

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PORTA SOPHIA,
Petitioner,

v.

GREGORY ELLIS,
Patent Owner.

Patent No. 11,235,110

PETITION FOR *INTER PARTES* REVIEW

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I. INTRODUCTION

Petitioner Porta Sophia (“PS”) seeks an *inter partes* review (“IPR”) of claims 1-20 of U.S. Patent 11,235,110 (“the ’110 Patent”; EX 1001), apparently¹ owned by inventor applicant Gregory Ellis (“Patent Owner”). This petition shows a reasonable likelihood that claims 1-20 are unpatentable. 35 U.S.C. § 314(a).

The ’110 Patent simply claims a device comprising a chamber where the chamber comprises a vaporizable formulation of one or more of dimethyltryptamine (DMT), 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT), or 2,5-dimethoxy-4-bromophenethylamine (2C-B).

The vaporization devices described and claimed in the ’110 Patent are well established in prior art and have historically been used to vaporize a wide variety of substances. Indeed, the drawings in the ’110 Patent are photographs of commercialized prior art vaporization devices. The specification admits that these devices are known in the art and that the claimed “chamber” refers to a feature of such devices known in the prior art:

¹ Other members of the patent family associated with US 11,235,110 have been assigned to the company Monster Color Carnival LLC (MCC), but no such assignment appears in the publicly accessible records at the USPTO. Monster Color Carnival LLC is registered in the state of Wyoming and lists Gregory Ellis as the Organizer. Petitioner’s EX 1002, page 1, paragraph 2, references MCC as the owner of the ’110 Patent based on information conveyed in public databases. It should be understood that EX 1002 is referring to the ’110 Patent apparently owned by Gregory Ellis.

Devices used to vaporize substances are known in the art, and are commonly referred to in the art as vaporizers, atomizers (e.g., ... rebuildable tank atomizers, clearomizers, ...), mods (including but not limited to ... sub ohm mods, ...), E-cigs, vape pens, etc.

EX 1001, col. 6, ll. 13-20.

As used herein, a “chamber” refers to a device that holds a vaporizable formulation. ... **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.

Id. at col. 7, ll. 10-17 (emphasis added). No novelty resides in these devices.

DMT, 5-MeO-DMT, and 2C-B are well-known psychedelic drugs of the prior art with known health benefits, as admitted in the '110 Patent specification. *Id.* at col. 1, ll. 23-30.

Claims 17-19 of the '110 Patent recite that the substance is an isotopomer of these well-known psychedelic drugs. Isotopomers of these drugs are known in the prior art. No novelty resides in these compounds.

The claimed vaporizable formulations of drugs, employing propylene glycol (PG), vegetable glycerin (VG), and/or polyethylene glycol (PEG), are well known in the art as admitted in the '110 Patent. *Id.* at col. 7, l. 65—col. 8, l. 5. No novelty resides in the formulation of vaporizable substances.

Rather, the '110 Patent rests its alleged patentability in the application of DMT, 5-MeO-DMT, or 2C-B to such vaporizable formulations as contained in such devices. As demonstrated herein, it was common practice in the prior art to formulate these compounds and isotopomers of these compounds into vaporizable formulations and to vaporize and use them in delivery devices. As such, the claims of the '110 Patent are unpatentable in view of the prior art.

This request for IPR of the '110 Patent is brought by Porta Sophia, a public-interest, non-profit, limited liability corporation whose mission is to protect the public domain by challenging patent applications and patents that block access to that which is already part of the public domain. The risk of bad patents is especially high in the psychedelic field, given the historical and cultural factors that obscure prior art related to psychedelics. Porta Sophia's mission is to protect the public domain, stimulate innovation, and support good patents to assure psychedelic therapies can one day be available at scale to the people who need them. The '110 Patent threatens the public domain by claiming well-known devices containing well-known vaporizable formulations of well-known drugs, taking from the public one of the limited mechanisms for delivery of these drugs and converting common prior art practices into potential patent infringement allegations with the associated costs and burdens associated therewith.

II. MANDATORY NOTICES

A. Real Parties-In-Interest

Porta Sophia is the real party-in-interest for Petitioner.

B. Related Matters

There are no related matters.

C. Identification of Counsel and Service Information

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Please direct all correspondence to lead counsel and back-up counsel at the contact information above.

Porta Sophia consents to electronic-mail service at docketing@casimirjones.com and all email addresses above. A power of attorney accompanies this petition.

III. CERTIFICATIONS

The '110 Patent is available for IPR. Porta Sophia is not barred or estopped from requesting IPR on these grounds.

IV. IDENTIFICATION OF CHALLENGE; STATEMENT OF PRECISE RELIEF REQUESTED

Porta Sophia seeks cancellation of the challenged claims for the reasons stated below, supported with exhibits, including a declaration from Dr. David Peyton (EX 1002). The claims are unpatentable under AIA 35 U.S.C. §§ 102 and 103 on the following grounds:

Ground	Claims	Basis
1	17-19	U.S. Pat. Publ. No. 2022/0081396 under 35 U.S.C. § 102(a)(2)
2	17-19	DMT-NEXUS 2012 in view of HALBERSTADT under 35 U.S.C. § 103
3	1, 7-9, 11, 12, 14-16, and 20	DMT-NEXUS 2012, under 35 U.S.C. § 102(a)(1)
4	2-8, 10, and 13	DMT-NEXUS 2012 in view of GIROUD and the Visual Vaping Dictionary, Int'l Pat. Publ. No. WO 2019/191712, U.S. Pat. Publ. No. 2018/0303165, and/or Int'l Pat. Publ. No. WO 2020/053392 under 35 U.S.C. § 103
5	1, 7-9, 11, 12, 16, and 20	DMT-NEXUS 2018 under 35 U.S.C. § 102(a)(1)
6	1-16 and 20	DMT-NEXUS 2015, DMT-NEXUS 2018, EROWID 2014, MUNOZ, and/or GREENHILL in view of GIROUD and/or the Visual Vaping Dictionary under 35 U.S.C. § 103
7	15	POWER and CALLAWAY under 35 U.S.C. § 103
8	20	DMT-NEXUS 2012, GIROUD, DMT-NEXUS 2018, and/or the Visual Vaping Dictionary under 35 U.S.C. § 103

V. THE '110 PATENT

The '110 Patent issued from U.S. Pat. App. Ser. No. 17/394,340 (“the '340 application”), which was filed on August 4, 2021, as a continuation of Int’l Patent App. No. PCT/US21/42123 (“PCT Application”; EX 1007), having an international filing date of July 18, 2021. The PCT Application claims the benefit of two U.S. provisional patent applications: 63/058,444 (“the '444 provisional application”; EX 1005), filed July 29, 2020; and 63/144,923 (“the '923 provisional application”; EX 1006), filed February 2, 2021. U.S. Pat. App. Ser. No. 17/555,763 was filed on December 20, 2021, and is pending as a continuation of the application from which the '110 Patent issued that is the subject of this petition. The '110 Patent names Gregory Ellis as the sole inventor. Gregory Ellis is a registered patent attorney (USPTO Registration Number 56,186).

A. The claims of the '110 Patent

The '110 Patent issued with 20 claims drawn to “a device for the delivery of a substance.” Claim 1 is the sole independent claim.

The claimed “device” comprises “a chamber comprising at least one vaporizable formulation.” Claim 1 further indicates that the “vaporizable formulation” comprises a “substance” and that “the substance comprises one or more of dimethyltryptamine, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-

bromophenethylamine.” While the ’110 Patent claims recite in the preamble that the device is “for the delivery of a substance,” reciting an intended use provides no patentable weight to a claim because the patentability of an apparatus claim depends on the claimed structure, not on the use or purpose of that structure. *See, e.g., In re Gardiner*, 171 F.2d 313, 315-16 (C.C.P.A. 1948). Furthermore, the claims recite a “vaporizable formulation” and thus do not recite a *vaporized* formulation. Accordingly, the claims generally relate to a chamber holding a chemical composition comprising one or more of DMT, 5-MeO-DMT, and 2C-B.

Dependent claims 2-14 recite sub-features of the device, reciting common prior art vaping device features. For example, dependent claim 11 recites that the chamber comprises one or more of a “401, 510, 601, 610, 710, 808, 901, 4081, CE-4, CE-5, E9, or eGo connector.” These are commercially available connectors or types of connector threads known in the art at the time of filing. Dependent claim 12 specifically recites that the chamber comprises a 510 connector, which is “a standard connection known in the art.” EX 1001, col. 9, ll. 42-54.

Claims 15, 16, and 20 recite sub-features of the vaporizable formulation: that it further comprises a monoamine oxidase inhibitor (claim 15), is DMT (claim 16), or comprises PG, VG, or PEG (claim 20).

Notably, claims 17, 18, and 19 of the ’110 Patent are not entitled to the benefit of either the ’444 or the ’923 provisional application. Claims 17 to 19 recite “an

isotopomer or isotopologue of the one or more of dimethyltryptamine, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine” and, in particular, recite an isotopomer or isotopologue comprising deuterium. However, isotopomers, isotopologues, isomers, and deuterated forms of dimethyltryptamine, 5-methoxy-N,N-dimethyltryptamine, or 2-5-dimethoxy-4-bromophenethylamine are not disclosed in the ’444 or ’923 provisional application. The terms “isotopomer”, “isotopologue”, and “deuterium” first appear in the PCT Application. *See infra* section “The ’110 Patent disclosures.” Accordingly, claims 17, 18, and 19 have an effective filing date that is no earlier than July 18, 2021.²

B. The drawings of the ’110 Patent

The ’110 Patent contains five drawings – Figures 1, 2A, 2B, and 3 are photographs showing “exemplary” chambers of the alleged invention. *Id.* at col. 5, l. 49 – col. 6, l. 3. Figure 4 shows an optional embodiment in which a chamber of the alleged invention is connected to a commercially available power unit. *Id.* at col. 5, l. 65 – col. 6, l. 3.

As shown in Dr. Peyton’s expert declaration, the drawings are all photographs

² While Petitioner specifically asserts that claims 17, 18, and 19 are not entitled to an effective filing date earlier than July 18, 2021, Petitioner does not thereby concede that any of the provisional, PCT, or non-provisional disclosures provide(s) sufficient written description of any issued claims under 35 U.S.C. § 112.

of commercially available vaping devices (i.e., “threaded connectors” or “power units”) known in the art at and prior to the time of filing. EX 1002, 6-11.

C. The example of the ’110 Patent

The ’110 Patent contains one example. EX 1001, col. 22, l. 35. The ’110 Patent example describes obtaining pure DMT “from readily available channels” and formulating a vaporizable formulation by mixing the DMT with VG, PEG, and/or PG. *Id.* at col. 22, ll. 44-64. The ’110 Patent states that DMT “was mixed at different concentrations varying from 250 mg/ml to 1 g/ml.” *Id.* at col. 22, ll. 65-67. “Optional [sic] formulation ratios” of PG:VG, PEG:VG, and PG:PEG are provided in Table 1. *Id.* at col. 23, ll. 1-12. Analytical DMT characterization was limited to determining a melting point of approximately 46 degrees Celsius. *Id.* at col. 22, ll. 47-49. The example describes producing a delivery device by placing the vaporizable formulation into a chamber and attaching that chamber to a power unit. *Id.* at col. 23, ll. 13-31. The example does not describe vaporizing the alleged vaporizable formulation with the device or using the device to administer DMT. The example provides no experimental data relating to vaporizing the alleged vaporizable formulation using the device or treating any indication using the device or vaporized DMT.

D. The ’110 Patent disclosures

The instant patent claims the benefit of two provisional applications. The ’444

provisional application was filed on July 29, 2020, and the '923 provisional application was filed on February 2, 2021. The disclosures of the two provisional applications are essentially the same with the additions to the '923 provisional of new matter in: Figure 3 and Figure 4; a revision to indicate that “[t]he vaporizable formulation may also include ... terpene”; a revision to indicate that flavorings may include “Pennsylvania fruit cake”; and an addition that “[m]ost 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.” EX 1006, 24, 25, 28, 49, 50. In addition to these revisions, substantial changes were made to replace the completely prophetic example of the '444 provisional application with an alleged experimental example in the '923 provisional application. In particular, the '444 provisional application's prophetic example described in present tense extracting DMT from bark or synthesizing DMT from chemical precursors; producing a vaporizable formulation by mixing DMT with PG and VG; and producing a delivery device by placing the vaporizable formulation into the chamber of a threaded connector of a commercially available 510 or eGo vape device. EX 1005, 42-43. The revised example provided in the '923 provisional application described acquiring DMT “through readily available channels” and performing a cursory melting point analysis; mixing DMT with VG and PG at a number of ratios; producing a delivery

device by placing the vaporizable formulation into the chamber of a threaded connector of a commercially available 510 or eGo vape device; and affixing a “commercially available power unit” to the delivery device. EX 1006, 34-36.

The PCT Application was filed July 18, 2021, and claims the benefit of the two provisional applications discussed above. The PCT Application revised the '923 provisional application's disclosure by adding new matter relating to preliminary reports of successful treatments of neurodegenerative disorders with DMT and by adding several instances of a short passage disclosing that the ayahuasca-like substance may comprise isotopomers or isotopologues of DMT, a monoamine oxidase inhibitor (MAOI), 5-MeO-DMT, or 2C-B and that the ayahuasca-like substance may be DMT comprising deuterium. *See, e.g.*, EX 1001, col. 2, ll. 40-46. The PCT Application added new matter to the example describing that DMT was mixed into a formulation comprising PEG and VG or PEG and PG to formulate a vaporizable formulation. *See id.* at col. 22, ll. 55-64. Table 1 was revised to add a number of “optional” [sic] PEG:VG and PEG:PG ratios in addition to the PG:VG ratios disclosed in the '923 provisional application that may be used in the vaporizable formulations. *See id.* at col. 23, ll. 1-12.

E. The prosecution history of the '110 Patent

The '340 application is the first U.S. non-provisional application prosecuted

by the applicant in this patent lineage.³ The '340 application was filed on August 4, 2021, as a continuation of the PCT Application, with a request for Track One status that was granted. See File History for U.S. Pat. App. Ser. No. 17/394,340 (EX 1004), Track One Request filed August 4, 2021, and Track One request Granted on November 1, 2021. EX 1004, 81, 174. The application was filed with the original set of 89 claims and was examined under the first inventor to file provisions of the America Invents Act.

An information disclosure statement (IDS) was filed on August 4, 2021, that disclosed U.S. patent application publications and two news articles published by *The Stranger* (entitled “New on the Black Market: Vape Pens Full of DMT”) and *Vapor Vanity* (entitled “DMT Vape Pens: What You Need to Know”). *Id.* at 178. Another IDS was filed by Applicant on November 3, 2021, disclosing the documents identified by the PCT Application international search report (ISR) – a U.S. patent application publication, two PCT application publications,⁴ and a scientific publication. *Id.* at 67-79. Notably, the applicant did not file an IDS disclosing the

³ U.S. Pat. App. Ser. No. 17/378,723 was filed on July 18, 2021, claiming benefit of the '923 provisional application, but was abandoned.

⁴ Including a “category X” reference WO 2017/122196 to Syqe Medical Ltd.

numerous references⁵, books⁶, and commercially available chambers and power units listed in the '110 Patent specification and shown in the '110 Patent drawings.

As noted by MPEP § 609.05(a):

listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, applications, or other information submitted for consideration by the Office, and MPEP § 609.04(a), subsection I states, “the list may not be incorporated into the specification but must be submitted in a separate paper.” Therefore,

⁵ Carhart-Harris et al., *Psychological Medicine* 2016, 46: 1379–90; Griffiths et al., *Psychopharmacology* 2011, 218: 649–65; MacLean et al., *Journal of Psychopharmacology* 2011, 25: 1453–61; Morales-Garcia et al., *Translational Psychiatry*, 10: 331 (2020); Moreno et al., *Journal of Clinical Psychiatry* 2006, 67: 1735–40; Garcia-Romeu et al., *Current Drug Abuse Reviews* 2014, 7: 157–64; Krebs and Johansen, *Psychopharmacology* 2012, 26.7: 994–1002; Bogenschutz et al., *Journal of Psychopharmacology* 2015, 29.3: 289–99; Savage and McCabe, *Psychiatry* 1973, 28.6: 808–14; Grob et al., *Archives of General Psychiatry* 2011, 68: 71–78; Griffiths et al., *Journal of Psychopharmacology* 2016, 30(12): 1181–97; Ross et al., *Journal of Psychopharmacology* 2016, 30(12): 1165–80; Carhart-Harris et al., *The Lancet Psychiatry* 2016; and Sanches et al., *Journal of Clinical Psychopharmacology* 2016, 36: 77–81.

⁶ Remington: *The Science and Practice of Pharmacy*, 21st Edition, (2005, Lippincott Williams & Wilkins), pages 1517–23; *Physicians' Desk Reference*, Edition 60 (2006, Thomson PDR) page 1499; *Comprehensive Organic Transformations*, Richard C. Larock, 1989; and *Diagnostic and Statistical Manual*, Version IV.

unless the references have been cited by the examiner on form PTO-892, they have not been considered.

A preliminary amendment was filed on August 4, 2021, canceling claims 21–89; thus, original claims 1–20 were entered for substantive examination. EX 1004, 252-254.

A first (and only) substantive Office Action (“Office Action”) was issued on November 19, 2021. *Id.* at 45-48. All claims (i.e., claims 1–20) were rejected under 35 U.S.C. § 102(a)(1) as being anticipated by Int’l Pat. App. Pub. No. WO 2017/122196 (“SYQE”), which was listed on the ISR and cited by Applicant in the IDS filed November 3, 2021. *Id.* at 46, 67-79. The examiner cited no other references in the Office Action.

Applicant requested an interview to discuss “possible claim amendments to overcome novelty rejection” on November 24, 2021. *Id.* at 38. A record of the substance of the interview was not entered into the record by Applicant or by the examiner.

Applicant filed a Reply to the Office Action on December 3, 2021 (“Reply to Office Action”), by amending the claims as follows:

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 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 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.

Id. at 30-32.

Further, Applicant amended the specification 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.” *Id.* at 33. Specifically, Applicant argued that the amended claims are novel over SYQE because SYQE does not describe any of DMT, 5-MeO-DMT, or 2C-B. *Id.* at 34-35. Applicant argued that the SYQE reference described a delivery device comprising “a plant material,” wherein *Banisteriopsis caapi* is a member of the described plant material Markush

group. *Id.* at 34. Applicant further argued that *Banisteriopsis caapi* contains and provides the MAOI component of ayahuasca but does not contain or produce any of DMT, 5-MeO-DMT, or 2C-B. *Id.* at 34-35.

The Office issued a Notice of Allowance on December 20, 2021, without providing reasons for the allowance. *Id.* at 13-17. Applicant paid the issue fee on December 20, 2021. *Id.* at 7. The application issued as U.S. Pat. No. 11,235,110 on February 1, 2022. *Id.* at 2.

VI. LEVEL OF ORDINARY SKILL

A person of ordinary skill in the art (POSA) on July 29, 2020 (the earliest possible priority date of any claim) through July 18, 2021 (the priority date of claims 17-19), would include someone who had, through education or experience, a basic science background at the level of an undergraduate student or early graduate student or working experience with vaping devices and vaping formulations, which could include a “citizen scientist” (a self-educated vaping enthusiast or hobbyist having hands-on experience with or without a scientific education or degree). EX 1002, 3-4.

VII. CLAIM CONSTRUCTION

The '110 Patent dependent claims 6 and 10 recite the phrase “lockably coupled” (claim 6: “the mouthpiece is lockably coupled to the top portion of the chamber”; claim 10: “the chamber is lockably coupled to the power unit”). This

phrase is expressly defined in the specification at col. 7, ll. 43-54 as being not intended to be removed by the end-using consumer.

The definition provides no technical details about the nature of a locking mechanism, but rather defines the term “lockably coupled” to refer to the intention that the device be single-use and meant to be discarded. This is contrasted to “releasably coupled,” which refers to a reusable device. Notably, the term is defined by intent and not structure – exemplifying mouthpieces that are “lockably coupled” to a chamber (paralleling the language in dependent claim 6) as those that “are intended for single-use”. *Id.* Thus, the phrase “lockably coupled” does not require that two components are inseparable, but rather that they are designed without intent to be separated. Likewise, there is no requirement for a locking mechanism with locked and unlocked settings or positions. The phrase “lockably coupled” is met by a single-use or disposable device design.

VIII. PRIOR ART

The following sections provide an overview of the relevant state of the art prior to the relevant priority dates of the claims of the '110 Patent and a summary of the applied references.

A. Background

1. Public use of DMT Vape

Devices used for the vaporized delivery of DMT, 5-MeO-DMT, or 2C-B have

been well known and publicly used before the '110 Patent's priority date of July 19, 2020. As noted above, the claims generally recite device components ubiquitous to commercially available vaporizers – such as a cartridge (“chamber”) that couples to both a battery providing power to vaporize the drug formulation and a mouthpiece permitting the flow of the vaporized drug from the chamber to the user.

Vaporization is commonly used to deliver DMT, 5-MeO-DMT, and 2C-B. EX 1028, 2; EX 1029, 8; EX 1030, 3. Vaporized delivery of these compounds has been described in patent documents for decades – demonstrating that what is claimed in the '110 Patent is public knowledge. Patent documents explicitly claiming the delivery of DMT and 5-MeO-DMT through vaporizers or inhalation of vaporizable formulations were published far before the priority date of the '110 Patent. EX 1031, ¶142; EX 1032, ¶49; EX 1033, ¶¶487, 489; EX 1034, ¶¶483, 485; EX 1035, ¶55; EX 1036, ¶4. Similarly, documents published prior to the '110 Patent's priority date describe the inhalation of these drugs, their class, and vaporizer administration of DMT containing plant formulations, including *Psychotria viridis*. EX 1037, 9 at l. 10, 15 at l. 8, 19 at l. 16, 33 at l. 1, 76 at l. 6, 158 at l. 7; EX 1038, 9, 15, 19, 33, 75, 152; EX 1039, 8, 14, 19, 32, 75, 158; EX 1040, 4, 6, 34, 58, 60; EX 1041, 12 at ¶¶2, 10. Applications either filed before or having effective filing dates predating the '110 Patent's priority date also describe devices, methods, and systems to deliver vaporizable formulations of the same compounds claimed in the '110 Patent. EX

1042, ¶162; EX 1043, ¶¶50, 123; EX 1044, ¶105; EX 1045, 7 at l. 41 – 8 at l. 4, 17 at l. 22-25; EX 1046, ¶¶55, 92.

Mainstream news reports documenting the use of commercially available vaporizer devices to administer the drugs as claimed also exist. For example, a 2015 report documents the ease of administration of DMT through commercial vaporizer devices and was, later that same year, cited by a peer reviewed manuscript focusing on vaporizer device trends. EX 1011, 9996; EX 1016, 1. Subsequent news reports document the sale and use of vaporizer cartridges containing DMT formulations for use in commercially available vaporizers. EX 1018, 2; EX 1047, 1.

Commercial vaporizer devices with the same device elements as claimed in the '110 Patent to deliver these drugs are suggested to be superior to other means of administration because of convenience, discretion, safety considerations, and “the ease of control” one has over dosage. EX 1017, 2; EX 1030, 3; EX 1048, 1. This extensive documentation in patent filings and mainstream news reports demonstrates widespread public use and commercial availability of vaporizer devices delivering the substances identified in the '110 Patent well before the patent's priority date.

2. Public discussion of psychedelics including DMT using vape delivery

There is a significant amount of public discussion regarding vape methodology for the drugs claimed in the '110 Patent. These communications include description and use of commercially available device components, “vape

juice” formulations, and drug combinations – all aspects claimed in the ’110 Patent.

The ’110 Patent presents no novel device and relies on common, commercially available components for the vaporized delivery of several drugs, including DMT. Of the 20 granted claims of the ’110 Patent, 14 are device-focused. Single use, integrally formed or “lockable” components as claimed in the ’110 Patent are well established in the prior art, as are the claimed reusable, modular vaporizer components. EX 1049, ¶4; EX 1050, ¶5; EX 1051, ¶¶8, 16, 59, 70, FIG. 10; EX 1052, 4 at l. 26; EX 1011, 9992, 9996; EX 1012, 8, 9. This substantial body of prior art demonstrates that these devices and their components have been successfully utilized to vape DMT as claimed in the ’110 Patent.

Public forum posts discuss “shopping lists” of commercially available components to effectively vape DMT – such as batteries and cartridges. EX 1008, 4. These components are likewise claimed in the ’110 Patent. Other posts provide highly detailed vaporizer set-ups used to vape DMT. EX 1013, 1; EX 1015, 2-3; EX 1053, 1-5. Additionally, prior art disclosures depict modularly assembled components in images or videos that further support the fact that the claimed subject matter of the ’110 Patent is not novel and would have been considered obvious to a POSA. EX 1015, 2; EX 1054, 1; EX 1055; EX 1056; EX 1057.

The Applicant admits that the vape solvents PG, VG, and PEG claimed in the ’110 Patent are “commonly used substances known in the field of vaporizing.” EX

1001 col. 7, 1. 65 – col. 8, 1. 5. These claimed vape solvents are well established in the prior art. EX 1011, 9993; EX 1012, 17. The importance of vape solvents and their proper ratios in regard to vaping DMT was also presented. EX 1053, 3-4; EX 1054, 2. Postings likewise demonstrate that DMT vape formulations utilize the same solutions as claimed in the '110 Patent. EX 1008, 4, 14-15; EX 1015, 2, 4; EX 1053, 3-4; EX 1054, 2. Including MAOIs in vaporizable DMT formulations as claimed in the '110 Patent has likewise been documented prior to the priority date of the '110 Patent. EX 1018, 4.

This extensive body of prior art clearly demonstrates that the claims of the '110 Patent are not novel and would be considered obvious to a POSA.

B. DMT-NEXUS 2012

“Ecig Method for Vaping DMT summarized – best thing since ...” (“DMT-NEXUS 2012,” EX 1008) is an online discussion posted in 2012, and publicly available at <https://www.dmt-nexus.me/forum/default.aspx?g=posts&t=38704>. The Internet Archive confirms the 2012 publication date of page 1. EX 1072, 44-48. Metadata confirms the publication dates of subsequent page 2. EX 1064, 8-10.

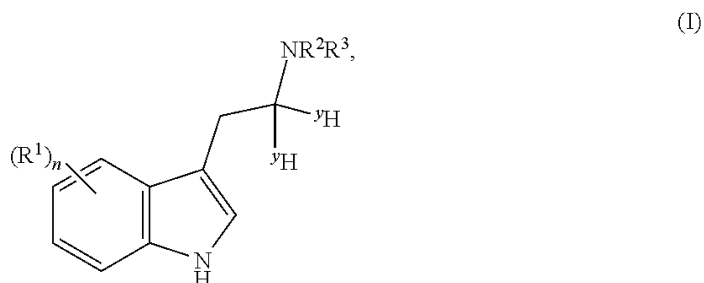
The opening three posts, posted November 19, 2012, describe the formulation and vaporization of DMT using vaporization devices based on a summary of work conducted by others. EX 1008, 1. The discussion thread continues, stating many benefits of utilizing electronic vaporizers to administer DMT including that it's

“efficient,” “always works,” there’s “no learning curve,” you can have multiple DMT cartridges immediately ready for use, and components are “mass produced” using standard elements (like 510 threads). *Id.* at 2-4. Common vaporizable formulation components are also discussed as being usable to administer DMT, including PEG, PG, and VG. *Id.* at 2, 15, 19.

C. U.S. Pat. Publ. No. 2022/0081396

U.S. Pat. Publ. No. 2022/0081396 (“the ’396 Application,” EX 1009) entitled “Deuterated compounds” was filed on March 22, 2021, published on March 17, 2023, and issued as U.S. Pat. No. 11,773,062 on October 3, 2023. The ’396 Application describes the synthesis, formulation, and use of a number of deuterated psychedelic compounds, including DMT and 5-MeO-DMT.

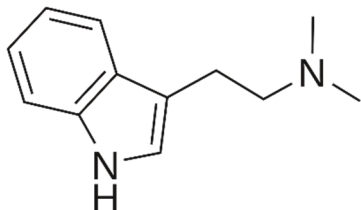
When discussing vaporizable formulations, the ’396 Application references compounds having a deuterated structure of Formula (I).



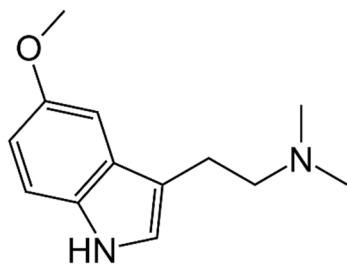
EX 1009, ¶ 23.

The Formula (I) structure includes DMT and 5-MeO-DMT:

DMT



5-MeO-DMT



Among other administration routes, the '396 Application emphasized inhalation using vaporizable formulations of its deuterated compounds through electronic vaporizers. *Id.* at ¶¶ 335-341. Notably, the '396 Application references the same formulation chemistries (PEG, glycerin, and mixtures thereof) as described in the '110 Patent and admitted by the '110 Patent as being known in the prior art. *Id.*

D. HALBERSTADT

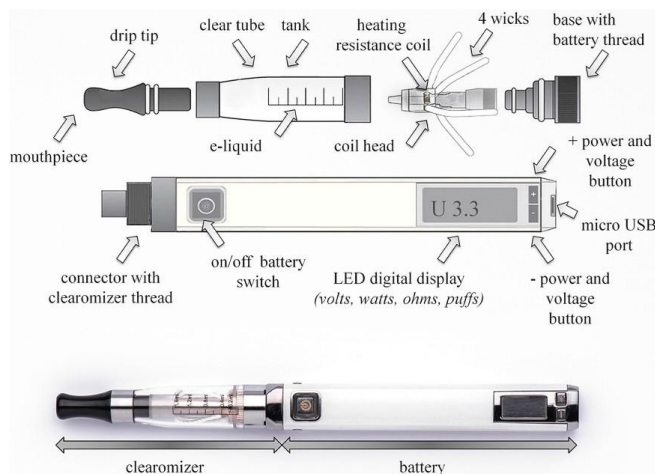
Halberstadt et al., *Psychopharmacology (Berl)*. 2012; 221(4): 709-18, entitled “Behavioral effects of $\alpha,\alpha,\beta,\beta$ -tetradeutero-5-MeO-DMT in rats: comparison with 5-MeO-DMT administered in combination with a monoamine oxidase inhibitor,” (“HALBERSTADT,” EX 1010) describes animal testing of deuterated 5-MeO-DMT

and 5-MeO-DMT alone or in combination with monoamine oxidase inhibitors (MAOIs). The paper concludes that deuterated tryptamines “may be useful in behavioral and pharmacological studies to mimic the effects of tryptamine/MAOI combinations.” EX 1010, 715-716.

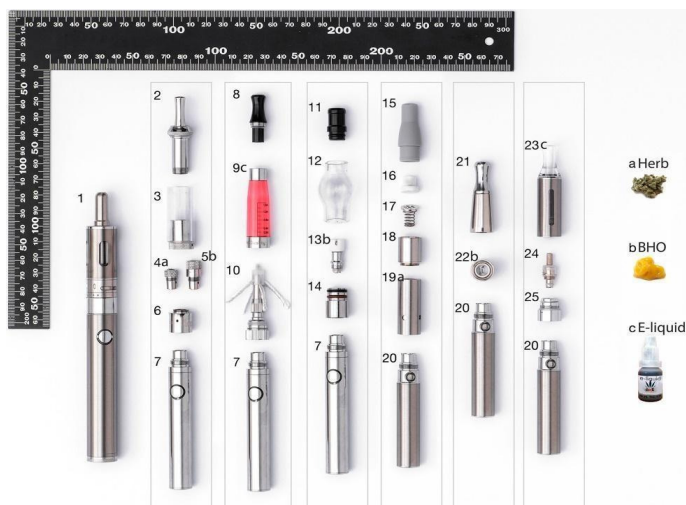
E. GIROUD

Giroud et al., *Int J Environ Res Public Health*. 2015; 12(8): 9988-10008, entitled “E-Cigarettes: A Review of New Trends in Cannabis Use,” (“GIROUD,” EX 1011) reviews the state of the art in 2015 related to e-cigarette systems. GIROUD focuses on cannabinoids, but describes that the devices are also used for a wide variety of compounds, including DMT. EX 1011, 9996.

GIROUD provides detailed descriptions of vaping device designs, sub-components, and functions.

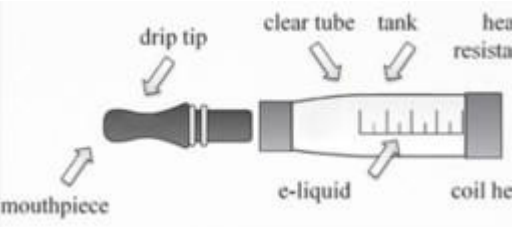
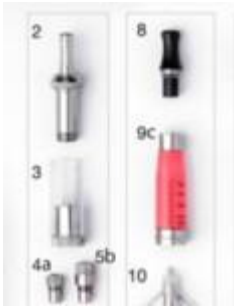
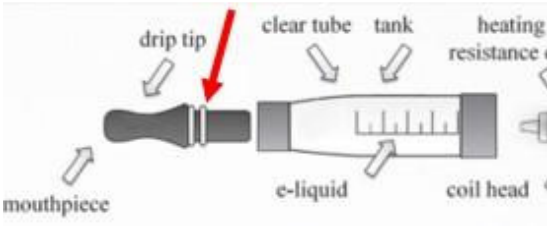


Id. at 9990.

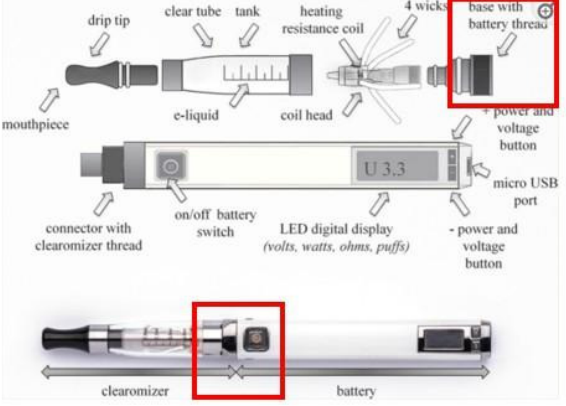
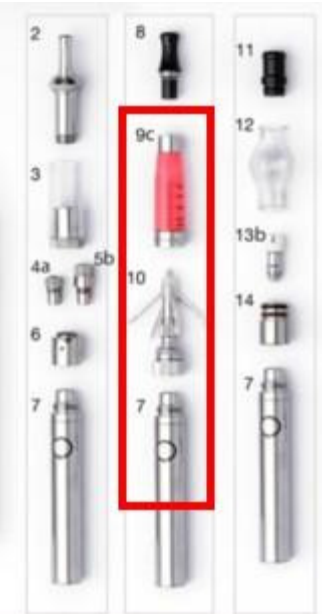


Id. at 9992.

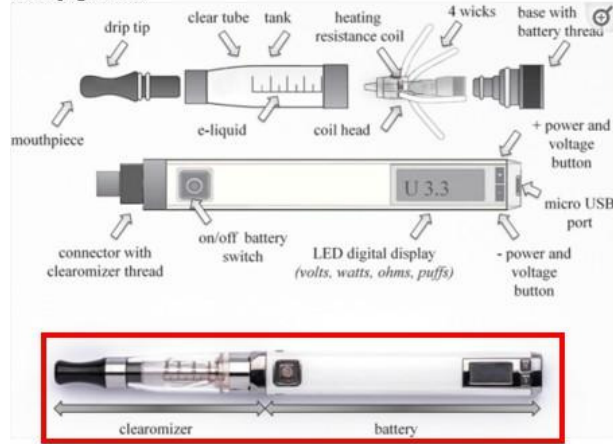
The disclosed devices include the claimed features of at least dependent claims 2-5, 7-9, and 13 of the '110 Patent.

GIROUD TEACHING #	The '110 Patent claim language	Exemplary GIROUD disclosure
1	2, 3	  EX 1011, 9990.  “2. Spring-loaded mouthpiece; 3. Vaporizer chamber; 4. Dry herb coil head; 5. Wax coil head; 6. Detachable base with air holes; 7. Medium capacity battery. 8–10. See-through clearomizer for e-liquids: 8. Clearomizer tip; 9. Clearomizer tube” <i>Id.</i> at 9992 (emphasis added).
2	4	

		<i>Id.</i> at 9990 (arrow added).
3	5	<i>Id.</i> at 9990. “2. Spring-loaded mouthpiece; 3. Vaporizer chamber; ..See-through clearomizer for e-liquids: 8. Clearomizer tip; 9. Clearomizer tube” <i>Id.</i> at 9992 (emphasis added).
4	7	

		 <i>Id.</i> at 9990 (boxes added).  “7. Medium capacity battery. 8–10. See-through clearomizer for e-liquids: 8. Clearomizer tip; 9. Clearomizer tube; 10. Clearomizer coil and four-wick head with base assembly” <i>Id.</i> at 9992 (emphasis and box added).
5	8	

From page 9990:



Id. at 9990 (box added).

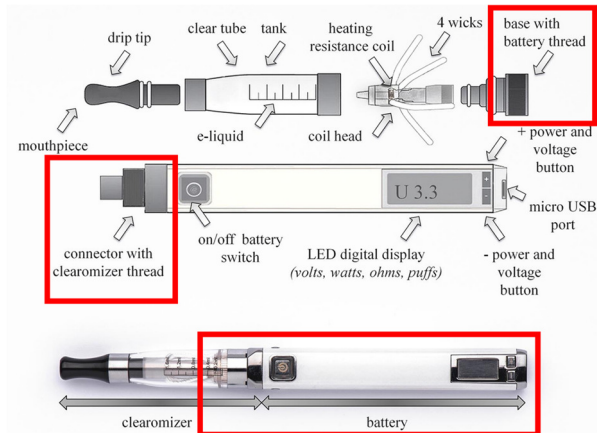


“1. Mega electronic cigarette (e-cig) with dual-coil clearomizer, adjustable airflow control ring, changeable resistance coils and high capacity, variable voltage battery. ... 3. Vaporizer chamber; ... 7.

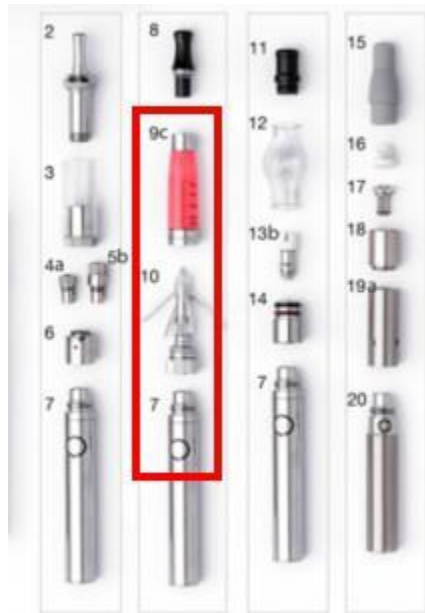
Medium capacity battery. 8–10. See-through clearomizer for e-liquids: 8. Clearomizer tip; 9. Clearomizer tube; 10. ... 20. Medium size battery. ... 22. Wax coil ceramic chamber and battery connector. 23–25. Clearomizer for e-liquids: 23. Shell (mouthpiece attached to metal tank with viewing window); 24. Bottom head changeable coil assembly; 25. Battery base connector.” *Id.* at 9992 (emphasis and boxes added).

6

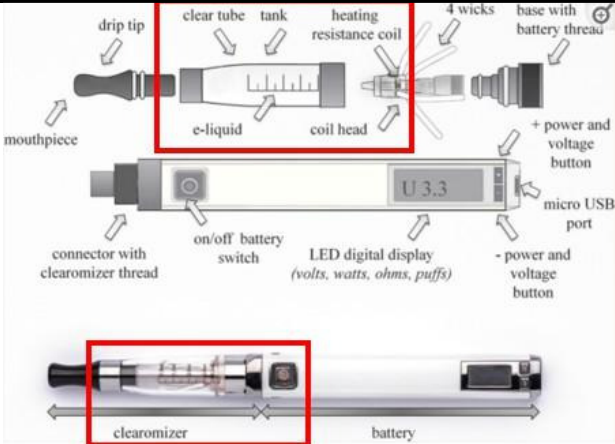
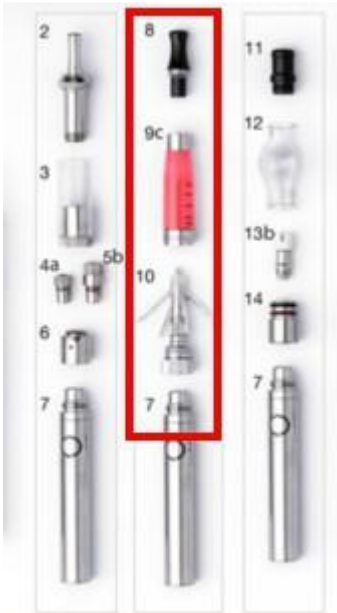
9



Id. at 9990 (boxes added).



“3. Vaporizer chamber; ... 8–10. See-through clearomizer for e-liquids: 8. Clearomizer tip; 9. Clearomizer tube” *Id.* at 9992 (emphasis and boxes added).

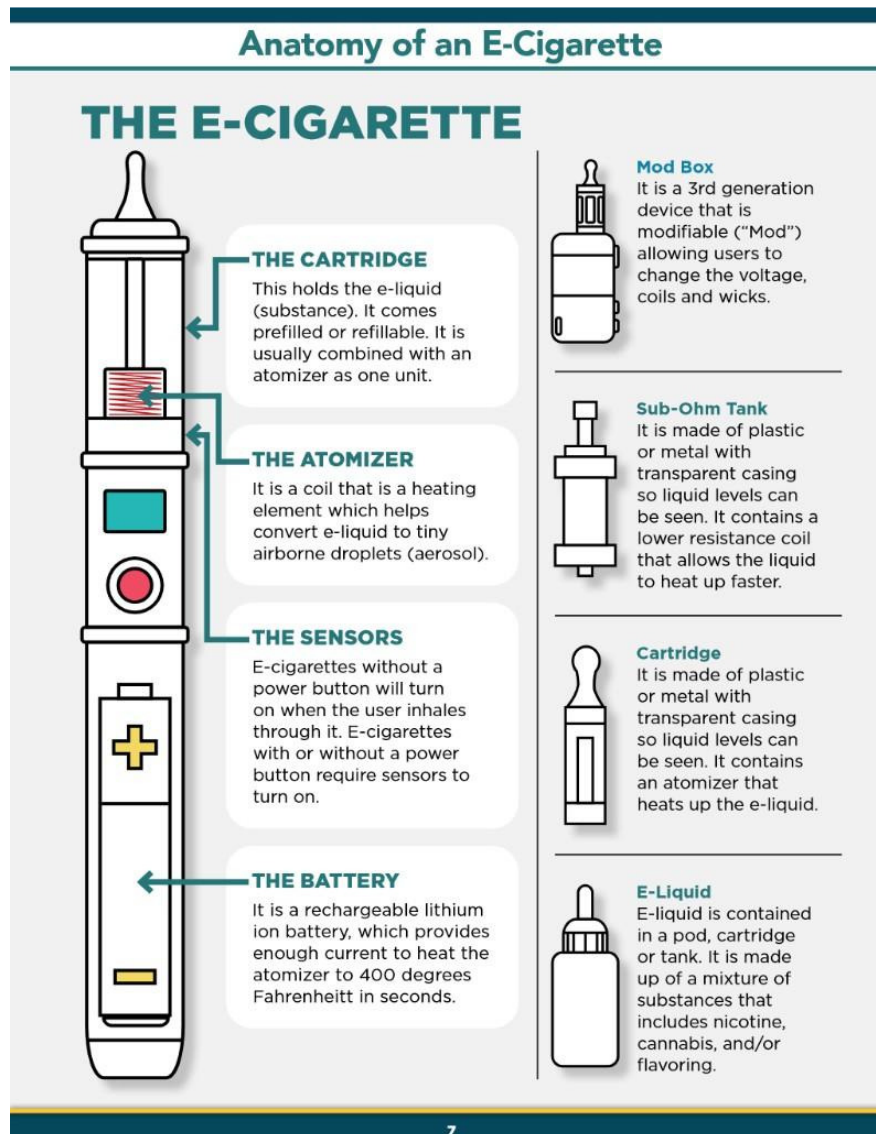
7	13	 <i>Id.</i> at 9990 (boxes added).  “8–10. See-through clearomizer for e-liquids: 8. Clearomizer tip; 9. Clearomizer tube;” <i>Id.</i> at 9992 (emphasis and boxes added).
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F. THE VISUAL VAPING DICTIONARY

The Center for Disease Control published the review “E-cigarette, or Vaping, Products Visual Dictionary” in 2019

(https://www.cdc.gov/tobacco/basic_information/e-cigarettes/pdfs/ecigarette-or-

vaping-products-visual-dictionary-508.pdf) (“the Visual Vaping Dictionary,” EX 1012). The Internet Archive confirms that the publication date of this document precedes the ’110 patent’s priority date. EX 1072, 51-77. The Visual Vaping Dictionary provides a contemporary review and history of e-cigarette, or vaping, products that can be used to produce vaporizable forms of chemicals and substances.



EX 1012, 7.



Id. at 15.

The Visual Vaping Dictionary discloses that “THE CARTRIDGE” “holds the e-liquid (substance).” *Id.* at 7. “It comes prefilled or refillable.” *Id.* at 15. “It is usually combined with an atomizer as one unit.” *Id.* at 7. Thus, the Visual Vaping Dictionary describes both single-use and reusable device configurations (i.e., the lockably coupled devices of the ’110 Patent dependent claims 6 and 10). EX 1002,

37.

G. DMT-NEXUS 2018

“I want to master Vaping DMT.” (“DMT-NEXUS 2018,” EX 1013) is an online discussion that is publicly available at <https://www.dmt-nexus.me/forum/default.aspx?g=posts&t=82998>. DMT-NEXUS 2018 was posted on December 2, 2018, which is confirmed by metadata. EX 1064, 15-16.

The opening December 2, 2018 post describes the user coming into possession of a DMT vape cartridge, attaching the cartridge to a battery, vaporizing DMT from the device, and subsequently using various power sources and solvents or solvent mixtures including PG, VG, and PEG to dissolve DMT for vaping. EX 1013, 1-2.

H. DMT-NEXUS 2015

“A guide to vaporizing DMT electronically” (“DMT-NEXUS 2015”; EX 1014) is an online discussion, posted in 2015, and publicly available at <https://www.dmt-nexus.me/forum/default.aspx?g=posts&t=63439>. Metadata confirms that this post predates the priority date of the ’110 Patent. EX 1064, 11-15.

The thread describes the vaporization of DMT using a vaporization device, variations of the device, and temperatures and solvent formulations used. EX 1014, 2, 4, 5, 17, 27.

I. EROWID 2014

“How to Build a Better Spaceship” (“EROWID 2014,” EX 1015) is a blog

post by author teafaerie, posted in 2014, and publicly available at <https://www.erowid.org/columns/teafaerie/2014/05/29/how-to-build-a-better-spaceship/>. The Internet Archive confirms the 2014 publication date of this prior art document. EX 1072, 40-42.

This post describes the author's first experience administering DMT via vaporizer, and its benefits over other methods of smoking DMT. The post provides instructions on how DMT is dissolved, the solvents used, filling a chamber with DMT, and different doses. EX 1015, 1-2.

A comment on the post discusses a method of producing a vaporizable DMT formulation using PG to dissolve DMT into solution without using ethanol. *Id.* at 4.

J. MUNOZ

“E-cigarettes rigged by drug users to smoke hallucinogen DMT” (“MUNOZ,” EX 1016) is an article published January 7, 2015, and is publicly available at <https://www.rt.com/uk/220551-vape-dmt-electronic-cigarette/>. The Internet Archive confirms the 2015 publication date of this prior art document and demonstrates its continued publication through to the present day. EX 1072, 35-38.

MUNOZ describes the widespread use of vaporizers as an “ideal tool” to administer DMT and mentions online discussions on Internet forums about modifying e-cigarettes to vaporize DMT. EX 1016, 1, 3-4.

K. GREENHILL

“Why Some Meth and DMT Users are Using Vapes” (“GREENHILL,” EX 1017) is an article published August 30, 2018, and is publicly available at <https://www.vice.com/en/article/why-some-meth-and-dmt-users-are-using-vapes/>. EX 1064, 18-19.

This article includes interviews with individuals who used DMT vaporizers. The interviewees describe their DMT vaporizer experiences and the advantages of DMT vaporization methods (like ease of use, dosage control, and preparation) over DMT smoking methods. EX 1017, 1-2.

L. POWER

“I Sell DMT Vape Pens So People Can ‘Break Through’ at Their Own Speed” (“POWER,” EX 1018) is an interview article published June 5, 2020, and is publicly available at <https://www.vice.com/en/article/i-sell-dmt-vape-pens-so-people-can-break-through-at-their-own-speed/>. EX 1064, 19.

Throughout the interview, a seller of DMT vaporization devices describes their devices as containing a battery and a cartridge, and the process of testing many different components to develop the device. EX 1018, 4. The interviewee also describes using ingredients contained in ayahuasca (MAOIs – specifically *Banisteriopsis Caapi*) for the purpose of producing a DMT vaporization device that provides an ayahuasca-like experience. *Id.*

M. CALLAWAY

Callaway et al., *J Psychoactive Drugs*. 2005; 37(2): 145-150, entitled “Phytochemical analyses of *Banisteriopsis caapi* and *Psychotria viridis*,” (“CALLAWAY,” EX 1019) reports the chemical analysis of the alkaloid content of *Psychotria viridis* (*P. viridis*) and *Banisteriopsis caapi* (*B. caapi*), two plants that are used to produce psychedelic ayahuasca preparations. This research article demonstrates that *B. caapi* contains high levels of various MAOIs and that *P. viridis* contains a high level of DMT, the synergy of which underlies the subjective effects of ayahuasca. EX 1019, 145-146.

N. U.S. Pat. Publ. No. 2018/0303165

U.S. Pat. Publ. No. 2018/0303165 (“the ’165 Application,” EX 1050) entitled “Vaporizer tank with atomizer” was filed on June 21, 2018, and was published on October 25, 2018. The ’165 Application describes a drug vaporization device and its various components, with a focus on the formulation-containing chamber, or “tank,” of the vaporizer.

The ’165 Application discloses multiple chamber and mouthpiece configurations, including configurations where the chamber and mouthpiece are “integrally” formed as a single unit and as such are lockably coupled in the sense that the device components are not intended to be removed by an end-using consumer. EX 1050, ¶¶ 5, 19.

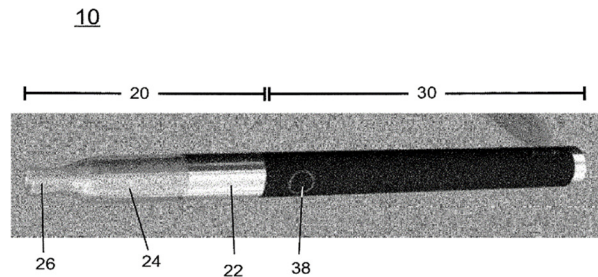


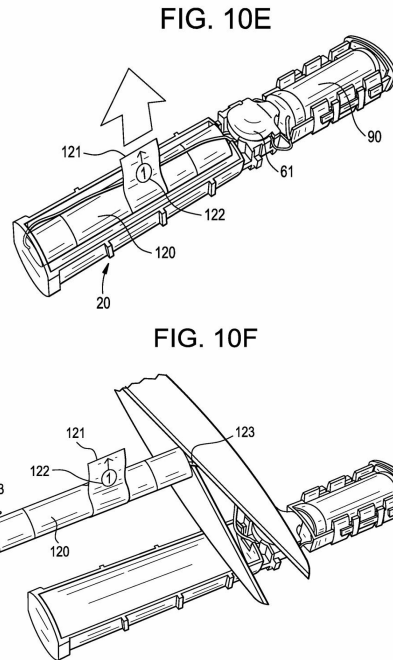
FIG. 1

Id. at FIG. 1.

O. Int’l Pat. Publ. No. WO 2019/191712

Int’l Pat. Publ. No. WO 2019/191712 (“the ’712 Application,” EX 1051) entitled “Portable vaporizer” was filed on March 29, 2019, and was published on October 3, 2019. The ’712 Application describes a drug vaporization device and its various components. The ’712 Application describes a portable vaporizer comprising multiple embodiments and also discloses methods for disassembling the vaporizer for recycling purposes.

The drug vaporizer disclosed in the ’712 Application is a single handheld unit with a mouthpiece that attaches in a “permanently locked fashion” to the top portion of the chamber and, below the chamber, a battery that is both wired into the device and “adhere[d] to” the device’s interior chassis. EX 1051, ¶¶ 16, 59, 70.



Id. at FIG. 10.

Figure 10 demonstrates the disassembly of the device for recycling. Specifically, “FIG. 10E [shows] ... the battery and a battery pull tab” and “FIG. 10F illustrates cutting battery lead wires with a scissor.” *Id.* at ¶¶ 32-33.

P. Int’l Pat. Publ. No. WO 2020/053392

Int’l Pat. Publ. No. WO 2020/053392 (“the ’392 Application,” EX 1052) entitled “Consumable” was filed on September 13, 2019, and was published on March 19, 2020. The ’392 Application describes a drug vaporization device and its components. The ’392 Application describes multiple portable vaporizer embodiments, including reusable or completely disposable varieties.

The drug vaporization device disclosed in the ’392 Application features a

mouthpiece “integrally formed” to the chamber, and therefore these components are not intended to be removed by an end-using consumer. EX 1052, 4, l. 26, 13, ll. 24-29.

IX. GROUND 1: CLAIMS 17-19 ARE ANTICIPATED BY THE '396 APPLICATION

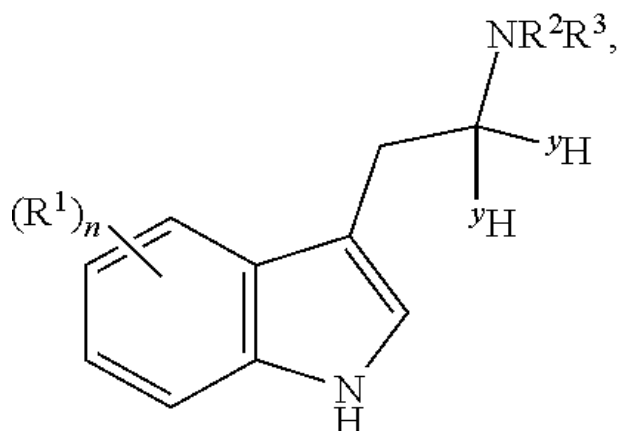
As demonstrated above, claims 17, 18, and 19 of the '110 Patent have an effective priority date of July 18, 2021.

The '396 Application was filed March 22, 2021, and is prior art under 35 U.S.C. § 102(a)(2), naming another inventor and having an effective filing date prior to the effective priority date of claims 17-19 of the '110 Patent. No exceptions under 35 U.S.C. § 102(b) or (c) apply.

As discussed above, the '396 Application, entitled “Deuterated compounds,” discloses deuterated DMT compounds and benefits and uses thereof – including increased metabolic stability. EX 1009, ¶ 20.

The '396 Application provides Formula I as an example of a class of deuterated DMT compounds (where ^xH and ^yH is independently protium or deuterium, wherein a ratio of deuterium:protium in a C(^xH)₃ moiety in the compound is greater than that found naturally in hydrogen):

(I)



Id. at ¶ 23.

The '396 Application discloses vaporization of such deuterated DMT compounds, formulated in vaporizable formulations, using electronic vaporization devices comprising chambers. *Id.* at ¶¶ 335-342.

Unlike the '110 Patent, which contains no working examples or data employing deuterated compounds, or any other isotopomers or isotopologues of the claimed compounds, the '396 Application synthesized, characterized, and tested deuterated DMT compounds. EX 1002, 45.

Claim 17

Claim 17 depends from claim 1 and recites that the one or more of DMT, 5-MeO-DMT, and 2C-B comprises an “isotopomer or isotopologue” of the one or more of DMT, 5-MeO-DMT, and 2C-B.

The '110 Patent states that “[a]yahuasca-like substances may include isotopomer or isotopologue variations ... including ... deuterium-containing substances” and includes “DMT ... comprising deuterium.” EX 1001, col. 7, ll. 3-5,

col. 17, ll. 51-54. The term isotopologue, as used in the '110 Patent, has its plain and ordinary meaning: i.e., isotopologues are molecules that differ only in their isotopic composition (e.g., replacing hydrogen with deuterium in otherwise identical molecules).

The '396 Application discloses an isotopologue of DMT. Indeed, deuterium-based isotopologues of DMT are the primary subject matter of the '396 Application. EX 1002, 39-41.

The '396 Application describes the DMT isotopologue as being in a vaporizable formulation, including using the same solvents (PG, VG, and PEG) disclosed in the '110 Patent. EX 1009, ¶¶ 341-342.

The term “chamber” is a defined term in the '110 Patent that expressly encompasses “cartridges” used in electronic vaping devices and admits that such structures are “well known in the art”. EX 1001, col. 7, ll. 10-17. The '396 Application’s vaporizable formulation containing the deuterated DMT is placed into a vaporizer chamber. EX 1002, 43; EX 1009, ¶ 338.

The '396 Application refers to using a commercially available vape device, Volcano Medic Vaporizer, that comprises a chamber. EX 1002, 44; EX 1009, ¶ 339. The structure and function of Volcano Medic Vaporizer, containing a filling chamber, in the contemporaneous time period, may be found in any number of public locations (*see, e.g.*, EX 1058; EX 1059, EX 1060, 5). The Volcano Medic device’s

structure and function, including the presence of a chamber containing the vaporizable formulation, is well known to a POSA. EX 1002, 44.

Claim 18

Claim 18 depends from claim 17 and further specifies that the isotopologue comprises deuterium.

As noted above, the DMT isotopologues disclosed in the '396 Application comprise deuterium.

Claim 19

Claim 19 depends from claim 17 and further specifies that the isotopologue is DMT comprising deuterium.

As noted above, the isotopologues disclosed in the '396 Application are deuterated DMT molecules.

X. GROUND 2: CLAIMS 17-19 ARE OBVIOUS OVER DMT-NEXUS 2012 IN VIEW OF HALBERSTADT

Claims 17-19 recite a device having a chamber comprising a vaporizable formulation of DMT, 5-MeO-DMT, or 2C-B that is not limited to any purpose for which the vaporizable formulation is in the device chamber. Thus, the claims encompass a wide variety of reasons why a vaporizable formulation may reside in a device chamber, including therapeutic, recreational, or research uses to study vaporizable formulations or drug activity and metabolism.

The scope and content of the prior art includes the vaporization of DMT and

DMT-related compounds, deuterated forms of DMT and DMT-related compounds, and the study of the metabolism of such deuterated compounds.

DMT-NEXUS 2012 describes several different vaporizable formulations of DMT, including PEG and glycerin formulations, being placed into a vaporization device chamber. EX 1008, 4, 14, 15. DMT-NEXUS 2012 describes the use of vaporizable DMT in combination with MAOIs. *Id.* at 15. DMT-NEXUS 2012 does not describe that the DMT was deuterated.

HALBERSTADT describes deuterated tryptamines, such as 5-MeO-DMT. HALBERSTADT teaches that deuterated tryptamines can be administered without MAOIs to provide potential benefits of altered metabolism and toxicity. EX 1010, 709. HALBERSTADT teaches that it is desirable to further study deuterated tryptamines. *Id.* at 716.

Based on the teachings of DMT-NEXUS 2012 and HALBERSTADT, it would have been obvious to make vaporizable formulations of deuterated tryptamines, such as DMT or 5-MeO-DMT, with or without MAOIs, and to place such formulations in vaporization devices for the purpose of experimenting with the metabolic effects of deuterated tryptamines compared to non-deuterated tryptamine with or without MAOIs.

XI. GROUND 3: CLAIMS 1, 7-9, 11, 12, 14, 16, AND 20 ARE ANTICIPATED BY DMT-NEXUS 2012

DMT-NEXUS 2012 describes formulating DMT for vaporization using vaporization devices, and specifically describes devices with chambers used for containing vaporizable DMT formulations. EX 1008, 2, 3, 4, 14.

Claim 1

The '110 Patent states that “[d]evices used to vaporize substances are known in the art” and that a chamber/vape cartridge holds the vaporizable formulation. EX 1001, col. 6, ll. 13-14, col. 7, ll. 10-13.

DMT-NEXUS 2012 describes devices with a chamber, wherein the chamber contains a vaporizable formulation of DMT. EX 1008, 2, 14. Specifically, DMT-NEXUS 2012 discloses that the vaporizable formulation of DMT in a solvent (e.g., PEG-400, VG) is placed into a chamber (e.g., a cartridge) of a vaporization device (e.g., an “e-cig”). *Id.* at 4, 14.

Claim 7

The '110 Patent states that “a ‘power unit’ ... provide[s] power ... to vaporize a vaporizable formulation ... within the chamber” which “may include a top portion connected to a mouthpiece, and a bottom portion connected to a battery.” EX 1001, col. 8, ll. 13-16, col. 7, ll. 12-15. The '110 Patent also states that “[n]umerous types ... of power units ... are well known in the art, any one ... may be sufficient to practice the present invention.” *Id.* at col. 13, ll. 55-57.

Chambers (i.e., “cartridges”) comprising a bottom portion adapted for coupling to a power source (i.e., a “charged battery”) to vaporize a vaporizable DMT formulation are described by DMT-NEXUS 2012. EX 1008, 3, 14.

Claim 8

DMT-NEXUS 2012 describes devices wherein the chamber (i.e., cartridge) is coupled to a power unit (i.e., “charged battery”) to provide the power to vaporize the vaporizable DMT formulation. *Id.*

Claim 9

The ’110 Patent states that “releasably coupled” components may be removed by an end-using consumer. EX 1001, col. 7, ll. 49-51. Thus, claim 9 recites a chamber that may be removed by a consumer.

As noted above, DMT-NEXUS 2012 describes devices wherein the chamber (i.e., cartridge) is releasably coupled (i.e., “screwed on”) to the power source (i.e., “charged battery”). DMT-NEXUS 2012 specifically discloses removing and replacing the cartridges by an end-using consumer (i.e., “you can have other filled cartridges in your pocket ready to go if needed”). EX 1008, 3, 14.

Claim 11

The ’110 Patent describes that a “connector” or “connection” is the type of connection between the chamber and the power unit, a 510 connector as having a 510 thread as is commonly referred to in the art, and an eGo connector as a thread

that “can have any diameter” but can be adapted to function with other connectors. EX 1001, col. 7, ll. 18-20, col. 7, ll. 28-38.

DMT-NEXUS 2012 discloses chambers (“tanks,” “tank cartridges”) having a 510 connector (“510 threads”) or an eGO connector (“ego tank cartridges”). EX 1008, 3, 4, 14.

Claim 12

As noted above, DMT-NEXUS 2012 discloses chambers with 510 connectors, and specifically notes that these are “standard” in the art. *Id.* at 3.

Claim 14

The ’110 Patent states that “refillable” chambers may be reused while a “single-use” chamber is not meant to be refillable, and that “[n]umerous ... chambers known in the art can be used to practice the present invention.” EX 1001, col. 8, il. 6-8, col. 9, ll. 16-19.

The chambers described in DMT-NEXUS 2012 are specifically noted as being refillable – stating that “empty tanks can be refilled as many times as you want.” EX 1008, 4.

Claim 16

As noted above, the vaporizable formulations disclosed in DMT-NEXUS 2012 comprise DMT. *Id.* at 2-3.

Claim 20

As noted above, DMT-NEXUS 2012 discloses vaporizable formulations comprising DMT dissolved in VG (“VG e-liquid”) or PEG (“a saturated PEG-400 / DMT solution”). EX 1008, 2, 14. DMT-NEXUS 2012 also discloses vaporizable formulations comprising DMT dissolved in PG. *Id.* at 15.

XII. GROUND 4: CLAIMS 2-8, 10, and 13 ARE OBVIOUS OVER DMT-NEXUS 2012 IN VIEW OF GIROUD, THE VISUAL VAPING DICTIONARY, WO 2019/191712, US 2018/0303165, AND/OR WO 2020/053392

As described in Ground 2, DMT-NEXUS 2012 teaches all of the elements of claims 1 and 8. Claims 2, 3, 4, 5, 6, 7, and 13 depend from claim 1; claim 8 depends from claim 7; and claim 10 depends from claim 8. Each of the dependent claims specifies elements associated with known prior art vaping devices. GIROUD teaches the components of claims 2, 3, 4, 5, 7, 8, and 13; and the Visual Vaping Dictionary teaches the components of claims 6 and 10 and further teaches that these features are commonly found in prior art describing commercial vaporizers.

It would have been obvious to use any of the devices described in GIROUD or the Visual Vaping Dictionary in place of the devices described in DMT-NEXUS 2012. The ’110 Patent admits that the claimed subject matter is premised on the use of vaporization devices known in the art. EX 1001, col. 6, ll. 13-31.

Further, the figures of the ’110 Patent show prior art devices, which are characterized in the figure descriptions as providing a “chamber of the present

invention.” For example, the description of Figure 2 states that exemplary chambers use “an adaptable ‘eGo’ threaded connector with a ‘closed’ chamber and a 510 connector” or “an adaptable ‘eGo’ threaded connector with an ‘open’ chamber exposing ‘eGo’ threads.” *Id.* at col. 5, ll. 55-60.

These connector features are admitted in the specification elsewhere as being part of the prior art devices. *Id.* at col. 7, ll. 27-38.

Additionally, a “chamber” in the ’110 Patent has a top portion connected to a mouthpiece and bottom portion connected to a battery. *Id.* at col. 7, ll. 12-17.

The specification of the ’110 Patent expressly acknowledges that “[n]umerous delivery device chambers known in the art can be used ... including ... portable or desktop vaporizable cartridges or tanks.” *Id.* at col 9, ll. 16-19.

GIROUD and the Visual Vaping Dictionary teach such portable or desktop vaporizable cartridges or tanks that are obvious to use in the field of vaporization of drugs generally and, as taught by GIROUD, specifically for DMT. EX 1011, 9996.

DMT-NEXUS 2012 describes vaporizable formulations of DMT placed in a chamber of a vaporizer. EX 1008, 2-4, 14. Many different devices and components are explored and described including ecig equipment. *Id.* at 14-15. Not all the subcomponent parts of the recited devices are expressly mentioned, though they are inherent in the products. DMT-NEXUS 2012 describes experimentation with many different devices and configurations and provides teaching and motivation for using

DMT with any of the known vaping devices on the market.

It would have been obvious to use any of the devices of GIROUD or the Visual Vaping Dictionary, or subcomponents or features thereof, with the vaporizable formulations of DMT-NEXUS 2012. DMT-NEXUS 2012 discloses the motivation to utilize and test a variety of different devices to optimize vaporization experience with DMT and related compounds. *Id.* at 1-4, 14-15. There is no unpredictability about placing the vaporizable formulations of DMT-NEXUS 2012 in the chamber of any of the devices or sub-components of GIROUD or the Visual Vaping Dictionary. EX 1002, 52.

Claim 2

The '110 Patent states that a “chamber” is analogous to a cartridge, a “mouthpiece” permits a user to inhale vapor produced within the chamber, and an “aperture” is an opening that permits the flow of air, liquids, solids, or vapor between device components. EX 1001, col. 6, ll. 60-64, col. 7, ll. 10-13, ll. 58-60.

Claim 2 is obvious over DMT-NEXUS 2012 in view of GIROUD and the Visual Vaping Dictionary. It would have been obvious to use any of the devices of GIROUD or the Visual Vaping Dictionary, or subcomponents or features thereof, with the vaporizable formulations of DMT-NEXUS 2012. EX 1008, 2, 14. GIROUD and the Visual Vaping Dictionary both provide detailed descriptions of vaping device designs, sub-components, and functions, including devices having a chamber

with a top portion adapted for coupling to a mouthpiece, comprising at least one aperture. EX 1011, GIROUD Teaching 1; EX 1012, 7, 9.

Claim 3

Claim 3 is obvious over DMT-NEXUS 2012 in view of GIROUD and the Visual Vaping Dictionary. It would have been obvious to use any of the devices of GIROUD or the Visual Vaping Dictionary, or subcomponents or features thereof, with the vaporizable formulations of DMT-NEXUS 2012. EX 1008, 2, 14. GIROUD and the Visual Vaping Dictionary both provide detailed descriptions of vaping device designs, mouthpieces comprising top and bottom apertures, a central open bore, and a bottom portion for coupling to the top portion of the chamber. EX 1011, GIROUD Teaching 1; EX 1012, 7, 9.

Claim 4

The '110 Patent states that a “seal” is an item that is situated between two components of the device, and functions to provide an efficient connection between the components. EX 1001, col. 8, ll. 30-37.

It would have been obvious to use any of the devices of GIROUD, or subcomponents or features thereof, with the vaporizable formulations of DMT-NEXUS 2012. EX 1008, 2, 14. GIROUD provides detailed descriptions of vaping devices, including a seal placed between the bottom portion of the mouthpiece and the top portion of the chamber. EX 1011, GIROUD Teaching 2.

Claim 5

The '110 Patent states that “‘releasably coupled’ refers to components that may be removed by an end-using consumer.” EX 1001, col. 7 l. 49-51.

It would have been obvious to use any of the devices of GIROUD, or subcomponents or features thereof, with the vaporizable formulations of DMT-NEXUS 2012. EX 1008, 2, 14. GIROUD provides detailed descriptions of vaping device designs, including a mouthpiece capable of releasably coupling to the top portion of the chamber. EX 1011, GIROUD Teaching 1.

Claim 6

The '110 Patent states that “lockably coupled” refers to components that are not intended to be removed by an end-using consumer, are intended for single-use, and are meant to be discarded once the chamber is emptied. EX 1001, col. 7, ll. 43-49.

Claim 6 is obvious over DMT-NEXUS 2012 in view of GIROUD, the Visual Vaping Dictionary, the '165 Application, the '712 Application, and the '392 Application. GIROUD discloses a variety of different vaporizer devices, including those that are lockably coupled, that can be used to deliver a variety of substances, and also includes a report of users utilizing such devices to effectively vape DMT. EX 1011, 9990, 9992, 9996. The Visual Vaping Dictionary discloses that vaporizers can be utilized to deliver a variety of “substances” and that vaporizers can be

designed for single use applications, which the '110 Patent describes as the intent of lockable coupling of mouthpiece and the chamber. EX 1001, col. 7, ll. 43-49; EX 1012, 8-9. The '165 Application, the '712 Application, and the '392 Application all disclose commercial vaporizers in which the “mouthpiece [is] integral with” the chamber or in which a mouthpiece is inserted into the device in a “permanently locked fashion.” EX 1050, ¶5; EX 1051, ¶59; EX 1052, 41. 26. DMT-NEXUS 2012 shows the utilization of commercial vaporizers to vape DMT. Therefore, it would have been considered obvious to utilize any of the devices disclosed in GIROUD, the Visual Vaping Dictionary, the '165 Application, the '712 Application, and the '392 Application to vape DMT in the manner described in DMT-NEXUS 2012. EX 1008, 2, 14.

Claim 7

The '110 Patent states that a “power unit” provides power to vaporize an ayahuasca-like substance vaporizable formulation within the chamber. EX 1001, col. 8, ll. 12-15.

Claim 7 is obvious over DMT-NEXUS 2012 in view of GIROUD and the Visual Vaping Dictionary. The Visual Vaping Dictionary depicts the bottom portion of the vaporizer cartridge connected to the battery. EX 1012, 7. GIROUD reports there exists a method for adapting vaporizers to vaporize DMT, and includes graphics showing a battery connected to the bottom portion of the vaporizer tank.

EX 1011, GIROUD Teaching 4. DMT-NEXUS 2012 discloses vaporizer set-ups used to vape DMT with vaporizer chambers coupled to a power unit. EX 1008, 3, 4, 25. Therefore, it would have been obvious to use the vaporizer devices described in GIROUD or the Visual Vaping Dictionary, or similar devices and components, to vape DMT in the manners disclosed in DMT-NEXUS 2012. *Id.* at 2, 14.

Claim 8

Claim 8 is obvious over DMT-NEXUS 2012 in view of GIROUD and the Visual Vaping Dictionary. The Visual Vaping Dictionary depicts the bottom portion of the e-cigarette cartridge connected to the battery. EX 1012, 7. GIROUD reports a method for adapting e-cigs to vaporize DMT, and shows a battery connected to the bottom portion of the tank. EX 1011, GIROUD Teaching 5. DMT-NEXUS 2012 discloses vaporizer set-ups used to vape DMT with vaporizer chambers coupled to a power unit. EX 1008, 3, 4, 25. Therefore, it would have been obvious to use the vaporizer devices described in GIROUD or the Visual Vaping Dictionary, or similar devices and components, to vape DMT in the manners disclosed in DMT-NEXUS 2012. *Id.* at 2, 14.

Claim 10

Claim 10 is obvious over DMT-NEXUS 2012 in view of the Visual Vaping Dictionary or the '712 Application. The Visual Vaping Dictionary discloses that there exist single-use vaporizer designs that are not intended to be recharged or

refillable. EX 1012, 8. The '712 Application describes a vaporizer for drug delivery in which the tank and the battery are not intended to be separated by the end user as demonstrated by the battery being both wired into the device and adhered to the device's inner chassis. EX 1051, ¶¶ 16, 68, 70, FIGS. 10E, 10F. Therefore, it would have been obvious to use the vaporizer devices described in the Visual Vaping Dictionary or the '712 Application, or similar devices and components, to vape DMT in the manners disclosed in DMT-NEXUS 2012. EX 1008, 2, 14.

Claim 13

Claim 13 is obvious over DMT-NEXUS 2012 in view of GIROUD. In addition to reporting that commercial vaporizer devices have been used to vape DMT, GIROUD specifically shows vaporizer devices with transparent chambers that allow for the visualization of the level of vaporizable formulation. EX 1011, 9996, GIROUD Teaching 7. Therefore, it would have been obvious to use the vaporizer devices described in the GIROUD, or similar devices and components, to vape DMT in the manners disclosed in DMT-NEXUS 2012. EX 1008, 2, 14.

XIII. GROUND 5: CLAIMS 1, 7-9, 11, 12, 16, AND 20 ARE ANTICIPATED BY DMT-NEXUS 2018

DMT-NEXUS 2018 describes a method of vaping DMT through the use of a vaporizer utilizing commercially available components.

Claim 1

DMT-NEXUS 2018 describes devices that comprise a chamber, wherein the

chamber comprises a vaporizable formulation of DMT. EX 1013, 1. DMT-NEXUS 2018 discloses that the vaporizable formulation of DMT in a solvent (e.g., “80/20 VG to PG”, “PG”, “PEG200”, “PEG400”) is placed into a chamber (e.g., “DMT vape cartridge”) of a vaporization device (e.g., a “cartridge vaporizer”, or a “sub-ohm Vape”).

Claim 7

The '110 Patent states that a “power unit” is well known in the art and provides power to vaporize an ayahuasca-like substance containing vaporizable formulation, a chamber is a vape cartridge well known in the art, and that a chamber includes a top portion connected to a mouthpiece and a bottom portion connected to a battery. *Id.* at col. 8, ll. 13-16, col. 7, ll. 12-15, col. 13, ll. 55-57.

A chamber (i.e., “cartridge”) comprising a bottom portion adapted for coupling to a power source (i.e., “510 battery”) to vaporize a vaporizable DMT formulation is described by DMT-NEXUS 2018. EX 1013, 1.

Claim 8

As noted above, DMT-NEXUS 2018 describes devices wherein the chamber (i.e., “cartridge”) is coupled to a power unit (i.e., “510 battery”) to provide the power to vaporize the vaporizable DMT formulation. EX 1013, 1.

Claim 9

The '110 Patent states that “releasably coupled” refers to components that

may be removed by an end-using consumer. EX 1001, col. 7, ll. 49-51.

As noted above, DMT-NEXUS 2018 describes devices wherein the chamber (i.e., cartridge) is releasably coupled (i.e., “plugged”) to the power source (i.e., “510 battery”). EX 1013, 1. DMT-NEXUS 2018 specifically discloses multiple types of power sources that can be used to vaporize a vaporizable DMT formulation. *Id.*

Claim 11

The ’110 Patent states a “connector” or “connection” refers to the connection between the chamber and the power unit and describes a 510 connector as having a 510 thread as is commonly known in the art. EX 1001, col. 7, ll. 18-33.

DMT-NEXUS 2018 discloses chambers (“cartridge”) having a 510 connector (“510 battery”). EX 1013, 1.

Claim 12

DMT-NEXUS 2018 discloses a chamber with a 510 connector. *Id.*

Claim 16

The vaporizable formulations disclosed in DMT-NEXUS 2018 comprise DMT. *Id.*

Claim 20

DMT-NEXUS 2018 discloses vaporizable formulations comprising DMT dissolved in VG, PG, or PEG (e.g., “80/20 VG to PG”, “PG”, “PEG200”, “PEG400”). *Id.*

XIV. GROUND 6: CLAIMS 1-16 and 20 ARE OBVIOUS OVER DMT-NEXUS 2015, DMT-NEXUS 2018, EROWID 2014, MUNOZ, AND/OR GREENHILL IN VIEW OF GIROUD AND/OR THE VISUAL VAPING DICTIONARY

Prior art demonstrates that vaporizing DMT by modifying commercially available vape devices was commonplace well before the earliest priority date of all claims of the '110 Patent. For example, MUNOZ describes the widespread use of commercial vaporizers to administer DMT. EX 1016, 1.

GREENHILL discloses interviews with DMT vape users. EX 1017, 2. DMT-NEXUS 2015, DMT-NEXUS 2018, and EROWID 2014 all describe vaporizing DMT using commercially available devices. EX 1013, 1; EX 1014, 2-4; EX 1015, 1-2.

Prior art demonstrates that vaporizable DMT formulations were well known before the earliest priority date of any of the claims of the '110 Patent. For example, EROWID 2014 describes a method of preparing a solution of DMT in glycerin and PG for use as a vaporizable DMT formulation in commercial vape devices. EX 1015, 2, 4.

MUNOZ, GREENHILL, DMT-NEXUS 2015, DMT-NEXUS 2018, and EROWID 2014 do not expressly disclose all of the subcomponent parts of the devices claimed in the '110 Patent, though they are inherent in these devices. However, GIROUD and the Visual Vaping Dictionary provide a review of known vaping devices, including sub-components and their use with vaporizable

formulations containing a variety of compounds, including DMT. EX 1011, 9996.

It would have been obvious to use GIROUD and the Visual Vaping Dictionary disclosed devices with a DMT vaporizable formulation described in MUNOZ, GREENHILL, DMT-NEXUS 2015, DMT-NEXUS 2018 and EROWID 2014.

Claim 1

The '110 Patent admits that e-cigarette chambers, also known as vape cartridges, are well known in the art, and that DMT can be readily available. *Id.* at col. 7, ll. 10-17, col.18, ll. 28-30. Public knowledge of using commercial vaporizers to vape DMT is further demonstrated in forum posts. DMT-NEXUS 2015, DMT-NEXUS 2018, EROWID 2014, and MUNOZ describe the use of vaporizers to administer DMT formulations. EX 1014, 2; EX 1015, 1-2, 4; EX 1016, 1. GREENHILL includes interviews with DMT vape users who describe the advantages of vaping over smoking DMT. EX 1017, 2. GIROUD describes the adaptation of vaporizers to administer DMT and provides descriptions and figures depicting e-cigarette configurations, which include a chamber for containing vaporizable formulations. EX 1011, 9990, 9992, 9996.

Therefore, it would have been obvious to combine GIROUD with any of DMT-NEXUS 2015, EROWID 2014, DMT-NEXUS 2018, MUNOZ, and GREENHILL to result in the claimed subject matter. As such, claim 1 fails to meet the standard of non-obviousness as defined by 35 U.S.C. § 103.

Claim 2

Claim 2 is obvious over DMT-NEXUS 2015, EROWID 2014, MUNOZ, and GREENHILL in view of GIROUD and/or the Visual Vaping Dictionary. It would have been obvious to use any of the devices in GIROUD or the Visual Vaping Dictionary, or equivalent subcomponents or features thereof, to deliver the vaporizable formulations utilized in EROWID 2014, DMT-NEXUS 2015, MUNOZ, or GREENHILL. GIROUD and the Visual Vaping Dictionary both provide detailed descriptions of vaping device designs, sub-components and functions, including devices having a chamber with a top portion adapted for coupling to a mouthpiece and comprising at least one aperture. EX 1011, 9990, 9992; EX 1012, 7, 9. GIROUD also describes users adapting electronic vaporizers with such aspects to administer DMT. EX 1011, 9996. DMT-NEXUS 2015, EROWID 2014, GREENHILL, and MUNOZ describe the use of e-cigarettes to vaporize DMT, thereby teaching adding vaporizable formulations containing DMT into an e-cigarette. EX 1014, 2; EX 1015, 1-2; EX 1016, 1; EX 1017, 2.

Claim 3

Claim 3 is obvious over DMT-NEXUS 2015, EROWID 2014, MUNOZ, and GREENHILL in view of GIROUD and/or the Visual Vaping Dictionary. It would have been obvious to use any of the devices in GIROUD or the Visual Vaping Dictionary, or equivalent subcomponents or features thereof, to deliver the

vaporizable formulations utilized in EROWID 2014, DMT-NEXUS 2015, MUNOZ, or GREENHILL. GIROUD and the Visual Vaping Dictionary both provide detailed descriptions of vaping device designs, mouthpieces comprising top and bottom apertures, a central open bore, and a bottom portion for coupling to the top portion of the chamber. EX 1011, GIROUD Teaching 1; EX 1012, 7, 9. DMT-NEXUS 2015, EROWID 2014, GREENHILL, and MUNOZ describe the use of e-cigarettes to vaporize DMT, thereby teaching adding vaporizable formulations containing DMT into an e-cigarette. EX 1014, 2; EX 1015, 1-2; EX 1016, 1; EX 1017, 2.

Claim 4

The '110 Patent states that a “seal” is situated between two components of the device to provide a more efficient connection between the components. EX 1001, col. 8, ll. 30-33.

It would have been obvious that the devices presented in GIROUD, which illustrates at least one seal being placed between the bottom portion of a vaporizer mouthpiece comprising an aperture and the top portion of a vaporizer chamber, could deliver the vaporizable formulations utilized in EROWID 2014, DMT-NEXUS 2015, MUNOZ, and GREENHILL. EX 1011, GIROUD Teaching 2. DMT-NEXUS 2015, EROWID 2014, GREENHILL, and MUNOZ describe the use of e-cigarettes to vaporize DMT, thereby teaching adding vaporizable formulations containing DMT into an e-cigarette. EX 1014, 2; EX 1015, 1-2; EX 1016, 1; EX

1017, 2.

Claim 5

As described throughout this document, the '110 Patent admits that vape devices already well known in the art are sufficient to practice the claimed subject matter. GIROUD describes a method of adapting e-cigs to vaporize DMT and includes multiple graphics of e-cig structures, showing mouthpieces (i.e., “spring-loaded mouthpiece,” “clearomizer tip”) uncoupled from chambers (i.e., “vaporizer chamber,” “clearomizer tube”). EX 1011, 9992. The Visual Vaping Dictionary also illustrates the anatomy of exemplary e-cigarette cartridges, and depicts the top portion of e-cigarette cartridges connected to mouthpieces that are described as being “refillable”, which the '110 Patent describes as the stated intent of releasable coupling between the mouthpiece and chamber. EX 1001, col. 7, ll. 49-54; EX 1012, 9. Because both GIROUD and the Visual Vaping Dictionary show vaporizer devices that include mouthpieces releasably coupled to the top portion of a chamber, it would have been obvious that the devices presented in GIROUD and the Visual Vaping Dictionary, which illustrate releasably coupled mouthpieces and chambers, could deliver the vaporizable DMT formulations utilized in EROWID 2014, DMT-NEXUS 2015, MUNOZ, or GREENHILL. EX 1011, GIROUD Teaching 3; EX 1012, 7, 9; EX 1014, 2; EX 1015, 1-2; EX 1016, 1; EX 1017, 2.

Claim 6

The '110 Patent admits that vape devices already well known in the art are sufficient to practice the subject matter of the claims. EX 1001, col. 13, ll. 55-57. Because these vape devices include mouthpieces lockably coupled to the top portion of a chamber, claim 6 is obvious as demonstrated from combinations of EROWID 2014, GIROUD, and the Visual Vaping Dictionary. EROWID 2014 describes an electronic, refillable e-cigarette containing vaporizable DMT and a photo illustrates a mouthpiece coupled to the top portion of a chamber. EX 1015, 2. GIROUD describes a method of adapting e-cigs to vaporize DMT, including multiple graphics of e-cig structures, showing a mouthpiece (i.e., “spring-loaded mouthpiece,” “soft drip tip (mouthpiece),” “metal mouthpiece,” “shell (mouthpiece attached to metal tank with viewing window)”) connected to the top portion of the e-cig clear tube and tank (i.e., “chamber” or “cartridge”). EX 1011, 9992. The Visual Vaping Dictionary also illustrates the anatomy of exemplary e-cigarette cartridges and describes prefilled, single use vaporizers – therefore, these elements are not intended to be removed, as is the intent of the “lockable” coupling of components described in the '110 Patent. EX 1001, col. 7, ll. 43-49; EX 1012, 8, 15.

Claim 7

The '110 Patent admits that vape devices already well known in the art are sufficient to practice the subject matter of the claims. EX 1001, col. 13, ll. 55-57.

Claim 7 is further obvious from combinations of EROWID 2014, GIROUD, and the Visual Vaping Dictionary. EROWID 2014 describes an electronic, refillable e-cigarette containing vaporizable DMT and a photo illustrates a chamber coupled to a power unit. EX 1015, 1-2. GIROUD describes a method of adapting e-cigs to vaporize DMT, including multiple graphics of e-cig structures and showing a battery (i.e., “power unit”) connected to the bottom portion of the e-cig clear tube and tank (i.e., “chamber” or “cartridge”). EX 1011, GIROUD Teaching 4. The Visual Vaping Dictionary also illustrates the anatomy of an e-cigarette and depicts the bottom portion of the e-cigarette cartridge (i.e., “chamber”) connected to the battery (i.e., “power source”). EX 1012, 7. As such, claim 7 fails to meet the standard of non-obviousness as defined by 35 U.S.C. § 103.

Claim 8

The ’110 Patent admits that vape devices already well known in the art are sufficient to practice the subject matter of the claims. EX 1001, col. 13, ll. 55-57. Claim 8, like claim 7, is obvious from combinations of EROWID 2014, GIROUD, and the Visual Vaping Dictionary. As depicted below, EROWID 2014 describes an electronic, refillable e-cigarette containing vaporizable DMT and a photo illustrates a chamber coupled to a power unit. EX 1015, 1-2. GIROUD describes a method of adapting e-cigs to vaporize DMT, including multiple graphics of e-cigarette structures and showing a battery (i.e., “power unit”) connected to the e-cigarette

clear tube and tank (i.e., “chamber” or “cartridge”). EX 1011, GIROUD Teaching 5. The Visual Vaping Dictionary also illustrates the anatomy of an e-cigarette and depicts the e-cigarette cartridge (i.e., “chamber”) connected to the battery (i.e., “power source”). EX 1012, 7.

These teachings thereby provide motivation for adding vaporizable DMT to e-cigarettes, including common e-cigarettes that have a power unit attached to the cartridge. As such, claim 8 is obvious as defined by 35 U.S.C. § 103.

Claim 9

The ’110 Patent states that “releasably coupled” refers to components that can be removed by a consumer. EX 1001, col. 7, ll. 49-51.

Claim 9 is obvious from the combined teachings of GIROUD and DMT-NEXUS 2018. Figure 2 in GIROUD illustrates a variety of e-cigarette anatomies where each individual piece is separated, including the chamber and power unit while DMT-NEXUS 2018 describes devices wherein the chamber (i.e., cartridge) is releasably coupled (i.e., “plugged”) to the power source (i.e., “510 battery”). EX 1011, GIROUD Teaching 6; EX 1013, 1. DMT-NEXUS 2018 specifically discloses multiple types of devices that can be used with a 510 battery power source to vaporize a vaporizable DMT formulation (i.e., “I moved on from a cartridge vaporizer to a bigger sub-ohm Vape”). EX 1013, 1.

Together, these references render obvious a device where the chamber is

releasably coupled to a power unit because they both emphasize modularity and interchangeability in vaporizing devices. Thus, claim 9 fails to meet the standard of non-obviousness as defined by 35 U.S.C. § 103.

Claim 10

The '110 Patent states that “lockably coupled” refers to components that are not intended to be removed by an end-using consumer, are intended for single-use, and are meant to be discarded once the chamber is empty.” EX 1001, col. 7, ll. 43-54.

Claim 10 is obvious from the combined teachings of the Visual Vaping Dictionary and DMT-NEXUS 2018. The Visual Vaping Dictionary illustrates a variety of e-cigarette anatomies for disposable devices that are discarded when they are depleted of e-liquid. EX 1012, 8, 15. Because these devices are not refillable, the device components, including the chamber and power unit, are not intended to be separated (i.e., are lockably coupled). DMT-NEXUS 2018 teaches that commercial vaporizers have been effectively used to vape DMT utilizing the same solvents utilized in vaporizers, as disclosed in the Visual Vaping Dictionary. EX 1013, 1. Therefore, it would have been obvious to utilize the lockable devices shown in the Visual Vaping Dictionary to vape the DMT formulation disclosed in DMT-NEXUS 2018.

Claim 11

Claim 11 is obvious from the combined teachings of EROWID 2014 and DMT-NEXUS 2018. The image in EROWID 2014 depicts a chamber with an eGo-T battery and DMT-NEXUS 2018 discusses the use of a 510 variable voltage battery plugged into the vape cartridge. EX 1013, 1; EX 1015, 1-2. As such, claim 11 fails to meet the 35 U.S.C. § 103 standard of non-obviousness.

Claim 12

The '110 Patent concedes that 510 connectors are well known in the art as utilized in the claimed subject matter. EX 1001, col. 7, ll. 43-44, col. 9, ll. 48-51. Claim 12 is further obvious from the teachings of DMT-NEXUS 2018, which discusses the use of a 510 variable voltage battery plugged into the vape cartridge that establishes a vaporizer setup used to vape DMT. EX 1013, 1.

Claim 13

Claim 13 is obvious over EROWID 2014 in view of GIROUD and/or the Visual Vaping Dictionary. GIROUD and the Visual Vaping Dictionary contain images of a variety of vaporizer devices with transparent chambers and disclose that vaporizers have been used to deliver “other substances” including DMT. EX 1011, GIROUD Teaching 7, 9996; EX 1012, 9. Therefore, it would have been obvious to use any of the devices disclosed in GIROUD and/or the Visual Vaping Dictionary, or equivalent subcomponents or features thereof, to deliver the vaporizable

formulation containing DMT utilized in EROWID 2014. This is directly supported by the image included in EROWID 2014, which shows a user holding a DMT formulation-filled vape pen with a transparent window that allows the user to visualize e-liquid levels. EX 1015, 2.

Claim 14

The '110 Patent admits that refillable vape devices, such as those that can practice the claimed subject matter, are well known in the art. *Id.* at col. 9, ll. 16-19. Claim 14 is further obvious from the combined teachings of EROWID 2014, the Visual Vaping Dictionary, and GIROUD. EROWID 2014 describes their delight of finding a refillable kind of e-cigarette for vaping DMT. EX 1015, 1-2. GIROUD identifies vapes for delivering vaporizable DMT, describes the see-through clearomizer that contains the e-liquid, and depicts an e-liquid bottle (far right of Figure 2), which contains e-liquid that can be used to refill the chamber. EX 1011, 9990, 9992. The Visual Vaping Dictionary depicts a separate bottle of e-liquid and describes chambers that are both prefillable and refillable. EX 1012, 7, 15, 17.

Any combination of these references provide the teaching and motivation to use a refillable chamber for a vape device designed to vaporize DMT formulations. As such, claim 14 fails to meet the standard of non-obviousness as defined by 35 U.S.C. § 103.

Claim 15

The '110 Patent admits that MAOIs are commonly combined with ayahuasca-like substances, including DMT. EX 1001, col. 7, ll. 5-7. Public knowledge of the combination of an “ayahuasca-like substance” such as DMT and an MAOI in a vaporizable formulation is demonstrated by DMT-NEXUS 2015, GIROUD, and the Visual Vaping Dictionary. EX 1011, 9996; EX 1014, 17; EX 1012, 23. DMT-NEXUS 2015 describes vaporizable formulations containing proposed combinations of DMT and MAOIs in the form of harmala alkaloids. EX 1014, 17. The '110 patent explicitly describes the harmala alkaloid “harmaline” as a MAOI that can be used in vaporizable formulations of the claimed subject matter. EX 1001, col. 16, l. 19. GIROUD teaches that e-cigarettes and vapes are capable of delivering “any type of psychoactive drug,” and have been used to deliver vaporizable formulations containing DMT. EX 1011, 9996. The Visual Vaping Dictionary teaches that e-cigarettes and vape cartridges can be modified to deliver various “other substances.” EX 1012, 23.

Therefore, claim 15 fails to meet the standard of non-obviousness as defined by 35 U.S.C. § 103.

Claim 16

Claim 16 is obvious from the combined teachings of DMT-NEXUS 2015, MUNOZ, and GREENHILL. The '110 Patent admits that e-cigarette chambers, also

known as vape cartridges, are well known in the art, and that DMT is readily available. EX 1001, col. 6, ll. 13-20. The use of e-cigarettes for vaporizing DMT is further demonstrated in forum posts. Claim 1 is obvious from combinations of DMT-NEXUS 2015, EROWID 2014, MUNOZ, GREENHILL, GIROUD, and the '396 Application. DMT-NEXUS 2015, EROWID 2014, and MUNOZ describe the use of e-cigarettes to vaporize DMT by drug user communities. EX 1014, 2; EX 1015, 1-2; EX 1016, 1. GREENHILL includes interviews with DMT vape users who describe their experiences with DMT vapes and their advantages over smoking DMT via other methods. EX 1017, 2. GIROUD describes the adaptation of e-cigarettes to vaporize DMT by users and provides descriptions and figures depicting e-cigarette configurations, which include a chamber for containing vaporizable formulations. EX 1011, 9996.

Therefore, it would have been obvious to combine GIROUD with any of DMT-NEXUS 2015, EROWID 2014, MUNOZ, and GREENHILL to result in the claimed subject matter.

Claim 20

Claim 20 is obvious from the combined teachings of GIROUD and the Visual Vaping Dictionary. GIROUD describes the use of PG, VG, and PEG being used in vaporizers to deliver a variety of substances and suggests that vaporizers utilizing these formulations have been successfully applied to deliver DMT. EX 1011, 9991,

9996. The Visual Vaping Dictionary establishes that PG and VG are commonly utilized in e-liquid for the vaporized delivery of a variety of drug “substances.” EX 1012, 25.

Together, these references suggest that using PG, VG, and PEG as vaporizable formulations would have been an obvious choice for vaping a variety of substances, including DMT, given their prominence in the art.

XV. GROUND 7: CLAIM 15 IS OBVIOUS OVER POWER AND CALLAWAY

Claim 15 of the '110 Patent has an earliest possible effective priority date of 29 July 2020. References POWER and CALLAWAY are prior art under 35 U.S.C. § 102(a)(1).

Claim 15 depends from claim 1 and recites that the vaporizable formulation further comprises a MAOI.

The '110 Patent states that “[a]yahuasca-like substances are often combined with MAOIs” in traditional preparations and that the vaporizable formulations disclosed can further include one or more MAOIs, which are “well known in the art.” EX 1001, col. 16, ll. 13-16, col. 17, ll. 55-56.

The '110 Patent therefore admits that MAOIs are commonly combined with ayahuasca-like substances, including DMT. EX 1001, col. 7, ll. 5-7. Public knowledge of the combination of DMT and an MAOI in a vaporizable formulation is demonstrated by POWER and CALLAWAY. EX 1018, 4; EX 1019, 145. POWER

describes vapes containing DMT and a *B. caapi* extract. EX 1018, 4. CALLAWAY teaches that plant ingredients in traditional ayahuasca preparations include *B. caapi*, and that *B. caapi* contains various MAOIs. EX 1019, 145. As such, claim 15 fails to meet the standard of non-obviousness as defined by 35 U.S.C. § 103.

XVI. GROUND 8: CLAIM 20 IS OBVIOUS OVER DMT-NEXUS 2012 IN VIEW OF GIROUD, DMT-NEXUS 2018, AND/OR THE VISUAL VAPING DICTIONARY

The '110 Patent applicant admits that PG, VG, and PEG are all common substances used in vaporizable drug delivery formulations, or “e-liquids.” EX 1001, col. 7, l. 65 – col. 8, l. 5. This is supported in both a federally produced vaping educational document, The Visual Vaping Dictionary, and a peer-reviewed publication, GIROUD. EX 1011, 9991; EX 1012, 17.

The Visual Vaping Dictionary teaches that e-liquids, including PG and VG formulation components recited in the '110 Patent, are used to deliver not only nicotine but also “other substances.” EX 1012, 17, 23.

GIROUD recites that vape users utilize VG, PG, and/or PEG in their vape devices. EX 1011, 9991. GIROUD also describes drug users successfully adapting vaporization devices in which those formulations are used to vaporize DMT. *Id.* at 9996.

DMT-NEXUS 2012 describes using individual vaporizable formulation components PEG, PG, and VG to vape DMT and discloses a method of vaping DMT

using commercially available vaporizer components – similarly to the '110 Patent. EX 1008, 3-4, 14-15.

Combining e-liquids for drug delivery is common and has been used to vape DMT, as taught by DMT-NEXUS 2018. EX 1002, 11, 58-59. DMT-NEXUS 2018 describes several of such combinations, including those that contain PEG and PG or PG and VG. EX 1013, 1. Specific ratios of e-liquids described in the '110 Patent at col. 15, ll. 29-42 are likewise disclosed in DMT-NEXUS 2018. *Id.*

Based on these teachings, the prior art establishes that it would have been obvious to a POSA to utilize one or more of the claimed vaporizable formulation components PG, VG, and PEG in a vaporization device to effectively deliver the drug substances as claimed in the '110 Patent.

XVII. CONCLUSION

The challenged claims are unpatentable. Porta Sophia respectfully requests that an IPR be instituted for U.S. Pat. No. 11,235,110.

XVIII. CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that this Petition complies with the type-volume limitation of to 37 C.F.R. §42.24(a). The word count application of the word processing program used to prepare this Petition indicates that the Petition contains 12,950 words, excluding the parts of the brief exempted by to 37 C.F.R. §42.24(a) (that is, the word count does not include the

table of contents, the exhibit list, mandatory notices under §42.8, the certificate of service or the certificate of compliance).

Dated: August 22, 2025

Respectfully submitted,

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XIX. LIST OF EXHIBITS

EXH.	DESCRIPTION
1001	U.S. Patent No. 11,235,110 “Delivery system for ayahuasca-like substances” (Ellis)
1002	Expert Declaration of David H. Peyton, Ph.D. in Support of Petition for Inter Partes Review of U.S. Patent No. 11,235,110
1003	<i>Curriculum Vitae</i> of David H. Peyton, Ph.D.
1004	File History of U.S. Patent 11,235,110 (U.S. Patent Application No. 17/394,340)
1005	U.S. Provisional Patent Application No. 63/058,444 “Delivery system for ayahuasca-like substances” (Ellis)
1006	U.S. Provisional Patent Application No. 63/144,923 “Delivery system for ayahuasca-like substances” (Ellis)
1007	Int’l Patent Application No. PCT/US21/42123 “Delivery system for ayahuasca-like substances” (Ellis)
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1039	Int’l Patent Application Publication No. 2016/001924 “Methods, devices and systems for pulmonary delivery of active agents” (Davidson)
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1041	Int’l Patent Application Publication No. 2019/081764 “Combination product for the treatment of neurological and/or psychiatric disorders” (Perez Castillo)
1042	U.S. Patent Application Publication No. 2020/0360239 “Dispenser devices and methods” (Campos)
1043	U.S. Patent Application Publication No. 2022/0071958 “5-methoxy-n,n-dimethyltryptamine (5-meo-dmt) for treating depression” (Terwey)

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1065	Metadata of above EX 1008 webpage 2, view-source: https://www.dmt-nexus.me/forum/default.aspx?g=posts&t=38704&p=2
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 22nd day of August 2025, the foregoing Petition for *Inter Partes* Review, including all Exhibits and the Power of Attorney were served in their entirety, via Priority Mail Express, on the following:

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