IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Confirmation No.: 4876
Serial No.: 18/229,286 Group No.:
Filing or 371(c) Date: August 2, 2023 Examiner:
Entitled: NOVEL COMPOSITIONS OF MATTER AND PHARMACEUTICAL COMPOSITIONS

THIRD-PARTY PRE-ISSUANCE SUBMISSION

Examiner:

The following documents, which are also identified in the Form PTO/SB/429 filed herewith, are submitted for your consideration as being of potential relevance to the examination of the present application

1. OTT (2001) "Pharmañopo—Psychonautics: Human Intranasal, Sublingual, Intrarectal, Pulmonary and Oral Pharmacology of Bufotenine" *Journal of Psychoactive Drugs*. 33(3): 273-281
2. VIRAOCHA (2008) "The DMT Handbook" Retrieved December 2008. URL: https://catbull.com/alamut/Bibliothek/DMT_Handbook.pdf
3. U.S. Pat. App. Doc. No. US2012/0108510A1 "METHODS OF IMPROVING BEHAVIORAL THERAPIES" (Published May 3, 2012)
4. DIMOITOU (2014) "Nasal spray #3 Posted : 6/27/2014 6:58:57 PM" DMT-NEXUS. Retrieved June 27, 2014. URL: https://www.dmt-nexus.me/forum/default.aspx?g=posts&m=549753

Attached hereto is a claim chart providing a concise description of the relevance of each reference in the document list of the elements of the presently pending claims.

U.S.S.N. 18/229,286 Pending Claims	References
1.-18. (canceled)	
19. An intranasal product, comprising an active ingredient, wherein the active ingredient is DMT or DMT fumarate, or a pharmaceutically acceptable salt of DMT or DMT fumarate or wherein the active ingredient is present in an amount of about 0.01%- about 20% (w/w); and a pharmaceutically acceptable carrier, wherein the intranasal product is in the form of a gel, a liquid, an emulsion, or an ointment.	3. U.S. Pat. App. Doc. No. US2012/0108510A1 "METHODS OF IMPROVING BEHAVIORAL THERAPIES" (Published May 3, 2012) From **claim 13** "The method of claim 1, wherein the **oxytocin releasing agent is** buspirone, gepirone, tandospirone serotonin, ergine, ergotamine, lysergic acid, lysergic acid diethylamide, psilocybin, 4-hydroxy-dimethyltryptamine, **N,N-dimethyltryptamine**, 5-methoxy-dimethyltryptamine, mescaline, 4-bromo-2,5-dimethoxyphenethylamine, 3,4-methylenedioxymethamphetamine, methylenedioxyethylamphetamine, tenamfetamine, lorcaserin or salts thereof." From **[0085]** "For use within the present disclosure, **oxytocin releasing compound preparations are provided for intranasal**, intrapulmonary, intramuscular, intravenous, transmucosal or transdermal administration that contain a oxytocin releasing compound in a biologically suitable, liquid or solid carrier. Typically, oxytocin releasing compound preparations contain between about 0.001 and 50 milligrams per milliliter and preferably about 0.1 to 50 mL of liquid carrier or per gram of solid carrier." From **[0095]** "…**The carrier can be a solvent or dispersion medium containing,** for example, water, ethanol, polyol (e.g. glycerol, propylene glycol and liquid polyethylene glycol), vegetable oils, and suitable mixtures thereof. Pharmaceutical compositions of the present disclosure can be in a form suitable for topical use such as, for example, an aerosol, cream, **ointment**, lotion, dusting powder, or the like. Further, the compositions can be in a form suitable for use in transdermal devices prepared via conventional processes As an example, a cream or ointment is **prepared by mixing hydrophilic material and water, together with about 5 wt % to about 10 wt % of the compound, to produce a cream or ointment having a desired consistency."** From **[0085]** "For use within the present disclosure, **oxytocin releasing compound preparations are provided for intranasal**, intrapulmonary, intramuscular, intravenous, transmucosal or transdermal administration that contain a oxytocin releasing compound in a biologically suitable, **liquid** or solid **carrier**. **Typically, oxytocin releasing compound preparations contain between about 0.001 and 50 milligrams per milliliter and preferably about 0.1 to 50 mL of liquid carrier or per gram of** solid carrier.

	From **[0091]** "Thus, the pharmaceutical compositions of this disclosure may include a pharmaceutically acceptable carrier and a compound or a pharmaceutically acceptable salt of a compound of the Examples. **The compounds or pharmaceutically acceptable salts thereof**, can also be included in pharmaceutical compositions in combination with one or more other therapeutically active compounds. The pharmaceutical carrier employed can be, for example, a solid, **liquid**, or gas. Examples of solid carriers include lactose, terra alba, sucrose, talc, **gelatin, agar, pectin,** acacia, magnesium stearate, and stearic acid. Examples of liquid carriers are sugar syrup, peanut oil, olive oil, and water. Examples of gaseous carriers include carbon dioxide and nitrogen." 1. OTT (2001) "Pharmañopo—Psychonautics: Human Intranasal, Sublingual, Intrarectal, Pulmonary and Oral Pharmacology of Bufotenine" *Journal of Psychoactive Drugs*. 33(3): 273-281 From **page 273** "In a previous paper on pharmahuasca psychonautics, modeling ayahuasca or Banisteriopsis caapi (Spr. ex Griseb.) Mort. (Malpighiaceae) potions via **self-experiments with** pure harmine and DMT or **N,N-dimethyltryptamine** (Ott 1999; 1994), I noted that Holmstedt and Lindgren had originally proposed in the context of shamanic snuffs what I called the "ayahuasca effect"-activation of the orally inactive (and, presumably, also intranasally-inactive) DMT by concomitant administration of monoamine-oxidase inhibiting (MAOI) P-carbolines, mainly harmine-later extended to encompass also orally-ingested ayahuasca potions in its purview." From **page 274** "**Considerable chemical work on Anadenanthera shows** conclusively and consistently that bufotenine is the only significant alkaloid **in mature seeds of both species used for snuffs** … Up to 7.4% bufotenine has been found in seeds of A. peregrina var. peregrina, only 0.04% 5-MeO-DMT and **0.16% DMT**; 1 2.4% bufotenine **in A. colubrina var. Cebil**, with but 0.06% and traces of both tryptamines, respectively" From **page 275** "Bufotenine free-base was isolated and purified as described below, **from a mixed collection of A. colubrina var. Cebil** gathered in Salta, Argentina, of which representative specimens were botanically vouchered. Harmine hydrochloride dihydrate and harmaline hydrochloride dihydrate were obtained from Acros Organics of Geel, Belgium. Reagent-grade solvents were utilized in the extraction of bufotenine. **Cebil-seed snuff was prepared by lightly toasting, then triturating to a coarse powder, freshly collected seeds** (with addition of reagent-grade sodium bicarbonate as a drying agent to facilitate finer pulverization, and **in emulation of shamanic use of** ashes or lime in

	Anadenanthera snuffs). Snuff analogues were made by finely pulverizing (and in some cases mixing) the crystalline alkaloids. In snuff bioassays, I first washed my **nose** with saline solution, which was exsufflated followed by drying with tissue. **Alkaloids were insufflated bilaterally through a short glass tube**, after which I reclined until the peak effects were perceived, at times elevating my head to ensure the material did not enter my throat"
20. The intranasal product of claim 19, wherein the active ingredient is DMT fumarate or a pharmaceutically acceptable salt of DMT fumarate.	3. U.S. Pat. App. Doc. No. US2012/0108510A1 "METHODS OF IMPROVING BEHAVIORAL THERAPIES" (Published May 3, 2012) From **[0091]** "Thus, the pharmaceutical compositions of this disclosure may include a pharmaceutically acceptable carrier and a compound or a pharmaceutically acceptable salt of a compound of the Examples. **The compounds or pharmaceutically acceptable salts thereof**, can also be included in pharmaceutical compositions in combination with one or more other therapeutically active compounds. The pharmaceutical carrier employed can be, for example, a solid, **liquid**, or gas. Examples of solid carriers include lactose, terra alba, sucrose, talc, **gelatin, agar, pectin,** acacia, magnesium stearate, and stearic acid. Examples of liquid carriers are sugar syrup, peanut oil, olive oil, and water. Examples of gaseous carriers include carbon dioxide and nitrogen." From **claim 13** "The method of claim 1, wherein the **oxytocin releasing agent is** buspirone, gepirone, tandospirone serotonin, ergine, ergotamine, lysergic acid, lysergic acid diethylamide, psilocybin, 4-hydroxy-dimethyltryptamine, **N,N-dimethyltryptamine**, 5-methoxy-dimethyltryptamine, mescaline, 4-bromo-2,5-dimethoxyphenethylamine, 3,4-methylenedioxymethamphetamine, methylenedioxyethylamphetamine, tenamfetamine, lorcaserin or salts thereof." From **[0085]** "For use within the present disclosure, **oxytocin releasing compound preparations are provided for intranasal**, intrapulmonary, intramuscular, intravenous, transmucosal or transdermal administration that contain a oxytocin releasing compound in a biologically suitable, liquid or solid carrier. Typically, oxytocin releasing compound preparations contain between about 0.001 and 50 milligrams per milliliter and preferably about 0.1 to 50 mL of liquid carrier or per gram of solid carrier." From **[0095]** "…**The carrier can be a solvent or dispersion medium containing,** for example, water, ethanol, polyol (e.g. glycerol, propylene glycol and liquid polyethylene glycol), vegetable oils, and suitable mixtures thereof. Pharmaceutical compositions of the present disclosure can be in a form suitable for topical use such as, for example, an aerosol, cream,

	ointment, lotion, dusting powder, or the like. Further, the compositions can be in a form suitable for use in transdermal devices prepared via conventional processes As an example, a cream or ointment is **prepared by mixing hydrophilic material and water, together with about 5 wt % to about 10 wt % of the compound, to produce a cream or ointment having a desired consistency."** From **[0085]** "For use within the present disclosure, **oxytocin releasing compound preparations are provided for intranasal**, intrapulmonary, intramuscular, intravenous, transmucosal or transdermal administration that contain a oxytocin releasing compound in a biologically suitable, **liquid** or solid **carrier**. **Typically, oxytocin releasing compound preparations contain between about 0.001 and 50 milligrams per milliliter and preferably about 0.1 to 50 mL of liquid carrier or per gram of** solid carrier. 2. VIRAOCHA (2008) "The DMT Handbook" Retrieved December 2008. URL: https://catbull.com/alamut/Bibliothek/DMT_Handbook.pdf From **page 26** "**Salts of DMT, in particular DMT Fumarate** which you perhaps made in Part 3: Salting, have different properties to freebase DMT. Foremost, **salts are water soluble, allowing for alternative methods of ingestion. Because our mucous membranes are mostly water based, a salt form of DMT will dissolve into them more freely than a freebase would, hence allowing the user to achieve the DMT experience by snorting**. If you've ever tried this with freebase DMT then you'd know that the bad far outweighs the good. On the other hand, **DMT Fumarate is a pleasure to insufflate.** The experience is quite like a shortened ayahuasca journey in the sense that it is longer and slower than a smoked experience. A higher dose is needed to achieve effects however, so I recommend you start with 100mg and tune to your liking from there. Personally, 150mg to 200mg is where it gets interesting. Preloading with MAOI (explained in Suggestion 4: Pharmahuasca) is a way in which you can and further enhance and potentiate the experience."
21. The intranasal product of claim 19 further comprising an MAOI.	1. OTT (2001) "Pharmañopo—Psychonautics: Human Intranasal, Sublingual, Intrarectal, Pulmonary and Oral Pharmacology of Bufotenine" *Journal of Psychoactive Drugs*. 33(3): 273-281 From **page 273** "In a previous paper on pharmahuasca psychonautics, modeling ayahuasca or Banisteriopsis caapi (Spr. ex Griseb.) Mort. (Malpighiaceae) potions via **self-experiments with pure harmine and DMT or N,N-dimethyltryptamine** (Ott 1999; 1994), I noted that Holmstedt and Lindgren had originally proposed in the context of shamanic

	snuffs what I called the "ayahuasca effect"-activation of the orally inactive (and, presumably, also intranasally-inactive) **DMT by concomitant administration of monoamine-oxidase inhibiting (MAOI) P-carbolines**, **mainly harmine**-later extended to encompass also orally-ingested ayahuasca potions in its purview." From **page 274** "**Considerable chemical work on Anadenanthera shows** conclusively and consistently that bufotenine is the only significant alkaloid **in mature seeds of both species used for snuffs** … Up to 7.4% bufotenine has been found in seeds of A. peregrina var. peregrina, only 0.04% 5-MeO-DMT and **0.16% DMT**; 1 2.4% bufotenine **in A. colubrina var. Cebil**, with but 0.06% and traces of both tryptamines, respectively" From **page 275** "Bufotenine free-base was isolated and purified as described below, **from a mixed collection of A. colubrina var. Cebil** gathered in Salta, Argentina, of which representative specimens were botanically vouchered. **Harmine hydrochloride dihydrate and harmaline hydrochloride dihydrate were obtained from Acros Organics of Geel, Belgium**. Reagent-grade solvents were utilized in the extraction of bufotenine. **Cebil-seed snuff was prepared by lightly toasting, then triturating to a coarse powder, freshly collected seeds** (with addition of reagent-grade sodium bicarbonate as a drying agent to facilitate finer pulverization, and **in emulation of shamanic use of** ashes or lime in **Anadenanthera snuffs**). Snuff analogues were made by finely pulverizing (and in some cases mixing) the crystalline alkaloids. **In snuff bioassays**, I first washed my **nose** with saline solution, which was exsufflated followed by drying with tissue. **Alkaloids were insufflated bilaterally through a short glass tube**, after which I reclined until the peak effects were perceived, at times elevating my head to ensure the material did not enter my throat" 3. U.S. Pat. App. Doc. No. US2012/0108510A1 "METHODS OF IMPROVING BEHAVIORAL THERAPIES" (Published May 3, 2012) From **claim 13** "The method of claim 1, wherein the **oxytocin releasing agent is** buspirone, gepirone, tandospirone serotonin, ergine, ergotamine, lysergic acid, lysergic acid diethylamide, psilocybin, 4-hydroxy-dimethyltryptamine, **N,N-dimethyltryptamine**, 5-methoxy-dimethyltryptamine, mescaline, 4-bromo-2,5-dimethoxyphenethylamine, 3,4-methylenedioxymethamphetamine, methylenedioxyethylamphetamine, tenamfetamine, lorcaserin or salts thereof."

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22. The intranasal product of claim 20	2. VIRAOCHA (2008) "The DMT Handbook" Retrieved December 2008. URL: https://catbull.com/alamut/Bibliothek/DMT_Handbook.pdf

further comprising an MAOI.	From **page 26** "**Salts of DMT, in particular DMT Fumarate** which you perhaps made in Part 3: Salting, have different properties to freebase DMT. Foremost, **salts are water soluble, allowing for alternative methods of ingestion. Because our mucous membranes are mostly water based, a salt form of DMT will dissolve into them more freely than a freebase would, hence allowing the user to achieve the DMT experience by snorting**. If you've ever tried this with freebase DMT then you'd know that the bad far outweighs the good. On the other hand, **DMT Fumarate is a pleasure to insufflate.** The experience is quite like a shortened ayahuasca journey in the sense that it is longer and slower than a smoked experience. A higher dose is needed to achieve effects however, so I recommend you start with 100mg and tune to your liking from there. Personally, 150mg to 200mg is where it gets interesting. **Preloading with MAOI (explained in Suggestion 4: Pharmahuasca) is a way in which you can and further enhance and potentiate the experience**."
23. The intranasal product of claim 21, wherein the MAOI is selected from the group consisting of harmala alkaloids, harmine, harmane, harmaline, hydrazine, iproniazid, isocarboxazid, nialamide, phenelzine, hydracarbazine, tranylcypromine, bifemelane, moclobemide, pirlindole, toloxatone, rasagiline, selegiline, and safinamide.	1. OTT (2001) "Pharmañopo—Psychonautics: Human Intranasal, Sublingual, Intrarectal, Pulmonary and Oral Pharmacology of Bufotenine" *Journal of Psychoactive Drugs*. 33(3): 273-281 From **page 273** "In a previous paper on pharmahuasca psychonautics, modeling ayahuasca or Banisteriopsis caapi (Spr. ex Griseb.) Mort. (Malpighiaceae) potions via **self-experiments with pure harmine and DMT or N,N-dimethyltryptamine** (Ott 1999; 1994), I noted that Holmstedt and Lindgren had originally proposed in the context of shamanic snuffs what I called the "ayahuasca effect"-activation of the orally inactive (and, presumably, also intranasally-inactive) **DMT by concomitant administration of monoamine-oxidase inhibiting (MAOI) P-carbolines**, **mainly harmine**-later extended to encompass also orally-ingested ayahuasca potions in its purview." From **page 274** "**Considerable chemical work on Anadenanthera shows** conclusively and consistently that bufotenine is the only significant alkaloid **in mature seeds of both species used for snuffs** … Up to 7.4% bufotenine has been found in seeds of A. peregrina var. peregrina, only 0.04% 5-MeO-DMT and **0.16% DMT**; 1 2.4% bufotenine **in A. colubrina var. Cebil**, with but 0.06% and traces of both tryptamines, respectively" From **page 275** "Bufotenine free-base was isolated and purified as described below, **from a mixed collection of A. colubrina var. Cebil** gathered in Salta, Argentina, of which representative specimens were botanically vouchered. **Harmine hydrochloride dihydrate and harmaline hydrochloride dihydrate were obtained from Acros Organics of Geel,**

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24. The intranasal product of claim 22, wherein the MAOI is selected from the group consisting of harmala alkaloids, harmine, harmane, harmaline, hydrazine, iproniazid, isocarboxazid, nialamide, phenelzine, hydracarbazine, tranylcypromine, bifemelane, moclobemide, pirlindole, toloxatone, rasagiline, selegiline, and safinamide.	2. VIRAOCHA (2008) "The DMT Handbook" Retrieved December 2008. URL: https://catbull.com/alamut/Bibliothek/DMT_Handbook.pdf From **page 26** "**Salts of DMT, in particular DMT Fumarate** which you perhaps made in Part 3: Salting, have different properties to freebase DMT. Foremost, **salts are water soluble, allowing for alternative methods of ingestion. Because our mucous membranes are mostly water based, a salt form of DMT will dissolve into them more freely than a freebase would, hence allowing the user to achieve the DMT experience by snorting**. If you've ever tried this with freebase DMT then you'd know that the bad far outweighs the good. On the other hand, **DMT Fumarate is a pleasure to insufflate.** The experience is quite like a shortened ayahuasca journey in the sense that it is longer and slower than a smoked experience. A higher dose is needed to achieve effects however, so I recommend you start with 100mg and tune to your liking from there. Personally, 150mg to 200mg is where it gets interesting. **Preloading with MAOI (explained in Suggestion 4: Pharmahuasca) is a way in which you can and further enhance and potentiate the experience**." From **page 27** "**There are many natural and synthetic sources of MAOI**. Some natural sources include **Peganum Harmala** (Syrian Rue) and Banisteriopsis Caapi. An example of a synthetic source is Moclebemide. Traditional Ayahuasca brews use the Caapi vine, but here I will suggest the use of Syrian Rue seeds due to their potency, ease to extract, and availability."
25. The intranasal product of claim 19, wherein the active ingredient is DMT or a pharmaceutically acceptable salt of DMT.	3. U.S. Pat. App. Doc. No. US2012/0108510A1 "METHODS OF IMPROVING BEHAVIORAL THERAPIES" (Published May 3, 2012) From **claim 13** "The method of claim 1, wherein the **oxytocin releasing agent is** buspirone, gepirone, tandospirone serotonin, ergine, ergotamine,

	lysergic acid, lysergic acid diethylamide, psilocybin, 4-hydroxy-dimethyltryptamine, **N,N-dimethyltryptamine**, 5-methoxy-dimethyltryptamine, mescaline, 4-bromo-2,5-dimethoxyphenethylamine, 3,4-methylenedioxymethamphetamine, methylenedioxyethylamphetamine, tenamfetamine, lorcaserin or salts thereof." From **[0085]** "For use within the present disclosure, **oxytocin releasing compound preparations are provided for intranasal**, intrapulmonary, intramuscular, intravenous, transmucosal or transdermal administration that contain a oxytocin releasing compound in a biologically suitable, liquid or solid carrier. Typically, oxytocin releasing compound preparations contain between about 0.001 and 50 milligrams per milliliter and preferably about 0.1 to 50 mL of liquid carrier or per gram of solid carrier." From **[0095]** "…**The carrier can be a solvent or dispersion medium containing,** for example, water, ethanol, polyol (e.g. glycerol, propylene glycol and liquid polyethylene glycol), vegetable oils, and suitable mixtures thereof. Pharmaceutical compositions of the present disclosure can be in a form suitable for topical use such as, for example, an aerosol, cream, **ointment**, lotion, dusting powder, or the like. Further, the compositions can be in a form suitable for use in transdermal devices prepared via conventional processes As an example, a cream or ointment is **prepared by mixing hydrophilic material and water, together with about 5 wt % to about 10 wt % of the compound, to produce a cream or ointment having a desired consistency."** From **[0085]** "For use within the present disclosure, **oxytocin releasing compound preparations are provided for intranasal**, intrapulmonary, intramuscular, intravenous, transmucosal or transdermal administration that contain a oxytocin releasing compound in a biologically suitable, **liquid** or solid **carrier**. Typically, oxytocin releasing compound preparations contain between about 0.001 and 50 milligrams per milliliter and preferably about 0.1 to 50 mL of liquid carrier or per gram of solid carrier. From **[0091]** "Thus, the pharmaceutical compositions of this disclosure may include a pharmaceutically acceptable carrier and a compound or a pharmaceutically acceptable salt of a compound of the Examples. **The compounds or pharmaceutically acceptable salts thereof**, can also be included in pharmaceutical compositions in combination with one or more other therapeutically active compounds. The pharmaceutical carrier employed can be, for example, a solid, **liquid**, or gas. Examples of solid carriers include lactose, terra alba, sucrose, talc, **gelatin, agar, pectin,** acacia, magnesium stearate, and stearic acid. Examples of liquid carriers are

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26. The intranasal product of claim 25 further comprising an MAOI.	1. OTT (2001) "Pharmañopo—Psychonautics: Human Intranasal, Sublingual, Intrarectal, Pulmonary and Oral Pharmacology of Bufotenine" *Journal of Psychoactive Drugs*. 33(3): 273-281 From **page 273** "In a previous paper on pharmahuasca psychonautics, modeling ayahuasca or Banisteriopsis caapi (Spr. ex Griseb.) Mort. (Malpighiaceae) potions via **self-experiments with pure harmine and DMT or N,N-dimethyltryptamine** (Ott 1999; 1994), I noted that Holmstedt and Lindgren had originally proposed in the context of shamanic snuffs what I called the "ayahuasca effect"-activation of the orally inactive (and, presumably, also intranasally-inactive) **DMT by concomitant administration of monoamine-oxidase inhibiting (MAOI) P-carbolines**, **mainly harmine**-later extended to encompass also orally-ingested ayahuasca potions in its purview." From **page 274** "**Considerable chemical work on Anadenanthera shows** conclusively and consistently that bufotenine is the only significant alkaloid **in mature seeds of both species used for snuffs** … Up to 7.4% bufotenine has been found in seeds of A. peregrina var. peregrina, only 0.04% 5-MeO-DMT and **0.16% DMT**; 1 2.4% bufotenine **in A. colubrina var. Cebil**, with but 0.06% and traces of both tryptamines, respectively" From **page 275** "Bufotenine free-base was isolated and purified as described below, **from a mixed collection of A. colubrina var. Cebil** gathered in Salta, Argentina, of which representative specimens were botanically vouchered. **Harmine hydrochloride dihydrate and harmaline hydrochloride dihydrate were obtained from Acros Organics of Geel, Belgium**. Reagent-grade solvents were utilized in the extraction of bufotenine. **Cebil-seed snuff was prepared by lightly toasting, then triturating to a coarse powder, freshly collected seeds** (with addition of reagent-grade sodium bicarbonate as a drying agent to facilitate finer pulverization, and **in emulation of shamanic use of** ashes or lime in **Anadenanthera snuffs**). Snuff analogues were made by finely pulverizing (and in some cases mixing) the crystalline alkaloids. **In snuff bioassays**, I first washed my **nose** with saline solution, which was exsufflated followed by drying with tissue. **Alkaloids were insufflated bilaterally through a short glass tube**, after which I reclined until the peak effects were perceived, at times elevating my head to ensure the material did not enter my throat"
27. The intranasal product of claim 26, wherein the MAOI is harmine.	1. OTT (2001) "Pharmañopo—Psychonautics: Human Intranasal, Sublingual, Intrarectal, Pulmonary and Oral Pharmacology of Bufotenine" *Journal of Psychoactive Drugs*. 33(3): 273-281 From **page 273** "In a previous paper on pharmahuasca psychonautics,

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28. The intranasal product of claim 19, wherein the intranasal product is in the form of a gel.	3. U.S. Pat. App. Doc. No. US2012/0108510A1 "METHODS OF IMPROVING BEHAVIORAL THERAPIES" (Published May 3, 2012) From **[0091]** "Thus, the pharmaceutical compositions of this disclosure may include a pharmaceutically acceptable carrier and a compound or a pharmaceutically acceptable salt of a compound of the Examples. **The compounds or pharmaceutically acceptable salts thereof**, can also be included in pharmaceutical compositions in combination with one or more other therapeutically active compounds. The pharmaceutical carrier

	employed can be, for example, a solid, **liquid**, or gas. Examples of solid carriers include lactose, terra alba, sucrose, talc, **gelatin, agar, pectin,** acacia, magnesium stearate, and stearic acid. Examples of liquid carriers are sugar syrup, peanut oil, olive oil, and water. Examples of gaseous carriers include carbon dioxide and nitrogen." From **claim 13** "The method of claim 1, wherein the **oxytocin releasing agent is** buspirone, gepirone, tandospirone serotonin, ergine, ergotamine, lysergic acid, lysergic acid diethylamide, psilocybin, 4-hydroxy-dimethyltryptamine, **N,N-dimethyltryptamine**, 5-methoxy-dimethyltryptamine, mescaline, 4-bromo-2,5-dimethoxyphenethylamine, 3,4-methylenedioxymethamphetamine, methylenedioxyethylamphetamine, tenamfetamine, lorcaserin or salts thereof." From **[0085]** "For use within the present disclosure, **oxytocin releasing compound preparations are provided for intranasal**, intrapulmonary, intramuscular, intravenous, transmucosal or transdermal administration that contain a oxytocin releasing compound in a biologically suitable, liquid or solid carrier. Typically, oxytocin releasing compound preparations contain between about 0.001 and 50 milligrams per milliliter and preferably about 0.1 to 50 mL of liquid carrier or per gram of solid carrier." From **[0095]** "…**The carrier can be a solvent or dispersion medium containing,** for example, water, ethanol, polyol (e.g. glycerol, propylene glycol and liquid polyethylene glycol), vegetable oils, and suitable mixtures thereof. Pharmaceutical compositions of the present disclosure can be in a form suitable for topical use such as, for example, an aerosol, cream, **ointment**, lotion, dusting powder, or the like. Further, the compositions can be in a form suitable for use in transdermal devices prepared via conventional processes As an example, a cream or ointment is **prepared by mixing hydrophilic material and water, together with about 5 wt % to about 10 wt % of the compound, to produce a cream or ointment having a desired consistency."** From **[0085]** "For use within the present disclosure, **oxytocin releasing compound preparations are provided for intranasal**, intrapulmonary, intramuscular, intravenous, transmucosal or transdermal administration that contain a oxytocin releasing compound in a biologically suitable, **liquid** or solid **carrier**. Typically, oxytocin releasing compound preparations contain between about 0.001 and 50 milligrams per milliliter and preferably about 0.1 to 50 mL of liquid carrier or per gram of solid carrier.

29. The intranasal product of claim 20, wherein the intranasal product is in the form of a gel.	4. DIMOITOU (2014) "Nasal spray #3 Posted : 6/27/2014 6:58:57 PM" DMT-NEXUS. Retrieved June 27, 2014. URL: https://www.dmt-nexus.me/forum/default.aspx?g=posts&m=549753 From **webpage** "At first, I used clear vinegar, but then I realized it messed up my mg/ml ratio, so I finished with fumaric acid. - 500mg Syrian rue harmalas (freebase) were mixed with 6ml hot water. - Around 2.5ml clear vinegar was added to the mix. - (Argh my ratio) 200mg more harmalas were added. - **some fumaric acid was added until everything was dissolved.** My extract was probably not very pure, I had an insoluble deposit at the bottom. I picked up the clear liquid and dumped the deposit. For some reason, there was only 7ml end product, don't ask me why! Wut? - **I put 3ml in a nasal spray** (RIMA nasal spray!), and the 4ml left went back into the shot glass. - **I added 200mg DMT freebase to these 4ml (supposedly containing ~400mg harmalas) for a 2:1 harmala/DMT ratio.** - I warmed it up and added **fumaric acid** little by little until everything was dissolved. I noticed impurities floating... It seems that my DMT freebase wasn't very pure either, hehe. - **I picked up the clear liquid, dumped the impurities and put that in a nasal spray**."
30. The intranasal product of claim 22, wherein the intranasal product is in the form of a gel.	4. DIMOITOU (2014) "Nasal spray #3 Posted : 6/27/2014 6:58:57 PM" DMT-NEXUS. Retrieved June 27, 2014. URL: https://www.dmt-nexus.me/forum/default.aspx?g=posts&m=549753 From **webpage** "At first, I used clear vinegar, but then I realized it messed up my mg/ml ratio, so I finished with fumaric acid. - 500mg Syrian rue harmalas (freebase) were mixed with 6ml hot water. - Around 2.5ml clear vinegar was added to the mix. - (Argh my ratio) 200mg more harmalas were added. - **some fumaric acid was added until everything was dissolved.** My extract was probably not very pure, I had an insoluble deposit at the bottom. I picked up the clear liquid and dumped the deposit. For some reason, there was only 7ml end product, don't ask me why! Wut? - **I put 3ml in a nasal spray** (RIMA nasal spray!), and the 4ml left went back into the shot glass.

	- I added 200mg DMT freebase to these 4ml (supposedly containing ~400mg harmalas) for a 2:1 harmala/DMT ratio. - I warmed it up and added **fumaric acid** little by little until everything was dissolved. I noticed impurities floating... It seems that my DMT freebase wasn't very pure either, hehe. - **I picked up the clear liquid, dumped the impurities and put that in a nasal spray**."
31. The intranasal product of claim 24, wherein the intranasal product is in the form of a gel.	4. DIMOITOU (2014) "Nasal spray #3 Posted : 6/27/2014 6:58:57 PM" DMT-NEXUS. Retrieved June 27, 2014. URL: https://www.dmt-nexus.me/forum/default.aspx?g=posts&m=549753 From **webpage** "At first, I used clear vinegar, but then I realized it messed up my mg/ml ratio, so I finished with fumaric acid. - 500mg Syrian rue harmalas (freebase) were mixed with 6ml hot water. - Around 2.5ml clear vinegar was added to the mix. - (Argh my ratio) 200mg more harmalas were added. - **some fumaric acid was added until everything was dissolved.** My extract was probably not very pure, I had an insoluble deposit at the bottom. I picked up the clear liquid and dumped the deposit. For some reason, there was only 7ml end product, don't ask me why! Wut? - **I put 3ml in a nasal spray** (RIMA nasal spray!), and the 4ml left went back into the shot glass. - **I added 200mg DMT freebase to these 4ml (supposedly containing ~400mg harmalas) for a 2:1 harmala/DMT ratio.** - I warmed it up and added **fumaric acid** little by little until everything was dissolved. I noticed impurities floating... It seems that my DMT freebase wasn't very pure either, hehe. - **I picked up the clear liquid, dumped the impurities and put that in a nasal spray**."
32. The intranasal product of claim 25, wherein the intranasal product is in the form of a gel.	3. U.S. Pat. App. Doc. No. US2012/0108510A1 "METHODS OF IMPROVING BEHAVIORAL THERAPIES" (Published May 3, 2012) From **[0091]** "Thus, the pharmaceutical compositions of this disclosure may include a pharmaceutically acceptable carrier and a compound or a pharmaceutically acceptable salt of a compound of the Examples. **The compounds or pharmaceutically acceptable salts thereof**, can also be included in pharmaceutical compositions in combination with one or more

	other therapeutically active compounds. The pharmaceutical carrier employed can be, for example, a solid, **liquid**, or gas. Examples of solid carriers include lactose, terra alba, sucrose, talc, **gelatin, agar, pectin,** acacia, magnesium stearate, and stearic acid. Examples of liquid carriers are sugar syrup, peanut oil, olive oil, and water. Examples of gaseous carriers include carbon dioxide and nitrogen." From **claim 13** "The method of claim 1, wherein the **oxytocin releasing agent is** buspirone, gepirone, tandospirone serotonin, ergine, ergotamine, lysergic acid, lysergic acid diethylamide, psilocybin, 4-hydroxy-dimethyltryptamine, **N,N-dimethyltryptamine**, 5-methoxy-dimethyltryptamine, mescaline, 4-bromo-2,5-dimethoxyphenethylamine, 3,4-methylenedioxymethamphetamine, methylenedioxyethylamphetamine, tenamfetamine, lorcaserin or salts thereof." From **[0085]** "For use within the present disclosure, **oxytocin releasing compound preparations are provided for intranasal**, intrapulmonary, intramuscular, intravenous, transmucosal or transdermal administration that contain a oxytocin releasing compound in a biologically suitable, liquid or solid carrier. Typically, oxytocin releasing compound preparations contain between about 0.001 and 50 milligrams per milliliter and preferably about 0.1 to 50 mL of liquid carrier or per gram of solid carrier." From **[0095]** "…**The carrier can be a solvent or dispersion medium containing,** for example, water, ethanol, polyol (e.g. glycerol, propylene glycol and liquid polyethylene glycol), vegetable oils, and suitable mixtures thereof. Pharmaceutical compositions of the present disclosure can be in a form suitable for topical use such as, for example, an aerosol, cream, **ointment**, lotion, dusting powder, or the like. Further, the compositions can be in a form suitable for use in transdermal devices prepared via conventional processes As an example, a cream or ointment is **prepared by mixing hydrophilic material and water, together with about 5 wt % to about 10 wt % of the compound, to produce a cream or ointment having a desired consistency."** From **[0085]** "For use within the present disclosure, **oxytocin releasing compound preparations are provided for intranasal**, intrapulmonary, intramuscular, intravenous, transmucosal or transdermal administration that contain a oxytocin releasing compound in a biologically suitable, **liquid** or solid **carrier**. Typically, oxytocin releasing compound preparations contain between about 0.001 and 50 milligrams per milliliter and preferably about 0.1 to 50 mL of liquid carrier or per gram of solid carrier.

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34. The intranasal product of claim 27, wherein the intranasal product is in the form of a gel.	3. U.S. Pat. App. Doc. No. US2012/0108510A1 "METHODS OF IMPROVING BEHAVIORAL THERAPIES" (Published May 3, 2012) From **claim 13** "The method of claim 1, wherein the **oxytocin releasing agent is** buspirone, gepirone, tandospirone serotonin, ergine, ergotamine, lysergic acid, lysergic acid diethylamide, psilocybin, 4-hydroxy-dimethyltryptamine, **N,N-dimethyltryptamine**, 5-methoxy-dimethyltryptamine, mescaline, 4-bromo-2,5-dimethoxyphenethylamine, 3,4-methylenedioxymethamphetamine, methylenedioxyethylamphetamine, tenamfetamine, lorcaserin or salts thereof." From **[0085]** "For use within the present disclosure, **oxytocin releasing compound preparations are provided for intranasal**, intrapulmonary, intramuscular, intravenous, transmucosal or transdermal administration that contain a oxytocin releasing compound in a biologically suitable, liquid or solid carrier. Typically, oxytocin releasing compound preparations contain between about 0.001 and 50 milligrams per milliliter and preferably about 0.1 to 50 mL of liquid carrier or per gram of solid carrier." From **[0095]** "…**The carrier can be a solvent or dispersion medium containing,** for example, water, ethanol, polyol (e.g. glycerol, propylene

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35. The intranasal product of claim 19, wherein the intranasal product is in the form of a liquid.	3. U.S. Pat. App. Doc. No. US2012/0108510A1 "METHODS OF IMPROVING BEHAVIORAL THERAPIES" (Published May 3, 2012) From **claim 13** "The method of claim 1, wherein the **oxytocin releasing agent is** buspirone, gepirone, tandospirone serotonin, ergine, ergotamine, lysergic acid, lysergic acid diethylamide, psilocybin, 4-hydroxy-dimethyltryptamine, **N,N-dimethyltryptamine**, 5-methoxy-dimethyltryptamine, mescaline, 4-bromo-2,5-dimethoxyphenethylamine, 3,4-methylenedioxymethamphetamine, methylenedioxyethylamphetamine, tenamfetamine, lorcaserin or salts thereof." From **[0085]** "For use within the present disclosure, **oxytocin releasing compound preparations are provided for intranasal**, intrapulmonary, intramuscular, intravenous, transmucosal or transdermal administration that

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36. The intranasal product of claim 22, wherein the intranasal product is in the form of a liquid.	4. DIMOITOU (2014) "Nasal spray #3 Posted : 6/27/2014 6:58:57 PM" DMT-NEXUS. Retrieved June 27, 2014. URL: https://www.dmt-nexus.me/forum/default.aspx?g=posts&m=549753 From **webpage** "At first, I used clear vinegar, but then I realized it messed up my mg/ml ratio, so I finished with fumaric acid.

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	ointment, lotion, dusting powder, or the like. Further, the compositions can be in a form suitable for use in transdermal devices prepared via conventional processes As an example, a cream or ointment is **prepared by mixing hydrophilic material and water, together with about 5 wt % to about 10 wt % of the compound, to produce a cream or ointment having a desired consistency."** From **[0085]** "For use within the present disclosure, **oxytocin releasing compound preparations are provided for intranasal**, intrapulmonary, intramuscular, intravenous, transmucosal or transdermal administration that contain a oxytocin releasing compound in a biologically suitable, **liquid** or solid **carrier**. Typically, oxytocin releasing compound preparations contain between about 0.001 and 50 milligrams per milliliter and preferably about 0.1 to 50 mL of liquid carrier or per gram of solid carrier. From **[0091]** "Thus, the pharmaceutical compositions of this disclosure may include a pharmaceutically acceptable carrier and a compound or a pharmaceutically acceptable salt of a compound of the Examples. **The compounds or pharmaceutically acceptable salts thereof**, can also be included in pharmaceutical compositions in combination with one or more other therapeutically active compounds. The pharmaceutical carrier employed can be, for example, a solid, **liquid**, or gas. Examples of solid carriers include lactose, terra alba, sucrose, talc, **gelatin, agar, pectin,** acacia, magnesium stearate, and stearic acid. Examples of liquid carriers are sugar syrup, peanut oil, olive oil, and water. Examples of gaseous carriers include carbon dioxide and nitrogen."
38. The intranasal product of claim 26, wherein the intranasal product is in the form of a liquid.	3. U.S. Pat. App. Doc. No. US2012/0108510A1 "METHODS OF IMPROVING BEHAVIORAL THERAPIES" (Published May 3, 2012) From **claim 13** "The method of claim 1, wherein the **oxytocin releasing agent is** buspirone, gepirone, tandospirone serotonin, ergine, ergotamine, lysergic acid, lysergic acid diethylamide, psilocybin, 4-hydroxy-dimethyltryptamine, **N,N-dimethyltryptamine**, 5-methoxy-dimethyltryptamine, mescaline, 4-bromo-2,5-dimethoxyphenethylamine, 3,4-methylenedioxymethamphetamine, methylenedioxyethylamphetamine, tenamfetamine, lorcaserin or salts thereof." From **[0085]** "For use within the present disclosure, **oxytocin releasing compound preparations are provided for intranasal**, intrapulmonary, intramuscular, intravenous, transmucosal or transdermal administration that contain a oxytocin releasing compound in a biologically suitable, liquid or solid carrier. Typically, oxytocin releasing compound preparations contain

	between about 0.001 and 50 milligrams per milliliter and preferably about 0.1 to 50 mL of liquid carrier or per gram of solid carrier." From **[0095]** "…**The carrier can be a solvent or dispersion medium containing,** for example, water, ethanol, polyol (e.g. glycerol, propylene glycol and liquid polyethylene glycol), vegetable oils, and suitable mixtures thereof. Pharmaceutical compositions of the present disclosure can be in a form suitable for topical use such as, for example, an aerosol, cream, **ointment**, lotion, dusting powder, or the like. Further, the compositions can be in a form suitable for use in transdermal devices prepared via conventional processes As an example, a cream or ointment is **prepared by mixing hydrophilic material and water, together with about 5 wt % to about 10 wt % of the compound, to produce a cream or ointment having a desired consistency."** From **[0085]** "For use within the present disclosure, **oxytocin releasing compound preparations are provided for intranasal**, intrapulmonary, intramuscular, intravenous, transmucosal or transdermal administration that contain a oxytocin releasing compound in a biologically suitable, **liquid** or solid **carrier**. Typically, oxytocin releasing compound preparations contain between about 0.001 and 50 milligrams per milliliter and preferably about 0.1 to 50 mL of liquid carrier or per gram of solid carrier. From **[0091]** "Thus, the pharmaceutical compositions of this disclosure may include a pharmaceutically acceptable carrier and a compound or a pharmaceutically acceptable salt of a compound of the Examples. **The compounds or pharmaceutically acceptable salts thereof**, can also be included in pharmaceutical compositions in combination with one or more other therapeutically active compounds. The pharmaceutical carrier employed can be, for example, a solid, **liquid**, or gas. Examples of solid carriers include lactose, terra alba, sucrose, talc, **gelatin, agar, pectin,** acacia, magnesium stearate, and stearic acid. Examples of liquid carriers are sugar syrup, peanut oil, olive oil, and water. Examples of gaseous carriers include carbon dioxide and nitrogen." 1. OTT (2001) "Pharmañopo—Psychonautics: Human Intranasal, Sublingual, Intrarectal, Pulmonary and Oral Pharmacology of Bufotenine" *Journal of Psychoactive Drugs*. 33(3): 273-281 From **page 273** "In a previous paper on pharmahuasca psychonautics, modeling ayahuasca or Banisteriopsis caapi (Spr. ex Griseb.) Mort. (Malpighiaceae) potions via **self-experiments with pure harmine and DMT or N,N-dimethyltryptamine** (Ott 1999; 1994), I noted that Holmstedt and Lindgren had originally proposed in the context of shamanic

	snuffs what I called the "ayahuasca effect"-activation of the orally inactive (and, presumably, also intranasally-inactive) DMT by concomitant administration of monoamine-oxidase inhibiting (MAOI) P-carbolines, mainly harmine-later extended to encompass also orally-ingested ayahuasca potions in its purview." From **page 274** "**Considerable chemical work on Anadenanthera shows** conclusively and consistently that bufotenine is the only significant alkaloid **in mature seeds of both species used for snuffs** … Up to 7.4% bufotenine has been found in seeds of A. peregrina var. peregrina, only 0.04% 5-MeO-DMT and **0.16% DMT**; 1 2.4% bufotenine **in A. colubrina var. Cebil**, with but 0.06% and traces of both tryptamines, respectively" From **page 275** "Bufotenine free-base was isolated and purified as described below, **from a mixed collection of A. colubrina var. Cebil** gathered in Salta, Argentina, of which representative specimens were botanically vouchered. Harmine hydrochloride dihydrate and harmaline hydrochloride dihydrate were obtained from Acros Organics of Geel, Belgium. Reagent-grade solvents were utilized in the extraction of bufotenine. **Cebil-seed snuff was prepared by lightly toasting, then triturating to a coarse powder, freshly collected seeds** (with addition of reagent-grade sodium bicarbonate as a drying agent to facilitate finer pulverization, and **in emulation of shamanic use of** ashes or lime in **Anadenanthera snuffs**). Snuff analogues were made by finely pulverizing (and in some cases mixing) the crystalline alkaloids. **In snuff bioassays**, I first washed my **nose** with saline solution, which was exsufflated followed by drying with tissue. **Alkaloids were insufflated bilaterally through a short glass tube**, after which I reclined until the peak effects were perceived, at times elevating my head to ensure the material did not enter my throat"

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/229,286	**03/06/2024 02:29:38 PM Z ET**	

Title of Invention

Application Information

APPLICATION TYPE		PATENT #	
CONFIRMATION #		FILED BY	Sisi Li
PATENT CENTER #	64572113	FILING DATE	08/02/2023
CUSTOMER #	–	FIRST NAMED INVENTOR	
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	-

Documents

TOTAL DOCUMENTS: 10

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
Concise-description-generated.pdf		2	Concise Description of Relevance	28 KB
Third-party-notification-request.pdf		1	Request for Notification of Non-compliant Third-Party Submission	13 KB
third-party-preissuance-submission.pdf		2	Third-Party Submission Under 37 CFR 1.290	51 KB
Claims_Chart.pdf		25	-	375 KB
Claims_Chart-3P.RELEVANCE.pdf	(1-25)	25	Concise Description of Relevance	307 KB
Claims_Chart-3P.RELEVANCE.pdf	(1-25)	25	Concise Description of Relevance	307 KB
Claims_Chart-3P.RELEVANCE.pdf	(1-25)	25	Concise Description of Relevance	307 KB

Claims_Chart-3P.RELEVANCE.pdf	(1-25)	25	Concise Description of Relevance	307 KB
1_OTT.pdf		10	-	2885 KB
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2_VIRAOCHA.pdf		31	-	4261 KB
2_VIRAOCHA-NPL.pdf	(1-31)	31	Non Patent Literature	4263 KB
4_DIMOITOU.pdf		4	-	924 KB
4_DIMOITOU-NPL.pdf	(1-4)	4	Non Patent Literature	915 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
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Claims_Chart-3P.RELEVANCE.pdf	6912FA5B31E7F41D0FF32983D9BF4DE860D86CFBD02F677ED0857BA3C38C55BB8AF8835D351BE021281FDF5F51120D5F9728A75DE5BC5FD7B9FBBA0ADB471F56
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If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

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

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APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/229,286	**03/06/2024 02:29:38 PM Z ET**	

Title of Invention

Application Information

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PATENT CENTER #	64572113	AUTHORIZED BY	-
CUSTOMER #	–	FILING DATE	08/02/2023
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	

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PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 0642	**E202436E30398707**	**Sisi Li**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2818	DOCUMENT FEE FOR THIRD-PARTY SUBMISSIONS (SEE 37 CFR 1.290(F))	72.00	1	72.00
			TOTAL AMOUNT:	**$72.00**

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