

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Confirmation No.:9849
Serial No.: 17/824,901 Group No.:
Filing or 371(c) Date: May 26, 2022 Examiner:
Entitled: DEVICES AND METHODS FOR THE TRANSDERMAL DELIVERY OF PSILOCYBIN

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. U.S. Pat. App. Pub. No. 2018/0325851 “Transdermally-Delivered Combination Drug Therapy for Pain” (Published November 15, 2018)
2. U.S. Pat. App. Pub. No. 2019/0110981 “Cannabinoid Patch” (Published April 18, 2019)
3. U.S. Pat. App. Pub. No. 2021/0085671 “COMPOSITIONS AND METHODS COMPRISING A COMBINATION OF SEROTONERGIC DRUGS” (Published March 25, 2021)

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. 17/824,901 Pending Claims	References
<p>1. A reservoir-type dermal patch that includes: (i) A backing and a hydrophilic, porous membrane, (ii) Wherein the backing and hydrophilic, porous membrane are attached to one another to define reservoir, wherein the reservoir comprises a pharmaceutical formulation, (iii) Wherein the hydrophilic, porous membrane comprises a first surface that is on the side of the hydrophilic, porous membrane that contacts the backing, (iv) Wherein the hydrophilic, porous membrane further comprises a second surface that is on the side of the hydrophilic, porous membrane that does not contact the backing and, wherein the second surface is coated with a skin adhesive, (v) Wherein the dermal patch further comprises a release liner that contacts the second surface that is coated with the skin adhesive, (vi) And wherein the pharmaceutical formulation comprises one or both of psilocybin and psilocin.</p>	<p>2. U.S. Pat. App. Pub. No. 2019/0110981 “Cannabinoid Patch” (Published April 18, 2019)</p> <p>From claim 1 “A composition capable of use in a buccal patch, a dermal patch, or a sublingual patch, tablet, capsule, pill, or strip, wherein the composition comprises one or more of: (a) An acrylic adhesive with non-functionality and an adhesive with only OH-functionality, further comprising one of more of enhancers selected from azone, oleic acid, and dimethylsulfoxide (DMSO);...”</p> <p>From [0004] “Regarding reservoir-style patch, the reservoir can contain a pharmaceutical agent that is a drug or a nutraceutical. The reservoir also contains a liquid carrier and a gelling agent. The reservoir can be defined by a backing and by a permeable membrane, which together assume a “ravioli” conformation. The permeable membrane is optionally coated with an adhesive that mediates binding of the adhesive to the skin. On one side of the adhesive is the permeable membrane, and on the other side is a release liner. Prior to applying the patch to the skin, a release liner is removed and discarded.”</p> <p>From [0049] “Porous membranes can take the form of hydrophilic porous membranes and hydrophobic porous membranes, without implying any limitation.”</p> <p>From abstract “The disclosure provides pharmaceuticals, cannabinoids, and nutraceuticals and dermal patches, as well as chemicals that enhance delivery of pharmaceuticals from a buccal patch or from a dermal patch, where the patch may include a film, adhesive, emulsifier, tackifier, or hydrogel.”</p> <p>1. U.S. Pat. App. Pub. No. 2018/0325851 “Transdermally-Delivered Combination Drug Therapy for Pain” (Published November 15, 2018)</p> <p>From [0010] “Transdermal delivery of pain medications is an important pharmacological approach selectively targeting the affected areas and primary afferent neurons.”</p> <p>From [0044] “As used herein, “formulation” is a preparation or composition in which various components are combined with an active ingredient. As used herein, a formulation may be in the form of an ointment, cream, lotion, gel, salve or the like, for topical application or delivery of the active ingredient to a patient (e.g., a patient in need of the active ingredient). In some embodiments, as appropriate, a formulation</p>

	<p>is used in conjunction with a delivery system (such as a transdermal patch) impregnated with or containing the formulation and suitable for topical application.”</p> <p>From [0071] “In some embodiments, the formulation described herein contains an osmolyte. A component whose main function in a formulation is to raise the osmolarity of the formulation may be referred to as an “osmolyte.” In some embodiments, an osmolyte is a molecule having an affinity for water (i.e., hydrophilicity or hygroscopicity).”</p> <p>From [0050] “Typically, such formulations are prepared either as topical formulations, liquid solutions or suspensions, solid forms suitable for solution in, or suspension in, liquid prior to use can also be prepared.”</p> <p>From [0088] “In some embodiments, the method for delivery of an active ingredient using the formulations and methods described herein includes optionally applying the formulation with a In some embodiments, the method for delivery of an active ingredient using the formulations and methods described herein includes optionally applying the formulation with a transpiration barrier. The transpiration barrier can be a water impermeable drug administration patch; for example, a sheet of water-resistant plastic with an adhesive layer or other attachment mechanism (e.g., a bandage). The patch can be applied atop a formulation applied to the skin or tissue surface. Alternately, the patch can be impregnated with the formulation and applied to the skin or tissue surface to contact active ingredients with the skin while forming the transpiration barrier. A water-impermeable wrap, glove, sock, mitten, or the like can also serve to create a physical barrier. Alternately, or in addition, the transpiration barrier can include a molecular (i.e., chemical) barrier; i.e., one that contains a plurality of molecules or particles that are at least initially unbonded and which dry on or embed in the skin or tissue surface to produce a moisture-resistant barrier...”</p> <p>From [0060] “In some embodiments, the topical formulation described herein may include a vasoactive agent such as a vasodilator or a vasoconstrictor...Commonly used vasoconstrictors include, without limitation, antihistamines, amphetamines, cocaine, caffeine (and other stimulants), psilocybin, tetrahydrozoline HCL, phenylephrine, pseudoephedrine, lysergic acid diethylamide (LSD), ergine (LSA or d-lysergic acid amide)...”</p>
<p>2. The dermal patch of claim 1, wherein the formulation further comprises one or more antioxidants, said one or more antioxidants</p>	<p>1. U.S. Pat. App. Pub. No. 2018/0325851 “Transdermally-Delivered Combination Drug Therapy for Pain” (Published November 15, 2018)</p> <p>From [0049] “The formulations of the present invention can also include any one of, any combination of, or all of the following additional ingredients: water, a chelating agent, a moisturizing agent, a</p>

<p>consisting of an antioxidatively effective concentration of an ascorbyl palmitate, or consisting of an antioxidatively effective concentration of ascorbic acid, or consisting of a combination of both an antioxidatively effective concentration of ascorbyl palmitate plus ascorbic acid, wherein the formulation includes psilocybin, and wherein said one or more antioxidants is capable of reducing the rate of oxidation of psilocybin.</p>	<p>preservative, a thickening agent, a silicone containing compound, an essential oil, a structuring agent, a vitamin, a pharmaceutical ingredient, or an antioxidant, or any combination of such ingredients or mixtures of such ingredients...”</p> <p>From [0010] “Transdermal delivery of pain medications is an important pharmacological approach selectively targeting the affected areas and primary afferent neurons.”</p> <p>From [0044] “As used herein, “formulation” is a preparation or composition in which various components are combined with an active ingredient. As used herein, a formulation may be in the form of an ointment, cream, lotion, gel, salve or the like, for topical application or delivery of the active ingredient to a patient (e.g., a patient in need of the active ingredient). In some embodiments, as appropriate, a formulation is used in conjunction with a delivery system (such as a transdermal patch) impregnated with or containing the formulation and suitable for topical application.”</p> <p>From [0071] “In some embodiments, the formulation described herein contains an osmolyte. A component whose main function in a formulation is to raise the osmolarity of the formulation may be referred to as an “osmolyte.” In some embodiments, an osmolyte is a molecule having an affinity for water (i.e., hydrophilicity or hygroscopicity).”</p> <p>From [0050] “Typically, such formulations are prepared either as topical formulations, liquid solutions or suspensions, solid forms suitable for solution in, or suspension in, liquid prior to use can also be prepared.”</p> <p>From [0088] “In some embodiments, the method for delivery of an active ingredient using the formulations and methods described herein includes optionally applying the formulation with a In some embodiments, the method for delivery of an active ingredient using the formulations and methods described herein includes optionally applying the formulation with a transpiration barrier. The transpiration barrier can be a water impermeable drug administration patch; for example, a sheet of water-resistant plastic with an adhesive layer or other attachment mechanism (e.g., a bandage). The patch can be applied atop a formulation applied to the skin or tissue surface. Alternately, the patch can be impregnated with the formulation and applied to the skin or tissue surface to contact active ingredients with the skin while forming the transpiration barrier. A water-impermeable wrap, glove, sock, mitten, or the like can also serve to create a physical barrier. Alternately, or in addition, the transpiration barrier can include a molecular (i.e., chemical) barrier; i.e., one that contains a plurality of molecules or particles that are at least initially unbonded and which dry on or embed in the skin or tissue surface to produce a moisture-resistant barrier...”</p>
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	<p>From [0060] “In some embodiments, the topical formulation described herein may include a vasoactive agent such as a vasodilator or a vasoconstrictor...Commonly used vasoconstrictors include, without limitation, antihistamines, amphetamines, cocaine, caffeine (and other stimulants), psilocybin, tetrahydrozoline HCL, phenylephrine, pseudoephedrine, lysergic acid diethylamide (LSD), ergine (LSA or d-lysergic acid amide)...”</p> <p>3. U.S. Pat. App. Pub. No. 2021/0085671 “COMPOSITIONS AND METHODS COMPRISING A COMBINATION OF SEROTONERGIC DRUGS” (Published March 25, 2021)</p> <p>From [0291] “In one embodiment, the methods and compositions disclosed herein comprise an antioxidant.”</p> <p>From [0293] “In one embodiment, an antioxidant is chosen from ascorbic acid, lycopene, tocopherol, melatonin, retinol, astaxanthin, lutein, apigenin, carnosine, selenium, zinc, curcumin, and/or a salt or derivative thereof.”</p> <p>From [0294] “In one embodiment, an antioxidant is ascorbic acid and/or its salts or derivatives. Within the context of this disclosure, the term “ascorbic acid” comprises Vitamin C and/or a salt or derivative thereof.”</p> <p>From [0295] “In one embodiment, an antioxidant prevents the oxidation of a composition comprising one or more compounds disclosed herein, e.g., psilocybin derivatives, cannabinoids, terpenes, and/or mixtures thereof. For example, preventing the oxidation of a phenolic group attached to a psilocybin derivative.”</p>
<p>3. The dermal patch of claim 1, wherein the formulation further comprises one or more antioxidants, wherein said one or more antioxidants comprises an antioxidantly effective concentration of an ascorbyl palmitate, or an antioxidantly effective concentration of ascorbic acid, or a combination of both an</p>	<p>3. U.S. Pat. App. Pub. No. 2021/0085671 “COMPOSITIONS AND METHODS COMPRISING A COMBINATION OF SEROTONERGIC DRUGS” (Published March 25, 2021)</p> <p>From [0291] “In one embodiment, the methods and compositions disclosed herein comprise an antioxidant.”</p> <p>From [0293] “In one embodiment, an antioxidant is chosen from ascorbic acid, lycopene, tocopherol, melatonin, retinol, astaxanthin, lutein, apigenin, carnosine, selenium, zinc, curcumin, and/or a salt or derivative thereof.”</p> <p>From [0294] “In one embodiment, an antioxidant is ascorbic acid and/or its salts or derivatives. Within the context of this disclosure, the term “ascorbic</p>

<p>antioxidatively effective concentration of ascorbyl palmitate plus ascorbic acid, wherein the formulation includes psilocin, and wherein said one or more antioxidants is capable of reducing the rate of oxidation of psilocin.</p>	<p>acid” comprises Vitamin C and/or a salt or derivative thereof.”</p> <p>From [0295] “In one embodiment, an antioxidant prevents the oxidation of a composition comprising one or more compounds disclosed herein, e.g., psilocybin derivatives, cannabinoids, terpenes, and/or mixtures thereof. For example, preventing the oxidation of a phenolic group attached to a psilocybin derivative.”</p> <p>From claim 1 “A composition comprising a combination of first serotonergic drug and a second serotonergic drug.”</p> <p>From claim 3 “The composition of claim 1, wherein the first serotonergic drug is chosen from 6-Allyl-N,N-diethyl-NL, N,N-Dibutyl-T, N,N-Diethyl-T, N,N-Diisopropyl-T, 5-Methoxy-alpha-methyl-T, N,N-Dimethyl-T, 2,alpha-Dimethyl-T, alpha,N-Dimethyl-T, N,N-Dipropyl-T, N-Ethyl-N-isopropyl-T, alpha-Ethyl-T, 6,N,N-Triethyl-NL, 3,4-Dihydro-7-methoxy-1-methyl-C, 7-Methoxy-1-methyl-C, N,N-Dibutyl-4-hydroxy-T, N,N-Diethyl-4-hydroxy-T, N,N-Diisopropyl-4-hydroxy-T, N,N-Dimethyl-4-hydroxy-T, N,N-Dimethyl-5-hydroxy-T, N,N-Dipropyl-4-hydroxy-T, N-Ethyl-4-hydroxy-N-methyl-T, 4-Hydroxy-N-isopropyl-N-methyl-T, 4-Hydroxy-N-methyl-N-propyl-T, 4-Hydroxy-N,N-tetramethylene-T Ibogaine, N,N-Diethyl-L, N-Butyl-N-methyl-T, N,N-Diisopropyl-4,5-methylenedioxy-T, N,N-Diisopropyl-5,6-methylenedioxy-T, N,N-Dimethyl-4,5-methylenedioxy-T, N,N-Dimethyl-5,6-methylenedioxy-T, N-Isopropyl-N-methyl-5,6-methylenedioxy-T, N,N-Diethyl-2-methyl-T, 2,N,N-Trimethyl-T, N-Acetyl-5-methoxy-T, N,N-Diethyl-5-methoxy-T, N,N-Diisopropyl-5-methoxy-T, 5-Methoxy-N,N-dimethyl-T, N-Isopropyl-4-methoxy-N-methyl-T, N-Isopropyl-5-methoxy-N-methyl-T, 5,6-Dimethoxy-N-isopropyl-N-methyl-T, 5-Methoxy-N-methyl-T, 5-Methoxy-N,N-tetramethylene-T, 6-Methoxy-1-methyl-1,2,3,4-tetrahydro-C, 5-Methoxy-2,N,N-trimethyl-T, N,N-Dimethyl-5-methylthio-T, N-Isopropyl-N-methyl-T, alpha-Methyl-T, N-Ethyl-T, N-Methyl-T, 6-Propyl-NL, N,N-Tetramethylene-T, Tryptamine, and 7-Methoxy-1-methyl-1,2,3,4-tetrahydro-C, and alpha,N-Dimethyl-5-methoxy-T.”</p> <p>From [0007] “Formulated and administered correctly, psilocin and psilocybin provide fast-acting and long-lasting changes to a person's mood. These effects can be accomplished with only minor side effects, low potential for addiction, low potential for abuse, and low risk of toxicity.”</p>
<p>4. The dermal patch of claim 1, wherein regarding the formulation, the sum of</p>	<p>1. U.S. Pat. App. Pub. No. 2018/0325851 “Transdermally-Delivered Combination Drug Therapy for Pain” (Published November 15, 2018)</p> <p>From [0049] “The formulations of the present invention can also include</p>

<p>the concentrations of psilocybin and psilocin is one of about 0.02% by weight (unit of wt./wt.), about 0.04% by weight, about 0.06% by weight, about 0.08% by weight, about 1.0% by weight, about 2.0% by weight, about 4% by weight, about 6% by weight, about 8% by weight, about 10% by weight, about 12% by weight, about 14% by weight, or about 16% by weight, wherein the unit of weight is weight of psilocybin in a gram of formulation were the formulation does not contain psilocin, or weight of psilocin in a gram of formulation where the formulation does not contain psilocybin, or weight of the sum of psilocybin plus psilocin where the formulation contains both psilocybin and psilocin.</p>	<p>any one of, any combination of, or all of the following additional ingredients: water, a chelating agent, a moisturizing agent, a preservative, a thickening agent, a silicone containing compound, an essential oil, a structuring agent, a vitamin, a pharmaceutical ingredient, or an antioxidant, or any combination of such ingredients or mixtures of such ingredients. In certain aspects, the formulation can include at least two, three, four, five, six, seven, eight, nine, ten, or all of these additional ingredients identified in the previous sentence. The amounts of such ingredients can range from 0.0001% to 99.9% by weight or volume of the formulation, or any integer or range in between.</p> <p>From [0060] “In some embodiments, the topical formulation described herein may include a vasoactive agent such as a vasodilator or a vasoconstrictor...Commonly used vasoconstrictors include, without limitation, antihistamines, amphetamines, cocaine, caffeine (and other stimulants), psilocybin, tetrahydrozoline HCL, phenylephrine, pseudoephedrine, lysergic acid diethylamide (LSD), ergine (LSA or d-lysergic acid amide)...”</p> <p>From [0049] “The formulations of the present invention can also include any one of, any combination of, or all of the following additional ingredients: water, a chelating agent, a moisturizing agent, a preservative, a thickening agent, a silicone containing compound, an essential oil, a structuring agent, a vitamin, a pharmaceutical ingredient, or an antioxidant, or any combination of such ingredients or mixtures of such ingredients...”</p> <p>From [0010] “Transdermal delivery of pain medications is an important pharmacological approach selectively targeting the affected areas and primary afferent neurons.”</p> <p>From [0044] “As used herein, “formulation” is a preparation or composition in which various components are combined with an active ingredient. As used herein, a formulation may be in the form of an ointment, cream, lotion, gel, salve or the like, for topical application or delivery of the active ingredient to a patient (e.g., a patient in need of the active ingredient). In some embodiments, as appropriate, a formulation is used in conjunction with a delivery system (such as a transdermal patch) impregnated with or containing the formulation and suitable for topical application.”</p> <p>From [0071] “In some embodiments, the formulation described herein contains an osmolyte. A component whose main function in a formulation is to raise the osmolarity of the formulation may be referred to as an “osmolyte.” In some embodiments, an osmolyte is a molecule having an affinity for water (i.e., hydrophilicity or hygroscopicity).”</p>
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	<p>From [0050] “Typically, such formulations are prepared either as topical formulations, liquid solutions or suspensions, solid forms suitable for solution in, or suspension in, liquid prior to use can also be prepared.”</p> <p>From [0088] “In some embodiments, the method for delivery of an active ingredient using the formulations and methods described herein includes optionally applying the formulation with a In some embodiments, the method for delivery of an active ingredient using the formulations and methods described herein includes optionally applying the formulation with a transpiration barrier. The transpiration barrier can be a water impermeable drug administration patch; for example, a sheet of water-resistant plastic with an adhesive layer or other attachment mechanism (e.g., a bandage). The patch can be applied atop a formulation applied to the skin or tissue surface. Alternately, the patch can be impregnated with the formulation and applied to the skin or tissue surface to contact active ingredients with the skin while forming the transpiration barrier. A water-impermeable wrap, glove, sock, mitten, or the like can also serve to create a physical barrier. Alternately, or in addition, the transpiration barrier can include a molecular (i.e., chemical) barrier; i.e., one that contains a plurality of molecules or particles that are at least initially unbonded and which dry on or embed in the skin or tissue surface to produce a moisture-resistant barrier...”</p>
<p>5. The dermal patch of claim 1, wherein the reservoir contains a hydrogel.</p>	<p>1. U.S. Pat. App. Pub. No. 2018/0325851 “Transdermally-Delivered Combination Drug Therapy for Pain” (Published November 15, 2018)</p> <p>From [0088] “In some embodiments, the method for delivery of an active ingredient using the formulations and methods described herein includes optionally applying the formulation with a In some embodiments, the method for delivery of an active ingredient using the formulations and methods described herein includes optionally applying the formulation with a transpiration barrier. The transpiration barrier can be a water impermeable drug administration patch; for example, a sheet of water-resistant plastic with an adhesive layer or other attachment mechanism (e.g., a bandage). The patch can be applied atop a formulation applied to the skin or tissue surface. Alternately, the patch can be impregnated with the formulation and applied to the skin or tissue surface to contact active ingredients with the skin while forming the transpiration barrier. A water-impermeable wrap, glove, sock, mitten, or the like can also serve to create a physical barrier. Alternately, or in addition, the transpiration barrier can include a molecular (i.e., chemical) barrier; i.e., one that contains a plurality of molecules or particles that are at least initially unbonded and which dry on or embed in the skin or tissue surface to produce a moisture-resistant barrier. For example, the molecular barrier can include silicone, titanium oxide, polyvinyl alcohol and hydrogels. It should be noted that both a chemical barrier and a physical barrier can be used together or</p>

	<p>sequentially...”</p> <p>From [0060] “In some embodiments, the topical formulation described herein may include a vasoactive agent such as a vasodilator or a vasoconstrictor...Commonly used vasoconstrictors include, without limitation, antihistamines, amphetamines, cocaine, caffeine (and other stimulants), psilocybin, tetrahydrozoline HCL, phenylephrine, pseudoephedrine, lysergic acid diethylamide (LSD), ergine (LSA or d-lysergic acid amide)...”</p> <p>From [0049] “The formulations of the present invention can also include any one of, any combination of, or all of the following additional ingredients: water, a chelating agent, a moisturizing agent, a preservative, a thickening agent, a silicone containing compound, an essential oil, a structuring agent, a vitamin, a pharmaceutical ingredient, or an antioxidant, or any combination of such ingredients or mixtures of such ingredients...”</p> <p>From [0010] “Transdermal delivery of pain medications is an important pharmacological approach selectively targeting the affected areas and primary afferent neurons.”</p> <p>From [0044] “As used herein, “formulation” is a preparation or composition in which various components are combined with an active ingredient. As used herein, a formulation may be in the form of an ointment, cream, lotion, gel, salve or the like, for topical application or delivery of the active ingredient to a patient (e.g., a patient in need of the active ingredient). In some embodiments, as appropriate, a formulation is used in conjunction with a delivery system (such as a transdermal patch) impregnated with or containing the formulation and suitable for topical application.”</p> <p>From [0071] “In some embodiments, the formulation described herein contains an osmolyte. A component whose main function in a formulation is to raise the osmolarity of the formulation may be referred to as an “osmolyte.” In some embodiments, an osmolyte is a molecule having an affinity for water (i.e., hydrophilicity or hygroscopicity).”</p> <p>From [0050] “Typically, such formulations are prepared either as topical formulations, liquid solutions or suspensions, solid forms suitable for solution in, or suspension in, liquid prior to use can also be prepared.”</p>
<p>6. The dermal patch of claim 1, wherein the reservoir does not contain any hydrogel.</p>	<p>1. U.S. Pat. App. Pub. No. 2018/0325851 “Transdermally-Delivered Combination Drug Therapy for Pain” (Published November 15, 2018)</p> <p>From [0088] “In some embodiments, the method for delivery of an active ingredient using the formulations and methods described herein includes</p>

optionally applying the formulation with a In some embodiments, the method for delivery of an active ingredient using the formulations and methods described herein includes optionally applying the formulation with a transpiration barrier. The transpiration barrier can be a water impermeable drug administration patch; for example, a sheet of water-resistant plastic with **an adhesive layer or other attachment mechanism (e.g., a bandage)**. The patch can be applied atop a formulation applied to the skin or tissue surface. Alternately, the patch can be impregnated with the formulation and applied to the skin or tissue surface to contact active ingredients with the skin while forming the transpiration barrier. A water-impermeable wrap, glove, sock, mitten, or the like can also serve to create a physical barrier. Alternately, or in addition, the transpiration barrier can include a molecular (i.e., chemical) barrier; i.e., one that contains a plurality of molecules or particles that are at least initially unbonded and which dry on or embed in the skin or tissue surface to produce a moisture-resistant barrier.”

From [0060] “In some embodiments, **the topical formulation described herein may include a vasoactive agent** such as a vasodilator or a **vasoconstrictor...Commonly used vasoconstrictors include**, without limitation, antihistamines, amphetamines, cocaine, caffeine (and other stimulants), **psilocybin**, tetrahydrozoline HCL, phenylephrine, pseudoephedrine, lysergic acid diethylamide (LSD), ergine (LSA or d-lysergic acid amide)...”

From [0049] “**The formulations of the present invention can also include any one of, any combination of, or all of the following additional ingredients:** water, a chelating agent, a moisturizing agent, a preservative, a thickening agent, a silicone containing compound, an essential oil, a structuring agent, a vitamin, a pharmaceutical ingredient, or an **antioxidant**, or any combination of such ingredients or mixtures of such ingredients...”

From [0010] “**Transdermal delivery of pain medications** is an important pharmacological approach selectively targeting the affected areas and primary afferent neurons.”

From [0044] “As used herein, “**formulation**” is a **preparation or composition in which various components are combined with an active ingredient**. As used herein, a formulation may be in the form of an ointment, cream, lotion, gel, salve or the like, for topical application or delivery of the active ingredient to a patient (e.g., a patient in need of the active ingredient). **In some embodiments, as appropriate, a formulation is used in conjunction with a delivery system (such as a transdermal patch) impregnated with or containing the formulation and suitable for topical application.**”

	<p>From [0071] “In some embodiments, the formulation described herein contains an osmolyte. A component whose main function in a formulation is to raise the osmolarity of the formulation may be referred to as an “osmolyte.” In some embodiments, an osmolyte is a molecule having an affinity for water (i.e., hydrophilicity or hygroscopicity).”</p> <p>From [0050] “Typically, such formulations are prepared either as topical formulations, liquid solutions or suspensions, solid forms suitable for solution in, or suspension in, liquid prior to use can also be prepared.”</p>
<p>7. The dermal patch of claim 1, wherein the reservoir contains a penetration enhancer, and wherein the penetration enhancer is at a concentration of about 2% (wt./wt.), about 4%, about 6%, about 8%, about 10%, about 12%, about 14%, about 16%, about 18%, or about 20%.</p>	<p>1. U.S. Pat. App. Pub. No. 2018/0325851 “Transdermally-Delivered Combination Drug Therapy for Pain” (Published November 15, 2018)</p> <p>From [0085] “Thus, in some embodiments, the formulation may include excipients, solvents, penetration enhancers, lipids, or other components. The formulation can also be a patch or a component of a patch or similar drug delivery device.”</p> <p>From [0079] “In some embodiments, the formulation can also include solvents, excipients, preservatives, skin conditions, emulsifiers, carriers, polymers, thickeners, phospholipids, fatty acids, cholesterol, complex lipids, prostaglandins, vitamins and vitamin derivatives, antioxidants, humectants, surfactants. Other components may be included in the pharmaceutical preparation that promote passive dermal penetration of chemicals and pharmaceuticals, including urea, organic solvents, such as dimethyl sulfoxide (DMSO), and others. Yet additional components include excipients or carries such as, without limitation, water, Stearyl Alcohol, Polysorbate 20, Caprylic/Capric Glyceride, Petrolatum, Beeswax, Lecithin, Dimethicone, Alkylmethyl Siloxane, Stearic Acid, Palmitic Acid, Lanolin, Linoleic Acid, Isopropyl Myristate, Stearyl Octanoate and Cetyl Octanoate, and Polysorbate 80.”</p> <p>From [0057] “In some embodiments, the compositions described herein may include one or more excipients selected from among the following: a tonicity enhancer, a preservative, a solubilizer, a viscosity enhancing agent, a demulcent, an emulsifier, a wetting agent, a sequestering agent, and a filler. The amount and type of excipient added is in accordance with the particular requirements of the composition and is generally present in the composition at a concentration of between about 0.0001% to 99% w/v, or between about 0.01% to 95% w/v, or between about 0.1% to 90% w/v, or between about 1% to about 75% w/v.</p> <p>From [0088] “In some embodiments, the method for delivery of an active ingredient using the formulations and methods described herein includes optionally applying the formulation with a In some embodiments, the</p>

method for delivery of an active ingredient using the formulations and methods described herein includes optionally applying the formulation with a transpiration barrier. The transpiration barrier can be a water impermeable drug administration patch; for example, a sheet of water-resistant plastic with **an adhesive layer or other attachment mechanism (e.g., a bandage)**. The patch can be applied atop a formulation applied to the skin or tissue surface. Alternately, the patch can be impregnated with the formulation and applied to the skin or tissue surface to contact active ingredients with the skin while forming the transpiration barrier. A water-impermeable wrap, glove, sock, mitten, or the like can also serve to create a physical barrier. Alternately, or in addition, the transpiration barrier can include a molecular (i.e., chemical) barrier; i.e., one that contains a plurality of molecules or particles that are at least initially unbonded and which dry on or embed in the skin or tissue surface to produce a moisture-resistant barrier.”

From [0060] “In some embodiments, **the topical formulation described herein may include a vasoactive agent** such as a vasodilator or a **vasoconstrictor...Commonly used vasoconstrictors include**, without limitation, antihistamines, amphetamines, cocaine, caffeine (and other stimulants), **psilocybin**, tetrahydrozoline HCL, phenylephrine, pseudoephedrine, lysergic acid diethylamide (LSD), ergine (LSA or d-lysergic acid amide)...”

From [0049] “**The formulations of the present invention can also include any one of, any combination of, or all of the following additional ingredients:** water, a chelating agent, a moisturizing agent, a preservative, a thickening agent, a silicone containing compound, an essential oil, a structuring agent, a vitamin, a pharmaceutical ingredient, or an **antioxidant**, or any combination of such ingredients or mixtures of such ingredients...”

From [0010] “**Transdermal delivery of pain medications** is an important pharmacological approach selectively targeting the affected areas and primary afferent neurons.”

From [0044] “As used herein, “**formulation**” is a **preparation or composition in which various components are combined with an active ingredient**. As used herein, a formulation may be in the form of an ointment, cream, lotion, gel, salve or the like, for topical application or delivery of the active ingredient to a patient (e.g., a patient in need of the active ingredient). **In some embodiments, as appropriate, a formulation is used in conjunction with a delivery system (such as a transdermal patch) impregnated with or containing the formulation and suitable for topical application.**”

From [0071] “In some embodiments, **the formulation described herein**

	<p>contains an osmolyte. A component whose main function in a formulation is to raise the osmolarity of the formulation may be referred to as an “osmolyte.” In some embodiments, an osmolyte is a molecule having an affinity for water (i.e., hydrophilicity or hygroscopicity).”</p> <p>From [0050] “Typically, such formulations are prepared either as topical formulations, liquid solutions or suspensions, solid forms suitable for solution in, or suspension in, liquid prior to use can also be prepared.”</p>
<p>8. The dermal patch of claim 1, wherein the reservoir does not contain any penetration enhancer, or wherein the reservoir contains under one percent penetration enhancer (wt./wt.).</p>	<p>1. U.S. Pat. App. Pub. No. 2018/0325851 “Transdermally-Delivered Combination Drug Therapy for Pain” (Published November 15, 2018)</p> <p>From [0088] “In some embodiments, the method for delivery of an active ingredient using the formulations and methods described herein includes optionally applying the formulation with a In some embodiments, the method for delivery of an active ingredient using the formulations and methods described herein includes optionally applying the formulation with a transpiration barrier. The transpiration barrier can be a water impermeable drug administration patch; for example, a sheet of water-resistant plastic with an adhesive layer or other attachment mechanism (e.g., a bandage). The patch can be applied atop a formulation applied to the skin or tissue surface. Alternately, the patch can be impregnated with the formulation and applied to the skin or tissue surface to contact active ingredients with the skin while forming the transpiration barrier. A water-impermeable wrap, glove, sock, mitten, or the like can also serve to create a physical barrier. Alternately, or in addition, the transpiration barrier can include a molecular (i.e., chemical) barrier; i.e., one that contains a plurality of molecules or particles that are at least initially unbonded and which dry on or embed in the skin or tissue surface to produce a moisture-resistant barrier.”</p> <p>From [0060] “In some embodiments, the topical formulation described herein may include a vasoactive agent such as a vasodilator or a vasoconstrictor...Commonly used vasoconstrictors include, without limitation, antihistamines, amphetamines, cocaine, caffeine (and other stimulants), psilocybin, tetrahydrozoline HCL, phenylephrine, pseudoephedrine, lysergic acid diethylamide (LSD), ergine (LSA or d-lysergic acid amide)...”</p> <p>From [0049] “The formulations of the present invention can also include any one of, any combination of, or all of the following additional ingredients: water, a chelating agent, a moisturizing agent, a preservative, a thickening agent, a silicone containing compound, an essential oil, a structuring agent, a vitamin, a pharmaceutical ingredient, or an antioxidant, or any combination of such ingredients or mixtures of such ingredients...”</p>

	<p>From [0010] “Transdermal delivery of pain medications is an important pharmacological approach selectively targeting the affected areas and primary afferent neurons.”</p> <p>From [0044] “As used herein, “formulation” is a preparation or composition in which various components are combined with an active ingredient. As used herein, a formulation may be in the form of an ointment, cream, lotion, gel, salve or the like, for topical application or delivery of the active ingredient to a patient (e.g., a patient in need of the active ingredient). In some embodiments, as appropriate, a formulation is used in conjunction with a delivery system (such as a transdermal patch) impregnated with or containing the formulation and suitable for topical application.”</p> <p>From [0071] “In some embodiments, the formulation described herein contains an osmolyte. A component whose main function in a formulation is to raise the osmolarity of the formulation may be referred to as an “osmolyte.” In some embodiments, an osmolyte is a molecule having an affinity for water (i.e., hydrophilicity or hygroscopicity).”</p> <p>From [0050] “Typically, such formulations are prepared either as topical formulations, liquid solutions or suspensions, solid forms suitable for solution in, or suspension in, liquid prior to use can also be prepared.”</p>
<p>9. The dermal patch of claim 1, wherein the formulation contains one or more penetration enhancers selected from transcutool, dimethylsulfoxide (DMSO), azone, oleic acid, dihydromyricetin, isopalmitate, propylene glycol, and isopropyl myristate.</p>	<p>I. U.S. Pat. App. Pub. No. 2018/0325851 “Transdermally-Delivered Combination Drug Therapy for Pain” (Published November 15, 2018)</p> <p>From [0079] “In some embodiments, the formulation can also include solvents, excipients, preservatives, skin conditions, emulsifiers, carriers, polymers, thickeners, phospholipids, fatty acids, cholesterol, complex lipids, prostaglandins, vitamins and vitamin derivatives, antioxidants, humectants, surfactants. Other components may be included in the pharmaceutical preparation that promote passive dermal penetration of chemicals and pharmaceuticals, including urea, organic solvents, such as dimethyl sulfoxide (DMSO), and others. Yet additional components include excipients or carries such as, without limitation, water, Stearyl Alcohol, Polysorbate 20, Caprylic/Capric Glyceride, Petrolatum, Beeswax, Lecithin, Dimethicone, Alkylmethyl Siloxane, Stearic Acid, Palmitic Acid, Lanolin, Linoleic Acid, Isopropyl Myristate, Stearyl Octanoate and Cetyl Octanoate, and Polysorbate 80.”</p> <p>From [0077] “In further embodiment, the formulation described herein comprises a penetration enhancer. By “penetration enhancer” is meant a compound, particle, or other substance or material that when included in a</p>

formulation that is applied topically to the skin or to the tissue surface, increases the rate or amount of transport of an active ingredient in the formulation past the cells (living or dead) of the epidermis. Non-limiting examples of penetration enhancers include individual fatty acids, fatty acid esters, polyols, amides, various anionic, cationic and nonionic surfactants such as but not limited to sodium laurate and sodium lauryl sulfate, phospholipids, cholesterol and cholesterol derivatives, m-pyrrole, dimethyl acetamide, limonene, sphingolipids, ceramides, terpenes, alkanones, menthol, various organic acids, such as but not limited to salicylic acid, citric and succinic acid, prostaglandin, decyl methyl sulfoxide, urea, sulfoxide alcohols, plant extract oils. Suitable fatty acids include without limitation: linoleic acids, linolenic acids, **oleic acids**, stearic acids, and myristic acids. Phospholipids include without limitation: phosphatidylcholine, phosphatidylethanolamine, and phosphatidylserine. Plant extract oils include oils of peanut, hemp, borage, olive, sunflower, soybean, monoi and macadamia. The plant extract oil can be mixed with an alcohol such as ethyl alcohol, isopropyl alcohol, and methyl alcohol.”

From [0088] “In some embodiments, the method for delivery of an active ingredient using the formulations and methods described herein includes optionally applying the formulation with a In some embodiments, the method for delivery of an active ingredient using the formulations and methods described herein includes optionally applying the formulation with a transpiration barrier. The transpiration barrier can be a water impermeable drug administration patch; for example, a sheet of water-resistant plastic with **an adhesive layer or other attachment mechanism (e.g., a bandage)**. The patch can be applied atop a formulation applied to the skin or tissue surface. Alternately, the patch can be impregnated with the formulation and applied to the skin or tissue surface to contact active ingredients with the skin while forming the transpiration barrier. A water-impermeable wrap, glove, sock, mitten, or the like can also serve to create a physical barrier. Alternately, or in addition, the transpiration barrier can include a molecular (i.e., chemical) barrier; i.e., one that contains a plurality of molecules or particles that are at least initially unbonded and which dry on or embed in the skin or tissue surface to produce a moisture-resistant barrier.”

From [0060] “In some embodiments, **the topical formulation described herein may include a vasoactive agent** such as a vasodilator or a **vasoconstrictor...Commonly used vasoconstrictors include**, without limitation, antihistamines, amphetamines, cocaine, caffeine (and other stimulants), **psilocybin**, tetrahydrozoline HCL, phenylephrine, pseudoephedrine, lysergic acid diethylamide (LSD), ergine (LSA or d-lysergic acid amide)...”

From [0049] “**The formulations of the present invention can also**

	<p>include any one of, any combination of, or all of the following additional ingredients: water, a chelating agent, a moisturizing agent, a preservative, a thickening agent, a silicone containing compound, an essential oil, a structuring agent, a vitamin, a pharmaceutical ingredient, or an antioxidant, or any combination of such ingredients or mixtures of such ingredients...”</p> <p>From [0010] “Transdermal delivery of pain medications is an important pharmacological approach selectively targeting the affected areas and primary afferent neurons.”</p> <p>From [0044] “As used herein, “formulation” is a preparation or composition in which various components are combined with an active ingredient. As used herein, a formulation may be in the form of an ointment, cream, lotion, gel, salve or the like, for topical application or delivery of the active ingredient to a patient (e.g., a patient in need of the active ingredient). In some embodiments, as appropriate, a formulation is used in conjunction with a delivery system (such as a transdermal patch) impregnated with or containing the formulation and suitable for topical application.”</p> <p>From [0071] “In some embodiments, the formulation described herein contains an osmolyte. A component whose main function in a formulation is to raise the osmolarity of the formulation may be referred to as an “osmolyte.” In some embodiments, an osmolyte is a molecule having an affinity for water (i.e., hydrophilicity or hygroscopicity).”</p> <p>From [0050] “Typically, such formulations are prepared either as topical formulations, liquid solutions or suspensions, solid forms suitable for solution in, or suspension in, liquid prior to use can also be prepared.”</p>
<p>10. The dermal patch of claim 1, wherein the formulation comprises psilocin and one or more cannabinoids.</p>	<p>3. U.S. Pat. App. Pub. No. 2021/0085671 “COMPOSITIONS AND METHODS COMPRISING A COMBINATION OF SEROTONERGIC DRUGS” (Published March 25, 2021)</p> <p>From [0343] “In one embodiment, the methods disclosed herein comprise transdermally administering a composition.”</p> <p>From [0344] “As used herein, the term “transdermally administering” refers to providing a compound by entering the blood or body through the dermis, or skin, of an organism. In one embodiment, transdermally administering comprises applying a composition to the skin of an organism, e.g., applying a topical composition, applying a liquid composition, etc. In one embodiment, transdermally administering a composition comprises applying a patch embedded with the composition to the skin of an organism.”</p>

	<p>From claim 1 “A composition comprising a combination of first serotonergic drug and a second serotonergic drug.”</p> <p>From claim 3 “The composition of claim 1, wherein the first serotonergic drug is chosen from 6-Allyl-N,N-diethyl-NL, N,N-Dibutyl-T, N,N-Diethyl-T, N,N-Diisopropyl-T, 5-Methoxy-alpha-methyl-T, N,N-Dimethyl-T, 2,alpha-Dimethyl-T, alpha,N-Dimethyl-T, N,N-Dipropyl-T, N-Ethyl-N-isopropyl-T, alpha-Ethyl-T, 6,N,N-Triethyl-NL, 3,4-Dihydro-7-methoxy-1-methyl-C, 7-Methoxy-1-methyl-C, N,N-Dibutyl-4-hydroxy-T, N,N-Diethyl-4-hydroxy-T, N,N-Diisopropyl-4-hydroxy-T, N,N-Dimethyl-4-hydroxy-T, N,N-Dimethyl-5-hydroxy-T, N,N-Dipropyl-4-hydroxy-T, N-Ethyl-4-hydroxy-N-methyl-T, 4-Hydroxy-N-isopropyl-N-methyl-T, 4-Hydroxy-N-methyl-N-propyl-T, 4-Hydroxy-N,N-tetramethylene-T Ibogaine, N,N-Diethyl-L, N-Butyl-N-methyl-T, N,N-Diisopropyl-4,5-methylenedioxy-T, N,N-Diisopropyl-5,6-methylenedioxy-T, N,N-Dimethyl-4,5-methylenedioxy-T, N,N-Dimethyl-5,6-methylenedioxy-T, N-Isopropyl-N-methyl-5,6-methylenedioxy-T, N,N-Diethyl-2-methyl-T, 2,N,N-Trimethyl-T, N-Acetyl-5-methoxy-T, N,N-Diethyl-5-methoxy-T, N,N-Diisopropyl-5-methoxy-T, 5-Methoxy-N,N-dimethyl-T, N-Isopropyl-4-methoxy-N-methyl-T, N-Isopropyl-5-methoxy-N-methyl-T, 5,6-Dimethoxy-N-isopropyl-N-methyl-T, 5-Methoxy-N-methyl-T, 5-Methoxy-N,N-tetramethylene-T, 6-Methoxy-1-methyl-1,2,3,4-tetrahydro-C, 5-Methoxy-2,N,N-trimethyl-T, N,N-Dimethyl-5-methylthio-T, N-Isopropyl-N-methyl-T, alpha-Methyl-T, N-Ethyl-T, N-Methyl-T, 6-Propyl-NL, N,N-Tetramethylene-T, Tryptamine, and 7-Methoxy-1-methyl-1,2,3,4-tetrahydro-C, and alpha,N-Dimethyl-5-methoxy-T.”</p> <p>From [0007] “Formulated and administered correctly, psilocin and psilocybin provide fast-acting and long-lasting changes to a person's mood. These effects can be accomplished with only minor side effects, low potential for addiction, low potential for abuse, and low risk of toxicity.”</p> <p>From [0027] “In one embodiment, the methods disclosed herein comprise administering the compositions disclosed herein. In one embodiment, the methods disclosed herein comprise treating a psychological disorder, e.g., an anxiety disorder, a compulsive disorder, a depressive disorder, etc., with the compositions disclosed herein, e.g., a composition with one or more psilocybin derivatives, a composition with one or more cannabinoids, a composition with one or more terpenes, and/or a combination thereof...”</p>
<p>11. The dermal patch of claim 1, wherein the formulation comprises</p>	<p>3. U.S. Pat. App. Pub. No. 2021/0085671 “COMPOSITIONS AND METHODS COMPRISING A COMBINATION OF SEROTONERGIC DRUGS” (Published March 25, 2021)</p>

<p>psilocybin and one or more cannabinoids.</p>	<p>From [0343] “In one embodiment, the methods disclosed herein comprise transdermally administering a composition.”</p> <p>From [0344] “As used herein, the term “transdermally administering” refers to providing a compound by entering the blood or body through the dermis, or skin, of an organism. In one embodiment, transdermally administering comprises applying a composition to the skin of an organism, e.g., applying a topical composition, applying a liquid composition, etc. In one embodiment, transdermally administering a composition comprises applying a patch embedded with the composition to the skin of an organism.”</p> <p>From [0027] “In one embodiment, the methods disclosed herein comprise administering the compositions disclosed herein. In one embodiment, the methods disclosed herein comprise treating a psychological disorder, e.g., an anxiety disorder, a compulsive disorder, a depressive disorder, etc., with the compositions disclosed herein, e.g., a composition with one or more psilocybin derivatives, a composition with one or more cannabinoids, a composition with one or more terpenes, and/or a combination thereof...”</p>
<p>12. The dermal patch of claim 1, wherein the formulation comprises both psilocin and psilocybin and one or more cannabinoids.</p>	<p>3. U.S. Pat. App. Pub. No. 2021/0085671 “COMPOSITIONS AND METHODS COMPRISING A COMBINATION OF SEROTONERGIC DRUGS” (Published March 25, 2021)</p> <p>From [0343] “In one embodiment, the methods disclosed herein comprise transdermally administering a composition.”</p> <p>From [0344] “As used herein, the term “transdermally administering” refers to providing a compound by entering the blood or body through the dermis, or skin, of an organism. In one embodiment, transdermally administering comprises applying a composition to the skin of an organism, e.g., applying a topical composition, applying a liquid composition, etc. In one embodiment, transdermally administering a composition comprises applying a patch embedded with the composition to the skin of an organism.”</p> <p>From [0007] “Formulated and administered correctly, psilocin and psilocybin provide fast-acting and long-lasting changes to a person's mood. These effects can be accomplished with only minor side effects, low potential for addiction, low potential for abuse, and low risk of toxicity.”</p> <p>From [0027] “In one embodiment, the methods disclosed herein comprise administering the compositions disclosed herein. In one embodiment, the</p>

	<p>methods disclosed herein comprise treating a psychological disorder, e.g., an anxiety disorder, a compulsive disorder, a depressive disorder, etc., with the compositions disclosed herein, e.g., a composition with one or more psilocybin derivatives, a composition with one or more cannabinoids, a composition with one or more terpenes, and/or a combination thereof...</p> <p>From claim 3 “The composition of claim 1, wherein the first serotonergic drug is chosen from 6-Allyl-N,N-diethyl-NL, N,N-Dibutyl-T, N,N-Diethyl-T, N,N-Diisopropyl-T, 5-Methoxy-alpha-methyl-T, N,N-Dimethyl-T, 2,alpha-Dimethyl-T, alpha,N-Dimethyl-T, N,N-Dipropyl-T, N-Ethyl-N-isopropyl-T, alpha-Ethyl-T, 6,N,N-Triethyl-NL, 3,4-Dihydro-7-methoxy-1-methyl-C, 7-Methoxy-1-methyl-C, N,N-Dibutyl-4-hydroxy-T, N,N-Diethyl-4-hydroxy-T, N,N-Diisopropyl-4-hydroxy-T, N,N-Dimethyl-4-hydroxy-T, N,N-Dimethyl-5-hydroxy-T, N,N-Dipropyl-4-hydroxy-T, N-Ethyl-4-hydroxy-N-methyl-T, 4-Hydroxy-N-isopropyl-N-methyl-T, 4-Hydroxy-N-methyl-N-propyl-T, 4-Hydroxy-N,N-tetramethylene-T Ibogaine, N,N-Diethyl-L, N-Butyl-N-methyl-T, N,N-Diisopropyl-4,5-methylenedioxy-T, N,N-Diisopropyl-5,6-methylenedioxy-T, N,N-Dimethyl-4,5-methylenedioxy-T, N,N-Dimethyl-5,6-methylenedioxy-T, N-Isopropyl-N-methyl-5,6-methylenedioxy-T, N,N-Diethyl-2-methyl-T, 2,N,N-Trimethyl-T, N-Acetyl-5-methoxy-T, N,N-Diethyl-5-methoxy-T, N,N-Diisopropyl-5-methoxy-T, 5-Methoxy-N,N-dimethyl-T, N-Isopropyl-4-methoxy-N-methyl-T, N-Isopropyl-5-methoxy-N-methyl-T, 5,6-Dimethoxy-N-isopropyl-N-methyl-T, 5-Methoxy-N-methyl-T, 5-Methoxy-N,N-tetramethylene-T, 6-Methoxy-1-methyl-1,2,3,4-tetrahydro-C, 5-Methoxy-2,N,N-trimethyl-T, N,N-Dimethyl-5-methylthio-T, N-Isopropyl-N-methyl-T, alpha-Methyl-T, N-Ethyl-T, N-Methyl-T, 6-Propyl-NL, N,N-Tetramethylene-T, Tryptamine, and 7-Methoxy-1-methyl-1,2,3,4-tetrahydro-C, and alpha,N-Dimethyl-5-methoxy-T.”</p>
<p>13. A monolithic-type dermal patch that includes: (i) A backing, (ii) A matrix comprising a skin adhesive, an adhesion/viscosity modifier, and a pharmaceutical formulation, wherein the pharmaceutical formulation comprises one or more of psilocybin, psilocin, a derivative of psilocybin, a derivative of psilocin,</p>	<p>2. U.S. Pat. App. Pub. No. 2019/0110981 “Cannabinoid Patch” (Published April 18, 2019)</p> <p>From [0003] “Dermal patches can take the form of a monolithic-style patch or a reservoir-style patch (see, US 2017/0071870 of Weimann, which is hereby incorporated herein in its entirety). Monolithic-style patch can take the form of a sandwich, where the face that is exposed to the atmosphere is a backing, where the opposite face is a release liner, and where the filling of the sandwich is a matrix that includes an adhesive and a pharmaceutical agent such as a drug or nutraceutical. Prior to applying the patch to the skin, a release liner is removed and discarded.”</p> <p>From claim 1 “A composition capable of use in a buccal patch, a dermal patch, or a sublingual patch, tablet, capsule, pill, or strip, wherein the</p>

<p>a cannabinoid, and an antioxidant, (iii) A release liner, wherein the release liner has an inner face and a outer face, and wherein the inner face is substantially in contact with the matrix, wherein the outer face does not contact the matrix, and wherein said release liner can be peelably removed from the surface of said adhesive matrix,</p>	<p>composition comprises one or more of: (a) An acrylic adhesive with non-functionality and an adhesive with only OH-functionality, further comprising one of more of enhancers selected from azone, oleic acid, and dimethylsulfoxide (DMSO);...</p> <p>From [0004] “Regarding reservoir-style patch, the reservoir can contain a pharmaceutical agent that is a drug or a nutraceutical. The reservoir also contains a liquid carrier and a gelling agent. The reservoir can be defined by a backing and by a permeable membrane, which together assume a “ravioli” conformation. The permeable membrane is optionally coated with an adhesive that mediates binding of the adhesive to the skin. On one side of the adhesive is the permeable membrane, and on the other side is a release liner. Prior to applying the patch to the skin, a release liner is removed and discarded.”</p> <p>3. U.S. Pat. App. Pub. No. 2021/0085671 “COMPOSITIONS AND METHODS COMPRISING A COMBINATION OF SEROTONERGIC DRUGS” (Published March 25, 2021)</p> <p>From [0343] “In one embodiment, the methods disclosed herein comprise transdermally administering a composition.”</p> <p>From [0344] “As used herein, the term “transdermally administering” refers to providing a compound by entering the blood or body through the dermis, or skin, of an organism. In one embodiment, transdermally administering comprises applying a composition to the skin of an organism, e.g., applying a topical composition, applying a liquid composition, etc. In one embodiment, transdermally administering a composition comprises applying a patch embedded with the composition to the skin of an organism.”</p> <p>From [0007] “Formulated and administered correctly, psilocin and psilocybin provide fast-acting and long-lasting changes to a person's mood. These effects can be accomplished with only minor side effects, low potential for addiction, low potential for abuse, and low risk of toxicity.”</p> <p>From [0027] “In one embodiment, the methods disclosed herein comprise administering the compositions disclosed herein. In one embodiment, the methods disclosed herein comprise treating a psychological disorder, e.g., an anxiety disorder, a compulsive disorder, a depressive disorder, etc., with the compositions disclosed herein, e.g., a composition with one or more psilocybin derivatives, a composition with one or more cannabinoids, a composition with one or more terpenes, and/or a combination thereof...”</p>
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	<p>From [0291] “In one embodiment, the methods and compositions disclosed herein comprise an antioxidant.”</p>
<p>14. The monolithic-type dermal patch of claim 13, wherein the adhesion/viscosity modifier is a mineral oil or a silicone fluid.</p>	<p>2. U.S. Pat. App. Pub. No. 2019/0110981 “Cannabinoid Patch” (Published April 18, 2019)</p> <p>From [0052] “Solubilizers such as detergents, surfactants, organic solvents, and chaotropic agents, are available for the present disclosure. These can be one or more of, polyethylene glycol (PEG), propylene glycol, dibutyl subacetate, glycerol, diethyl phthalate (phthalate esters), triacetin, citrate esters-triethyl citrate, acetyltriethyl citrate, tributyl citrate, acetyltributyl citrate, benzyl benzoate, sorbitol, xylitol, bis(2-ethylhexyl) adipate, mineral oil, polyhydric alcohols such as glycerin and sorbitol, glycerol esters such as glycerol, triacetate; fatty acid triglycerides, polyoxyethylene sorbitan, fatty acid esters such as TWEENS, polyoxyethylene monoalkyl ethers such as BRIJ series and MYRJ series, sucrose monoesters, lanolin esters, lanolin ethers. These are available from Sigma-Aldrich, St. Louis, Mo. In exclusionary embodiments, what can be excluded is any composition, formulation, dermal patch, and methods that comprise one or more of these solubilizers or surfactants.”</p> <p>From [0032] “In methods of manufacturing embodiments, monolith patch can be made as follows. Cannabis oil or one or more pure cannabinoids can be combined with permeation enhancers such as oleic acid and dodecylmethyl sulfoxide. Then one or more pure terpenes, or an essential oil, or a combination of an essential oil and one or more pure terpenes, is mixed with the above combination. Then, a pressure sensitive adhesive such as silicone adhesive BIO PSA 7-4302 (Dow Corning), or other suitable ones are mixed in...”</p> <p>From [0003] “Dermal patches can take the form of a monolithic-style patch or a reservoir-style patch (see, US 2017/0071870 of Weimann, which is hereby incorporated herein in its entirety). Monolithic-style patch can take the form of a sandwich, where the face that is exposed to the atmosphere is a backing, where the opposite face is a release liner, and where the filling of the sandwich is a matrix that includes an adhesive and a pharmaceutical agent such as a drug or nutraceutical. Prior to applying the patch to the skin, a release liner is removed and discarded.”</p> <p>From claim 1 “A composition capable of use in a buccal patch, a dermal patch, or a sublingual patch, tablet, capsule, pill, or strip, wherein the composition comprises one or more of: (a) An acrylic adhesive with non-functionality and an adhesive with only OH-functionality, further comprising</p>

one of more of enhancers selected from azone, oleic acid, and dimethylsulfoxide (DMSO);...

From [0004] “Regarding **reservoir-style patch, the reservoir can contain a pharmaceutical agent that is a drug or a nutraceutical.** The reservoir also contains a liquid carrier and a gelling agent. **The reservoir can be defined by a backing and by a permeable membrane, which together assume a “ravioli” conformation.** The permeable membrane is optionally coated with an adhesive that mediates binding of the adhesive to the skin. On one side of the adhesive is the permeable membrane, and on the other side is a release liner. Prior to applying the patch to the skin, a release liner is removed and discarded.”

3. U.S. Pat. App. Pub. No. 2021/0085671 “COMPOSITIONS AND METHODS COMPRISING A COMBINATION OF SEROTONERGIC DRUGS” (Published March 25, 2021)

From [0343] “In one embodiment, the methods disclosed herein comprise **transdermally administering** a composition.”

From [0344] “As used herein, the term “**transdermally administering**” refers to providing a compound by entering the blood or body through the dermis, or skin, of an organism. In one embodiment, transdermally administering comprises applying a composition to the skin of an organism, e.g., applying a topical composition, applying a liquid composition, etc. In one embodiment, **transdermally administering a composition comprises applying a patch** embedded with the composition to the skin of an organism.”

From [0007] “Formulated and administered correctly, **psilocin** and psilocybin provide fast-acting and long-lasting changes to a person's mood. These effects can be accomplished with only minor side effects, low potential for addiction, low potential for abuse, and low risk of toxicity.”

From [0027] “In one embodiment, the methods disclosed herein comprise administering the compositions disclosed herein. In one embodiment, the methods disclosed herein comprise treating a psychological disorder, e.g., an anxiety disorder, a compulsive disorder, a depressive disorder, etc., with **the compositions disclosed herein, e.g., a composition with one or more psilocybin derivatives, a composition with one or more cannabinoids, a composition with one or more terpenes, and/or a combination thereof...**”

From [0291] “In one embodiment, the methods and compositions disclosed

	herein comprise an antioxidant. ”
<p>15. The monolithic-type dermal patch of claim 14, wherein the mineral oil or the silicone fluid is present in an amount ranging from zero percent to about ten percent of the weight of the matrix.</p>	<p>2. U.S. Pat. App. Pub. No. 2019/0110981 “Cannabinoid Patch” (Published April 18, 2019)</p> <p>From [0020] “...Also, what can be excluded is any one of the above chemicals, where the chemical is dissolved or suspended or dispersed in a liquid, in an oil, in a paste, in an adhesive, and where the chemical occurs at concentration of over 0.1%, over 0.5%, over 1.0%, over 2%, over 5%, over 10%, over 15%, over 20%, over 25%, over 30%, over 40%, over 50%, over 60%, over 70%, over 80%, or over 90% of the liquid, oil, paste, or adhesive.”</p> <p>From [0032] “In methods of manufacturing embodiments, monolith patch can be made as follows. Cannabis oil or one or more pure cannabinoids can be combined with permeation enhancers such as oleic acid and dodecylmethyl sulfoxide. Then one or more pure terpenes, or an essential oil, or a combination of an essential oil and one or more pure terpenes, is mixed with the above combination. Then, a pressure sensitive adhesive such as silicone adhesive BIO PSA 7-4302 (Dow Corning), or other suitable ones are mixed in...”</p> <p>From [0003] “Dermal patches can take the form of a monolithic-style patch or a reservoir-style patch (see, US 2017/0071870 of Weimann, which is hereby incorporated herein in its entirety). Monolithic-style patch can take the form of a sandwich, where the face that is exposed to the atmosphere is a backing, where the opposite face is a release liner, and where the filling of the sandwich is a matrix that includes an adhesive and a pharmaceutical agent such as a drug or nutraceutical. Prior to applying the patch to the skin, a release liner is removed and discarded.”</p> <p>From claim 1 “A composition capable of use in a buccal patch, a dermal patch, or a sublingual patch, tablet, capsule, pill, or strip, wherein the composition comprises one or more of: (a) An acrylic adhesive with non-functionality and an adhesive with only OH-functionality, further comprising one of more of enhancers selected from azone, oleic acid, and dimethylsulfoxide (DMSO);...”</p> <p>From [0004] “Regarding reservoir-style patch, the reservoir can contain a pharmaceutical agent that is a drug or a nutraceutical. The reservoir also contains a liquid carrier and a gelling agent. The reservoir can be defined by a backing and by a permeable membrane, which together assume a “ravioli” conformation. The permeable membrane is optionally coated with an adhesive that mediates binding of the adhesive to the skin. On one side of</p>

	<p>the adhesive is the permeable membrane, and on the other side is a release liner. Prior to applying the patch to the skin, a release liner is removed and discarded.”</p> <p>3. U.S. Pat. App. Pub. No. 2021/0085671 “COMPOSITIONS AND METHODS COMPRISING A COMBINATION OF SEROTONERGIC DRUGS” (Published March 25, 2021)</p> <p>From [0343] “In one embodiment, the methods disclosed herein comprise transdermally administering a composition.”</p> <p>From [0344] “As used herein, the term “transdermally administering” refers to providing a compound by entering the blood or body through the dermis, or skin, of an organism. In one embodiment, transdermally administering comprises applying a composition to the skin of an organism, e.g., applying a topical composition, applying a liquid composition, etc. In one embodiment, transdermally administering a composition comprises applying a patch embedded with the composition to the skin of an organism.”</p> <p>From [0007] “Formulated and administered correctly, psilocin and psilocybin provide fast-acting and long-lasting changes to a person's mood. These effects can be accomplished with only minor side effects, low potential for addiction, low potential for abuse, and low risk of toxicity.”</p> <p>From [0027] “In one embodiment, the methods disclosed herein comprise administering the compositions disclosed herein. In one embodiment, the methods disclosed herein comprise treating a psychological disorder, e.g., an anxiety disorder, a compulsive disorder, a depressive disorder, etc., with the compositions disclosed herein, e.g., a composition with one or more psilocybin derivatives, a composition with one or more cannabinoids, a composition with one or more terpenes, and/or a combination thereof...”</p> <p>From [0291] “In one embodiment, the methods and compositions disclosed herein comprise an antioxidant.”</p>
<p>16. The monolithic-type dermal patch of claim 14, wherein the mineral oil has a molecular weight ranging from 200-400 Daltons, from 200-500 Daltons, from</p>	

<p>300-500 Daltons, from 300-600 Daltons, from 400-600 Daltons, from 400-700 Daltons, from 500-700 Daltons, from 500-800 Daltons, from 600-800 Daltons, from 600-900 Daltons, from 700-900 Daltons, from 700-1000 Daltons, or from any combination of said ranges.</p>	
<p>17. The monolithic-type dermal patch of claim 14, wherein the silicone fluid comprises hydroxyl group (—OH) end-capped polydimethylsiloxanes having a kinematic viscosity at 20 degrees C. ranging from 100 cSt to about 1000 sCt, or wherein the kinematic viscosity at 20 degrees C. is about 20 cSt, or about 100 cSt, or about 350 cSt, or about 1000 cSt, or about 12,500 cSt.</p>	
<p>18. The monolithic-type dermal patch of claim 13, wherein the skin adhesive is a polyisobutylene that is supplied in mineral oil, or wherein the skin adhesive is a polyisobutylene that is not supplied in mineral oil.</p>	<p>2. U.S. Pat. App. Pub. No. 2019/0110981 “Cannabinoid Patch” (Published April 18, 2019)</p> <p>From claim 1 “A composition capable of use in a buccal patch, a dermal patch, or a sublingual patch, tablet, capsule, pill, or strip, wherein the composition comprises one or more of:</p> <p>(a) An acrylic adhesive with non-functionality and an adhesive with only OH-functionality, further comprising one of more of enhancers selected from azone, oleic acid, and dimethylsulfoxide (DMSO);</p> <p>(b) A polyisobutylene (PIB adhesive) with tackifiers that improve adhesion to skin using acrylic pressure sensitive adhesive mixed in at 1-50%, optionally with a cycloaliphatic hydrocarbon resin;”</p> <p>From [0032] “In methods of manufacturing embodiments, monolith patch can be made as follows. Cannabis oil or one or more pure cannabinoids can be combined with permeation enhancers such as oleic acid and dodecylmethyl sulfoxide. Then one or more pure terpenes, or an essential oil, or a</p>

combination of an essential oil and one or more pure terpenes, is mixed with the above combination. Then, **a pressure sensitive adhesive such as silicone adhesive BIO PSA 7-4302 (Dow Corning)**, or other suitable ones are mixed in...”

From [0003] **“Dermal patches can take the form of a monolithic-style patch** or a reservoir-style patch (see, US 2017/0071870 of Weimann, which is hereby incorporated herein in its entirety). Monolithic-style patch can take the form of a sandwich, where the face that is exposed to the atmosphere is a **backing**, where the opposite face is a **release liner**, and where the filling of the sandwich is a matrix that includes an adhesive and a pharmaceutical agent such as a drug or nutraceutical. **Prior to applying the patch to the skin, a release liner is removed and discarded.**”

From **claim 1** “A composition capable of use in a buccal patch, **a dermal patch**, or a sublingual patch, tablet, capsule, pill, or strip, wherein the composition comprises one or more of: (a) An acrylic **adhesive** with non-functionality and an adhesive with only OH-functionality, further comprising one of more of enhancers selected from azone, oleic acid, and dimethylsulfoxide (DMSO);...”

3. U.S. Pat. App. Pub. No. 2021/0085671 “COMPOSITIONS AND METHODS COMPRISING A COMBINATION OF SEROTONERGIC DRUGS” (Published March 25, 2021)

From [0343] “In one embodiment, the methods disclosed herein comprise **transdermally administering** a composition.”

From [0344] “As used herein, the term **“transdermally administering”** refers to providing a compound by entering the blood or body through the dermis, or skin, of an organism. In one embodiment, transdermally administering comprises applying a composition to the skin of an organism, e.g., applying a topical composition, applying a liquid composition, etc. In one embodiment, **transdermally administering a composition comprises applying a patch** embedded with the composition to the skin of an organism.”

From [0007] “Formulated and administered correctly, **psilocin** and psilocybin provide fast-acting and long-lasting changes to a person's mood. These effects can be accomplished with only minor side effects, low potential for addiction, low potential for abuse, and low risk of toxicity.”

From [0027] “In one embodiment, the methods disclosed herein comprise

	<p>administering the compositions disclosed herein. In one embodiment, the methods disclosed herein comprise treating a psychological disorder, e.g., an anxiety disorder, a compulsive disorder, a depressive disorder, etc., with the compositions disclosed herein, e.g., a composition with one or more psilocybin derivatives, a composition with one or more cannabinoids, a composition with one or more terpenes, and/or a combination thereof..."</p> <p>From [0291] "In one embodiment, the methods and compositions disclosed herein comprise an antioxidant."</p>
<p>19. The monolithic-type dermal patch of claim 13, wherein the skin adhesive comprises a blend of acrylic adhesive and polyisobutylene adhesive.</p>	<p>2. U.S. Pat. App. Pub. No. 2019/0110981 "Cannabinoid Patch" (Published April 18, 2019)</p> <p>From [0008] "Briefly stated, the present disclosure provides a composition capable of use in a buccal patches, sublingual patch, pill, tablet, or a dermal patch, wherein the composition comprises one or more of, an acrylic adhesive with non-functionality and an adhesive with only OH-functionality, further comprising one of more of enhancers selected from azone, oleic acid, and dimethylsulfoxide (DMSO); a polyisobutylene (PIB adhesive) with tackifiers that improve adhesion to skin using acrylic pressure sensitive adhesive mixed in at 1-50%, optionally with a cycloaliphatic hydrocarbon..."</p> <p>From claim 1 "A composition capable of use in a buccal patch, a dermal patch, or a sublingual patch, tablet, capsule, pill, or strip, wherein the composition comprises one or more of:</p> <p>(a) An acrylic adhesive with non-functionality and an adhesive with only OH-functionality, further comprising one of more of enhancers selected from azone, oleic acid, and dimethylsulfoxide (DMSO);</p> <p>(b) A polyisobutylene (PIB adhesive) with tackifiers that improve adhesion to skin using acrylic pressure sensitive adhesive mixed in at 1-50%, optionally with a cycloaliphatic hydrocarbon resin;"</p> <p>From [0032] "In methods of manufacturing embodiments, monolith patch can be made as follows. Cannabis oil or one or more pure cannabinoids can be combined with permeation enhancers such as oleic acid and dodecylmethyl sulfoxide. Then one or more pure terpenes, or an essential oil, or a combination of an essential oil and one or more pure terpenes, is mixed with the above combination. Then, a pressure sensitive adhesive such as silicone adhesive BIO PSA 7-4302 (Dow Corning), or other suitable ones are mixed in..."</p> <p>From [0003] "Dermal patches can take the form of a monolithic-style patch or a reservoir-style patch (see, US 2017/0071870 of Weimann, which is</p>

hereby incorporated herein in its entirety). Monolithic-style patch can take the form of a sandwich, where the face that is exposed to the atmosphere is a **backing**, where the opposite face is a **release liner**, and where the filling of the sandwich is a matrix that includes an adhesive and a pharmaceutical agent such as a drug or nutraceutical. **Prior to applying the patch to the skin, a release liner is removed and discarded.**”

From **claim 1** “A composition capable of use in a buccal patch, a **dermal patch**, or a sublingual patch, tablet, capsule, pill, or strip, wherein the composition comprises one or more of: (a) An acrylic **adhesive** with non-functionality and an adhesive with only OH-functionality, further comprising one of more of enhancers selected from azone, oleic acid, and dimethylsulfoxide (DMSO);...”

3. U.S. Pat. App. Pub. No. 2021/0085671 “COMPOSITIONS AND METHODS COMPRISING A COMBINATION OF SEROTONERGIC DRUGS” (Published March 25, 2021)

From **[0343]** “In one embodiment, the methods disclosed herein comprise **transdermally administering** a composition.”

From **[0344]** “As used herein, the term “**transdermally administering**” refers to providing a compound by entering the blood or body through the dermis, or skin, of an organism. In one embodiment, transdermally administering comprises applying a composition to the skin of an organism, e.g., applying a topical composition, applying a liquid composition, etc. In one embodiment, **transdermally administering a composition comprises applying a patch** embedded with the composition to the skin of an organism.”

From **[0007]** “Formulated and administered correctly, **psilocin** and psilocybin provide fast-acting and long-lasting changes to a person's mood. These effects can be accomplished with only minor side effects, low potential for addiction, low potential for abuse, and low risk of toxicity.”

From **[0027]** “In one embodiment, the methods disclosed herein comprise administering the compositions disclosed herein. In one embodiment, the methods disclosed herein comprise treating a psychological disorder, e.g., an anxiety disorder, a compulsive disorder, a depressive disorder, etc., with **the compositions disclosed herein, e.g., a composition with one or more psilocybin derivatives, a composition with one or more cannabinoids, a composition with one or more terpenes, and/or a combination thereof...**”

	<p>From [0291] “In one embodiment, the methods and compositions disclosed herein comprise an antioxidant.”</p>
<p>20. The monolithic-type dermal patch of claim 13, wherein the skin adhesive an amine-compatible silicone adhesive.</p>	<p>2. U.S. Pat. App. Pub. No. 2019/0110981 “Cannabinoid Patch” (Published April 18, 2019)</p> <p>From [0090] “In embodiments, what can be excluded is an adhesive polymer, or a device comprising an adhesive polymer, where the adhesive polymer reacts with amines...”</p> <p>From [0032] “In methods of manufacturing embodiments, monolith patch can be made as follows. Cannabis oil or one or more pure cannabinoids can be combined with permeation enhancers such as oleic acid and dodecylmethyl sulfoxide. Then one or more pure terpenes, or an essential oil, or a combination of an essential oil and one or more pure terpenes, is mixed with the above combination. Then, a pressure sensitive adhesive such as silicone adhesive BIO PSA 7-4302 (Dow Corning), or other suitable ones are mixed in...”</p> <p>From [0003] “Dermal patches can take the form of a monolithic-style patch or a reservoir-style patch (see, US 2017/0071870 of Weimann, which is hereby incorporated herein in its entirety). Monolithic-style patch can take the form of a sandwich, where the face that is exposed to the atmosphere is a backing, where the opposite face is a release liner, and where the filling of the sandwich is a matrix that includes an adhesive and a pharmaceutical agent such as a drug or nutraceutical. Prior to applying the patch to the skin, a release liner is removed and discarded.”</p> <p>From claim 1 “A composition capable of use in a buccal patch, a dermal patch, or a sublingual patch, tablet, capsule, pill, or strip, wherein the composition comprises one or more of: (a) An acrylic adhesive with non-functionality and an adhesive with only OH-functionality, further comprising one of more of enhancers selected from azone, oleic acid, and dimethylsulfoxide (DMSO);...”</p> <p>3. U.S. Pat. App. Pub. No. 2021/0085671 “COMPOSITIONS AND METHODS COMPRISING A COMBINATION OF SEROTONERGIC DRUGS” (Published March 25, 2021)</p> <p>From [0343] “In one embodiment, the methods disclosed herein comprise transdermally administering a composition.”</p> <p>From [0344] “As used herein, the term “transdermally administering”</p>

	<p>refers to providing a compound by entering the blood or body through the dermis, or skin, of an organism. In one embodiment, transdermally administering comprises applying a composition to the skin of an organism, e.g., applying a topical composition, applying a liquid composition, etc. In one embodiment, transdermally administering a composition comprises applying a patch embedded with the composition to the skin of an organism.”</p> <p>From [0007] “Formulated and administered correctly, psilocin and psilocybin provide fast-acting and long-lasting changes to a person's mood. These effects can be accomplished with only minor side effects, low potential for addiction, low potential for abuse, and low risk of toxicity.”</p> <p>From [0027] “In one embodiment, the methods disclosed herein comprise administering the compositions disclosed herein. In one embodiment, the methods disclosed herein comprise treating a psychological disorder, e.g., an anxiety disorder, a compulsive disorder, a depressive disorder, etc., with the compositions disclosed herein, e.g., a composition with one or more psilocybin derivatives, a composition with one or more cannabinoids, a composition with one or more terpenes, and/or a combination thereof...”</p> <p>From [0291] “In one embodiment, the methods and compositions disclosed herein comprise an antioxidant.”</p>
<p>21. The monolithic-type dermal patch of claim 13, that comprises a penetration enhancer, and wherein said penetration enhancer comprises one or more of oleic acid, isopropyl palmitate (IPP), DMSO, 1,2 propylene glycol, and isopropyl myristate (IPM).</p>	<p>1. U.S. Pat. App. Pub. No. 2018/0325851 “Transdermally-Delivered Combination Drug Therapy for Pain” (Published November 15, 2018)</p> <p>From [0079] “In some embodiments, the formulation can also include solvents, excipients, preservatives, skin conditions, emulsifiers, carriers, polymers, thickeners, phospholipids, fatty acids, cholesterol, complex lipids, prostaglandins, vitamins and vitamin derivatives, antioxidants, humectants, surfactants. Other components may be included in the pharmaceutical preparation that promote passive dermal penetration of chemicals and pharmaceuticals, including urea, organic solvents, such as dimethyl sulfoxide (DMSO), and others. Yet additional components include excipients or carriers such as, without limitation, water, Stearyl Alcohol, Polysorbate 20, Caprylic/Capric Glyceride, Petrolatum, Beeswax, Lecithin, Dimethicone, Alkylmethyl Siloxane, Stearic Acid, Palmitic Acid, Lanolin, Linoleic Acid, Isopropyl Myristate, Stearyl Octanoate and Cetyl Octanoate, and Polysorbate 80.”</p> <p>From [0077] “In further embodiment, the formulation described herein comprises a penetration enhancer. By “penetration enhancer” is meant a compound, particle, or other substance or material that when included in a</p>

	<p>formulation that is applied topically to the skin or to the tissue surface, increases the rate or amount of transport of an active ingredient in the formulation past the cells (living or dead) of the epidermis. Non-limiting examples of penetration enhancers include individual fatty acids, fatty acid esters, polyols, amides, various anionic, cationic and nonionic surfactants such as but not limited to sodium laurate and sodium lauryl sulfate, phospholipids, cholesterol and cholesterol derivatives, m-pyrrole, dimethyl acetamide, limonene, sphingolipids, ceramides, terpenes, alkanones, menthol, various organic acids, such as but not limited to salicylic acid, citric and succinic acid, prostaglandin, decyl methyl sulfoxide, urea, sulfoxide alcohols, plant extract oils. Suitable fatty acids include without limitation: linoleic acids, linolenic acids, oleic acids, stearic acids, and myristic acids. Phospholipids include without limitation: phosphatidylcholine, phosphatidylethanolamine, and phosphatidylserine. Plant extract oils include oils of peanut, hemp, borage, olive, sunflower, soybean, monoi and macadamia. The plant extract oil can be mixed with an alcohol such as ethyl alcohol, isopropyl alcohol, and methyl alcohol.”</p>
<p>22. The monolithic-type dermal patch of claim 21, wherein the amount of penetration enhancer preferably ranges from zero to about ten percent by weight of the matrix.</p>	<p>1. U.S. Pat. App. Pub. No. 2018/0325851 “Transdermally-Delivered Combination Drug Therapy for Pain” (Published November 15, 2018)</p> <p>From [0057] “In some embodiments, the compositions described herein may include one or more excipients selected from among the following: a tonicity enhancer, a preservative, a solubilizer, a viscosity enhancing agent, a demulcent, an emulsifier, a wetting agent, a sequestering agent, and a filler. The amount and type of excipient added is in accordance with the particular requirements of the composition and is generally present in the composition at a concentration of between about 0.0001% to 99% w/v, or between about 0.01% to 95% w/v, or between about 0.1% to 90% w/v, or between about 1% to about 75% w/v.</p> <p>From [0079] “In some embodiments, the formulation can also include solvents, excipients, preservatives, skin conditions, emulsifiers, carriers, polymers, thickeners, phospholipids, fatty acids, cholesterol, complex lipids, prostaglandins, vitamins and vitamin derivatives, antioxidants, humectants, surfactants. Other components may be included in the pharmaceutical preparation that promote passive dermal penetration of chemicals and pharmaceuticals, including urea, organic solvents, such as dimethyl sulfoxide (DMSO), and others. Yet additional components include excipients or carries such as, without limitation, water, Stearyl Alcohol, Polysorbate 20, Caprylic/Capric Glyceride, Petrolatum, Beeswax, Lecithin, Dimethicone, Alkylmethyl Siloxane, Stearic Acid, Palmitic Acid, Lanolin, Linoleic Acid, Isopropyl Myristate, Stearyl Octanoate and Cetyl Octanoate, and Polysorbate 80.”</p>

From [0077] “In further embodiment, the formulation described herein comprises a penetration enhancer. By “**penetration enhancer**” is meant a compound, particle, or other substance or material that when included in a formulation that is applied topically to the skin or to the tissue surface, increases the rate or amount of transport of an active ingredient in the formulation past the cells (living or dead) of the epidermis. Non-limiting examples of penetration enhancers include individual fatty acids, fatty acid esters, polyols, amides, various anionic, cationic and nonionic surfactants such as but not limited to sodium laurate and sodium lauryl sulfate, phospholipids, cholesterol and cholesterol derivatives, m-pyrrole, dimethyl acetamide, limonene, sphingolipids, ceramides, terpenes, alkanones, menthol, various organic acids, such as but not limited to salicylic acid, citric and succinic acid, prostaglandin, decyl methyl sulfoxide, urea, sulfoxide alcohols, plant extract oils. Suitable fatty acids include without limitation: linoleic acids, linolenic acids, **oleic acids**, stearic acids, and myristic acids. Phospholipids include without limitation: phosphatidylcholine, phosphatidylethanolamine, and phosphatidylserine. Plant extract oils include oils of peanut, hemp, borage, olive, sunflower, soybean, monoi and macadamia. The plant extract oil can be mixed with an alcohol such as ethyl alcohol, isopropyl alcohol, and methyl alcohol.”



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APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
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Title of Invention

Application Information

APPLICATION TYPE	PATENT #
CONFIRMATION #	FILED BY Sisi Li
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CUSTOMER # -	FIRST NAMED INVENTOR
CORRESPONDENCE ADDRESS -	AUTHORIZED BY -

Documents

TOTAL DOCUMENTS: 12

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
third-party-preissuance-submission.pdf	2	Third-Party Submission Under 37 CFR 1.290	45 KB
Concise-description-generated.pdf	2	Concise Description of Relevance	26 KB
Third-party-notification-request.pdf	1	Request for Notification of Non-compliant Third-Party Submission	13 KB
Claims_Chart.pdf	32	-	368 KB
Claims_Chart-3P.RELEVANCE.pdf	(1-32) 32	Concise Description of Relevance	288 KB
Claims_Chart-3P.RELEVANCE.pdf	(1-32) 32	Concise Description of Relevance	288 KB
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Claims_Chart-3P.RELEVANCE.pdf	(1-32)	32	Concise Description of Relevance	288 KB

Digest

DOCUMENT

MESSAGE DIGEST(SHA-512)

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Claims_Chart-3P.RELEVANCE.pdf	8917F3C2A8F8AFA9D86009F8F113A1553B0439466620F852E37084724FA99F5E9CA202945807D8A06E35A8C74AE41FCEE5BD7C26B175E1172BDB3FE677D18DFA
Claims_Chart-3P.RELEVANCE.pdf	D26FF4B9130111CAFFABB839D5A0363618BF8568BE4E0A0EEC85141A8C8A7514C8AC27AF8E8982C40456ED483C36AD83151016B6EDE2A871397C98234B31CCF6
Claims_Chart-3P.RELEVANCE.pdf	DA9AD306478F4214952285E93209D3BF6A3EA94462CDCE62157EC15D229C64A2C10E9C1FA34102FC85D5685A5F8FB1F04FA8F6545C38622FE363B5DB6EADA603
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Claims_Chart- 3P.RELEVANCE.pdf	4688C8F7C2D2EEFFDE99C2DFC2D7E390F6DAFCB8567565F CDA4AF2AD9CCF2F2166EEBE3AFE629D6E0562766ECF47CE 89DFBD852C4788FA590EDE7EEF4791D6ED
Claims_Chart- 3P.RELEVANCE.pdf	755A1D9FAA333F4AB6D515428CCCD52C0BF4C506B812FCCA 38276202E3DFCBBC7EC6B572AF71EA95351FCA2325D9C19C B788F73A9EB75A243E398C72F825B710
Claims_Chart- 3P.RELEVANCE.pdf	D39C2406095D363CE3039DFF1BD26C74F35D6396B15F6EFF6 FA8B2BA2A1E01A3B0997E55C82F7BE1CA5BDD08F6C4CA434 7FA572F2CD0B04E37E369A583BCCC22
Claims_Chart- 3P.RELEVANCE.pdf	48753BD6594B655BF5FDCDC8F61977CE5A22C8F5201B0D8B 6FD01481518B1F05FC8208C661D9AF6B519481DA2194900431 41019D6B853F8E32C20921930B6410
Claims_Chart- 3P.RELEVANCE.pdf	A52F2926744872D09ED42F87376384C02EBA32C3F7E423EEE 44F4593B92B2820316D1EA84A62CBA49899FFF28FF4F40E599 F9898A425533B7E0CA7895BD96C68

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

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

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