IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Complex Matrix Solutions	Confirmation No.: 5748
Serial No.:	18/467,857	Group No.:
Filing or 371(c) Date:	September 15, 2023	Examiner:

Entitled: Oral soft gel capsule containing psychedelic compound

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. US Pat. No. 9,433,625 “Pharmaceutical compositions for treating or preventing pain” (Published September 6, 2016)
2. US Pat. No. 4,800,083 “Sustained release method and product” (Published January 24, 1989)
3. US Pat. No. 11,590,120 “Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin” (Published January 25, 2018)
4. LYONS (2018) “More Realistic Forecasting of Future Life Events After Psilocybin for Treatment-Resistant Depression” Frontiers in Psychology. Vol #8

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

U.S.S.N. 18/467,857 Pending Claims	References
1. A method comprising orally administering to a subject an oral soft gel capsule comprising: (i) a capsule shell formed from the plasticizer glycerin, sorbitol, or combination thereof; the solvent water, and at least one of gelatin, cellulose, hypromellose, vegetable starch, tapioca starch, carrageenan, potato starch, cassava starch, cornstarch, and arrowroot; (ii) a psychedelic compound comprising at least one of psilocybin, psilocin, and baeocystin; and (iii) liquid vehicle comprising one or more oils; wherein, the psilocybin, psilocin, baeocystin, or combination thereof is present in a combined amount of 0.01 to 5 mg, the psilocybin, psilocin, baeocystin, or combination thereof has a purity of at least 99 wt. % pure, the psilocybin, psilocin, baeocystin, or combination thereof is obtained from the genera Copelandia, Gymnopilis, Inocybe, Micena, Panaeolus,	1. US Pat. No. 9,433,625 "Pharmaceutical compositions for treating or preventing pain" (Published September 6, 2016) From **Exemplary Routes of Administration: In any of the embodiments disclosed herein, a composition of the invention can be administered using one or more different dosage forms which are further described herein.** For example, a composition comprising multiple active agents can be administered in solid, semi-solid, micro-emulsion, gel, patch or liquid form. **Such dosage forms are further described herein. Examples of such dosage forms are known in the art. For example, the tablet forms disclosed in... U.S. Pat. Nos. 4,800,083,** From **Exemplary Intravenous and Liquid Dosage Forms:** "The compositions described herein can also be in liquid or liquid tannate form. **The liquid formulations can comprise, for example,** an agent in water-in-Solution and/or Suspension form; and **a vehicle comprising polyethoxylated castor oil**, alcohol and/or a polyoxyethylated Sorbitan mono-oleate with or without flavoring." (Column 43 Line 28) From **Description**: **In some embodiments, the invention is directed to the combination of an effective amount of an opioid with an effective amount of least one other active ingredient.** From **Description**: **In some embodiments, another active agent in combination with the opioid analgesic or triptan analgesic** are beta blockers, **serotonin receptor agonists** From **Description**: **Non-limiting examples of serotonin receptor agonists useful in the present invention include** buspirone, mescaline, **psilocybin**, cisapride, triptans, and lysergic acid diethylamide. From **Description, Column 9, Line 13: In specific embodiments of the invention disclosed herein, each active agent in the composition is administered in a dosage of about 0.01 mg to 500 mg per kg body weight** per day, e.g. about 20 mg/day for an average person. In some embodiments, dosage for each active agent in the composition is from about **0.01 to 5 mg,** 1 to 10 mg, 5 to 20 mg. 10 to 50 mg, 20 to 100 mg, 50 to 150 mg, 100 to 250 mg, 150 to 300 mg, 250 to 500 mg,300 to 600 mg or 500 to 1000 ng. From **Description**: **To prepare the compositions of the present invention, an effective amount of active agents can be mixed with a suitable pharmaceutically acceptable carrier. Upon mixing of the compounds, the resulting composition can be a** solid, a half-solid, a **solution, suspension,** or an emulsion

Pholiotina, Pluteus, or Psilocybe; the liquid vehicle is compatible with the capsule shell; the liquid vehicle effectively dissolves and/or suspends the psychedelic compound; and the psychedelic compound and the liquid vehicle are contained within the capsule shell.	From **Description**: **In another embodiment the compositions described herein comprise** an opioid agent, **a non opioid agent** and an antiemetic agent, **where each agent can have a purity of 90-100% by weight.** 2. US Pat. No. 4,800,083 "Sustained release method and product" (Published January 24, 1989) From **Description**: **In a preferred aspect of the present invention, the fill material is filled into a soft elastic gelatin shell which encloses the fill material, including the drug,** which does not attack the walls of the seamless, one piece soft elastic gelatin capsule. **The gelatin capsule shell is formulated in accordance with conventional techniques for masking filled, seamless, soft elastic gelatin capsules containing therapeutically effective unit dosage amounts of an active drug ingredient. In one conventional shell formulation, there is included about 30-53 parts by weight of gelatin, about 15-48 parts by weight of a plasticizer, such as glycerin or sorbitol, and about 16-40 parts by weight of water.** From **Description: Thus, the fill material comprises, as its essential components, the desired drug** and the masticatory substance**. Other materials**, such as paraffin, **mineral oil, neutral oils, and the like may be added to the fill material in order to attain the desired consistency of the fill material for filling purposes,** that is, for **filling of the fill material into a gelatin capsule, preferably a soft elastic gelatin capsule** 3. US Pat. No. 11,590,120 "Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin" (Published January 25, 2018) From **[0021]**: **Light stimulation triggers the production of psilocybin and psilocin in the mycelium of, for instance Psilocybe azurescens, Psilocybe cyanescens and Psilocybe cubensis**, possibly by stimulation of the enzymatic reactions.
2. The method of claim 1, which is a method comprising improving creativity, boosting physical energy level, attaining emotional balance, increasing performance on problems-solving tasks, treating anxiety, treating depression, treating addiction, or any combination thereof.	1. US Pat. No. 9,433,625 "Pharmaceutical compositions for treating or preventing pain" (Published September 6, 2016) From **Exemplary Routes of Administration: In any of the embodiments disclosed herein, a composition of the invention can be administered using one or more different dosage forms which are further described herein.** For example, a composition comprising multiple active agents can be administered in solid, semi-solid, micro-emulsion, gel, patch or liquid form. **Such dosage forms are further described herein. Examples of such dosage forms are known in the art. For example, the tablet forms disclosed in... U.S. Pat. Nos. 4,800,083,** From **Exemplary Intravenous and Liquid Dosage Forms:** "The compositions described herein can also be in liquid or liquid tannate form.

	The liquid formulations can comprise, for example, an agent in water-in-Solution and/or Suspension form; and **a vehicle comprising polyethoxylated castor oil**, alcohol and/or a polyoxyethylated Sorbitan mono-oleate with or without flavoring." (Column 43 Line 28) From **Description**: **In some embodiments, the invention is directed to the combination of an effective amount of an opioid with an effective amount of least one other active ingredient.** From **Description**: **In some embodiments, another active agent in combination with the opioid analgesic or triptan analgesic** are beta blockers, **serotonin receptor agonists** From **Description**: **Non-limiting examples of serotonin receptor agonists useful in the present invention include** buspirone, mescaline, **psilocybin**, cisapride, triptans, and lysergic acid diethylamide. From **Description, Column 9, Line 13: In specific embodiments of the invention disclosed herein, each active agent in the composition is administered in a dosage of about 0.01 mg to 500 mg per kg body weight** per day, e.g. about 20 mg/day for an average person. In some embodiments, dosage for each active agent in the composition is from about **0.01 to 5 mg,** 1 to 10 mg, 5 to 20 mg. 10 to 50 mg, 20 to 100 mg, 50 to 150 mg, 100 to 250 mg, 150 to 300 mg, 250 to 500 mg,300 to 600 mg or 500 to 1000 ng. From **Description**: **To prepare the compositions of the present invention, an effective amount of active agents can be mixed with a suitable pharmaceutically acceptable carrier. Upon mixing of the compounds, the resulting composition can be a** solid, a half-solid, a **solution, suspension,** or an emulsion From **Description**: **In another embodiment the compositions described herein comprise** an opioid agent, **a non opioid agent** and an antiemetic agent, **where each agent can have a purity of 90-100% by weight.** 2. US Pat. No. 4,800,083 "Sustained release method and product" (Published January 24, 1989) From **Description**: **In a preferred aspect of the present invention, the fill material is filled into a soft elastic gelatin shell which encloses the fill material, including the drug,** which does not attack the walls of the seamless, one piece soft elastic gelatin capsule. **The gelatin capsule shell is formulated in accordance with conventional techniques for masking filled, seamless, soft elastic gelatin capsules containing therapeutically effective unit dosage amounts of an active drug ingredient. In one conventional shell formulation, there is included about 30-53 parts by weight of gelatin, about 15-48 parts by weight of a plasticizer, such as glycerin or sorbitol, and about 16-40 parts by weight of water.**

	From **Description: Thus, the fill material comprises, as its essential components, the desired drug** and the masticatory substance**. Other materials**, such as paraffin, **mineral oil, neutral oils, and the like may be added to the fill material in order to attain the desired consistency of the fill material for filling purposes,** that is, for **filling of the fill material into a gelatin capsule, preferably a soft elastic gelatin capsule** 3. US Pat. No. 11,590,120 "Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin" (Published January 25, 2018) From **[0021]**: **Light stimulation triggers the production of psilocybin and psilocin in the mycelium of, for instance Psilocybe azurescens, Psilocybe cyanescens and Psilocybe cubensis**, possibly by stimulation of the enzymatic reactions. 4. LYONS (2018) "More Realistic Forecasting of Future Life Events After Psilocybin for Treatment-Resistant Depression" Frontiers in Psychology. Vol #8 From **Introduction**: Randomized controlled trials (RCTs) have demonstrated that **psilocybin can rapidly alleviate depression and anxiety in patients with life-threatening cancer**
3. The method of claim 1, which is a method comprising treating at least one of obsessive compulsive disorder (OCD), pain, irritability, fibromyalgia, post-traumatic stress disorder (PTSD), cluster headaches, paranoia, psychosis, anxiety, panic attacks, flashbacks, smoking addiction, alcohol addiction, and cocaine addiction.	1. US Pat. No. 9,433,625 "Pharmaceutical compositions for treating or preventing pain" (Published September 6, 2016) From **Description**: **The present compositions and methods are useful for treating or preventing a headache. Preventable or treatable headaches include but are not limited to** migraine headaches (with or without aura), **cluster headaches...** From **Exemplary Routes of Administration: In any of the embodiments disclosed herein, a composition of the invention can be administered using one or more different dosage forms which are further described herein.** For example, a composition comprising multiple active agents can be administered in solid, semi-solid, micro-emulsion, gel, patch or liquid form. **Such dosage forms are further described herein. Examples of such dosage forms are known in the art. For example, the tablet forms disclosed in... U.S. Pat. Nos. 4,800,083,** From **Exemplary Intravenous and Liquid Dosage Forms:** "The compositions described herein can also be in liquid or liquid tannate form. **The liquid formulations can comprise, for example,** an agent in water-in-Solution and/or Suspension form; and **a vehicle comprising polyethoxylated castor oil**, alcohol and/or a polyoxyethylated Sorbitan mono-oleate with or without flavoring." (Column 43 Line 28)

	From **Description**: **In some embodiments, the invention is directed to the combination of an effective amount of an opioid with an effective amount of least one other active ingredient.** From **Description**: **In some embodiments, another active agent in combination with the opioid analgesic or triptan analgesic** are beta blockers, **serotonin receptor agonists** From **Description**: **Non-limiting examples of serotonin receptor agonists useful in the present invention include** buspirone, mescaline, **psilocybin**, cisapride, triptans, and lysergic acid diethylamide. From **Description, Column 9, Line 13: In specific embodiments of the invention disclosed herein, each active agent in the composition is administered in a dosage of about 0.01 mg to 500 mg per kg body weight** per day, e.g. about 20 mg/day for an average person. In some embodiments, dosage for each active agent in the composition is from about 0.01 to 5 mg, 1 to 10 mg, 5 to 20 mg. 10 to 50 mg, 20 to 100 mg, 50 to 150 mg, 100 to 250 mg, 150 to 300 mg, 250 to 500 mg,300 to 600 mg or 500 to 1000 ng. From **Description**: **To prepare the compositions of the present invention, an effective amount of active agents can be mixed with a suitable pharmaceutically acceptable carrier. Upon mixing of the compounds, the resulting composition can be a** solid, a half-solid, a **solution, suspension,** or an emulsion From **Description**: **In another embodiment the compositions described herein comprise** an opioid agent, **a non opioid agent** and an antiemetic agent, **where each agent can have a purity of 90-100% by weight.** 2. US Pat. No. 4,800,083 “Sustained release method and product” (Published January 24, 1989) From **Description**: **In a preferred aspect of the present invention, the fill material is filled into a soft elastic gelatin shell which encloses the fill material, including the drug,** which does not attack the walls of the seamless, one piece soft elastic gelatin capsule. **The gelatin capsule shell is formulated in accordance with conventional techniques for masking filled, seamless, soft elastic gelatin capsules containing therapeutically effective unit dosage amounts of an active drug ingredient. In one conventional shell formulation, there is included about 30-53 parts by weight of gelatin, about 15-48 parts by weight of a plasticizer, such as glycerin or sorbitol, and about 16-40 parts by weight of water.** From **Description: Thus, the fill material comprises, as its essential components, the desired drug** and the masticatory substance**. Other materials**, such as paraffin, **mineral oil, neutral oils, and the like may be**

	added to the fill material in order to attain the desired consistency of the fill material for filling purposes, that is, for **filling of the fill material into a gelatin capsule, preferably a soft elastic gelatin capsule** 3. US Pat. No. 11,590,120 "Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin" (Published January 25, 2018) From **[0021]**: **Light stimulation triggers the production of psilocybin and psilocin in the mycelium of, for instance Psilocybe azurescens, Psilocybe cyanescens and Psilocybe cubensis**, possibly by stimulation of the enzymatic reactions.
4. The method of claim 1, wherein 1-5 oral soft gel capsules are orally administered a day.	1. US Pat. No. 9,433,625 "Pharmaceutical compositions for treating or preventing pain" (Published September 6, 2016) From **Column 27, Line 10**: "**In one embodiment, compositions described herein are administered to a subject at about every 4 to about 6 hours, about every 8 hours, about every 12 hours, or about every 24 hours. In one embodiment, a composition of the invention is administered once daily.**" From **Exemplary Routes of Administration: In any of the embodiments disclosed herein, a composition of the invention can be administered using one or more different dosage forms which are further described herein.** For example, a composition comprising multiple active agents can be administered in solid, semi-solid, micro-emulsion, gel, patch or liquid form. **Such dosage forms are further described herein. Examples of such dosage forms are known in the art. For example, the tablet forms disclosed in... U.S. Pat. Nos. 4,800,083,** From **Exemplary Intravenous and Liquid Dosage Forms:** "The compositions described herein can also be in liquid or liquid tannate form. **The liquid formulations can comprise, for example,** an agent in water-in-Solution and/or Suspension form; and **a vehicle comprising polyethoxylated castor oil**, alcohol and/or a polyoxyethylated Sorbitan mono-oleate with or without flavoring." (Column 43 Line 28) From **Description**: **In some embodiments, the invention is directed to the combination of an effective amount of an opioid with an effective amount of least one other active ingredient.** From **Description**: **In some embodiments, another active agent in combination with the opioid analgesic or triptan analgesic** are beta blockers, **serotonin receptor agonists**

	From **Description**: **Non-limiting examples of serotonin receptor agonists useful in the present invention include** buspirone, mescaline, **psilocybin**, cisapride, triptans, and lysergic acid diethylamide. From **Description, Column 9, Line 13: In specific embodiments of the invention disclosed herein, each active agent in the composition is administered in a dosage of about 0.01 mg to 500 mg per kg body weight** per day, e.g. about 20 mg/day for an average person. In some embodiments, dosage for each active agent in the composition is from about 0.01 to 5 mg, 1 to 10 mg, 5 to 20 mg. 10 to 50 mg, 20 to 100 mg, 50 to 150 mg, 100 to 250 mg, 150 to 300 mg, 250 to 500 mg,300 to 600 mg or 500 to 1000 ng. From **Description**: **To prepare the compositions of the present invention, an effective amount of active agents can be mixed with a suitable pharmaceutically acceptable carrier. Upon mixing of the compounds, the resulting composition can be a** solid, a half-solid, a **solution, suspension,** or an emulsion From **Description**: **In another embodiment the compositions described herein comprise** an opioid agent, **a non opioid agent** and an antiemetic agent, **where each agent can have a purity of 90-100% by weight.** 2. US Pat. No. 4,800,083 "Sustained release method and product" (Published January 24, 1989) From **Description**: **In a preferred aspect of the present invention, the fill material is filled into a soft elastic gelatin shell which encloses the fill material, including the drug,** which does not attack the walls of the seamless, one piece soft elastic gelatin capsule. **The gelatin capsule shell is formulated in accordance with conventional techniques for masking filled, seamless, soft elastic gelatin capsules containing therapeutically effective unit dosage amounts of an active drug ingredient. In one conventional shell formulation, there is included about 30-53 parts by weight of gelatin, about 15-48 parts by weight of a plasticizer, such as glycerin or sorbitol, and about 16-40 parts by weight of water.** From **Description: Thus, the fill material comprises, as its essential components, the desired drug** and the masticatory substance**. Other materials**, such as paraffin, **mineral oil, neutral oils, and the like may be added to the fill material in order to attain the desired consistency of the fill material for filling purposes,** that is, for **filling of the fill material into a gelatin capsule, preferably a soft elastic gelatin capsule** 3. US Pat. No. 11,590,120 "Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin" (Published January 25, 2018)

	From **[0021]**: **Light stimulation triggers the production of psilocybin and psilocin in the mycelium of, for instance Psilocybe azurescens, Psilocybe cyanescens and Psilocybe cubensis**, possibly by stimulation of the enzymatic reactions.
5. The method of claim 1, wherein the psilocybin, psilocin, baeocystin, or combination thereof is delivered enterally.	*From the application of interest 18/467,857 "The term "**enteral administration" refers to a drug administration via the human gastrointestinal tract.** Enteral administration involves the esophagus, stomach, and small and large intestines (i.e., the gastrointestinal tract). **Methods of administration include oral** and rectal. Enteral administration may be divided into three different categories, depending on the entrance point into the GI tract: **oral (by mouth),** gastric (through the stomach), and rectal (from the rectum)."* 1. US Pat. No. 9,433,625 "Pharmaceutical compositions for treating or preventing pain" (Published September 6, 2016) From **Description**: **In various embodiments, the active agents are formulated to be administered through oral dosage forms** (e.g., tablets, capsules, gels, lollipops), inhalations, nasal sprays, patches, absorbing gels, liquids, liquid tannates, suppositories, injections, I.V. drips, other delivery methods, or a combination thereof to treat subjects. From **Exemplary Routes of Administration: In any of the embodiments disclosed herein, a composition of the invention can be administered using one or more different dosage forms which are further described herein.** For example, a composition comprising multiple active agents can be administered in solid, semi-solid, micro-emulsion, gel, patch or liquid form. **Such dosage forms are further described herein. Examples of such dosage forms are known in the art. For example, the tablet forms disclosed in... U.S. Pat. Nos. 4,800,083,** From **Exemplary Intravenous and Liquid Dosage Forms:** "The compositions described herein can also be in liquid or liquid tannate form. **The liquid formulations can comprise, for example,** an agent in water-in-Solution and/or Suspension form; and **a vehicle comprising polyethoxylated castor oil**, alcohol and/or a polyoxyethylated Sorbitan mono-oleate with or without flavoring." (Column 43 Line 28) From **Description**: **In some embodiments, the invention is directed to the combination of an effective amount of an opioid with an effective amount of least one other active ingredient.** From **Description**: **In some embodiments, another active agent in combination with the opioid analgesic or triptan analgesic** are beta blockers, **serotonin receptor agonists**

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6. The method of claim 1, wherein the psilocybin, psilocin, baeocystin, or combination thereof is present in a combined amount of 0.05 to 2.5 mg.	1. US Pat. No. 9,433,625 "Pharmaceutical compositions for treating or preventing pain" (Published September 6, 2016) From **Exemplary Routes of Administration: In any of the embodiments disclosed herein, a composition of the invention can be administered using one or more different dosage forms which are further described herein.** For example, a composition comprising multiple active agents can be administered in solid, semi-solid, micro-emulsion, gel, patch or liquid form. **Such dosage forms are further described herein. Examples of such dosage forms are known in the art. For example, the tablet forms disclosed in... U.S. Pat. Nos. 4,800,083,** From **Exemplary Intravenous and Liquid Dosage Forms:** "The compositions described herein can also be in liquid or liquid tannate form. **The liquid formulations can comprise, for example,** an agent in water-in-Solution and/or Suspension form; and **a vehicle comprising polyethoxylated castor oil**, alcohol and/or a polyoxyethylated Sorbitan mono-oleate with or without flavoring." (Column 43 Line 28) From **Description**: **In some embodiments, the invention is directed to the combination of an effective amount of an opioid with an effective amount of least one other active ingredient.** From **Description**: **In some embodiments, another active agent in combination with the opioid analgesic or triptan analgesic** are beta blockers, **serotonin receptor agonists** From **Description**: **Non-limiting examples of serotonin receptor agonists useful in the present invention include** buspirone, mescaline, **psilocybin**, cisapride, triptans, and lysergic acid diethylamide. From **Description, Column 9, Line 13: In specific embodiments of the invention disclosed herein, each active agent in the composition is administered in a dosage of about 0.01 mg to 500 mg per kg body weight** per day, e.g. about 20 mg/day for an average person. **In some embodiments, dosage for each active agent in the composition is from about 0.01 to 5 mg,** 1 to 10 mg, 5 to 20 mg. 10 to 50 mg, 20 to 100 mg, 50 to 150 mg, 100 to 250 mg, 150 to 300 mg, 250 to 500 mg,300 to 600 mg or 500 to 1000 ng. From **Description**: **To prepare the compositions of the present invention, an effective amount of active agents can be mixed with a suitable pharmaceutically acceptable carrier. Upon mixing of the compounds,**

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7. The method of claim 1, wherein the psilocybin, psilocin, baeocystin, or combination thereof is present in a combined amount of 0.05 to 1 mg.	1. US Pat. No. 9,433,625 "Pharmaceutical compositions for treating or preventing pain" (Published September 6, 2016) From **Exemplary Routes of Administration: In any of the embodiments disclosed herein, a composition of the invention can be administered using one or more different dosage forms which are further described herein.** For example, a composition comprising multiple active agents can be administered in solid, semi-solid, micro-emulsion, gel, patch or liquid form. **Such dosage forms are further described herein. Examples of such dosage forms are known in the art. For example, the tablet forms disclosed in... U.S. Pat. Nos. 4,800,083,**

	From **Exemplary Intravenous and Liquid Dosage Forms:** "The compositions described herein can also be in liquid or liquid tannate form. **The liquid formulations can comprise, for example,** an agent in water-in-Solution and/or Suspension form; and **a vehicle comprising polyethoxylated castor oil**, alcohol and/or a polyoxyethylated Sorbitan mono-oleate with or without flavoring." (Column 43 Line 28) From **Description**: **In some embodiments, the invention is directed to the combination of an effective amount of an opioid with an effective amount of least one other active ingredient.** From **Description**: **In some embodiments, another active agent in combination with the opioid analgesic or triptan analgesic** are beta blockers, **serotonin receptor agonists** From **Description**: **Non-limiting examples of serotonin receptor agonists useful in the present invention include** buspirone, mescaline, **psilocybin**, cisapride, triptans, and lysergic acid diethylamide. From **Description, Column 9, Line 13: In specific embodiments of the invention disclosed herein, each active agent in the composition is administered in a dosage of about 0.01 mg to 500 mg per kg body weight** per day, e.g. about 20 mg/day for an average person. **In some embodiments, dosage for each active agent in the composition is from about 0.01 to 5 mg,** 1 to 10 mg, 5 to 20 mg. 10 to 50 mg, 20 to 100 mg, 50 to 150 mg, 100 to 250 mg, 150 to 300 mg, 250 to 500 mg,300 to 600 mg or 500 to 1000 ng. From **Description**: **To prepare the compositions of the present invention, an effective amount of active agents can be mixed with a suitable pharmaceutically acceptable carrier. Upon mixing of the compounds, the resulting composition can be a** solid, a half-solid, a **solution, suspension,** or an emulsion From **Description**: **In another embodiment the compositions described herein comprise** an opioid agent, **a non opioid agent** and an antiemetic agent, **where each agent can have a purity of 90-100% by weight.** 2. US Pat. No. 4,800,083 "Sustained release method and product" (Published January 24, 1989) From **Description**: **In a preferred aspect of the present invention, the fill material is filled into a soft elastic gelatin shell which encloses the fill material, including the drug,** which does not attack the walls of the seamless, one piece soft elastic gelatin capsule. **The gelatin capsule shell is formulated in accordance with conventional techniques for masking filled, seamless, soft elastic gelatin capsules containing therapeutically effective unit dosage amounts of an active drug ingredient. In one**

	conventional shell formulation, there is included about 30-53 parts by weight of gelatin, about 15-48 parts by weight of a plasticizer, such as glycerin or sorbitol, and about 16-40 parts by weight of water. From **Description: Thus, the fill material comprises, as its essential components, the desired drug** and the masticatory substance**. Other materials**, such as paraffin, **mineral oil, neutral oils, and the like may be added to the fill material in order to attain the desired consistency of the fill material for filling purposes,** that is, for **filling of the fill material into a gelatin capsule, preferably a soft elastic gelatin capsule** 3. US Pat. No. 11,590,120 "Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin" (Published January 25, 2018) From **[0021]**: **Light stimulation triggers the production of psilocybin and psilocin in the mycelium of, for instance Psilocybe azurescens, Psilocybe cyanescens and Psilocybe cubensis**, possibly by stimulation of the enzymatic reactions.
8. The method of claim 1, wherein the psilocybin, psilocin, baeocystin, or combination thereof is present in a combined amount of 0.1 to 1 mg.	1. US Pat. No. 9,433,625 "Pharmaceutical compositions for treating or preventing pain" (Published September 6, 2016) From **Exemplary Routes of Administration: In any of the embodiments disclosed herein, a composition of the invention can be administered using one or more different dosage forms which are further described herein.** For example, a composition comprising multiple active agents can be administered in solid, semi-solid, micro-emulsion, gel, patch or liquid form. **Such dosage forms are further described herein. Examples of such dosage forms are known in the art. For example, the tablet forms disclosed in... U.S. Pat. Nos. 4,800,083,** From **Exemplary Intravenous and Liquid Dosage Forms:** "The compositions described herein can also be in liquid or liquid tannate form. **The liquid formulations can comprise, for example,** an agent in water-in-Solution and/or Suspension form; and **a vehicle comprising polyethoxylated castor oil**, alcohol and/or a polyoxyethylated Sorbitan mono-oleate with or without flavoring." (Column 43 Line 28) From **Description**: **In some embodiments, the invention is directed to the combination of an effective amount of an opioid with an effective amount of least one other active ingredient.** From **Description**: **In some embodiments, another active agent in combination with the opioid analgesic or triptan analgesic** are beta blockers, **serotonin receptor agonists**

	From **Description**: **Non-limiting examples of serotonin receptor agonists useful in the present invention include** buspirone, mescaline, **psilocybin**, cisapride, triptans, and lysergic acid diethylamide. From **Description, Column 9, Line 13: In specific embodiments of the invention disclosed herein, each active agent in the composition is administered in a dosage of about 0.01 mg to 500 mg per kg body weight** per day, e.g. about 20 mg/day for an average person. **In some embodiments, dosage for each active agent in the composition is from about 0.01 to 5 mg,** 1 to 10 mg, 5 to 20 mg. 10 to 50 mg, 20 to 100 mg, 50 to 150 mg, 100 to 250 mg, 150 to 300 mg, 250 to 500 mg,300 to 600 mg or 500 to 1000 ng. From **Description**: **To prepare the compositions of the present invention, an effective amount of active agents can be mixed with a suitable pharmaceutically acceptable carrier. Upon mixing of the compounds, the resulting composition can be a** solid, a half-solid, a **solution, suspension,** or an emulsion From **Description**: **In another embodiment the compositions described herein comprise** an opioid agent, **a non opioid agent** and an antiemetic agent, **where each agent can have a purity of 90-100% by weight.** 2. US Pat. No. 4,800,083 "Sustained release method and product" (Published January 24, 1989) From **Description**: **In a preferred aspect of the present invention, the fill material is filled into a soft elastic gelatin shell which encloses the fill material, including the drug,** which does not attack the walls of the seamless, one piece soft elastic gelatin capsule. **The gelatin capsule shell is formulated in accordance with conventional techniques for masking filled, seamless, soft elastic gelatin capsules containing therapeutically effective unit dosage amounts of an active drug ingredient. In one conventional shell formulation, there is included about 30-53 parts by weight of gelatin, about 15-48 parts by weight of a plasticizer, such as glycerin or sorbitol, and about 16-40 parts by weight of water.** From **Description: Thus, the fill material comprises, as its essential components, the desired drug** and the masticatory substance**. Other materials**, such as paraffin, **mineral oil, neutral oils, and the like may be added to the fill material in order to attain the desired consistency of the fill material for filling purposes,** that is, for **filling of the fill material into a gelatin capsule, preferably a soft elastic gelatin capsule** 3. US Pat. No. 11,590,120 "Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin" (Published January 25, 2018)

	From **[0021]**: **Light stimulation triggers the production of psilocybin and psilocin in the mycelium of, for instance Psilocybe azurescens, Psilocybe cyanescens and Psilocybe cubensis**, possibly by stimulation of the enzymatic reactions.
9. The method of claim 1, wherein the liquid vehicle comprises at least one of vegetable oil, glycerin, hydrogenated vegetable oil, lecithin, beeswax, tochopherols, polyethylene glycols, polyoxyethylene—polyoxypropylene copolymers, propylene glycol, and Miglyol® 812.	*From the application of interest 18/467,857 "The term "**enteral administration" refers to a drug administration via the human gastrointestinal tract.** Enteral administration involves the esophagus, stomach, and small and large intestines (i.e., the gastrointestinal tract). **Methods of administration include oral** and **rectal**. Enteral administration may be divided into three different categories, depending on the entrance point into the GI tract: **oral (by mouth),** gastric (through the stomach), and **rectal** (from the rectum)."* 1. US Pat. No. 9,433,625 "Pharmaceutical compositions for treating or preventing pain" (Published September 6, 2016) From **Exemplary Suppository Dosage Forms: The compositions described herein can also be administered in a suppository form,** comprising an outer layer containing the composition in a suppository base. **The suppository base may, for example, be any conventional suppository base material such as** glycogelatin, **polyethylene glycol, f**ractionated palm kernel oil, or one or more natural, synthetic or semi synthetic hard fats such as cocoa butter. **In one embodiment the suppository is useful for** vaginal or **rectal administration.** From **Exemplary Routes of Administration: In any of the embodiments disclosed herein, a composition of the invention can be administered using one or more different dosage forms which are further described herein.** For example, a composition comprising multiple active agents can be administered in solid, semi-solid, micro-emulsion, gel, patch or liquid form. **Such dosage forms are further described herein. Examples of such dosage forms are known in the art. For example, the tablet forms disclosed in... U.S. Pat. Nos. 4,800,083,** From **Exemplary Intravenous and Liquid Dosage Forms:** "The compositions described herein can also be in liquid or liquid tannate form. **The liquid formulations can comprise, for example,** an agent in water-in-Solution and/or Suspension form; and **a vehicle comprising polyethoxylated castor oil**, alcohol and/or a polyoxyethylated Sorbitan mono-oleate with or without flavoring." (Column 43 Line 28) From **Description**: **In some embodiments, the invention is directed to the combination of an effective amount of an opioid with an effective amount of least one other active ingredient.** From **Description**: **In some embodiments, another active agent in combination with the opioid analgesic or triptan analgesic** are beta blockers, **serotonin receptor agonists**

	From **Description**: **Non-limiting examples of serotonin receptor agonists useful in the present invention include** buspirone, mescaline, **psilocybin**, cisapride, triptans, and lysergic acid diethylamide. From **Description, Column 9, Line 13: In specific embodiments of the invention disclosed herein, each active agent in the composition is administered in a dosage of about 0.01 mg to 500 mg per kg body weight** per day, e.g. about 20 mg/day for an average person. In some embodiments, dosage for each active agent in the composition is from about 0.01 to 5 mg, 1 to 10 mg, 5 to 20 mg. 10 to 50 mg, 20 to 100 mg, 50 to 150 mg, 100 to 250 mg, 150 to 300 mg, 250 to 500 mg,300 to 600 mg or 500 to 1000 ng. From **Description**: **To prepare the compositions of the present invention, an effective amount of active agents can be mixed with a suitable pharmaceutically acceptable carrier. Upon mixing of the compounds, the resulting composition can be a** solid, a half-solid, a **solution, suspension,** or an emulsion From **Description**: **In another embodiment the compositions described herein comprise** an opioid agent, **a non opioid agent** and an antiemetic agent, **where each agent can have a purity of 90-100% by weight.** 2. US Pat. No. 4,800,083 "Sustained release method and product" (Published January 24, 1989) From **Description**: **In a preferred aspect of the present invention, the fill material is filled into a soft elastic gelatin shell which encloses the fill material, including the drug,** which does not attack the walls of the seamless, one piece soft elastic gelatin capsule. **The gelatin capsule shell is formulated in accordance with conventional techniques for masking filled, seamless, soft elastic gelatin capsules containing therapeutically effective unit dosage amounts of an active drug ingredient. In one conventional shell formulation, there is included about 30-53 parts by weight of gelatin, about 15-48 parts by weight of a plasticizer, such as glycerin or sorbitol, and about 16-40 parts by weight of water.** From **Description: Thus, the fill material comprises, as its essential components, the desired drug** and the masticatory substance**. Other materials**, such as paraffin, **mineral oil, neutral oils, and the like may be added to the fill material in order to attain the desired consistency of the fill material for filling purposes,** that is, for **filling of the fill material into a gelatin capsule, preferably a soft elastic gelatin capsule** 3. US Pat. No. 11,590,120 "Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin" (Published January 25, 2018)

	From **[0021]**: **Light stimulation triggers the production of psilocybin and psilocin in the mycelium of, for instance Psilocybe azurescens, Psilocybe cyanescens and Psilocybe cubensis**, possibly by stimulation of the enzymatic reactions.
12. The method of claim 1, wherein the oral soft gel capsule further comprises a preservative.	1. US Pat. No. 9,433,625 "Pharmaceutical compositions for treating or preventing pain" (Published September 6, 2016) From **Description**: **If desired, the tablets can also comprise nontoxic auxiliary substances such as** pH buffering agents, **preservatives**, e.g., antioxidants, wetting or emulsifying agents, solubilizing agents, coating agents, flavoring agents, and the like. From **Exemplary Routes of Administration: In any of the embodiments disclosed herein, a composition of the invention can be administered using one or more different dosage forms which are further described herein.** For example, a composition comprising multiple active agents can be administered in solid, semi-solid, micro-emulsion, gel, patch or liquid form. **Such dosage forms are further described herein. Examples of such dosage forms are known in the art. For example, the tablet forms disclosed in... U.S. Pat. Nos. 4,800,083,** From **Exemplary Intravenous and Liquid Dosage Forms:** "The compositions described herein can also be in liquid or liquid tannate form. **The liquid formulations can comprise, for example,** an agent in water-in-Solution and/or Suspension form; and **a vehicle comprising polyethoxylated castor oil**, alcohol and/or a polyoxyethylated Sorbitan mono-oleate with or without flavoring." (Column 43 Line 28) From **Description**: **In some embodiments, the invention is directed to the combination of an effective amount of an opioid with an effective amount of least one other active ingredient.** From **Description**: **In some embodiments, another active agent in combination with the opioid analgesic or triptan analgesic** are beta blockers, **serotonin receptor agonists** From **Description**: **Non-limiting examples of serotonin receptor agonists useful in the present invention include** buspirone, mescaline, **psilocybin**, cisapride, triptans, and lysergic acid diethylamide. From **Description, Column 9, Line 13: In specific embodiments of the invention disclosed herein, each active agent in the composition is administered in a dosage of about 0.01 mg to 500 mg per kg body weight** per day, e.g. about 20 mg/day for an average person. In some embodiments, dosage for each active agent in the composition is from **about 0.01 to 5 mg,** 1 to 10 mg, 5 to 20 mg. 10 to 50 mg, 20 to 100 mg, 50 to 150

	mg, 100 to 250 mg, 150 to 300 mg, 250 to 500 mg,300 to 600 mg or 500 to 1000 ng. From **Description**: **To prepare the compositions of the present invention, an effective amount of active agents can be mixed with a suitable pharmaceutically acceptable carrier. Upon mixing of the compounds, the resulting composition can be a** solid, a half-solid, a **solution, suspension,** or an emulsion From **Description**: **In another embodiment the compositions described herein comprise** an opioid agent, **a non opioid agent** and an antiemetic agent, **where each agent can have a purity of 90-100% by weight.** 2. US Pat. No. 4,800,083 "Sustained release method and product" (Published January 24, 1989) From **Description**: **In a preferred aspect of the present invention, the fill material is filled into a soft elastic gelatin shell which encloses the fill material, including the drug,** which does not attack the walls of the seamless, one piece soft elastic gelatin capsule. **The gelatin capsule shell is formulated in accordance with conventional techniques for masking filled, seamless, soft elastic gelatin capsules containing therapeutically effective unit dosage amounts of an active drug ingredient. In one conventional shell formulation, there is included about 30-53 parts by weight of gelatin, about 15-48 parts by weight of a plasticizer, such as glycerin or sorbitol, and about 16-40 parts by weight of water.** From **Description: Thus, the fill material comprises, as its essential components, the desired drug** and the masticatory substance**. Other materials**, such as paraffin, **mineral oil, neutral oils, and the like may be added to the fill material in order to attain the desired consistency of the fill material for filling purposes,** that is, for **filling of the fill material into a gelatin capsule, preferably a soft elastic gelatin capsule** 3. US Pat. No. 11,590,120 "Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin" (Published January 25, 2018) From **[0021]**: **Light stimulation triggers the production of psilocybin and psilocin in the mycelium of, for instance Psilocybe azurescens, Psilocybe cyanescens and Psilocybe cubensis**, possibly by stimulation of the enzymatic reactions.
13. The method of claim 1, wherein the oral soft gel capsule further comprises an opacifier.	*From the application of interest 18/467,857 "The term "opacifier" refers to an agent or a mixture of agents which when added to a preparation make the ensuing system opaque. Representative opacifier agents include, but are not limited to, pharmaceutically acceptable metal oxides, especially* ***titanium dioxide****."*

	1. US Pat. No. 9,433,625 “Pharmaceutical compositions for treating or preventing pain” (Published September 6, 2016) From **Description**: **In another embodiment the compositions are enteric-coated controlled-release tablets for oral administration. The compositions can further comprise** carnauba wax, crospovidone, diacetylated monoglycerides, ethylcellulose, hydroxypropyl cellulose, hypromellose phthalate, magnesium stearate, mannitol, sodium hydroxide, sodium stearyl fumarate, talc, **titanium dioxide**, or yellow ferric oxide. From **Exemplary Routes of Administration: In any of the embodiments disclosed herein, a composition of the invention can be administered using one or more different dosage forms which are further described herein.** For example, a composition comprising multiple active agents can be administered in solid, semi-solid, micro-emulsion, gel, patch or liquid form. **Such dosage forms are further described herein. Examples of such dosage forms are known in the art. For example, the tablet forms disclosed in... U.S. Pat. Nos. 4,800,083,** From **Exemplary Intravenous and Liquid Dosage Forms:** “The compositions described herein can also be in liquid or liquid tannate form. **The liquid formulations can comprise, for example,** an agent in water-in-Solution and/or Suspension form; and **a vehicle comprising polyethoxylated castor oil**, alcohol and/or a polyoxyethylated Sorbitan mono-oleate with or without flavoring.” (Column 43 Line 28) From **Description**: **In some embodiments, the invention is directed to the combination of an effective amount of an opioid with an effective amount of least one other active ingredient.** From **Description**: **In some embodiments, another active agent in combination with the opioid analgesic or triptan analgesic** are beta blockers, **serotonin receptor agonists** From **Description**: **Non-limiting examples of serotonin receptor agonists useful in the present invention include** buspirone, mescaline, **psilocybin**, cisapride, triptans, and lysergic acid diethylamide. From **Description, Column 9, Line 13: In specific embodiments of the invention disclosed herein, each active agent in the composition is administered in a dosage of about 0.01 mg to 500 mg per kg body weight** per day, e.g. about 20 mg/day for an average person. In some embodiments, dosage for each active agent in the composition is from about 0.01 to 5 mg, 1 to 10 mg, 5 to 20 mg. 10 to 50 mg, 20 to 100 mg, 50 to 150 mg, 100 to 250 mg, 150 to 300 mg, 250 to 500 mg,300 to 600 mg or 500 to 1000 ng.

	From **Description**: **To prepare the compositions of the present invention, an effective amount of active agents can be mixed with a suitable pharmaceutically acceptable carrier. Upon mixing of the compounds, the resulting composition can be a** solid, a half-solid, a **solution, suspension,** or an emulsion From **Description**: **In another embodiment the compositions described herein comprise** an opioid agent, **a non opioid agent** and an antiemetic agent, **where each agent can have a purity of 90-100% by weight.** 2. US Pat. No. 4,800,083 "Sustained release method and product" (Published January 24, 1989) From **Description**: **In a preferred aspect of the present invention, the fill material is filled into a soft elastic gelatin shell which encloses the fill material, including the drug,** which does not attack the walls of the seamless, one piece soft elastic gelatin capsule. **The gelatin capsule shell is formulated in accordance with conventional techniques for masking filled, seamless, soft elastic gelatin capsules containing therapeutically effective unit dosage amounts of an active drug ingredient. In one conventional shell formulation, there is included about 30-53 parts by weight of gelatin, about 15-48 parts by weight of a plasticizer, such as glycerin or sorbitol, and about 16-40 parts by weight of water.** From **Description: Thus, the fill material comprises, as its essential components, the desired drug** and the masticatory substance**. Other materials**, such as paraffin, **mineral oil, neutral oils, and the like may be added to the fill material in order to attain the desired consistency of the fill material for filling purposes,** that is, for **filling of the fill material into a gelatin capsule, preferably a soft elastic gelatin capsule** 3. US Pat. No. 11,590,120 "Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin" (Published January 25, 2018) From **[0021]**: **Light stimulation triggers the production of psilocybin and psilocin in the mycelium of, for instance Psilocybe azurescens, Psilocybe cyanescens and Psilocybe cubensis**, possibly by stimulation of the enzymatic reactions.
14. The method of claim 1, wherein the oral soft gel capsule further comprises a flavorant.	1. US Pat. No. 9,433,625 "Pharmaceutical compositions for treating or preventing pain" (Published September 6, 2016) From **Description**: **If desired, the tablets can also comprise nontoxic auxiliary substances such as** pH buffering agents, preservatives, e.g., antioxidants, wetting or emulsifying agents, solubilizing agents, coating agents, **flavoring agents**, and the like.

	From **Exemplary Routes of Administration: In any of the embodiments disclosed herein, a composition of the invention can be administered using one or more different dosage forms which are further described herein.** For example, a composition comprising multiple active agents can be administered in solid, semi-solid, micro-emulsion, gel, patch or liquid form. **Such dosage forms are further described herein. Examples of such dosage forms are known in the art. For example, the tablet forms disclosed in... U.S. Pat. Nos. 4,800,083,** From **Exemplary Intravenous and Liquid Dosage Forms:** "The compositions described herein can also be in liquid or liquid tannate form. **The liquid formulations can comprise, for example,** an agent in water-in-Solution and/or Suspension form; and **a vehicle comprising polyethoxylated castor oil**, alcohol and/or a polyoxyethylated Sorbitan mono-oleate with or without flavoring." (Column 43 Line 28) From **Description**: **In some embodiments, the invention is directed to the combination of an effective amount of an opioid with an effective amount of least one other active ingredient.** From **Description**: **In some embodiments, another active agent in combination with the opioid analgesic or triptan analgesic** are beta blockers, **serotonin receptor agonists** From **Description**: **Non-limiting examples of serotonin receptor agonists useful in the present invention include** buspirone, mescaline, **psilocybin**, cisapride, triptans, and lysergic acid diethylamide. From **Description, Column 9, Line 13: In specific embodiments of the invention disclosed herein, each active agent in the composition is administered in a dosage of about 0.01 mg to 500 mg per kg body weight** per day, e.g. about 20 mg/day for an average person. In some embodiments, dosage for each active agent in the composition is from about 0.01 to 5 mg, 1 to 10 mg, 5 to 20 mg. 10 to 50 mg, 20 to 100 mg, 50 to 150 mg, 100 to 250 mg, 150 to 300 mg, 250 to 500 mg,300 to 600 mg or 500 to 1000 ng. From **Description**: **To prepare the compositions of the present invention, an effective amount of active agents can be mixed with a suitable pharmaceutically acceptable carrier. Upon mixing of the compounds, the resulting composition can be a** solid, a half-solid, a **solution, suspension,** or an emulsion From **Description**: **In another embodiment the compositions described herein comprise** an opioid agent, **a non opioid agent** and an antiemetic agent, **where each agent can have a purity of 90-100% by weight.** 2. US Pat. No. 4,800,083 "Sustained release method and product" (Published January 24, 1989)

	From **Description**: **In a preferred aspect of the present invention, the fill material is filled into a soft elastic gelatin shell which encloses the fill material, including the drug,** which does not attack the walls of the seamless, one piece soft elastic gelatin capsule. **The gelatin capsule shell is formulated in accordance with conventional techniques for masking filled, seamless, soft elastic gelatin capsules containing therapeutically effective unit dosage amounts of an active drug ingredient. In one conventional shell formulation, there is included about 30-53 parts by weight of gelatin, about 15-48 parts by weight of a plasticizer, such as glycerin or sorbitol, and about 16-40 parts by weight of water.** From **Description: Thus, the fill material comprises, as its essential components, the desired drug** and the masticatory substance**. Other materials**, such as paraffin, **mineral oil, neutral oils, and the like may be added to the fill material in order to attain the desired consistency of the fill material for filling purposes,** that is, for **filling of the fill material into a gelatin capsule, preferably a soft elastic gelatin capsule** 3. US Pat. No. 11,590,120 "Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin" (Published January 25, 2018) From **[0021]**: **Light stimulation triggers the production of psilocybin and psilocin in the mycelium of, for instance Psilocybe azurescens, Psilocybe cyanescens and Psilocybe cubensis**, possibly by stimulation of the enzymatic reactions.
15. The method of claim 1, wherein the oral soft gel capsule further comprises a colorant.	1. US Pat. No. 9,433,625 "Pharmaceutical compositions for treating or preventing pain" (Published September 6, 2016) From **Description**: **Each dosage form comprises an effective amount of an active agent and can optionally comprise pharmaceutically inert agents, such as** conventional excipients, vehicles, fillers, binders, disintegrants, pH adjusting substances, buffer, solvents, solubilizing agents, sweeteners, **coloring agents** and any other inactive agents that can be included in pharmaceutical dosage forms for oral administration From **Exemplary Routes of Administration: In any of the embodiments disclosed herein, a composition of the invention can be administered using one or more different dosage forms which are further described herein.** For example, a composition comprising multiple active agents can be administered in solid, semi-solid, micro-emulsion, gel, patch or liquid form. **Such dosage forms are further described herein. Examples of such dosage forms are known in the art. For example, the tablet forms disclosed in... U.S. Pat. Nos. 4,800,083,** From **Exemplary Intravenous and Liquid Dosage Forms:** "The compositions described herein can also be in liquid or liquid tannate form.

	The liquid formulations can comprise, for example, an agent in water-in-Solution and/or Suspension form; and **a vehicle comprising polyethoxylated castor oil**, alcohol and/or a polyoxyethylated Sorbitan mono-oleate with or without flavoring." (Column 43 Line 28) From **Description**: **In some embodiments, the invention is directed to the combination of an effective amount of an opioid with an effective amount of least one other active ingredient.** From **Description**: **In some embodiments, another active agent in combination with the opioid analgesic or triptan analgesic** are beta blockers, **serotonin receptor agonists** From **Description**: **Non-limiting examples of serotonin receptor agonists useful in the present invention include** buspirone, mescaline, **psilocybin**, cisapride, triptans, and lysergic acid diethylamide. From **Description, Column 9, Line 13: In specific embodiments of the invention disclosed herein, each active agent in the composition is administered in a dosage of about 0.01 mg to 500 mg per kg body weight** per day, e.g. about 20 mg/day for an average person. In some embodiments, dosage for each active agent in the composition is from about 0.01 to 5 mg, 1 to 10 mg, 5 to 20 mg. 10 to 50 mg, 20 to 100 mg, 50 to 150 mg, 100 to 250 mg, 150 to 300 mg, 250 to 500 mg,300 to 600 mg or 500 to 1000 ng. From **Description**: **To prepare the compositions of the present invention, an effective amount of active agents can be mixed with a suitable pharmaceutically acceptable carrier. Upon mixing of the compounds, the resulting composition can be a** solid, a half-solid, a **solution, suspension,** or an emulsion From **Description**: **In another embodiment the compositions described herein comprise** an opioid agent, **a non opioid agent** and an antiemetic agent, **where each agent can have a purity of 90-100% by weight.** 2. US Pat. No. 4,800,083 "Sustained release method and product" (Published January 24, 1989) From **Description**: **In a preferred aspect of the present invention, the fill material is filled into a soft elastic gelatin shell which encloses the fill material, including the drug,** which does not attack the walls of the seamless, one piece soft elastic gelatin capsule. **The gelatin capsule shell is formulated in accordance with conventional techniques for masking filled, seamless, soft elastic gelatin capsules containing therapeutically effective unit dosage amounts of an active drug ingredient. In one conventional shell formulation, there is included about 30-53 parts by weight of gelatin, about 15-48 parts by weight of a plasticizer, such as glycerin or sorbitol, and about 16-40 parts by weight of water.**

	From **Description: Thus, the fill material comprises, as its essential components, the desired drug** and the masticatory substance**. Other materials**, such as paraffin, **mineral oil, neutral oils, and the like may be added to the fill material in order to attain the desired consistency of the fill material for filling purposes,** that is, for **filling of the fill material into a gelatin capsule, preferably a soft elastic gelatin capsule** 3. US Pat. No. 11,590,120 "Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin" (Published January 25, 2018) From **[0021]**: Light stimulation triggers **the production of psilocybin and psilocin in the mycelium of, for instance Psilocybe azurescens, Psilocybe cyanescens and Psilocybe cubensis**, possibly by stimulation of the enzymatic reactions.
17. An oral soft gel capsule comprising: (i) a capsule shell formed from a plasticizer glycerin, sorbitol, or combination thereof; a solvent water, and at least one of gelatin, cellulose, hypromellose, vegetable starch, tapioca starch, carrageenan, potato starch, cassava starch, cornstarch, and arrowroot; (ii) a psychedelic compound comprising at least one of psilocybin, psilocin, and baeocystin; and (iii) a liquid vehicle comprising one or more oils; wherein, the psilocybin, psilocin, baeocystin, or combination thereof is present in a combined amount of 0.01 to 5 mg, the psilocybin, psilocin, baeocystin, or combination thereof has	1. US Pat. No. 9,433,625 "Pharmaceutical compositions for treating or preventing pain" (Published September 6, 2016) From **Exemplary Routes of Administration: In any of the embodiments disclosed herein, a composition of the invention can be administered using one or more different dosage forms which are further described herein.** For example, a composition comprising multiple active agents can be administered in solid, semi-solid, micro-emulsion, gel, patch or liquid form. **Such dosage forms are further described herein. Examples of such dosage forms are known in the art. For example, the tablet forms disclosed in... U.S. Pat. Nos. 4,800,083,** From **Exemplary Intravenous and Liquid Dosage Forms:** "The compositions described herein can also be in liquid or liquid tannate form. **The liquid formulations can comprise, for example,** an agent in water-**in-Solution and/or Suspension form**; and **a vehicle comprising polyethoxylated castor oil**, alcohol and/or a polyoxyethylated Sorbitan mono-oleate with or without flavoring." (Column 43 Line 28) From **Description**: **In some embodiments, the invention is directed to the combination of an effective amount of an opioid with an effective amount of least one other active ingredient.** From **Description**: **In some embodiments, another active agent in combination with the opioid analgesic or triptan analgesic** are beta blockers, **serotonin receptor agonists** From **Description**: **Non-limiting examples of serotonin receptor agonists useful in the present invention include** buspirone, mescaline, **psilocybin**, cisapride, triptans, and lysergic acid diethylamide.

a purity of at least 99 wt. % pure, the psilocybin, psilocin, baeocystin, or combination thereof is obtained from genera Copelandia, Gynnwpilus, Inocybe, Mycena, Panaeolus, Pholiolina, Pluteus, or Psilocybe; the liquid vehicle is compatible with the capsule shell; the liquid vehicle effectively dissolves and/or suspends the psychedelic compound; and the psychedelic compound and the liquid vehicle are contained within the capsule shell.	From **Description, Column 9, Line 13: In specific embodiments of the invention disclosed herein, each active agent in the composition is administered in a dosage of about 0.01 mg to 500 mg per kg body weight** per day, e.g. about 20 mg/day for an average person. In some embodiments, dosage for each active agent in the composition is from about **0.01 to 5 mg,** 1 to 10 mg, 5 to 20 mg. 10 to 50 mg, 20 to 100 mg, 50 to 150 mg, 100 to 250 mg, 150 to 300 mg, 250 to 500 mg,300 to 600 mg or 500 to 1000 ng. From **Description**: **To prepare the compositions of the present invention, an effective amount of active agents can be mixed with a suitable pharmaceutically acceptable carrier. Upon mixing of the compounds, the resulting composition can be a** solid, a half-solid, a **solution, suspension,** or an emulsion From **Description**: **In another embodiment the compositions described herein comprise** an opioid agent, **a non opioid agent** and an antiemetic agent, **where each agent can have a purity of 90-100% by weight.** 2. US Pat. No. 4,800,083 "Sustained release method and product" (Published January 24, 1989) From **Description**: **In a preferred aspect of the present invention, the fill material is filled into a soft elastic gelatin shell which encloses the fill material, including the drug,** which does not attack the walls of the seamless, one piece soft elastic gelatin capsule. **The gelatin capsule shell is formulated in accordance with conventional techniques for masking filled, seamless, soft elastic gelatin capsules containing therapeutically effective unit dosage amounts of an active drug ingredient. In one conventional shell formulation, there is included about 30-53 parts by weight of gelatin, about 15-48 parts by weight of a plasticizer, such as glycerin or sorbitol, and about 16-40 parts by weight of water.** From **Description: Thus, the fill material comprises, as its essential components, the desired drug** and the masticatory substance**. Other materials**, such as paraffin, **mineral oil, neutral oils, and the like may be added to the fill material in order to attain the desired consistency of the fill material for filling purposes,** that is, for **filling of the fill material into a gelatin capsule, preferably a soft elastic gelatin capsule** 3. US Pat. No. 11,590,120 "Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin" (Published January 25, 2018) From **[0021]**: **Light stimulation triggers the production of psilocybin and psilocin in the mycelium of, for instance Psilocybe azurescens, Psilocybe cyanescens and Psilocybe cubensis**, possibly by stimulation of the enzymatic reactions.

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/467,857	**04/26/2024 12:55:22 PM Z ET**	

Title of Invention

Application Information

APPLICATION TYPE		PATENT #	
CONFIRMATION #		FILED BY	Jeremy Rolquin
PATENT CENTER #	65261087	FILING DATE	09/15/2023
CUSTOMER #	–	FIRST NAMED INVENTOR	
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	-

Documents

TOTAL DOCUMENTS: 8

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
Third-party-notification-request.pdf		1	Request for Notification of Non-compliant Third-Party Submission	14 KB
third-party-preissuance-submission.pdf		2	Third-Party Submission Under 37 CFR 1.290	51 KB
Concise-description-generated.pdf		2	Concise Description of Relevance	29 KB
3PS_Embedded.pdf		27	-	365 KB
3PS_Embedded-3P.RELEVANCE.pdf	(1-27)	27	Concise Description of Relevance	365 KB
3PS_Embedded-	(1-27)	27	Concise Description of	365 KB

3P.RELEVANCE.pdf			Relevance	
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4_Lyons et al_Embedded.pdf		11	-	798 KB
4_Lyons et al_Embedded-NPL.pdf	(1-11)	11	Non Patent Literature	802 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

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

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

New International Application Filed with the USPTO as a Receiving Office

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

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/467,857	**04/26/2024 12:55:22 PM Z ET**	

Title of Invention

Application Information

APPLICATION TYPE		PATENT #	
CONFIRMATION #		FILED BY	Jeremy Rolquin
PATENT CENTER #	65261087	AUTHORIZED BY	-
CUSTOMER #	–	FILING DATE	09/15/2023
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 7409	**E20244PC56568803**	**Jeremy Rolquin**

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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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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