as described herein.

Step 4: Attachment to a power unit

[0114] An optional embodiment of the present invention includes a power unit. The delivery device comprising the chamber of Step 3 comprising the vaporizable

formulation of Step 2 comprising the ayahuasca-like substance derived from Step 1 was affixed to a commercially available power unit as shown in Figure 4.

[0115] All publications and patent applications cited in this specification are herein incorporated by reference as if each individual publication or patent application were specifically and individually indicated to be incorporated by reference.

[0116] Although the foregoing invention has been described in some detail by way of illustration and example for purposes of clarity of understanding, it will be readily apparent to one of ordinary skill in the art in light of the teachings of this invention that certain changes and modifications may be made thereto without departing from the spirit or scope of the invention as defined in the appended claims.

Electronic Acknowledgement Receipt

EFS ID:	43567342
Application Number:	17394340
International Application Number:	
Confirmation Number:	7359
Title of Invention:	Delivery System For Ayahuasca-Like Substances
First Named Inventor/Applicant Name:	Gregory Ellis
Customer Number:	173064
Filer:	Gregory Ellis
Filer Authorized By:	
Attorney Docket Number:	1001-US2
Receipt Date:	20-AUG-2021
Filing Date:	04-AUG-2021
Time Stamp:	18:08:29
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant Response to Pre-Exam Formalities Notice	1001-US2_NoticeOmittedItem.pdf	170079 b33a21f9ae4b11effa3fdb80b786976c16e8742c	no	3

Warnings:

Information:					
2	Applicant Response to Pre-Exam Formalities Notice	1001-US2_Response_Ol.pdf	101562	no	2
			337f74209520b1bdcbff569485c4cd29e5eb3001		
Warnings:					
Information:					
3	Specification	1001-US2_SubSpec_marked.pdf	306490	no	37
			e53dcea053d600f23e630bf6c884269f31a032e9		
Warnings:					
Information:					
4	Specification	1001-US2_SubSpec_clean.pdf	305153	no	37
			f538f8c35bfe1b7e02dd02240c84ffcbabd114c0		
Warnings:					
Information:					
Total Files Size (in bytes):			883284		
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. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Ellis, Gregory

Confirmation No.: 7359

Application No.: 17/394,340

Art Unit: Not yet assigned

Filed: 08/04/2021

Examiner: Not yet assigned

For: Delivery System for Ayahuasca-Like Substances

Amendment

Mail Stop Amendment
Commission for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

This paper is being submitted in response to the Notice of Omitted Item(s) In A Nonprovisional Application, mailed August 18, 2021, and is timely filed on or before October 18, 2021.

Remarks begin on page 2 of this paper.

A **Substitute Specification** is included with this paper.

REMARKS

The Notice of Omitted Item(s) In A Nonprovisional Application (the "Notice") alleges that Figure 2 described in the specification has been omitted. However, the specification does not include a Figure 2, but includes as of the filing date a Figure 2A and a Figure 2B. Applicant chooses to respond to the Notice as set forth in Option III (A) of the Notice.

Please find included herewith a clean and marked-up substitute specification that removes reference to a Figure 2 in paragraph [0014] and includes reference only to Figure 2A and Figure 2B in paragraph [0014]. The substitute specification includes no new matter.

CONCLUSION

All stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding objections and rejections, and respectfully requests that they be withdrawn.

Applicant submits that a full and complete reply has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

Respectfully submitted

/Gregory Ellis/

Gregory Ellis
Applicant
USPTO Registration No: 56,186

August 20, 2021



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/394,340	08/04/2021	Gregory Ellis	1001-US2

173064
Gregory Ellis
PO Box 86924
Portland, OR 97286

CONFIRMATION NO. 7359
FORMALITIES LETTER



Date Mailed: 08/18/2021

NOTICE OF OMITTED ITEM(S) IN A NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

A filing date has been accorded to the above-identified nonprovisional application papers; however, the following item(s) appear to have been omitted from the application:

- Figure(s) 2 described in the specification.

Applicant must reply to this notice within the time period set forth in this notice to avoid abandonment of this application. Applicant must select one of the three following options and the reply must comply with the requirements set forth in the selected option and any other requirements set forth in this notice. **The reply should also indicate which option applicant has selected.**

I. Petition for date of deposit: Should applicant contend that the above-noted omitted item(s) was in fact deposited in the U.S. Patent and Trademark Office (USPTO) with the nonprovisional application papers, a copy of this Notice and a petition (and the petition fee set forth in 37 CFR 1.17(f) with evidence of such deposit must be filed within **TWO MONTHS** of the date of this Notice. The petition fee will be refunded if it is determined that the item(s) was received by the USPTO. THIS TWO MONTH PERIOD IS EXTENDABLE UNDER 37 CFR 1.136(a) or (b).

Applicant should review their application file and determine whether their file differs from USPTO's records. In some situations there may be a mislabeling of the drawings and/or a failure to describe in the brief description each of the figures as labeled. See 37 CFR 1.74, 1.77(b)(9), and 1.84(u)(1).

The brief description of the drawings in the specification must correspond with the figures and the figures must be labeled in accordance with 37 CFR 1.84(u)(1). For example, if the brief description describes Figure 1 and Figure 2 only, but the drawings show Fig. 1 and Fig. 2A and Fig. 2B, then the specification must be amended to refer to Figure 2A and Figure 2B and delete the reference to Figure 2 and a substitute specification in compliance with 37 CFR 1.52, 1.121(b)(3), and 1.125, is required. As another example, if a drawing is labeled Figure 2, but there are actually multiple figures within the labeled Figure 2 having labels A, B, and C, then the drawings must be relabeled in accordance with 37 CFR 1.84(u)(1) (e.g., Fig. 2A, Fig. 2B, and Fig. 2C). If the specification does not refer to the figures as relabeled, then the specification must be amended to refer to the relabeled figures (e.g., Fig. 2A, Fig. 2B, and Fig. 2C) and a substitute specification in compliance with 37 CFR 1.52, 1.121(b)(3), and 1.125, is required. A petition for date of deposit under option I should NOT be filed in either situation or in similar situations where there is simply a mislabeling of the drawings and/or a failure to describe in the brief description each of the figures. Instead, applicant should file a reply under option III.A below (including replacement drawing sheets and/or a substitute specification as required in III.A.2).

A petition for date of deposit under option I should NOT be filed in situations where there is simply a mislabeling of the drawings and/or a failure to describe in the brief description each of the figures. Instead, applicant should file a reply under option III(A) below (including replacement drawing sheets and/or a substitute specification as described).

II. Petition for later filing date: Should applicant desire to supply the omitted item(s) and accept the date that such omitted item(s) was filed in the USPTO as the filing date of the above-identified application, a copy of this Notice, the omitted item(s), and a petition under 37 CFR 1.182 with the petition fee set forth in 37 CFR 1.17(f) requesting the later filing date must be filed within **TWO MONTHS** of the date of this Notice. THIS TWO MONTH PERIOD IS EXTENDABLE UNDER 37 CFR 1.136(a) or (b).

Applicant is advised that generally the filing fee required for an application is the filing fee in effect on the filing date accorded the application and that payment of the requisite basic filing fee on a date later than the filing date of the application requires payment of a surcharge (37 CFR 1.16(f)). To avoid processing delays and payment of a surcharge, applicant should submit any balance due for the requisite filing fee based on the later filing date being requested when submitting the omitted item(s) and the petition (and petition fee) requesting the later filing date.

III. Acceptance of application as deposited: Applicant may accept the application as deposited in the USPTO by filing an appropriate amendment as set forth in either (A) or (B) below within **TWO MONTHS** of the date of this Notice. THIS TWO MONTH PERIOD IS EXTENDABLE UNDER 37 CFR 1.136(a) or (b). The application will maintain a filing date as of the date of deposit of the application papers in the USPTO, and original application papers (i.e., the original disclosure of the invention) will include only those application papers present in the USPTO on the date of deposit. A petition is not required for this option.

(A) If applicant wants to accept the application as deposited without adding the subject matter that was in the omitted item, applicant is required to submit one or more of the following items without adding any new matter (see 35 U.S.C. 132(a)):

To remove a missing figure of the drawings or to correct the figure labeling,

- replacement drawing sheets in compliance with 37 CFR 1.121(d) to renumber the drawing figures consecutively (if necessary), and/or
- a substitute specification excluding claims in compliance with 37 CFR 1.121(b)(3) and 1.125 that amends the specification to cancel any references to any omitted drawing(s) and corrects the references in the specification to the drawing figures to correspond with any relabeled drawing figures,

A proper substitute specification in compliance with 37 CFR 1.121(b)(3) and 1.125 consists of:

- A copy of the previously-submitted specification, with deletions shown with strikethrough or brackets and insertions shown with underlining (marked-up version) unless it is indicated above that a marked-up version is not required for each of the correction(s).
- A copy of the amended specification without markings (clean version).
- A statement that the substitute specification contains no new matter, in compliance with 37 CFR 1.121(b)(3) and 1.125.

(B) Alternatively, if applicant wants to accept the application as deposited but wishes to add the subject matter in the omitted item by relying on an incorporation by reference under 37 CFR 1.57 or other portions of the original disclosure, applicant is required to submit the following without adding any new matter (see 35 U.S.C. 132(a)):

To add a missing figure of the drawings, new and replacement drawing sheets in compliance with 37 CFR 1.121(d);

If applicant is relying on an incorporation by reference under 37 CFR 1.57 to add the omitted subject matter, then applicant must also comply with the requirements of 37 CFR 1.57.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

Replies must be received in the USPTO within the set time period or must include a proper Certificate of Mailing or Transmission under 37 CFR 1.8 with a mailing or transmission date within the set time period. For more information and a suggested format, see Form PTO/SB/92 and MPEP 512.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web, including a copy of this Notice and selecting the document description "Applicant response to Pre-Exam Formalities Notice".
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

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**.

/dtdinh/

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 17/394,340				
APPLICATION AS FILED - PART I										
(Column 1)		(Column 2)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY				
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)			
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	80			
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A	175			
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	200			
TOTAL CLAIMS (37 CFR 1.16(j))	20	minus 20 = *			OR	x 25 =	0.00			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1	minus 3 = *				x 120 =	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			
				TOTAL		TOTAL	455			
* If the difference in column 1 is less than zero, enter "0" in column 2.										
APPLICATION AS AMENDED - PART II										
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY		
AMENDMENT A		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	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))							OR		
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
AMENDMENT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	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))							OR		
	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
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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
17/394,340	08/04/2021		455	1001-US2	20	1

CONFIRMATION NO. 7359

FILING RECEIPT

173064
Gregory Ellis
PO Box 86924
Portland, OR 97286



Date Mailed: 08/18/2021

Receipt is acknowledged of this non-provisional utility 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 FIRST INVENTOR, 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 corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction 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 provided that the request is grantable.

Inventor(s)

Gregory Ellis, Portland, OR;

Applicant(s)

Gregory Ellis, Portland, OR;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of PCT/US21/42123 07/18/2021
which claims benefit of 63/144,923 02/02/2021
and claims benefit of 63/058,444 07/29/2020

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: Yes

Permission to Access Search Results: Yes

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: 08/17/2021

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/394,340**

Projected Publication Date: To Be Determined - pending completion of Omitted Items

Non-Publication Request: No

Early Publication Request: No

**** MICRO ENTITY ****

Title

Delivery System For Ayahuasca-Like Substances

Preliminary Class

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 Assets Control, 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).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit <http://www.SelectUSA.gov> or call +1-202-482-6800.

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

First Named Inventor:	Gregory Ellis	Nonprovisional Application Number (if known):	
Title of Invention:	Delivery System For Ayahuasca-Like Substances		

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 /Gregory Ellis/	Date August 04, 2021
Name Gregory Ellis (Print/Typed)	Practitioner Registration Number 56,186

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 1 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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		
	Filing Date		2021-08-04
	First Named Inventor	Ellis, Gregory	
	Art Unit		
	Examiner Name	Not Yet Assigned	
	Attorney Docket Number		1001-US2

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS						
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20190290862		2019-09-26	SYQE Medical	
	2	20190001087		2019-01-03	SYQE Medical	
	3	20190009039		2019-01-10	SYQE Medical	
	4	20180318529		2018-11-08	SYQE Medical	
	5	20180104425		2018-04-18	Phillip Morris	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		
Filing Date		2021-08-04
First Named Inventor	Ellis, Gregory	
Art Unit		
Examiner Name	Not Yet Assigned	
Attorney Docket Number		1001-US2

	6	20200178616		2020-06-11	KSY Technologies	
	7	20170095624		2017-04-06	SYQE Medical	
	8	20170106153		2017-04-20	SYQE Medical	
	9	20170119979		2017-05-04	SYQE Medical	
	10	20170119981		2017-05-04	SYQE Medical	
	11	20170127727		2017-05-11	SYQE Medical	
	12	20170157343		2017-06-08	SYQE Medical	
	13	20170203058		2017-07-20	SYQE Medical	
	14	20180042305		2018-02-15	Phillip Morris	
	15	20160081395		2016-03-24	Phillip Morris	
	16	20180042304		2018-02-15	Phillip Morris	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number			
	Filing Date		2021-08-04	
	First Named Inventor	Ellis, Gregory		
	Art Unit			
	Examiner Name	Not Yet Assigned		
	Attorney Docket Number	1001-US2		

	17	20160120220		2016-05-05	Phillip Morris	
	18	20180289905		2016-03-24	Phillip Morris	
	19	20200360239		2020-11-19	Eric Campos	

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	BLACK, LESTER, New on the Black Market: Vape Pens Full of DMT, The Stranger, August 15, 2018. United States.	☐
	2	VAPOR VANITY STAFF, DMT Vape Pens: What You Need to Know, Vapor Vanity, May 12, 2019.	☐

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

EXAMINER SIGNATURE

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

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

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		
Filing Date		2021-08-04
First Named Inventor	Ellis, Gregory	
Art Unit		
Examiner Name	Not Yet Assigned	
Attorney Docket Number		1001-US2

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

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2021-08-04
First Named Inventor	Ellis, Gregory
Art Unit	
Examiner Name	Not Yet Assigned
Attorney Docket Number	1001-US2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

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

OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Gregory Ellis	Date (YYYY-MM-DD)	2021-08-04
Name/Print	Gregory Ellis	Registration Number	56,186

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

CERTIFICATION OF MICRO ENTITY STATUS (GROSS INCOME BASIS)					
Application Number or Control Number (if applicable):			Patent Number (if applicable):		
First Named Inventor: Gregory Ellis			Title of Invention: Delivery System For Ayahuasca-Like Substances		
The applicant hereby certifies the following—					
(1) SMALL ENTITY REQUIREMENT – The applicant qualifies as a small entity as defined in 37 CFR 1.27. (2) APPLICATION FILING LIMIT – Neither the applicant nor the inventor nor a joint inventor has been named as the inventor or a joint inventor on more than four previously filed U.S. patent applications, excluding provisional applications and international applications under the Patent Cooperation Treaty (PCT) for which the basic national fee under 37 CFR 1.492(a) was not paid, and also excluding patent applications for which the applicant has assigned all ownership rights, or is obligated to assign all ownership rights, as a result of the applicant's previous employment. (3) GROSS INCOME LIMIT ON APPLICANTS AND INVENTORS – Neither the applicant nor the inventor nor a joint inventor, in the calendar year preceding the calendar year in which the applicable fee is being paid, had a gross income, as defined in section 61(a) of the Internal Revenue Code of 1986 (26 U.S.C. 61(a)), exceeding the "Maximum Qualifying Gross Income" reported on the USPTO Web site at http://www.uspto.gov/patents/law/micro_entity.jsp which is equal to three times the median household income for that preceding calendar year, as most recently reported by the Bureau of the Census. (4) GROSS INCOME LIMIT ON PARTIES WITH AN "OWNERSHIP INTEREST" – Neither the applicant nor the inventor nor a joint inventor has assigned, granted, or conveyed, nor is under an obligation by contract or law to assign, grant, or convey, a license or other ownership interest in the application concerned to an entity that, in the calendar year preceding the calendar year in which the applicable fee is being paid, had a gross income, as defined in section 61(a) of the Internal Revenue Code of 1986, exceeding the "Maximum Qualifying Gross Income" reported on the USPTO Web site at http://www.uspto.gov/patents/law/micro_entity.jsp which is equal to three times the median household income for that preceding calendar year, as most recently reported by the Bureau of the Census.					
SIGNATURE by an authorized party set forth in 37 CFR 1.33(b)					
Signature		/Gregory Ellis/			
Name		Gregory Ellis			
Date		08.04.21	Telephone	Registration No.	56,186
☐		There is more than one inventor and I am one of the inventors who are jointly identified as the applicant. The required additional certification form(s) signed by the other joint inventor(s) are included with this form.			

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.

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

**Title of
Invention**

Delivery System For Ayahuasca-Like Substances

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 _____
 filed on _____.

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: Gregory Ellis Date (Optional): August 4, 2021

Signature: /Gregory Ellis/

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.**

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

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.
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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.

DELIVERY SYSTEM FOR AYAHUASCA-LIKE SUBSTANCES

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation under 35 USC 365(c) of International Application No. PCT/US21/42123, filed July 18, 2021, which claims priority benefit to U.S. Provisional Application No. 63/058,444, filed July 29, 2020, and U.S. Provisional Application No. 63/144,923, filed February 02, 2021, the entire contents of each of which are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

[0002] In certain jurisdictions, ayahuasca-like substances and other psychedelic medicines are being legalized or decriminalized, hence allowing for breakthrough alternative medicines and/or recreational experiences. Psychedelic research is still in its infancy, which in part is a consequence of legal barriers to such research that has existed for decades. Yet preliminary reports are encouraging. For example, it was recently reported that dimethyltryptamine, which is the active ingredient in ayahuasca, can promote the proliferation of neural stem cells and subsequent neurogenesis, thus leading to improvements in memory. Such results have significant implications for neurodegenerative disorders such as Alzheimer's, Parkinson's, and dementia (Morales-Garcia *et al.*, *Translational Psychiatry*, 10:331 (2020)).

[0003] However, the ability to distribute reliably consistent amounts and types of ayahuasca-like substances having a particular level of therapeutic or recreational quality is limited. Safety concerns may also arise when ayahuasca-like substances are obtained in a manner where the exact composition is unknown due to risks of contamination, tampering, misrepresentation, etc.

[0004] The ability to store and seal a dose-specific vaporizable formulation comprising an ayahuasca-like substance in a controlled environment with a labelled package that is easily portable provides a tremendous benefit to patients and other consumers. When

an ayahuasca-like substance comes pre-processed and stored in a dry, secure, contamination-free environment, a patient or other consumer is provided with a level of confidence and convenience that has not previously been available. The devices and methods of the present invention thus solve problems associated with both ease of use and safety, and further provide a greater degree of legitimacy so that a patient or consumer can be confident that the contents of the packaged product is in fact what is listed by the labelling.

[0005] The invention described herein provides a device, formulation, methods of use, methods of treatment of psychological disorders, and kits for the delivery of ayahuasca-like substances, which has significant commercial and medicinal potential in jurisdictions that have legalized or decriminalized psychedelic substances.

SUMMARY OF THE INVENTION

[0006] The present teachings relate to a system for the delivery of a vaporizable formulation comprising an ayahuasca-like substance.

[0007] In an embodiment, a device for the delivery of an ayahuasca-like substance is provided. The device comprises a chamber comprising at least one vaporizable formulation wherein the vaporizable formulation comprises the ayahuasca-like substance. In an embodiment, the chamber of the device comprises a top portion adapted for coupling to a mouthpiece wherein the top portion of the chamber comprises at least one aperture adapted to permit flow of air, liquid, solids, or vapor between the top portion of the chamber and the mouthpiece. In an embodiment, a mouthpiece of the device coupled to the top portion of the chamber is provided wherein the mouthpiece comprises a top aperture, a central open bore, a bottom portion comprising an aperture, and wherein the bottom portion of the mouthpiece is coupled to the top portion of the chamber. In an embodiment, at least one seal situated between the bottom portion of the mouthpiece of the device comprising an aperture and the top portion of the chamber is provided. In an embodiment, the mouthpiece of the device is releasably coupled to the top portion of the chamber. In an embodiment, the mouthpiece of the device is lockably coupled to the top portion of the chamber. In an embodiment, the chamber of

the device comprises a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the vaporizable formulation. In an embodiment, the chamber of the device is coupled to the power unit capable of providing power to vaporize the vaporizable formulation. In an embodiment, the chamber of the device is releasably coupled to the power unit. In an embodiment, the chamber of the device is lockably coupled to the power unit. In an embodiment, the chamber of the device comprises one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector. In an embodiment, the chamber of the device comprises a 510 connector. In an embodiment, the chamber of the device is transparent to permit visualization of levels of the vaporizable formulation. In an embodiment, the chamber of the device is refillable. In an embodiment, the ayahuasca-like substance or vaporizable formulation of the device comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the device comprises dimethyltryptamine. In an embodiment, the ayahuasca-like substance of the device comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the device is dimethyltryptamine comprising deuterium. In an embodiment, the vaporizable formulation of the device comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG).

[0008] In another embodiment, a method for delivering an ayahuasca-like substance is provided. In this embodiment the method comprises heating a vaporizable formulation comprising the ayahuasca-like substance to vaporize at least a portion of the vaporizable formulation. In an embodiment, the vaporizable formulation of the method is housed in a chamber comprising a top portion adapted for coupling to a mouthpiece wherein the top portion of the chamber comprises at least one aperture adapted to permit flow of air, liquid, solids, or vapor between the top portion of the chamber and the mouthpiece. In an embodiment, the chamber of the method comprises a mouthpiece coupled to the top portion of the chamber wherein the mouthpiece comprises a top aperture, a central open bore, a bottom portion comprising an aperture, and wherein the

bottom portion of the mouthpiece is coupled to the top portion of the chamber. In an embodiment, the chamber of the method comprises at least one seal situated between the bottom portion of the mouthpiece comprising an aperture and the top portion of the chamber. In an embodiment, the mouthpiece of the method is releasably coupled to the top portion of the chamber. In an embodiment, the mouthpiece of the method is lockably coupled to the top portion of the chamber. In an embodiment, the chamber of the method comprises a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the vaporizable formulation. In an embodiment, the chamber of the method is coupled to the power unit capable of providing power to vaporize the vaporizable formulation. In an embodiment, the chamber of the method is releasably coupled to the power unit. In an embodiment, the chamber of the method is lockably coupled to the power unit. In an embodiment, the chamber of the method comprises one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector. In an embodiment, the chamber of the method comprises an eGo connector. In an embodiment, the chamber of the method comprises a 510 connector. In an embodiment, the chamber of the method is refillable. In an embodiment, the chamber of the method is single-use. In an embodiment, the chamber of the method is transparent to permit visualization of levels of the vaporizable formulation. In an embodiment, the ayahuasca-like substance or vaporizable formulation of the method comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the method comprises dimethyltryptamine. In an embodiment, the ayahuasca-like substance of the method comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the method is dimethyltryptamine comprising deuterium. In an embodiment, the vaporizable formulation of the method comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG).

[0009] In another embodiment, a vaporizable formulation is provided. In this embodiment the vaporizable formulation comprises an ayahuasca-like substance. In an

embodiment, the ayahuasca-like substance or vaporizable formulation comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the vaporizable formulation comprises dimethyltryptamine. In an embodiment, the ayahuasca-like substance of the vaporizable formulation comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the vaporizable formulation is dimethyltryptamine comprising deuterium. In an embodiment, the vaporizable formulation comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG).

[0010] In another embodiment, a method of treating a psychological disorder is provided. In this embodiment the method comprises administering to a patient an effective amount of an ayahuasca-like substance, wherein the method comprises heating a vaporizable formulation comprising the ayahuasca-like substance to vaporize at least a portion of the vaporizable formulation. In an embodiment, the vaporizable formulation of the method of treatment is housed in a chamber comprising a top portion adapted for coupling to a mouthpiece wherein the top portion of the chamber comprises at least one aperture adapted to permit flow of air, liquid, solids, or vapor between the top portion of the chamber and the mouthpiece. In an embodiment, the chamber of the method of treatment comprises a mouthpiece coupled to the top portion of the chamber wherein the mouthpiece comprises a top aperture, a central open bore, a bottom portion comprising an aperture, and wherein the bottom portion of the mouthpiece is coupled to the top portion of the chamber. In an embodiment, the chamber of the method of treatment comprises at least one seal situated between the bottom portion of the mouthpiece comprising an aperture and the top portion of the chamber. In an embodiment, the mouthpiece of the method of treatment is releasably coupled to the top portion of the chamber. In an embodiment, the mouthpiece of the method of treatment is lockably coupled to the top portion of the chamber. In an embodiment, the chamber of the method of treatment comprises a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the vaporizable formulation. In an

embodiment, the chamber of the method of treatment is coupled to the power unit capable of providing power to vaporize the vaporizable formulation. In an embodiment, the chamber of the method of treatment is releasably coupled to the power unit. In an embodiment, the chamber of the method of treatment is lockably coupled to the power unit. In an embodiment, the chamber of the method of treatment comprises one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector. In an embodiment, the chamber of the method of treatment comprises an eGo connector. In an embodiment, the chamber of the method of treatment comprises a 510 connector. In an embodiment, the chamber of the method of treatment is refillable. In an embodiment, the chamber of the method of treatment is single-use. In an embodiment, the chamber of the method of treatment is transparent to permit visualization of levels of the vaporizable formulation. In an embodiment, the ayahuasca-like substance or vaporizable formulation of the method of treatment comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the method of treatment comprises dimethyltryptamine. In an embodiment, the ayahuasca-like substance of the method of treatment comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the method of treatment is dimethyltryptamine comprising deuterium. In an embodiment, the vaporizable formulation of the method of treatment comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG). In an embodiment, the psychological disorder of the method of treatment comprises one or more of obsessive compulsive disorder, nicotine addiction, alcoholism, narcotic addiction, depression and anxiety related to diagnosis of a life-threatening or terminal illness, major depressive disorder, depression, bipolar disorder, dysthymic disorder, panic attacks, schizophrenia, attention deficit disorder, attention deficit hyperactivity disorder, general anxiety disorder, impulse disorders, delusional disorders, cluster headaches, migraines, personality disorders, gambling disorders, eating disorder, body dysmorphic disorder, or post traumatic stress disorder.

[0011] In another embodiment, a kit is provided. The kit comprises a chamber comprising at least one vaporizable formulation wherein the vaporizable formulation comprises an ayahuasca-like substance. In an embodiment, the chamber of the kit comprises a mouthpiece coupled to the top portion of the chamber wherein the mouthpiece comprises a top aperture, a central open bore, a bottom portion comprising an aperture, and wherein the bottom portion of the mouthpiece is coupled to the top portion of the chamber. In an embodiment, the mouthpiece of the kit is releasably coupled to the top portion of the chamber. In an embodiment, the mouthpiece of the kit is lockably coupled to the top portion of the chamber. In an embodiment, the chamber of the kit is coupled to the power unit capable of providing power to vaporize the vaporizable formulation. In an embodiment, the chamber of the kit is releasably coupled to the power unit. In an embodiment, the chamber of the kit is lockably coupled to the power unit. In an embodiment, the chamber of the kit comprises one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector. In an embodiment, the chamber of the kit comprises a 510 connector. In an embodiment, the chamber of the kit is transparent to permit visualization of levels of the vaporizable formulation. In an embodiment, the chamber of the kit is refillable. In an embodiment, the ayahuasca-like substance or vaporizable formulation of the kit comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the kit comprises dimethyltryptamine. In an embodiment, the ayahuasca-like substance of the kit comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the kit is dimethyltryptamine comprising deuterium. In an embodiment, the vaporizable formulation of the kit comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG).

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] A skilled artisan will understand that the drawings, described below, are for illustrative purposes only. The drawings are not intended to limit the scope of the present teachings in any way.

[0013] FIG. 1 illustrates an exemplary chamber of the present invention. The chamber comprises a mouthpiece (101) coupled to the top portion of the chamber, a transparent wall (102) to permit visualization of a vaporizable formulation that may be present within the hollow section of the chamber, and a threaded 510 connector (103).

[0014] FIG. 2 illustrates an exemplary chamber of the present invention using an adaptable “eGo” threaded connector. Figure 2A illustrates a “closed” chamber with a 510 connector. Figure 2B illustrates an “open” chamber exposing “eGo” threads.

[0015] FIG. 3 illustrates an exemplary chamber of the present invention having a threaded 510 connector and containing a vaporizable formulation (301) comprising dimethyltryptamine.

[0016] FIG. 4 illustrates an optional embodiment of the present invention wherein a chamber comprising a vaporizable formulation comprising dimethyltryptamine (401) is connected via a 510 threaded connector to a commercially available power unit capable of connecting to 510 threaded connectors (402).

DETAILED DESCRIPTION OF THE INVENTION

[0017] The present teachings relate generally to a delivery device that provides users with the ability to safely, reliably, and conveniently obtain a high-quality, therapeutic, and vaporizable formulation comprising an ayahuasca-like substance, such as dimethyltryptamine.

[0018] Devices used to vaporize substances are known in the art, and are commonly referred to in the art as vaporizers, atomizers (e.g., rebuildable atomizers, rebuildable dripping atomizers, rebuildable tank atomizers, clearomizers, or cartomizers), mods (including but not limited to squonk mods, sub ohm mods, box mods, tube modes, temperature control mods, regulated mods, and mechanical mods), E-cigs, vape pens, etc.

[0019] During use, power may be generated by a power unit through the application of voltage generated by the power unit, which is then passed through to threads of a chamber, thus permitting a heating element that may be positioned within the chamber to generate heat. The heat may then vaporize a vaporizable formulation in the chamber adjacent to the heating element present in the chamber. The vaporizable formulation comprising the ayahuasca-like substance may then be inhaled by the user of the chamber. These and other features of the present teachings will become more apparent from the description herein. While the present teachings are described in conjunction with various embodiments, it is not intended that the present teachings be limited to such embodiments. On the contrary, the present teachings encompass various alternatives, modifications, and equivalents, as will be appreciated by those of skill in the art.

[0020] The terminology used in the disclosure herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the disclosure. As used in the description of the embodiments of the disclosure and the appended claims, the singular forms of “a,” “an,” and “the” are intended to include the plural forms as well, unless the context clearly indicates otherwise. Also, as used herein, “and/or” refers to and encompasses any and all possible combinations of one or more of the associated listed items. Furthermore, the term “about,” as used herein when referring to a measurable value such as an amount of a compound, amount, dose, time, temperature of the specified amount. It will be further understood that the terms “comprises” and/or “comprising,” when used in this specification, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components, and/or groups thereof. Unless otherwise defined, all terms, including technical and scientific terms used in the description, have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosure belongs.

Definitions

[0021] As used herein, an “aperture” refers to an opening, e.g. within a mouthpiece, chamber, or power unit, that permits the flow of air, liquids, solids, or vapor between components of the invention as described herein.

[0022] As used herein, an “ayahuasca-like substance” refers to an substance having any amount or sort of psychological or psychedelic effect, which can include, but is not limited to, dimethyltryptamine (also known as *N,N*-dimethyltryptamine, or DMT), a monoamine oxidase inhibitor, 5-methoxy-*N,N*-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. Ayahuasca-like substances may include isotopomer or isotopologue variations thereof, including but not limited to deuterium-containing substances. In some embodiments the ayahuasca-like substance is dimethyltryptamine. The ayahuasca-like substances of the present invention can be mixed with additional substances in the vaporizable formulation, e.g., monoamine oxidase inhibitors.

[0023] As used herein, a “chamber” refers to a device that holds a vaporizable formulation comprising an ayahuasca-like substance. A chamber is analogous to a “vape cartridge” well known in the art that may include a top portion connected to a mouthpiece, and a bottom portion connected to a battery or power supply that provides power to a heating element that may be present in the chamber that functions to heat the vaporizable formulation to produce vapor.

[0024] As used herein, a “connector” or “connection” refers to the type of connection between the chamber and the power unit. A connector may include a tenon (or “male” component) to connect the chamber to a mortise (or “female” component) configured within the power unit. In most embodiments the chamber will have the tenon and the power unit will have the mortise. The type of connectors described herein are usually referred to by the thread type, which can include, but is not limited to, 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo thread. By way of example, a “510 connector” is a connector having a 510 thread as is commonly referred to in the art. In preferred embodiments a “510 connector” means the chamber is adapted with a 510 threaded tenon and the power unit has a 510 mortise able to accept a 510 threaded tenon, as is commonly referred to in the art. An eGo thread can have any diameter, but in most cases as used herein refers to an approximately 14mm diameter. An eGo

thread is usually larger than other threads used in the art, such that a smaller thread, e.g., a 510 thread, can be adapted to function with an eGo connector.

[0025] As used here, “delivery” or “delivering” refers to the delivery of an ayahuasca-like substance present within a vaporizable formulation-produced vapor generated by power supplied to the chamber of the present invention.

[0026] As used herein, “lockably coupled” refers to components that are not intended to be removed by an end-using consumer. For illustrative purposes, a mouthpiece that is lockably coupled to a chamber is not intended to be removed. Lockably coupled chambers are intended for single-use and are meant to be discarded following vaporization of all the vaporizable formulation present in a chamber. As used herein, “releasably coupled” refers to components that may be removed by an end-using consumer. For illustrative purposes, a mouthpiece that is releasably coupled to a chamber may be removed so that a user may reuse and refill a chamber with additional vaporizable formulation.

[0027] As used herein, “monoamine oxidase inhibitor” or “MAO inhibitor” refers to a compound that acts by inhibiting the activity of monoamine oxidase.

[0028] As used herein, a “mouthpiece” refers to a component that permits a user to easily inhale vapor produced within the chamber. Mouthpieces may be many different sizes and shapes, for example, flat, round, oval, square, rectangular, etc. The mouthpiece may be made of any suitable material, including but not limited to, plastic, glass, ceramic, silicon, or wood.

[0029] As used herein, the terms “propylene glycol (PG),” “vegetable glycerin (VG),” and “polyethylene glycol (PEG)” refer to components of vaporizable formulations that are substances commonly used as food additives, and have other medical applications, and which are commonly used substances known in the field of vaporizing. The components can be an molecular weight variation, for example but not limited to, PEG 200, PEG 400, and the like.

[0030] As used herein, “refillable” refers to a chamber that may be refilled and reused. This is opposed to a “single-use” chamber, which is not meant to be refillable.

[0031] As used herein, “power” refers to energy capable of generating heat within a heating element capable of producing vapor as described herein.

[0032] As used herein, a “power unit” refers to a device meant to provide power, e.g., voltage, to vaporize a vaporizable formulation comprising an ayahuasca-like substance within the chamber of the present invention.

[0033] As used herein, a “psychological disorder” refers to any disorder that may be treated by the methods and devices of the present invention. Non-limiting examples of psychological disorders may include, but are not limited to, obsessive compulsive disorder, nicotine addiction, alcoholism, narcotic addiction, depression and anxiety related to diagnosis of a life-threatening or terminal illness, major depressive disorder, depression, bipolar disorder, dysthymic disorder, panic attacks, schizophrenia, attention deficit disorder, attention deficit hyperactivity disorder, general anxiety disorder, impulse disorders, delusional disorders, cluster headaches, personality disorders, gambling disorders, eating disorder, body dysmorphic disorder, or post traumatic stress disorder.

[0034] As used herein, a “seal” refers to an item that is situated between two components of the device of the present invention, and may function to provide a more efficient and/or stronger connection between the components. A seal may also function to prevent tampering of the devices described herein. The seal can be made of any material known in the art, including but not limited to, PTFE, nitrile, neoprene, silicone, EDPM rubber, fluorocarbon, etc.

[0035] As used herein, “treating” or “treatment” or “therapy” refers to ameliorating, preventing, or improving at least one psychological disorder.

[0036] As used herein, “vapor” refers to both a substance in the gaseous state and a suspension of finely divided solid particles or liquid droplets in a gas, including aerosols and mists, which functions to deliver the ayahuasca-like substances of the present

invention to an end-using consumer. The term “vaporize” refers to the process to producing vapor, e.g., from a vaporizable formulation.

[0037] As used herein, a “vaporizable formulation” refers to a liquid (e.g., an oil) and/or solid (e.g., a wax) solution that may be contained within the chamber of the present invention, and which produces a mist or vapour when heated by a heating element that functions to provide a vaporizable carrier for the ayahuasca-like substances described herein.

Delivery Device Chambers

[0038] The present invention provides a chamber filled with a vaporizable formulation comprising an ayahuasca-like substance. Non-limiting exemplary chambers are illustrated in Figure 1 and Figure 2. An exemplary chamber comprising an ayahuasca-like substance (301) is illustrated in Figure 3. In some embodiments the chamber is coupled to a power unit capable of providing power to vaporize the formulation (Figure 4). The heat generated within the chamber via a heating element may vaporize the vaporizable formulation in the chamber adjacent to the heating element present in the chamber. Following vaporization, the vaporizable formulation comprising the ayahuasca-like substance may then mix with air and subsequently be inhaled by the user, which in some embodiments is through a mouthpiece of the chamber that results in an aerosol that is delivered to the user.

[0039] A user may desire to have a pre-loaded or manually loaded vaporizable formulation comprising a therapeutic ayahuasca-like substance in the chamber to permit an efficient vaporization of the vaporizable formulation for inhalation and delivery of the substance to the user without having to measure, weigh, touch, or risk spilling the vaporizable formulation to be vaporized and consumed. A pre-loaded chamber further reduces the risk of contact of the vaporizable formulation during many aspects of the supply chain, thus reducing the potential for improper dosing or contamination. Alternatively, a user may desire to have the ability to load the chamber themselves. The chamber may be either refillable or single-use, pre-loaded or loaded prior to use. Numerous delivery device chambers known in the art can be used to practice the

present invention, including but not limited to portable or desktop vaporizable cartridges or tanks.

[0040] In an embodiment the chamber comprises a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the vaporizable formulation. In an embodiment the chamber is coupled to the power unit capable of providing power to vaporize the vaporizable formulation. Any manner of coupling the power unit to the chamber is sufficient. The chamber may be locked to the power unit. In such embodiments the power unit may be locked as a single use device, or maybe locked to a reusable chamber. In some embodiments the power unit may be releasable from the chamber, which a user may find useful for recharging the power unit.

[0041] In an embodiment a connector (103) is provided to connect the chamber to the power unit to permit a heating element that may be integrated within the chamber to provide heat for vaporization of the vaporizable formulation. Such connections are well known in the art. For example, the connector may include a tenon (or “male” component) to connect the chamber to a mortise (or “female” component) configured within the power unit. In most embodiments the chamber will have the tenon and the power unit will have the mortise.

[0042] In an embodiment, the tenon may include threads complementary to the threads of the power unit in a standard connection known in the art as a “510 connection,” or a “510 connector,” or as having “510 threads,” or any colloquial variation thereof. By way of example, a “510 connector” is a connector having a 510 thread as commonly referred to in the art. In preferred embodiments a “510 connector” means the chamber is adapted with a 510 threaded tenon and the power unit has a 510 compatible mortise able to accept a 510 threaded tenon, as is commonly referred to in the art. In another embodiment the threads of the power unit may utilize an “eGo connection,” or an “eGo connector,” or have “eGo threads.”

[0043] In other embodiments the chamber may utilize a “401 connection,” or a “401 connector,” or have “401 threads.” In an embodiment the chamber unit may utilize a “601 connection,” or a “601 connector,” or have “601 threads.” In an embodiment the

chamber may utilize a “610 connection,” or a “610 connector,” or have “610 threads.” In an embodiment the chamber may utilize a “710 connection,” or an “710 connector,” or have “710 threads.” In an embodiment the chamber may utilize an “808 connection,” or an “808 connector,” or have “808 threads.” In an embodiment the chamber may utilize a “901 connection,” or a “901 connector,” or have “901 threads.” In an embodiment the chamber may utilize a “4081 connection,” or a “4081 connector,” or have “4081 threads.” In an embodiment the chamber may utilize a “CE-4 connection,” or a “CE-4 connector,” or have “CE-4 threads.” In an embodiment the chamber may utilize an “E9 connection,” or an “E9 connector,” or have “601 threads.” In an embodiment the chamber may utilize a “CE-5 connection,” or a “CE-5 connector,” or have “CE-5 threads.” Any other suitable connections for providing an electrical connection to the chamber from the power unit as is known in the art may be used.

[0044] In some embodiments the chamber may include more than one, or multiple types of thread connections that are easily adaptable to create numerous permutations of thread types for adaptability between connection types. In an embodiment, both 510 and eGo threads are configured to the same chamber such that a 510 thread connector is adapted to be used with an eGo thread connector to permit connection versatility (Figure 2). In an embodiment, both 401 and eGo threads are configured to the same chamber such that a 401 thread connector is adapted to be used with an eGo thread connector to permit connection versatility. In an embodiment, both 601 and eGo threads are configured to the same chamber such that a 601 thread connector is adapted to be used with an eGo thread connector to permit connection versatility. In an embodiment, both 610 and eGo threads are configured to the same chamber such that a 610 thread connector is adapted to be used with an eGo thread connector to permit connection versatility. In an embodiment, both 710 and eGo threads are configured to the same chamber such that a 710 thread connector is adapted to be used with an eGo thread connector to permit connection versatility. In an embodiment, both 808 and eGo threads are configured to the same chamber such that an 808 thread connector is adapted to be used with an eGo thread connector to permit connection versatility. In an embodiment, both 901 and eGo threads are configured to the same chamber such that

a 901 thread connector is adapted to be used with an eGo thread connector to permit connection versatility.

[0045] In some embodiments the chamber comprises a top portion adapted for coupling to a mouthpiece (101) wherein the top portion of the chamber comprises at least one air aperture adapted to permit the flow of air, liquid, or vapor between the top portion of the chamber and the mouthpiece.

[0046] The mouthpiece may be many different sizes and shapes, for example, flat, round, oval, square, rectangular, etc. The mouthpiece may be made of any suitable material, including but not limited to, plastic, glass, ceramic, silicon, stainless steel, or wood. In some embodiments the mouthpiece is coupled to the top portion of the chamber and the mouthpiece has a bottom portion comprising an aperture to permit liquids, solids, vapor, or air to flow from the chamber to the mouthpiece. In some embodiments the mouthpiece has a central open bore to permit liquids, solids, vapor, or air to flow through the mouthpiece; and in some embodiments, the mouthpiece has a top aperture to permit liquids, solids, vapor, or air to exit the mouthpiece in order to be inhaled or utilized by a user.

[0047] In an embodiment, the chamber includes a seal that is situated between the bottom opening of the mouthpiece and the top portion of the chamber. The seal can be made of any material known in the art, including but not limited to, PTFE, nitrile, neoprene, silicone, EDPM rubber, fluorocarbon, etc. In an embodiment, the mouthpiece is releasably coupled to the top portion of the chamber. Releasably coupled mouthpieces may be useful for refilling and multiple uses of chambers. Any mechanism known in the art can be used to permit the mouthpiece to be releasable from the top portion of the chamber, including but not limited to tenon and mortises with or without threads. In an embodiment, the mouthpiece is lockably coupled to the top portion of the chamber. Locked configurations are useful to prevent tampering with the chamber and/or vaporizable formulation.

[0048] The chamber may include a heating element to provide heat that will vaporize the vaporizable formulation comprising the ayahuasca-like substance present within the

chamber. During use, power may be supplied to a heating element positioned within the chamber through the application of voltage generated by the power unit to the threads of the tenon, as described herein, which is then transferred to the heating element positioned within the chamber.

[0049] Many different types of heating elements may be used. The heating element may include a coil and wick, many of which are well known in the art. Exemplary coils are the kanthal ceramic coil, kanthal (FeCrAl) derivatives, nichrome, aluminum, stainless steel, nickel, and titanium. Many different grades of stainless steel wire may be used. The most popular gauges for the wire are 32, 30, 28, 26, 24, and 22. The type of wicking material can vary and preferably includes the organic cotton for the use with botanical extracts, but in some cases, Japanese cotton pads, ekowool, silica, and rayon fiber may be used. The heating element may also be wickless, as is sometimes used in the art.

[0050] The chamber of the present invention will be hollow to some respects such that the vaporizable formulation may be held within the chamber (102). The chamber thus may further include a wall that provides a structural element that further defines an internal volume for containing the vaporizable formulation. The chamber wall can be transparent to permit a user to visualize the amount of vaporizable formulation present within the chamber. An exemplary embodiment of a chamber having a transparent chamber wall permitting visualization of vaporizable formulation is shown in Figure 3 and Figure 4. A transparent chamber wall can be glass or plastic. The chamber wall may also include materials that are opaque, or non-light transmitting. For example the chamber may prevent light from entering into the internal volume. As a result, while stored within the chamber, the vaporizable formulation may be free from exposure to light, thus, reducing degradative effects that may arise due to the light.

[0051] The chamber may include a lid may provide a seal for the chamber so that the vaporizable formulation located within the internal volume is isolated from the external environment and, for example, is kept from degrading. The sealed chamber may further provide quality control for the vaporizable formulation, which may be pre-processed and packaged therein, providing consistency and reliability of its contents. The chamber may

also provide an appropriate environment (e.g., dark, low in relative humidity, inert, etc.) to provide the vaporizable formulation with a relatively long shelf-life. Thus, the chamber in accordance with the present disclosure may be kept for long periods of time without suffering degradation of the contents therein and, for example, may be easily transported, sold in stores, used in vending dispense machines, etc.

[0052] The chamber may further include readable information, for example, given by clear labelling (e.g., markings) on an exterior surface of the chamber, for providing to a user and/or system information regarding its contents. Such information may ultimately be relevant in subjecting the vaporizable formulation to conditions that predictably result in a preferred vapor, with consistency in effects/experience, quality, taste and/or smell.

[0053] The chamber may include a filtering mechanism, such as one or more filters located on either side of the vaporizable formulation, for removing undesirable particulates and/or other contaminants from the vaporizable formulation as it travels away from the internal volume of the chamber.

[0054] The chamber may also include a support member to hold the vaporizable formulation within the internal volume of the chamber during vaporization. The support member may suspend or otherwise distribute the vaporizable formulation within the internal volume during exposure to vaporization heat.

[0055] It can be appreciated that a number of different types, shapes, sizes of chambers may be possible, for use with a variety of different power units. The chamber of the present invention can be commonly used cartridges having 0.25 ml, 0.50 ml, and 1.0 ml capacities. The chamber of the present invention can be commonly used tanks or sub ohm tanks having non-limiting capacities of 2 ml, 3 ml, 4 ml, 5 ml or greater.

[0056] The chamber wall may have a cylindrical shape, a conical shape, a domed shape and/or a tapered construction. In some cases, the particular shape or structure of the chamber may allow it to be suitably placed within a complementary receptacle of a power unit. The shape/structure of the chamber may also provide for a suitable funneling or Venturi effect of the vapor. For instance, an upper end of the chamber may be tapered or dome-shaped such that vapor arising from the chamber is funneled

upward toward an opening and into a collection area (e.g., bag, canister, mouthpiece, flow tube, etc.) where the vapor may be stored or otherwise contained for subsequent consumption.

[0057] In some embodiments it may be preferable to provide a chamber that holds a number of different vaporizable formulations (e.g., having varying types/blends) inside. And it may be further preferable for these different vaporizable formulations to be kept separate during storage. The chamber can include a dividing wall that partitions the internal volume of the chamber into multiple sub-chambers or compartments. For example, the chamber and the power unit may be arranged such that only one of the different types/blends of vaporizable formulations comprising an ayahuasca-like substance is vaporized at a time. Or, vaporization may occur in succession, where the process of vaporization/extraction occurs for each of the vaporizable formulations comprising an ayahuasca-like substance during offset time periods. In some cases, it may be preferable for the power unit to have multiple lines through which separate parts of the chamber may be subject to vaporization and extraction. That is, different compartments of the chamber may be individually heated and subject to separate air flows, allowing for more customized vapors to be produced, with blending of the ingredients at different times during the vaporization process. In various embodiments, the chamber may include materials that exhibit high temperature tolerance that are able to withstand relatively high heat temperatures.

[0058] The chamber further provides dose-specific and consistent amounts of vaporizable formulations and ayahuasca-like substance concentrations for ease of use applications.. Doses can be measured and pre-packaged, and heated precisely to a temperature that produces a therapeutically-active concentration of ayahuasca-like substances. Such dose-specific efficiency increases the present invention's commercial and medicinal value. The chamber may also be configured to permit control over the airflow to the heating element or through the mouthpiece so that the user may adjust the amount of vapor being released.

[0059] The chamber may also be configured to have inlet holes to regulate flow of the vaporizable formulation from the chamber to the external environment for inhalation,

which may be desirable for vaporizable formulations having different viscosities. Commonly used sizes in the art, for example, may inlet holes can have non-limiting diameters of less than or equal to 1.2mm, 1.4mm, 1.6mm, 1.8mm, 2.0mm, or greater.

[0060] The internal volume of the chamber within which the vaporizable formulation is stored may be substantially removed of oxidizing or otherwise deleterious substances. For instance, prolonged exposure of the vaporizable formulation to oxygen may have negative consequences and may reduce the overall quality of the vapor produced therefrom. For example, exposure to oxygen may result in the occurrence of undesirable oxidation or other reaction(s), which may remove a number of desirable qualities from the vaporizable formulation comprising the ayahuasca-like substance. To remove oxygen, an inert air (e.g., nitrogen gas, noble gas, etc.) may be flushed through the chamber. Accordingly, when suitably packaged, the vaporizable formulation may be stored in a relatively inert environment substantially devoid of oxygen. When appropriately packaged, the internal volume of the chamber may also be maintained at a suitable level of relative humidity, as measured according to methods known in the art. It may be preferable for the vaporizable formulation to be stored within a relatively dry environment to reduce opportunities for degradation.

[0061] The chamber may further include a filtering system. For instance, the filter(s) may be constructed to trap unwanted particles that may arise during vaporization of the vaporizable formulation comprising the ayahuasca-like substance. However, in some instances, it may be preferable for the filter(s) to be constructed such that the vaporizable formulation, or derivatives therefrom (e.g., oils, residue, vapor, etc.), does not clog the filter(s). In some embodiments, the filter(s) may include a fine mesh that allows vapor produced from the vaporizable formulation to pass freely therethrough, for example, without an undesirable amount of condensation or accumulation of debris.

Power Units

[0062] An optional embodiment of the present invention is a chamber connected to a power unit, as illustrated in Figure 4. Power units (also sometimes referred to in the art as batteries) are devices used to provide power to vaporize a vaporizable formulation

comprising an ayahuasca-like substance within the chamber of the present invention, for the purpose of inhalation. During use, the application of voltage is generated by a power source within the power unit, which is then passed through to the threads of the chamber. This permits a heating element positioned within the chamber to generate heat in order to vaporize the vaporizable formulation in the chamber adjacent to a heating element present in the chamber.

[0063] Numerous types and examples of power units, both portable and “desktop,” are well known in the art, any one of which may be sufficient to practice the present invention. The power unit may generate heat using many methods well known in the art, and may be configured to heat the vaporizable formulation through a wide range of incremental heats based on the preferences of the user.

[0064] The power unit may be charged by any method well known in the art to provide power to the heating unit, including but not limited to the use of rechargeable batteries. Rechargeable batteries can be recharged using many methods known in the art, for example, via a USB recharging system.

[0065] In some embodiments, a power unit may be equipped with a controller that is configured to obtain information regarding the contents of the vaporizable formulation comprising an ayahuasca-like substance based on the readable information. For instance, the power unit may have an information reader, such as a digital code reader (e.g., for barcodes, QR codes, etc.) for reading the readable information on the surface of the chamber and/or user interface, for providing input to the controller of the information about the vaporizable formulation comprising an ayahuasca-like substance. Based on this input, the power unit may process the vaporizable formulation comprising an ayahuasca-like substance within the chamber according to a specific vaporization recipe, to produce a vapor having particularly desirable characteristics. For example, the power unit may flow air through the chamber as well as provide a temperature profile within the chamber for extracting a suitable combination of chemical compounds according to a specified protocol. In some embodiments, this temperature profile may include a number of timed temperature adjustments that occur during the period of vaporization when extraction of the vaporization formulation comprising an ayahuasca-

like substance occurs. In some cases, the power unit may provide this temperature profile as part of an automated process of vaporization and extraction, or a user may input such a profile into the power unit. Vapor generated from the vaporizable formulation comprising an ayahuasca-like substance is then passed from the internal volume of the chamber externally, or alternatively, to a bag, canister and/or other collection region, for consumption by a user.

[0066] The power unit may include sensors to provide a user with an appropriate notification (e.g., audio/visual/tactile signal(s)) as the production of vapor is ongoing, or completed. In some embodiments, a sensor coupled with the power unit that tracks the progress of vapor production may be employed so as to present the user with a real-time status report of the vapor being generated, or even if the vapor is being generated at all. For example, such a report may be an indicator for how full the chamber is, the particular concentration of one or more ayahuasca-like substances within the vapor, whether the vaporization cycle has been completed, the existence of vapor produced, etc. Hence, at an appropriate time (e.g., when the chamber is full of vapor, when the user wants to stop the cycle, etc.), the chamber may be removed from the power unit and the user may sip and/or breathe the vapor through a suitable mouthpiece.

[0067] The power unit may be configured to process the chamber and its contents so as to extract the ayahuasca-like substances as fully as possible therefrom. Accordingly, the power may control the overall dosage of vapor and extraction by varying a number of parameters during certain steps such as cycle time, start/stop times, temperature settings, rate of air flow therethrough, relative humidity, amongst others, the combination of which may play a substantial role in producing a desirable amount of substance and flavor.

[0068] The power unit may also be configured as a smart machine that learns the preferences of a user. For example, a user may input a number of parameters and/or the power unit may track the particular conditions for vaporizing the contents of the chamber. The user may determine that a certain set of conditions may be especially effective in producing a vapor that achieves a favorable experience. The vaporizer may also track specific combinations of chamber and vaporization conditions that correspond

to favorable user experiences, and may communicate such combinations to the user for later use, as suitably desired.

[0069] In an embodiment a power unit may be made available in combination with the chamber, and may be releasably coupled to the chamber. In an embodiment a power unit may be made available in combination with the chamber, and may be lockably coupled to the chamber. In embodiments where the power unit is lockably coupled to the chamber, the purpose may be for a “all in one” single use application. However, power units may be lockably coupled to a refillable chamber as described herein, if desired by a consumer.

Vaporizable Formulations

[0070] Included in the present invention are vaporizable formulations, sometimes referred to in the art as “vape juice,” or “e-liquid,” or “e-juice,” and which refers to a liquid (e.g., an oil) and/or solid (e.g., a wax) solution that may be contained within the chamber of the present invention, and which produces a mist or vapour when heated by a heating element that functions to provide a vaporizable carrier for the ayahuasca-like substances described herein.

[0071] The vapor may include a mist, aerosol and/or nebulized composition that includes fine solid and/or liquid particles suspended in a gas or, in some cases, the vapor may be substantially formed as a gas. The vapor may also include a gaseous substance having small droplets of oil, water and/or other chemical compounds suspended therein. In some cases, a vapor includes liquid (e.g., water, oil, etc.) particles mixed with hot ambient air, which is cooled down so as to condense into a fine cloud of visible airborne droplets. Accordingly, the vaporizable formulation may be breathed or otherwise administered as medication and/or as therapy in a vaporized form.

[0072] In an embodiment, the vaporizable formulation is a mix of propylene glycol (PG) and vegetable glycerin (VG). The vaporizable formulation of the present invention may contain any ratio of PG/VG based on user preference, for example, between 0:100 PG:VG and 10:90 PG:VG, between 10:90 PG:VG and 20:80 PG:VG, between 20:80

PG:VG and 30:70 PG:VG, between 30:70 PG:VG and 40:60 PG:VG, between 40:60 PG:VG and 50:50 PG:VG, between 50:50 PG:VG and 60:40 PG:VG, between 60:40 PG:VG and 70:30 PG:VG, between 70:30 PG:VG and 80:20 PG:VG, between 80:20 PG:VG and 90:10 PG:VG, or between 90:10 PG:VG and 100:0 PG:VG.

[0073] The vaporizable formulation may also include water, terpene, and/or polyethylene glycol (PEG) as the vaporizable formulation, and in combination with any ratio of PG and VG. The PEG can be of any molecular weight, including but not limited to, PEG200 and PEG 400. The vaporizable formulation of the present invention may contain any ratio of PEG/VG based on user preference, for example, between 0:100 PEG:VG and 10:90 PEG:VG, between 10:90 PEG:VG and 20:80 PEG:VG, between 20:80 PEG:VG and 30:70 PEG:VG, between 30:70 PEG:VG and 40:60 PEG:VG, between 40:60 PEG:VG and 50:50 PEG:VG, between 50:50 PEG:VG and 60:40 PEG:VG, between 60:40 PEG:VG and 70:30 PEG:VG, between 70:30 PEG:VG and 80:20 PEG:VG, between 80:20 PEG:VG and 90:10 PEG:VG, or between 90:10 PEG:VG and 100:0 PEG:VG. The vaporizable formulation of the present invention may contain any ratio of PG/PEG based on user preference, for example, between 0:100 PG:PEG and 10:90 PG:PEG, between 10:90 PG:PEG and 20:80 PG:PEG, between 20:80 PG:PEG and 30:70 PG:PEG, between 30:70 PG:PEG and 40:60 PG:PEG, between 40:60 PG:PEG and 50:50 PG:PEG, between 50:50 PG:PEG and 60:40 PG:PEG, between 60:40 PG:PEG and 70:30 PG:PEG between 70:30 PG:PEG and 80:20 PG:PEG, between 80:20 PG:PEG and 90:10 PG:PEG, or between 90:10 PG:PEG and 100:0 PG:PEG.

[0074] The present invention should not be limited by variability in the purity, kinds and concentrations of chemicals used in liquids, and significant variability between labeled content and concentration and actual content and concentration.

[0075] A skilled artisan will be familiar with a substantial range of vaporizable formulations that can be used with the present invention, and any substance that is vaporizable and capable of acting as a carrier for the ayahuasca-like substance will suffice. Numerous naturally extracted e-liquids may be used as the vaporizable

formulation for the present invention, for example, the e-liquids described in United States Patent Application No. 20160309775.

[0076] Traditional ayahuasca preparations include monoamine oxidase inhibitors (MAOIs). Thus the vaporizable formulation of the present invention can further include one or more MAOIs, which are well known in the art, and can include, but not be limited to, Clorgyline, Minaprine, and the reversible MAO-A inhibitors Befloxatone, Brofaromine, Cimoxatone, Harmaline, Moclobemide, Pirlindole and Toloxatone. Examples of MAO-B inhibitors include, but are not limited to, Rasagiline, Selegiline and Pargyline. Examples of unselective MAO-A and MAO-B inhibitors include, but are not limited to, Iproclozide (Sursum), Iproniazid (Marsilid, Iprozid, Ipronid, Rivivol, Propilniazida), Isocarboxazid (Marplan), Mebanazine (Actomol), Metfendrazine (H.M.-11), Nialamide (Niamid), Phenelzine (Nardil), Pheniprazine (Caton), Phenoxypropazine (Drazine), Pivalylbenzhydrazine (Tersavid, Neomarsilid), Safrazine (Safra) and Tranylcypromine (Parnate). See, for example, Remington: The Science and Practice of Pharmacy, 21st Edition, (2005, Lippincott Williams & Wilkins), pages 1517-1523, and Physicians' Desk Reference, Edition 60 (2006, Thomson PDR) page 1499 (each of which is incorporated herein by reference).

[0077] The vaporizable formulation may further include additional components so that users may choose to modify or boost their flavor or concentration of the ayahuasca-like substance with various offerings, including flavorings (non-limiting examples known in art such terpenes, flavonoids, mint, ginger, cinnamon, vanilla, pepper jack cheese, chocolate and peanut butter, Pennsylvania fruit cake, chamomile, ginko, Izzy treats, mango, etc.), and other additives or ingredients, as suitably desired.

[0078] Other compositions may also be included in the vaporizable formulation to complement the ayahuasca-like substance. For example, the vaporizable formulation may also include flavonoids, terpenoids, amino acids, proteins, sugars, enzymes, fatty acids, esters and/or other compounds, including but not limited to cannabinoid extracts from cannabis, THC, THCV, ketorolac, morphine, testosterone, ibuprofen, codeine, nicotine, Vitamin A, Vitamin E acetate, Vitamin E, nitroglycerin, pilocarpine, mescaline, testosterone enanthate, menthol, phencaramide, methsuximide, eptastigmine,

promethazine, procaine, retinol, lidocaine, trimeprazine, isosorbide dinitrate, timolol, methypylon, etamiphyllin, propoxyphene, salmetrol, vitamin E succinate, methadone, oxprenolol, isoproterenol bitartrate, etaqualone, Vitamin D3, ethambutol, ritodrine, omoconazole, lomustine, ketamine, ketoprofen, cilazaprol, propranolol, sufentanil, metaproterenol, pentoxapylline, captopril, loxapine, cyproheptidine, carvediol, trihexylphenadine, alprostadiol, melatonin, testosterone propionate, valproic acid, acebutolol, terbutaline, diazepam, topiramate, pentobarbital, alfentanil HCl, papaverine, nicergoline, fluconazole, zafirlukast, testosterone acetate, droperidol, atenolol, metoclopramide, enalapril, albuterol, ketotifen, isoproterenol, amiodarone HCl, zileuton, midazolam, oxycodone, cilostazol, propofol, nabilone, gabapentin, famotidine, lorezepam, naltrexone, acetaminophen, sumatriptan, bitolterol, nifedipine, phenobarbital, phentolamine, 13-cis retinoic acid, droprenilamine HCl, amlodipine, caffeine, zopiclone, tramadol HCl, pirbuterol, naloxone, meperidine HCl, trimethobenzamide, nalmeferine, scopolamine, sildenafil, carbamazepine, procaterol HCl, methysergide, glutathione, olanzapine, zolpidem, levorphanol, buspirone, and mixtures thereof.

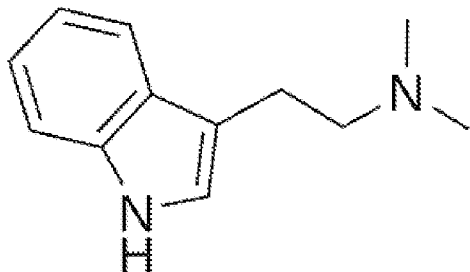
[0079] The vaporizable formulations of the present invention need not be limited to oils, and may also include other liquids or waxes. In some embodiments the vaporizable formulation can be adapted for dry vaporization, or be adapted for wax vaporization. In some embodiments, the vaporizable formulation can be adapted for a combination of one or more oil, dry, or wax vaporizable formulations

[0080] The present invention may be practiced using a variety of different embodiments, including pre-filled chambers that are single use, or refillable. In another embodiment, a vaporizable substance is provided comprising an ayahuasca-like substance, which can be made available separately from the other components of the devices described herein, such that an end-using consumer can refill their chamber after the initial chamber prefilled with the vaporizable formulation is depleted. In another embodiment, the vaporizable formulation can be made available separate from the chamber such that a consumer can adapt their own chamber to be configured with the vaporizable formulations.

Ayahuasca-like Substances

[0081] In some embodiments the vaporizable formulations as described herein comprise an ayahuasca-like substance that is provided for medicinal, therapeutic and/or recreational purposes. The substance may include matter derived from a plant, used for consumption, such as for medicinal, therapeutic, aromatic and/or culinary purposes.

[0082] In an embodiment, ayahuasca-like substance may be dimethyltryptamine (also referred to as *N,N*-dimethyltryptamine, or DMT):



[0083] The ayahuasca-like substance does not need to be limited to substances commonly found in ayahuasca, and can include other substances as well, by way of example and not meant to be limiting, 5-methoxy-*N,N*-dimethyltryptamine or 2-5-dimethoxy-4-bromophenethylamine. The ayahuasca-like substance can further include isotopomer and isotopologue variations, for example, a DMT isotopomer or isotopologue comprising deuterium or tritium.

[0084] Ayahuasca-like substances are often combined with MAOIs, many of which are included in the vaporizable formulation and described elsewhere herein.

[0085] The ayahuasca-like substances of the present invention can be synthesized by a variety of methods known to one of skill in the art (see Comprehensive Organic Transformations Richard C. Larock, 1989) or by an appropriate combination of generally well known synthetic methods. Dimethyltryptamine can be synthesized through several possible pathways from different starting materials. A common method skilled artisans use to synthesize dimethyltryptamine is through reaction of indole with oxalyl chloride followed by reaction with dimethylamine and reduction of the carbonyl functionalities with lithium aluminum hydride. Another method commonly known for the synthesis of

dimethyltryptamine is through the n,n-dimethylation of tryptamine using formaldehyde followed by reduction with sodium cyanoborohydride or sodium triacetoxyborohydride. Techniques useful in synthesizing the ayahuasca-like substances of the present invention are both readily apparent and accessible to those of skill in the relevant art.

[0086] A skilled artisan will appreciate that other methods of making the ayahuasca-like substances of the present invention are possible, including but not limited to the extraction and/or purification from plants and other natural substances.

Dimethyltryptamine is found in many naturally occurring substances, including but not limited to, *Mimosa hostilis*, *Mimosa tenuiflora*, *Banisteriopsis caapi*, *Phalaris arundinacea*, *Phalaris aquatica*, *Diplopterys cabrerana*, *Psychotria viridis*, *Acacia confusa*, *Anadenanthera peregrina*, and *Anadenanthera colubrina*. Methods of extracting dimethyltryptamine from natural substances are well known in the art, and may include the non-limiting methods incorporating the use of a non-polar hydrocarbon solvent and a subsequent alkaline purification, or an acid-base extraction.

[0087] It should be stressed that dimethyltryptamine can be synthesized or extracted using a variety of different well known methodologies, and need not be limited to any specific synthesis and/or extraction method specifically described herein.

[0088] Most ayahuasca-like substances are readily available and need not be synthesized or extracted. For example, dimethyltryptamine, which was first synthesized in 1931, is readily available in decriminalized jurisdictions.

[0089] The present invention is not intended to be limited to any specific weight per volume concentration of the ayahuasca-like substance dissolved in the vaporizable formulation, and may comprise a weight per volume content of greater than 0.1 w/v %, greater than 1.0 w/v %, greater than 10.0 w/v %, greater than 20.0 w/v %, greater than 30.0 w/v %, greater than 40.0 w/v %, greater than 50.0 w/v %, greater than 60.0 w/v %, greater than 70.0 w/v %, greater than 80.0 w/v %, greater than 90.0 w/v %, greater than 100.0 w/v %, greater than 125.0 w/v %, greater than 150.0 w/v %, greater than 200.0 w/v %; or less than 200.0 w/v %, less than 150.0 w/v %, less than 125.0 w/v %, less than 100.0 w/v %, less than 90.0 w/v %, less than 80.0 w/v %, less than 70.0 w/v %, less than 60.0 w/v %, less than 50.0 w/v %, less than 40.0 w/v %, less than 30.0 w/v %, less than 20.0 w/v %, less than 10.0 w/v %, less than 1.0 w/v %, or less than 0.1 w/v %.

less than 60.0 w/v %, less than 50.0 w/v %, less than 40.0 w/v %, less than 30.0 w/v %, less than 20.0 w/v %, less than 10.0 w/v %, less than 1.0 w/v %, or less than 0.1 w/v %. Combinations of the above-noted ranges, or values outside of these ranges, may be possible for the ayahuasca-like substance content levels of the vaporizable formulation based on user preference or for medicinal optimization.

Methods of Use

[0090] In some embodiments, the present invention describes methods of using the chambers described herein. Such methods are particularly useful for refillable chambers or for end users who wish to load chambers with the vaporizable formulations comprising the anahuasca-like substances themselves.

[0091] In an embodiment, a method for delivering an ayahuasca-like substance as described herein is provided wherein the method of use comprises heating a vaporizable formulation comprising the ayahuasca-like substance as described herein to vaporize at least a portion of the vaporizable formulation.

[0092] In some embodiments the vaporizable formulation of the methods of use of the present invention may be housed in a chamber comprising a top portion adapted for coupling to a mouthpiece and wherein the top portion comprises at least one air aperture adapted to permit flow of air, liquid, or vapor between the chamber and the mouthpiece as described herein. In some embodiments the mouthpiece used by the method of use may comprise a top aperture, a central open bore, and a bottom portion comprising an aperture and coupled to the chamber as described herein. In some embodiments the chamber used by the method of use may comprise at least one seal situated between the bottom opening of the mouthpiece and the top portion of the chamber as described herein. In some embodiments the mouthpiece used in the method of use may be releasably coupled to the top portion of the chamber as described herein. In some embodiments, the mouthpiece used in the method of use may be lockably coupled to the top portion of the chamber as described herein. In some embodiments the chamber used in the method of use may comprise a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the

vaporizable formulation as described herein. In some embodiments the chamber used in the method of use may be transparent to permit visualization of levels of the vaporizable formulation.

[0093] In some embodiments the chamber used by the methods of use of the present invention may be coupled to the power unit capable of providing power to vaporize the vaporizable formulation as described herein; in some embodiments the chamber used by the method is releasably coupled to the power unit as described herein. In some embodiments the chamber used by the methods of use of the present invention may be lockably coupled to the power unit as described herein; in some embodiments the chamber used by the method may comprise one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector to couple the chamber to the power unit as described herein; in an embodiment the chamber used by the methods of use of the present invention comprises a 510 connector as described herein.

[0094] In some embodiments the chamber used in the methods of use of the present invention is refillable as described herein, although it should be noted that the methods of the present invention should not be limited to refillable chambers, and users may choose to practice the methods of use of the present invention using single use applications.

[0095] In some embodiments the ayahuasca-like substance used in the methods of use of the present invention may comprise one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine as described herein. In an embodiment the ayahuasca-like substance used by the methods of use of the present invention comprises dimethyltryptamine as described herein. In an embodiment, the ayahuasca-like substance of the methods of use of the present invention comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance of the methods of use of the present invention is dimethyltryptamine comprising deuterium.

[0096] In some embodiments the vaporizable formulation used in the methods of the present invention may comprise one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG), or any other compound as described herein.

Methods of Treatment

[0097] Therapeutic benefits of psychedelic drugs, such as dimethyltryptamine, lysergic acid diethylamide and psilocybin, are being actively researched in humans. Studies in healthy volunteers have shown long-term increases in trait optimism (Carhart-Harris et al., *Psychological Medicine* 2016, 46:1379-1390), well-being (Id. and Griffiths et al., *Psychopharmacology* 2011, 218:649-665), and openness (Carhart-Harris et al., *Psychological Medicine* 2016, 46:1379-1390; MacLean et al., *Journal of Psychopharmacology* 2011, 25:1453-1461), neurodegenerative disorders (Morales-Garcia et al, *Translational Psychiatry*, 10:331 (2020)), and studies in patients have found long-term improvements in obsessive compulsive disorder (Moreno et al., *Journal of Clinical Psychiatry* 2006, 67:1735-1740), nicotine addiction (Garcia-Romeu et al., *Current Drug Abuse Reviews* 2014, 7:157-164), alcoholism (Krebs and Johansen, *Psychopharmacology* 2012, 26.7:994-1002; Bogenschutz et al., *Journal of Psychopharmacology* 2015, 29.3:289-299), narcotic addiction (Savage and McCabe, *Psychiatry* 1973, 28.6:808-814), depression and anxiety related to diagnosis of a life-threatening or terminal illness (Grob et al., *Archives of General Psychiatry* 2011, 68:71-78; Griffiths et al., *Journal of Psychopharmacology* 2016, 30(12):1181-1197; Ross et al., *Journal of Psychopharmacology* 2016, 30(12):1165-1180), and depression (Carhart-Harris et al., *The Lancet Psychiatry* 2016; Sanches et al., *Journal of Clinical Psychopharmacology* 2016, 36:77-81) after treatment with psychedelics. Other psychological disorders can include, but are not limited to general anxiety, major depressive disorder, dysthymic disorder, bipolar disorder, panic attacks, schizophrenia, attention deficit disorder, attention deficit hyperactivity disorder, impulse disorders, delusional disorders, cluster headaches, migraines, personality disorders, gambling disorders, eating disorder, body dysmorphic disorder, and other psychological disorders described in the "Diagnostic and Statistical Manual, Version IV." These long-term

positive effects can endure for several months, if not years, even after the compound has been metabolized and has been excreted from the body.

[0098] In some embodiments, the present invention includes methods of treating a psychological disorder comprising administering to a patient an effective amount of an ayahuasca-like substance, wherein the method comprises heating a vaporizable formulation comprising the ayahuasca-like substance to vaporize at least a portion of the vaporizable formulation.

[0099] In some embodiments the vaporizable formulation of the methods of treatment of the present invention may be housed in a chamber comprising a top portion adapted for coupling to a mouthpiece and wherein the top portion comprises at least one air aperture adapted to permit flow of air, liquid, or vapor between the chamber and the mouthpiece as described herein. In some embodiments the mouthpiece used by the methods of treatment may comprise a top aperture, a central open bore, and a bottom portion comprising an aperture that is coupled to the chamber as described herein. In some embodiments the chamber used by the methods of treatment may comprise at least one seal situated between the bottom opening of the mouthpiece and the top portion of the chamber as described herein. In some embodiments the mouthpiece used in the methods of treatment may be releasably coupled to the top portion of the chamber as described herein. In some embodiments, the mouthpiece used in the methods of treatment may be lockably coupled to the top portion of the chamber as described herein. In some embodiments the chamber used in the methods of treatment may comprise a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the vaporizable formulation as described herein. In some embodiments the chamber used in the methods of treatment may be transparent to permit visualization of levels of the vaporizable formulation.

[0100] In some embodiments the chamber used by the methods of treatment of the present invention may be coupled to the power unit capable of providing power to vaporize the vaporizable formulation as described herein. In some embodiments the chamber used by the methods of treatment is releasably coupled to the power unit as described herein. In some embodiments the chamber used by the methods of treatment

of the present invention may be lockably coupled to the power unit as described herein. In some embodiments the chamber used by the methods of treatment may comprise one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector to couple the chamber to the power unit as described herein. In an embodiment the chamber used by the methods of treatment of the present invention comprises a 510 connector as described herein.

[0101] In some embodiments the chamber used in the methods of treatment of the present invention is refillable as described herein, although it should be noted that the methods of treatment of the present invention should not be limited to refillable chambers, and users may choose to practice the methods of the present invention using single use applications.

[0102] In some embodiments the ayahuasca-like substance used in the methods of treatment of the present invention may comprise one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine as described herein. In an embodiment the ayahuasca-like substance used by the methods of treatment of the present invention comprises dimethyltryptamine as described herein. In an embodiment, the ayahuasca-like substance used in the methods of treatment of the present invention comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance used in the methods of treatment is dimethyltryptamine comprising deuterium.

[0103] In some embodiments the vaporizable formulation used in the methods of treatment of the present invention may comprise one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG), or any other compound as described herein.

[0104] The methods of treatment as described herein may be administered by an individual qualified to administer the vaporizable formulations of the present invention in

accordance with local jurisdictional laws, which may include, but is not limited to, a psychiatrist, psychologist, therapist, shaman, or any other qualified individual.

Kits

[0105] In other embodiments the present invention provides components packaged together in the form of a kit for performing any of the methods described herein.

[0106] In some embodiments, the kit comprises a chamber comprising at least one vaporizable formulation wherein the vaporizable formulation comprises an ayahuasca-like substance. In some embodiments, the chamber that is part of the kit comprises a mouthpiece coupled to a top portion of the chamber. In some embodiments the mouthpiece comprises a top aperture, a central open bore, a bottom portion comprising an aperture, and wherein the bottom portion of the mouthpiece is coupled to the top portion of the chamber. In some embodiments, the mouthpiece that is part of the kit is releasably coupled to the top portion of the chamber. In some embodiments, the mouthpiece that is part of the kit is lockably coupled to the top portion of the chamber. In some embodiments, the chamber that is part of the kit is coupled to the power unit capable of providing power to vaporize the vaporizable formulation. In some embodiments, the chamber that is part of the kit is releasably coupled to the power unit. In some embodiments, the chamber that is part of the kit is lockably coupled to the power unit. In some embodiments, the chamber that is part of the kit comprises one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector to couple the chamber to the power unit. In some embodiments, the chamber that is part of the kit comprises a 510 connector. In some embodiments, the chamber that is part of the kit is transparent to permit visualization of levels of the vaporizable formulation. In some embodiments, the chamber that is part of the kit is refillable. In some embodiments, the ayahuasca-like substance that is part of the kit comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In some embodiments, the ayahuasca-like substance that is part of the kit comprises dimethyltryptamine. In an embodiment, the ayahuasca-like substance that is part of the kit comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase

inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine. In an embodiment, the ayahuasca-like substance that is part of the kit is dimethyltryptamine comprising deuterium. In some embodiments, the vaporizable formulation that is part of the kit comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG).

EXAMPLE

[0107] Aspects of the present teachings can be further understood in light of the following example, which should not be construed as limiting the scope of the present teachings in any way.

[0108] The following example was performed in a jurisdiction where each substance described has been decriminalized.

Step 1: Dimethyltryptamine

[0109] Pure dimethyltryptamine was acquired through readily available channels. Melting point analyses were taken from two samples to confirm the chemical makeup. The two samples each melted at approximately 46 degrees celsius, confirming that the chemical makeup was dimethyltryptamine.

Step 2: Formulating a vaporizable formulation

[0110] The dimethyltryptamine (i.e., the ayahuasca-like substance) derived from Step 1 was mixed into a formulation comprising propylene glycol (PG) and vegetable glycerin (VG) to formulate a vaporizable formulation comprising the ayahuasca-like substance. The dimethyltryptamine (i.e., the ayahuasca-like substance) derived from Step 1 was also mixed into a formulation comprising polyethylene glycol (PEG) and vegetable glycerin (VG) to formulate a vaporizable formulation comprising the ayahuasca-like substance. Finally, the dimethyltryptamine (i.e., the ayahuasca-like substance) derived from Step 1 was mixed into a formulation comprising propylene glycol (PG) and polyethylene glycol (PEG) to formulate a vaporizable formulation comprising the ayahuasca-like substance.

[0111] Dimethyltryptamine was mixed at different concentrations varying from 250mg/ml to 1g/ml. Optional formulation ratios are described in Table 1.

PG:VG	0:100	PEG:VG	0:100	PG:PEG	0:100
PG:VG	10:90	PEG:VG	10:90	PG:PEG	10:90
PG:VG	20:80	PEG:VG	20:80	PG:PEG	20:80
PG:VG	30:70	PEG:VG	30:70	PG:PEG	30:70
PG:VG	40:60	PEG:VG	40:60	PG:PEG	40:60
PG:VG	50:50	PEG:VG	50:50	PG:PEG	50:50
PG:VG	60:40	PEG:VG	60:40	PG:PEG	60:40
PG:VG	70:30	PEG:VG	70:30	PG:PEG	70:30
PG:VG	80:20	PEG:VG	80:20	PG:PEG	80:20
PG:VG	90:10	PEG:VG	90:10	PG:PEG	90:10
PG:VG	100:0	PEG:VG	100:0	PG:PEG	100:0

Table 1.

Step 3: Production of delivery device

[0112] Step 3 describes an embodiment of the invention wherein a chamber as described herein is combined with an ayahuasca-like substance. The vaporizable formulation of Step 2 comprising the ayahuasca-like substance derived from Step 1 was placed into the hollow portion of a chamber comprising a 510 threaded connector as described herein and illustrated in Figure 3.

[0113] The vaporizable formulation of Step 2 comprising the ayahuasca-like substance derived from Step 1 was also placed into the hollow portion of a chamber comprising an eGo threaded connector as described herein.

Step 4: Attachment to a power unit

[0114] An optional embodiment of the present invention includes a power unit. The delivery device comprising the chamber of Step 3 comprising the vaporizable

formulation of Step 2 comprising the ayahuasca-like substance derived from Step 1 was affixed to a commercially available power unit as shown in Figure 4.

[0115] All publications and patent applications cited in this specification are herein incorporated by reference as if each individual publication or patent application were specifically and individually indicated to be incorporated by reference.

[0116] Although the foregoing invention has been described in some detail by way of illustration and example for purposes of clarity of understanding, it will be readily apparent to one of ordinary skill in the art in light of the teachings of this invention that certain changes and modifications may be made thereto without departing from the spirit or scope of the invention as defined in the appended claims.

CLAIMS

What is claimed is:

Claim 1. A device for the delivery of an ayahuasca-like substance, comprising: a chamber comprising at least one vaporizable formulation wherein the vaporizable formulation comprises the ayahuasca-like substance.

Claim 2. The device of claim 1 wherein the chamber comprises a top portion adapted for coupling to a mouthpiece wherein the top portion of the chamber comprises at least one aperture adapted to permit flow of air, liquid, solids, or vapor between the top portion of the chamber and the mouthpiece.

Claim 3. The device of claim 2 additionally comprising a mouthpiece coupled to the top portion of the chamber wherein the mouthpiece comprises a top aperture, a central open bore, a bottom portion comprising an aperture, and wherein the bottom portion of the mouthpiece is coupled to the top portion of the chamber.

Claim 4. The device of claim 3 additionally comprising at least one seal situated between the bottom portion of the mouthpiece comprising an aperture and the top portion of the chamber.

Claim 5. The device of claim 2 wherein the mouthpiece is releasably coupled to the top portion of the chamber.

Claim 6. The device of claim 2 wherein the mouthpiece is lockably coupled to the top portion of the chamber.

Claim 7. The device of claim 1 wherein the chamber comprises a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the vaporizable formulation.

Claim 8. The device of claim 7 wherein the chamber is coupled to the power unit capable of providing power to vaporize the vaporizable formulation.

Claim 9. The device of claim 8 wherein the chamber is releasably coupled to the power unit.

Claim 10. The device of claim 8 wherein the chamber is lockably coupled to the power unit.

Claim 11. The device of claim 1 wherein the chamber comprises one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector.

Claim 12. The device of claim 11 wherein the chamber comprises a 510 connector.

Claim 13. The device of claim 1 wherein the chamber is transparent to permit visualization of levels of the vaporizable formulation.

Claim 14. The device of claim 1 wherein the chamber is refillable.

Claim 15. The device of claim 1 wherein the ayahuasca-like substance or vaporizable formulation comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine.

Claim 16. The device of claim 15 wherein the ayahuasca-like substance comprises dimethyltryptamine.

Claim 17. The device of claim 15 wherein the ayahuasca-like substance comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine.

Claim 18. The device of claim 17 wherein the isotopomer or isotopologue comprises deuterium.

Claim 19. The device of claim 17 wherein ayahuasca-like substance is dimethyltryptamine comprising deuterium.

Claim 20. The device of claim 1 wherein the vaporizable formulation comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG).

Claim 21. A method for delivering an ayahuasca-like substance, wherein the method comprises heating a vaporizable formulation comprising the ayahuasca-like substance to vaporize at least a portion of the vaporizable formulation.

Claim 22. The method of claim 21 wherein the vaporizable formulation is housed in a chamber comprising a top portion adapted for coupling to a mouthpiece wherein the top portion of the chamber comprises at least one aperture adapted to permit flow of air, liquid, solids, or vapor between the top portion of the chamber and the mouthpiece.

Claim 23. The method of claim 22 wherein the chamber comprises a mouthpiece coupled to the top portion of the chamber wherein the mouthpiece comprises a top aperture, a central open bore, a bottom portion comprising an aperture, and wherein the bottom portion of the mouthpiece is coupled to the top portion of the chamber.

Claim 24. The method of claim 23 wherein the chamber comprises at least one seal situated between the bottom portion of the mouthpiece comprising an aperture and the top portion of the chamber.

Claim 25. The method of claim 23 wherein the mouthpiece is releasably coupled to the top portion of the chamber.

Claim 26. The method of claim 23 wherein the mouthpiece is lockably coupled to the top portion of the chamber.

Claim 27. The method of claim 22 wherein the chamber comprises a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the vaporizable formulation.

Claim 28. The method of claim 27 wherein the chamber is coupled to the power unit capable of providing power to vaporize the vaporizable formulation.

Claim 29. The method of claim 28 wherein the chamber is releasably coupled to the power unit.

Claim 30. The method of claim 28 wherein the chamber is lockably coupled to the power unit.

Claim 31. The method of claim 22 wherein the chamber comprises one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector.

Claim 32. The method of claim 31 wherein the chamber comprises an eGo connector.

Claim 33. The method of claim 31 wherein the chamber comprises a 510 connector.

Claim 34. The method of claim 22 wherein the chamber is refillable.

Claim 35. The method of claim 22 wherein the chamber is single-use.

Claim 36. The method of claim 23 wherein the chamber is transparent to permit visualization of levels of the vaporizable formulation.

Claim 37. The method of claim 21 wherein the ayahuasca-like substance or vaporizable formulation comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine.

Claim 38. The method of claim 37 wherein the ayahuasca-like substance comprises dimethyltryptamine.

Claim 39. The method of claim 37 wherein the ayahuasca-like substance comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine.

Claim 40. The method of claim 39 wherein the isotopomer or isotopologue comprises deuterium.

Claim 41. The method of claim 39 wherein ayahuasca-like substance is dimethyltryptamine comprising deuterium.

Claim 42. The method of claim 21 wherein the vaporizable formulation comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG).

Claim 43. A vaporizable formulation, wherein the vaporizable formulation comprises an ayahuasca-like substance.

Claim 44. The vaporizable formulation of claim 43, wherein the ayahuasca-like substance or vaporizable formulation comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine.

Claim 45. The vaporizable formulation of claim 44, wherein the ayahuasca-like substance comprises dimethyltryptamine.

Claim 46. The vaporizable formulation of claim 43 wherein the ayahuasca-like substance comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine.

Claim 47. The vaporizable formulation of claim 46 wherein the isotopomer or isotopologue comprises deuterium.

Claim 48. The vaporizable formulation of claim 46 wherein ayahuasca-like substance is dimethyltryptamine comprising deuterium.

Claim 49. The vaporizable formulation of claim 43, wherein the vaporizable formulation comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG).

Claim 50. A method of treating a psychological disorder comprising administering to a patient an effective amount of an ayahuasca-like substance, wherein the method comprises heating a vaporizable formulation comprising the ayahuasca-like substance to vaporize at least a portion of the vaporizable formulation.

Claim 51. The method of claim 50 wherein the vaporizable formulation is housed in a chamber comprising a top portion adapted for coupling to a mouthpiece wherein the top portion of the chamber comprises at least one aperture adapted to permit flow of air, liquid, solids, or vapor between the top portion of the chamber and the mouthpiece.

Claim 52. The method of claim 51 wherein the chamber comprises a mouthpiece coupled to the top portion of the chamber wherein the mouthpiece comprises a top aperture, a central open bore, a bottom portion comprising an aperture, and wherein the bottom portion of the mouthpiece is coupled to the top portion of the chamber.

Claim 53. The method of claim 52 wherein the chamber comprises at least one seal situated between the bottom portion of the mouthpiece comprising an aperture and the top portion of the chamber.

Claim 54. The method of claim 52 wherein the mouthpiece is releasably coupled to the top portion of the chamber.

Claim 55. The method of claim 52 wherein the mouthpiece is lockably coupled to the top portion of the chamber.

Claim 56. The method of claim 51 wherein the chamber comprises a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the vaporizable formulation.

Claim 57. The method of claim 56 wherein the chamber is coupled to the power unit capable of providing power to vaporize the vaporizable formulation.

Claim 58. The method of claim 57 wherein the chamber is releasably coupled to the power unit.

Claim 59. The method of claim 57 wherein the chamber is lockably coupled to the power unit.

Claim 60. The method of claim 51 wherein the chamber comprises one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector.

Claim 61. The method of claim 60 wherein the chamber comprises an eGo connector.

Claim 62. The method of claim 60 wherein the chamber comprises a 510 connector.

Claim 63. The method of claim 51 wherein the chamber is refillable.

Claim 64. The method of claim 51 wherein the chamber is single-use.

Claim 65. The method of claim 51 wherein the chamber is transparent to permit visualization of levels of the vaporizable formulation.

Claim 66. The method of claim 50 wherein the ayahuasca-like substance or vaporizable formulation comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine.

Claim 67. The method of claim 66 wherein the ayahuasca-like substance comprises dimethyltryptamine.

Claim 68. The method of claim 66 wherein the ayahuasca-like substance comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine.

Claim 69. The method of claim 68 wherein the isotopomer or isotopologue comprises deuterium.

Claim 70. The method of claim 68 wherein ayahuasca-like substance is dimethyltryptamine comprising deuterium.

Claim 71. The method of claim 50 wherein the vaporizable formulation comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG).

Claim 72. The method of claim 50 wherein the psychological disorder comprises one or more of obsessive compulsive disorder, nicotine addiction, alcoholism, narcotic addiction, depression and anxiety related to diagnosis of a life-threatening or terminal illness, major depressive disorder, depression, bipolar disorder, dysthymic disorder,

panic attacks, schizophrenia, attention deficit disorder, attention deficit hyperactivity disorder, general anxiety disorder, impulse disorders, delusional disorders, cluster headaches, migraines, personality disorders, gambling disorders, eating disorder, body dysmorphic disorder, or post traumatic stress disorder.

Claim 73. A kit comprising a chamber comprising at least one vaporizable formulation wherein the vaporizable formulation comprises an ayahuasca-like substance.

Claim 74. The kit of claim 73 wherein the chamber comprises a mouthpiece coupled to the top portion of the chamber wherein the mouthpiece comprises a top aperture, a central open bore, a bottom portion comprising an aperture, and wherein the bottom portion of the mouthpiece is coupled to the top portion of the chamber.

Claim 75. The kits of claim 74 wherein the mouthpiece is releasably coupled to the top portion of the chamber.

Claim 76. The kit of claim 74 wherein the mouthpiece is lockably coupled to the top portion of the chamber.

Claim 77. The kit of claim 73 wherein the chamber is coupled to the power unit capable of providing power to vaporize the vaporizable formulation.

Claim 78. The kit of claim 77 wherein the chamber is releasably coupled to the power unit.

Claim 79. The kit of claim 77 wherein the chamber is lockably coupled to the power unit.

Claim 80. The kit of claim 73 wherein the chamber comprises one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector.

Claim 81. The kit of claim 80 wherein the chamber comprises a 510 connector.

Claim 82. The kit of claim 73 wherein the chamber is transparent to permit visualization of levels of the vaporizable formulation.

Claim 83. The kit of claim 73 wherein the chamber is refillable.

Claim 84. The kit of claim 73 wherein the ayahuasca-like substance or vaporizable formulation comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine.

Claim 85. The kit of claim 84 wherein the ayahuasca-like substance comprises dimethyltryptamine.

Claim 86. The kit of claim 84 wherein the ayahuasca-like substance comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine.

Claim 87. The kit of claim 86 wherein the isotopomer or isotopologue comprises deuterium.

Claim 88. The kit of claim 86 wherein ayahuasca-like substance is dimethyltryptamine comprising deuterium.

Claim 89. The kit of claim 73 wherein the vaporizable formulation comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG).

ABSTRACT

Provided herein is a delivery device and vaporizable formulations that provide users or patients with the ability to safely, reliably, and conveniently obtain a high-quality, therapeutic vapor comprising an ayahuasca-like substance. The delivery device includes a chamber coupled to a power unit capable of providing power to vaporize the formulations for consumption of the substance in a consistently desirable and safe manner. Further included are kits and methods of treating psychological disorders using the delivery device and vaporizable formulations provided herein.

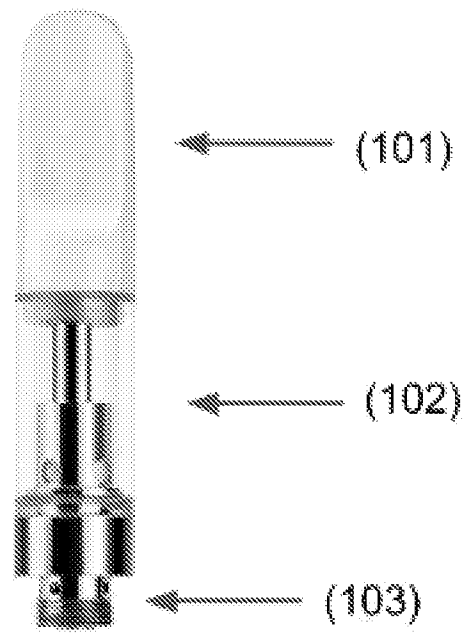


Figure 1

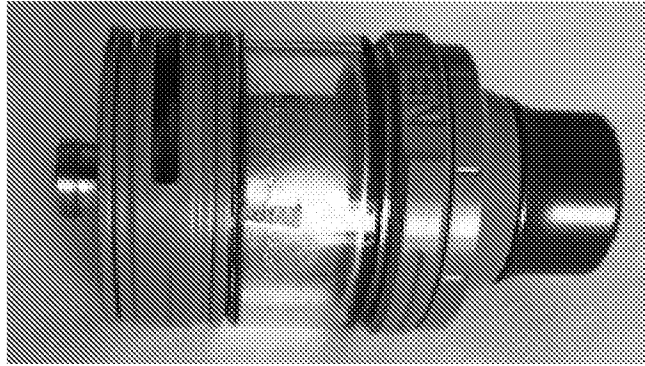


Figure 2A



Figure 2B

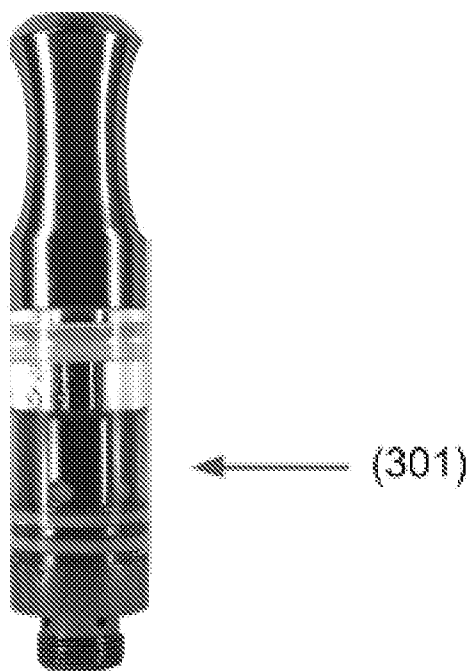


Figure 3

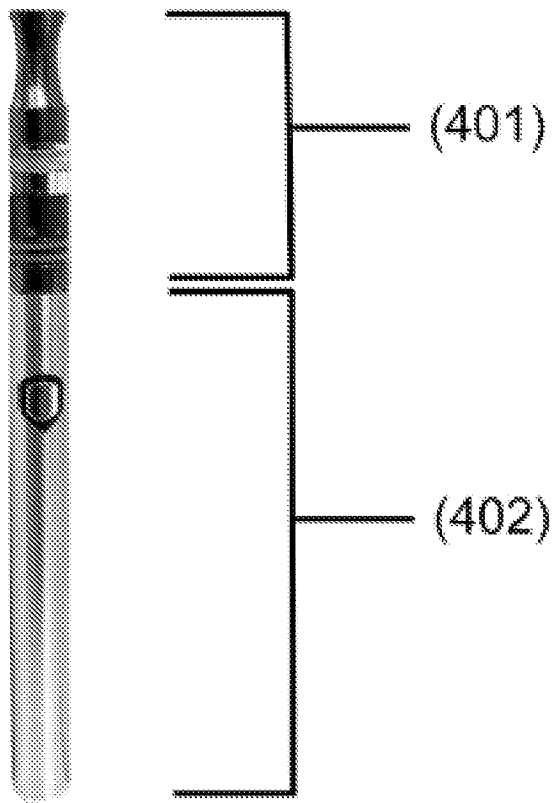


Figure 4

Electronic Patent Application Fee Transmittal				
Application Number:				
Filing Date:				
Title of Invention:		Delivery System For Ayahuasca-Like Substances		
First Named Inventor/Applicant Name:		Gregory Ellis		
Filer:		Gregory Ellis		
Attorney Docket Number:		1001-US2		
Filed as Micro 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:				
BASIC FILING FEE-UTILITY	3011	1	80	80
UTILITY SEARCH FEE	3111	1	175	175
UTILITY EXAMINATION FEE	3311	1	200	200
REQUEST FOR PRIORITIZED EXAMINATION	3817	1	1050	1050
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.	3830	1	35	35
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				1540

Electronic Acknowledgement Receipt

EFS ID:	43430430
Application Number:	17394340
International Application Number:	
Confirmation Number:	7359
Title of Invention:	Delivery System For Ayahuasca-Like Substances
First Named Inventor/Applicant Name:	Gregory Ellis
Customer Number:	173064
Filer:	Gregory Ellis
Filer Authorized By:	
Attorney Docket Number:	1001-US2
Receipt Date:	04-AUG-2021
Filing Date:	
Time Stamp:	21:36:34
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$ 1540
RAM confirmation Number	E202184L38313446
Deposit Account	
Authorized User	

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

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	WebADS.pdf	173507	no	7
			33664a6d34ffc6bc21da977b3b5053506e4e09e4		
Warnings:					
Information:					
2	Transmittal Letter	1001-US2_IDSresponse.pdf	92861	no	2
			b6153aaee132017a8a587d0f2f28027ff064ca89		
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	1001-US2_IDS_2021-08-04.pdf	567261	no	5
			48a424ea514637c5016086042375699c15b90675		
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
4	Certification of Micro Entity (Gross Income Basis)	1001-US2_micro.pdf	83957	no	1
			7ca35e0d988089fa3e3d7a49c6e72400964f95c0		
Warnings:					
Information:					
5	Oath or Declaration filed	1001-US2_declaration.pdf	204610	no	2
			732f35aae21a94d885f01889009a12380a14cb0b		
Warnings:					
Information:					
6	Specification	1001-US2_Spec.pdf	302148	no	37
			eccd451153a6d5e3f50aa7c54460568d35c51ca6		
Warnings:					

Information:					
7	Claims	1001-US2_claims.pdf	119342	no	10
			380bc6a4bb7f32da050455311e1b154c4f795e4d		
Warnings:					
Information:					
8	Abstract	1001-US2_abstract.pdf	68444	no	1
			f4a0d47cdbc00047a1ff52aca74f5ee8897e9e1a		
Warnings:					
Information:					
9	Drawings-only black and white line drawings	1001-US2_drawings.pdf	1304508	no	4
			359b2c720dcb18d7c9dee402b1ba0faa12946850		
Warnings:					
Information:					
10	TrackOne Request	1001-US2_Fasttrack.pdf	126603	no	2
			a8cf8364e43547f5db279a8a020e216e7cad6b09		
Warnings:					
Information:					
11	Preliminary Amendment	1001-US2_Preliminary_Amendment.pdf	102232	no	5
			403fb1eb007eb42adc1d713ee8f8f9f9b8eb3d9c		
Warnings:					
Information:					
12	Fee Worksheet (SB06)	fee-info.pdf	50752	no	2
			7aeb6143b1c5bc00fd9563b0ff00f43fb332c1d		
Warnings:					
Information:					
Total Files Size (in bytes):			3196225		

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.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	1001-US2
		Application Number	
Title of Invention	Delivery System For Ayahuasca-Like Substances		
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:

Inventor 1				
Legal Name				
Prefix	Given Name	Middle Name	Family Name	Suffix
	Gregory		Ellis	
Residence Information (Select One)		☒ US Residency ☐ Non US Residency ☐ Active US Military Service		
City	Portland	State/Province	OR	Country of Residence ⁱ US
Mailing Address of Inventor:				
Address 1	PO Box 86924			
Address 2				
City	Portland	State/Province	OR	
Postal Code	97286	Country ⁱ	US	
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button. Add				

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).	
☐ An Address is being provided for the correspondence information of this application.	
Customer Number	173064
Email Address	ellisgreg503@gmail.com Add Email Remove Email

Application Information:

Title of the Invention	Delivery System For Ayahuasca-Like Substances		
Attorney Docket Number	1001-US2	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	4	Suggested Figure for Publication (if any)	3

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	1001-US2
		Application Number	
Title of Invention	Delivery System For Ayahuasca-Like Substances		

Filing By Reference:

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

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

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

Publication Information:

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

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

Representative Information:

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

Please Select One:						
☐ Customer Number		☒ US Patent Practitioner		☐ Limited Recognition (37 CFR 11.9)		
Prefix	Given Name	Middle Name	Family Name	Suffix	Remove	
	Gregory		Ellis			
Registration Number	56186					
Additional Representative Information blocks may be generated within this form by selecting the Add button.						

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim 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" field blank.

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	1001-US2
		Application Number	
Title of Invention	Delivery System For Ayahuasca-Like Substances		

Prior Application Status	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	PCT/US21/42123	2021-07-18
Prior Application Status	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US21/42123	Claims benefit of provisional	63/144,923	2021-02-02
Prior Application Status	Expired	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US21/42123	Claims benefit of provisional	63/058,444	2020-07-29
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.			

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. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(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).

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.			

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.

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	1001-US2
		Application Number	
Title of Invention	Delivery System For Ayahuasca-Like Substances		

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is 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 State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

- ☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.
- ☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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	1001-US2
		Application Number	
Title of Invention	Delivery System For Ayahuasca-Like Substances		

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.

Applicant 1

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.

☐ 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 For Applicant:

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.

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	1001-US2
		Application Number	
Title of Invention	Delivery System For Ayahuasca-Like Substances		

Assignee Information including Non-Applicant Assignee 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.

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.				
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.				

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	1001-US2
		Application Number	
Title of Invention	Delivery System For Ayahuasca-Like Substances		

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Gregory Ellis/			Date (YYYY-MM-DD)	
First Name	Gregory	Last Name	Ellis	Registration Number	56186
Additional Signature may be generated within this form by selecting the Add button.					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Ellis, Gregory

Confirmation No.: Not Yet Assigned

Application No.: Not Yet Assigned

Art Unit: Not Yet Assigned

Filed: Herewith

Examiner: Not Yet Assigned

For: Delivery System for Ayahuasca-
Like Substances

Information Disclosure Statement

Mail Stop Amendment
Commission for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

The references cited on attached form PTO/SB/08A are being called to the attention of the Examiner. In accordance with the provisions of 37 CFR §1.98(a)(2), copies of any cited U.S. Patents and U.S. Patent Application Publications are not provided. Copies of the remaining cited references, if any, are provided.

It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR §1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information. This Information Disclosure Statement is being filed before the mailing date of the first Office Action on the merits.

Applicant believes that no fee is required for submission of this statement.

Respectfully submitted

/Gregory Ellis/
Gregory Ellis
Registration No: 56,186
August 4, 2021

Application No.: Not Yet Assigned

Docket No.: 1001-US2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Ellis, Gregory

Confirmation No.: Not Yet Assigned

Application No.: Not Yet Assigned

Art Unit: Not Yet Assigned

Filed: Herewith

Examiner: Not Yet Assigned

For: Delivery System for Ayahuasca-
Like Substances

Preliminary Amendment

Mail Stop Amendment
Commission for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

Prior to examination of the above-referenced application, please enter the following amendments and consider the following remarks.

AMENDMENTS TO THE CLAIMS

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

Listing of Claims:

Claim 1. (Original) A device for the delivery of an ayahuasca-like substance, comprising: a chamber comprising at least one vaporizable formulation wherein the vaporizable formulation comprises the ayahuasca-like substance.

Claim 2. (Original) The device of claim 1 wherein the chamber comprises a top portion adapted for coupling to a mouthpiece wherein the top portion of the chamber comprises at least one aperture adapted to permit flow of air, liquid, solids, or vapor between the top portion of the chamber and the mouthpiece.

Claim 3. (Original) The device of claim 2 additionally comprising a mouthpiece coupled to the top portion of the chamber wherein the mouthpiece comprises a top aperture, a central open bore, a bottom portion comprising an aperture, and wherein the bottom portion of the mouthpiece is coupled to the top portion of the chamber.

Claim 4. (Original) The device of claim 3 additionally comprising at least one seal situated between the bottom portion of the mouthpiece comprising an aperture and the top portion of the chamber.

Claim 5. (Original) The device of claim 2 wherein the mouthpiece is releasably coupled to the top portion of the chamber.

Claim 6. (Original) The device of claim 2 wherein the mouthpiece is lockably coupled to the top portion of the chamber.

Claim 7. (Original) The device of claim 1 wherein the chamber comprises a bottom portion adapted for coupling to a power unit capable of providing power to vaporize the vaporizable formulation.

Claim 8. (Original) The device of claim 7 wherein the chamber is coupled to the power unit capable of providing power to vaporize the vaporizable formulation.

Claim 9. (Original) The device of claim 8 wherein the chamber is releasably coupled to the power unit.

Claim 10. (Original) The device of claim 8 wherein the chamber is lockably coupled to the power unit.

Claim 11. (Original) The device of claim 1 wherein the chamber comprises one or more of a 401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector.

Claim 12. (Original) The device of claim 11 wherein the chamber comprises a 510 connector.

Claim 13. (Original) The device of claim 1 wherein the chamber is transparent to permit visualization of levels of the vaporizable formulation.

Claim 14. (Original) The device of claim 1 wherein the chamber is refillable.

Claim 15. (Original) The device of claim 1 wherein the ayahuasca-like substance or vaporizable formulation comprises one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine.

Claim 16. (Original) The device of claim 15 wherein the ayahuasca-like substance comprises dimethyltryptamine.

Claim 17. (Original) The device of claim 15 wherein the ayahuasca-like substance comprises an isotopomer or isotopologue of one or more of dimethyltryptamine, a monoamine oxidase inhibitor, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine.

Claim 18. (Original) The device of claim 17 wherein the isotopomer or isotopologue comprises deuterium.

Claim 19. (Original) The device of claim 17 wherein ayahuasca-like substance is dimethyltryptamine comprising deuterium.

Claim 20. (Original) The device of claim 1 wherein the vaporizable formulation comprises one or more of propylene glycol (PG), vegetable glycerin (VG), or polyethylene glycol (PEG).

Claims 21-89 (Canceled)

REMARKS/ARGUMENTS

Applicant requestfully requests that this Preliminary Amendment be entered prior to examination of this application.

Respectfully submitted

/Gregory Ellis/
Gregory Ellis
Registration No: 56,186
August 04, 2021

SCORE Placeholder Sheet for IFW Content

Application Number: 17394340

Document Date: 08/04/2021

The presence of this form in the IFW record indicates that the following document type was received in electronic format on the date identified above. This content is stored in the SCORE database.

Since this was an electronic submission, there is no physical artifact folder, no artifact folder is recorded in PALM, and no paper documents or physical media exist. The TIFF images in the IFW record were created from the original documents that are stored in SCORE.

- Drawing

At the time of document entry (noted above):

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