IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Compass Pathfinder Limited
Serial No.: 18/285,109
Filing or 371(c) Date: September 29, 2023
Entitled: PSILOCYBIN COMPOSITIONS, METHODS OF MAKING AND METHODS OF USING THE SAME

Confirmation No.: 4885
Group No.:
Examiner:

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. 2021/0015738A1 "ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND" (Published January 21, 2021)
2. U.S. Pat. App. Pub. No. 2019/0119310A1 "PREPARATION OF PSILOCYBIN, DIFFERENT POLYMORPHIC FORMS, INTERMEDIATES, FORMULATIONS AND THEIR USE" (Published April 25, 2019)
3. GOTVALDOVA (2021) "Stability of psilocybin and its four analogs in the biomass of the psychotropic mushroom Psilocybe cubensis" *Drug Testing and Analysis*. 13(2):439-446
4. U.S. Pat. App. Pub. No. 2021/0069170A1 "TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH" (Published March 11, 2021)

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. 18/285,109 Pending Claims	References
1. A pharmaceutical composition comprising: a therapeutically effective amount of psilocybin; and one or more pharmaceutically acceptable excipients, wherein, after storage of the composition at 40° C. and 75% relative humidity for one month, the potency of the psilocybin in the composition decreases by less than 5% and the mass balance of psilocybin and related substances is greater than 97%.	1. U.S. Pat. App. Pub. No. 2021/0015738A1 "ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND" (Published January 21, 2021) From [**0009**] "The present invention is directed to an oral dissolvable film that includes a psychedelic compound. The present invention is also directed to a method of treating in a subject a disease or disorder ameliorated by a psychedelic compound, that includes orally administering to a subject an oral dissolvable film that includes a **therapeutically effective amount of the psychedelic compound**. The present invention is also a method of orally administering to a subject an oral dissolvable film that includes a therapeutically effective amount of the psychedelic compound. The present invention is also a method of orally administering to a subject an oral dissolvable film that includes a low dose (e.g., microdose or sub-therapeutic dose) of the psychedelic compound." From [**0013**] "The oral dissolvable film described herein includes a polymeric matrix formed from a film forming agent (e.g., film-forming polymer), **active pharmaceutical ingredient (API), and solvent. Optional additional excipients** (alternatively referred to as "additives") used to manufacture the oral film can include one or more of: mucoadhesive polymer, plasticizer, binder, filler, bulking agent, saliva stimulating agent, stabilizing and thickening agent, gelling agent, flavoring agent, taste masking agent, coloring agent, pigment, lubricant, release modifier, adjuvant, sweetening agent, solubilizer & emulsifier, fragrance, emulsifier, surfactant, pH adjusting agent, buffering agent, lipid, glidant, stabilizer, antioxidant, anti-tacking agent, humectant, solvent, permeation enhancer, and preservative." From [**0320**] "<30.> The oral dissolvable film of any one of the above embodiments, **exhibiting a high stability such that at least 97.5 wt. % of the psychedelic compound** remains in the oral dissolvable film, under accelerated stability **conditions of ≥40° C., relative humidity (RH) 75±5%,** over a period of time of ≥3 months." From [**0075**] "In specific embodiments, the psychedelic compound selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof." From [**0135**] "In specific embodiments, **the psychedelic compound has a purity of at least 99.5 wt. % pure."**

2. U.S. Pat. App. Pub. No. 2019/0119310A1 “PREPARATION OF PSILOCYBIN, DIFFERENT POLYMORPHIC FORMS, INTERMEDIATES, FORMULATIONS AND THEIR USE” (Published April 25, 2019)

From **TABLE-US-00029** “TABLE 29 One Month Stability Data for Batch 170231 Test Specification Limit T = 0 T = 1 month T = 1 month T = 1 month Condition N/A N/A 2° C.-8° C. 25° C./60% RH 40° C./75% RH Appearance For information only. An off white solid. An off white solid. An off white solid. An off white solid. Free from visible Free from visible Free from visible Free from visible contamination contamination contamination contamination Chemical Purity By For information only. 99.28% 99.20% 99.16% 99.17% HPLC Impurities by HPLC: (Quote all GT 0.05%) RRT 1.49 For Information only. 0.06% 0.05% 0.05% 0.06% RRT 1.62 (Psilocin) 0.39% 0.36% 0.37% 0.36% RRT 1.70 0.05% LT 0.05% LT 0.05% LT 0.05% Impurity at RRT 1.89 LT 0.05% LT 0.05% LT 0.05% LT 0.05% Impurity at RRT 2.45 LT 0.05% LT 0.05% LT 0.05% LT 0.05% Impurities LT 0.05% 0.22% 0.39% 0.42% 0.41% Total Impurities 0.72% 0.80% 0.84% 0.83% Assay by HPLC For information only 98.65% w/w 98.76% w/w 97.98% w/w 98.52% w/w (on a dry basis) Water content by loss For information only. 0.32% w/w 0.27% w/w 0.17% w/w 0.19% w/w on drying”

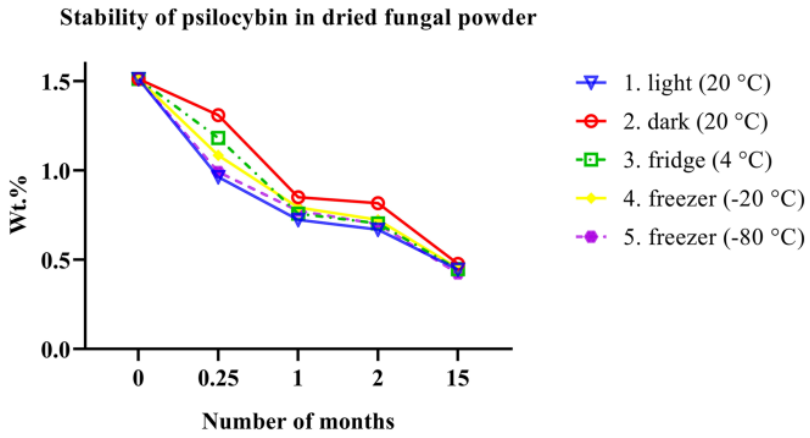
TABLE 29

One Month Stability Data for Batch 170231

Test	Specification Limit	T = 0	T = 1 month	T = 1 month	T = 1 month
Condition	N/A	N/A	2° C.-8° C.	25° C./60% RH	40° C./75% RH
Appearance	For information only.	An off white solid. Free from visible contamination	An off white solid. Free from visible contamination	An off white solid. Free from visible contamination	An off white solid. Free from visible contamination
Chemical Purity By HPLC	For information only.	99.28%	99.20%	99.16%	99.17%
Impurities by HPLC: (Quote all GT 0.05%)					
RRT 1.49	For Information only.	0.06%	0.05%	0.05%	0.06%
RRT 1.62 (Psilocin)		0.39%	0.36%	0.37%	0.36%
RRT 1.70		0.05%	LT 0.05%	LT 0.05%	LT 0.05%
Impurity at RRT 1.89		LT 0.05%	LT 0.05%	LT 0.05%	LT 0.05%
Impurity at RRT 2.45		LT 0.05%	LT 0.05%	LT 0.05%	LT 0.05%
Impurities LT 0.05%		0.22%	0.39%	0.42%	0.41%
Total Impurities		0.72%	0.80%	0.84%	0.83%
Assay by HPLC (on a dry basis)	For information only	98.65% w/w	98.76% w/w	97.98% w/w	98.52% w/w
Water content by loss on drying	For information only.	0.32% w/w	0.27% w/w	0.17% w/w	0.19% w/w

3. GOTVALDOVA (2021) “Stability of psilocybin and its four analogs in the biomass of the psychotropic mushroom Psilocybe cubensis” *Drug Testing and Analysis*. 13(2):439-446

From **page 444** “

	 FIGURE 3 **Stability of psilocybin as a major tryptamine in fungal powder after 15 months**"
2-38. (canceled)	
39. A method of making a pharmaceutical composition comprising: a) direct mixing psilocybin and one or more pharmaceutically acceptable excipients to provide a blend, and b) filling a capsule with the blend to provide the pharmaceutical composition, wherein the content uniformity of the composition complies with the European Pharmacopeia 2.96. or USP <905>.	1. U.S. Pat. App. Pub. No. 2021/0015738A1 "ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND" (Published January 21, 2021) From [**0075**] "In specific embodiments, the psychedelic compound selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof." From [**0013**] "The oral dissolvable film described herein includes a polymeric matrix formed from a film forming agent (e.g., film-forming polymer), **active pharmaceutical ingredient (API), and solvent. Optional additional excipients** (alternatively referred to as "additives")..." From [**0073**] "The term "enteral administration" refers to a drug administration via the human gastrointestinal tract… Enteral medications come in various forms, including, e.g., tablets to swallow, chew or dissolve in water; **capsules** and chewable **capsules** (with a coating that dissolves in the stomach or bowel to release the medication there), oral soluble films, time-release or sustained-release tablets and **capsules** (which release the medication gradually), osmotic delivery systems, powders or granules, and liquid medications or syrups." Form [**0059**] "The term "**drug content uniformity**," "uniformity of dosage unit" or "CU" refers to the degree of uniformity in the amount of drug substance among dosage units, and unless otherwise specified, is set forth in **USP-NF General Chapter <905> Uniformity of Dosage Units**."

40-**52**. (canceled)	
53. A pharmaceutical composition comprising: a therapeutically effective amount of psilocybin; and about 85% to about 99%, by weight, partially pregelatinized starch.	4. U.S. Pat. App. Pub. No. 2021/0069170A1 "TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH" (Published March 11, 2021) From [**0010**] "Another embodiment described herein is a method of treating or preventing serotonin (5-hydroxytryptamine, 5-HT) receptor disorders, neuronal injuries, neurodegeneration, neurological diseases, congenital or organic cognitive impairment, learning disabilities, autism spectrum disorder, psychiatric and mood disorders, cognitive enhancement, physical or motor neuron enhancement, or general improvement of mental health in a subject in need thereof, **the method comprising administering to the subject a therapeutically effective amount** of a composition comprising norpsilocin, norbaeocystin, baeocystin, or **psilocybin**, combined with one or more erinacines or hericenones in pure form or pharmaceutically acceptable salts, hydrates, solvates, prodrugs, stereoisomers, or tautomer thereof, or combinations thereof, extracts or isolates from Hericium mushroom species, combinations thereof and one or more pharmaceutically acceptable excipients." From [**0091**] "… In certain embodiments , the compound is made up of at least about 90 % by weight of a preferred enantiomer . In other embodiments, the compound is made up of at least about **95%, 98 %, or 99% by weight of** a preferred enantiomer. Preferred enantiomers may be isolated from racemic mixtures by any method known to those skilled in the art, including chiral high pressure liquid chromatography (HPLC) and the formation and crystallization of chiral salts or prepared by asymmetric syntheses." From [**0143**] "Pharmaceutical excipients useful for the compositions as described herein comprise: acidifying agents… tablet binders (acacia, alginic acid, sodium carboxymethylcellulose, microcrystalline cellulose, dextrin, ethylcellulose, gelatin, liquid glucose, guar gum, hydroxypropyl methylcellulose, methylcellulose, polyethylene oxide, povidone, **pregelatinized starch**, syrup); tablet and/or capsule diluents (calcium carbonate, dibasic calcium phosphate, tribasic calcium phosphate, calcium sulfate, microcrystalline cellulose, powdered cellulose, dextrates, dextrin…" 1. U.S. Pat. App. Pub. No. 2021/0015738A1 "ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND" (Published January 21, 2021) From [**0132**] "In specific embodiments, the **psychedelic compound** has a

	purity of at least 97.5 wt. % pure." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof."
54. The pharmaceutical composition of claim 53, further comprising a lubricant.	1. U.S. Pat. App. Pub. No. 2021/0015738A1 "ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND" (Published January 21, 2021) From [**0182**] "In specific embodiments, the flowable water-soluble or water swellable film-forming matrix includes at least one of coloring agent, flavoring agent, sweetening agent, filler, bulking agent, saliva stimulating agent, stabilizing and thickening agent, gelling agent, taste masking agent, pigment, **lubricant**, release modifier, adjuvant, solubilizer & emulsifier, fragrance, emulsifier, surfactant, pH adjusting agent, buffering agent, lipid, glidant, stabilizer, antioxidant, anti-tacking agent, and humectant." From [**0132**] "In specific embodiments, the **psychedelic compound** has a **purity of at least 97.5 wt. % pure**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof."
55. The pharmaceutical composition of claim 54, wherein the composition comprises about 0.5% to about 2.0%, by weight, the lubricant.	1. U.S. Pat. App. Pub. No. 2021/0015738A1 "ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND" (Published January 21, 2021) From **claim 21** "The method of claim 1, wherein the oral dissolvable film comprises: (a) 15±10 wt. % plasticizer, (b) 10±5 wt. % solvent, (c) 12±8 wt. % sweetener, **(d) 8±7 wt. % flavoring agent,** (e) 30±20 wt. % binder, (f) 0.02±0.01 wt. % coloring agent, (g) 0.02±0.01 wt. % preservative, and (h) 1.25±1 wt. % of psilocybin, psilocin, baeocystin, or combination thereof." From [**0036**] "**The term "lubricant" or "glidant" refers to** a substance added to the formulation (e.g., slurry) to improve processing characteristics. For example, the lubricant can enhance flow of the slurry

	by reducing interparticulate friction. Suitable lubricants include, e.g., magnesium stearate, calcium stearate, stearic acid, hydrogenated vegetable oil (e.g., Sterotex, Lubritab, and Cutina), mineral oil, polyethylene glycol 4000-6000 (PEG), sodium lauryl sulfate (SLS), sodium hyaluronate, **sucrose esters**, glyceryl behenate (stelliesters), dimethyl phthalate, diethyl phthalate, dibutyl phthalate, tributyl citrate, triethyl citrate, acetyl citrate, triacetin, dioctyl adipate, diethyl adipate, di(2-methylethyl) adipate, dihexyl adipate, partial fatty acid esters of sugars, polyethylene glycol fatty acid esters, polyethylene glycol fatty alcohol ethers, polyethylene glycol sorbitan fatty acid esters, 2-ethoxy ethanol, ethyl alcohol, propyl alcohol, butyl alcohol, pentyl alcohol, hexyl alcohol, heptyl alcohol, octyl alcohol, dibutyl tartrate, castor oil, or any combination thereof."
56. The pharmaceutical composition of claim 55, wherein the lubricant is sodium stearyl fumarate.	2. U.S. Pat. App. Pub. No. 2019/0119310A1 "PREPARATION OF PSILOCYBIN, DIFFERENT POLYMORPHIC FORMS, INTERMEDIATES, FORMULATIONS AND THEIR USE" (Published April 25, 2019) From [**0111**] "The formulation may further comprise or consist of a disintegrant, preferably sodium starch glycolate, a glidant, preferably colloidal silicon dioxide and **a lubricant**, preferably **sodium stearyl fumarate.**" From [**0001**] "This invention relates to the **large-scale production of psilocybin for use in medicine**."
57. The pharmaceutical composition of claim 53, wherein the composition is a capsule.	1. U.S. Pat. App. Pub. No. 2021/0015738A1 "ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND" (Published January 21, 2021) From [**0073**] "The term "enteral administration" refers to a drug administration via the human gastrointestinal tract… Enteral medications come in various forms, including, e.g., tablets to swallow, chew or dissolve in water; **capsules** and chewable **capsules** (with a coating that dissolves in the stomach or bowel to release the medication there), oral soluble films, time-release or sustained-release tablets and **capsules** (which release the medication gradually), osmotic delivery systems, powders or granules, and liquid medications or syrups." From [**0075**] "In specific embodiments, the psychedelic compound selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof." From [**0132**] "In specific embodiments, the **psychedelic compound** has a **purity of at least 97.5 wt. % pure**."

	From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof."
58. The pharmaceutical composition of claim 53, wherein the composition comprises about 1% to about 10%, by weight, psilocybin.	1. U.S. Pat. App. Pub. No. 2021/0015738A1 "ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND" (Published January 21, 2021) From [**0113**] "In specific embodiments, **the psychedelic compound is present in 0.01-10 wt. %** of the oral dissolvable film." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof." From [**0132**] "In specific embodiments, the **psychedelic compound** has a **purity of at least 97.5 wt. % pure**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof."
59. The pharmaceutical composition of claim 53, wherein the composition does not contain silicified microcrystalline cellulose.	4. U.S. Pat. App. Pub. No. 2021/0069170A1 "TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH" (Published March 11, 2021) From [**0023**] "The term "binder" refers to a substance, typically a polymer, used to hold the ingredients together. Binders ensure that the oral dissolvable films can be formed with the requisite mechanical strength. The binders also provide the requisite volume to low amount of active present in dissolvable films. The presence of the binder also facilitates the formation of the cured film. As such, the binder includes those substances, which when present in the cast slurry and upon curing, will effectively provide for a cured film. The binder may also be referred to as a "film forming agent," or more specifically a "film forming polymer" when it is a polymer. The polymer can be a natural polymer or a synthetic polymer. Natural polymers include, e.g., pullulan, sodium alginate (Na alginate), pectin, gelatin, chitosan, and maltodextrin. Synthetic polymers include, **e.g., hydroxpropyl cellulose (HPC), hydroxpropyl methylcellulose (HPMC), carboxymethyl cellulose (CMC), sodium carboxymethylcellulose (CMC-Na), microcrystalline cellulose** (MCC), polyvinyl alcohol (PVA), polyethylene oxide (PEO), polyvinylpyrrolidone (PVP), and Kollicoat® (e.g., Kollicoat® Protect or

	Kollicoat® IR).” From [**0010**] “Another embodiment described herein is a method of treating or preventing serotonin (5-hydroxytryptamine, 5-HT) receptor disorders, neuronal injuries, neurodegeneration, neurological diseases, congenital or organic cognitive impairment, learning disabilities, autism spectrum disorder, psychiatric and mood disorders, cognitive enhancement, physical or motor neuron enhancement, or general improvement of mental health in a subject in need thereof, **the method comprising administering to the subject a therapeutically effective amount** of a composition comprising norpsilocin, norbaeocystin, baeocystin, or **psilocybin**, combined with one or more erinacines or hericenones in pure form or pharmaceutically acceptable salts, hydrates, solvates, prodrugs, stereoisomers, or tautomer thereof, or combinations thereof, extracts or isolates from Hericium mushroom species, combinations thereof and one or more pharmaceutically acceptable excipients.” From [**0091**] “… In certain embodiments , the compound is made up of at least about 90 % by weight of a preferred enantiomer . In other embodiments, the compound is made up of at least about **95%, 98 %, or 99% by weight of** a preferred enantiomer. Preferred enantiomers may be isolated from racemic mixtures by any method known to those skilled in the art, including chiral high pressure liquid chromatography (HPLC) and the formation and crystallization of chiral salts or prepared by asymmetric syntheses.” From [**0143**] “Pharmaceutical excipients useful for the compositions as described herein comprise: acidifying agents… tablet binders (acacia, alginic acid, sodium carboxymethylcellulose, microcrystalline cellulose, dextrin, ethylcellulose, gelatin, liquid glucose, guar gum, hydroxypropyl methylcellulose, methylcellulose, polyethylene oxide, povidone, **pregelatinized starch**, syrup); tablet and/or capsule diluents (calcium carbonate, dibasic calcium phosphate, tribasic calcium phosphate, calcium sulfate, microcrystalline cellulose, powdered cellulose, dextrates, dextrin…” 1. U.S. Pat. App. Pub. No. 2021/0015738A1 “ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND” (Published January 21, 2021) From [**0132**] “In specific embodiments, the **psychedelic compound** has a **purity of at least 97.5 wt. % pure**.” From [**0075**] “In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin,

	mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof."
60. The pharmaceutical composition of claim 53, wherein the composition comprises 1 mg of psilocybin.	1. U.S. Pat. App. Pub. No. 2021/0015738A1 "ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND" (Published January 21, 2021) From [**0091**] "In specific embodiments, **the psychedelic compound is present in up to 1 mg**. From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof." From [**0132**] "In specific embodiments, the **psychedelic compound** has a **purity of at least 97.5 wt. % pure**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof."
61. The pharmaceutical composition of claim 53, wherein the composition comprises 5 mg of psilocybin.	1. U.S. Pat. App. Pub. No. 2021/0015738A1 "ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND" (Published January 21, 2021) From [**0089**] "In specific embodiments**, the psychedelic compound is present in up to 5 mg**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof." From [**0132**] "In specific embodiments, the **psychedelic compound** has a **purity of at least 97.5 wt. % pure**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof."
62. The pharmaceutical composition of claim 53, wherein the composition comprises 10 mg of	1. U.S. Pat. App. Pub. No. 2021/0015738A1 "ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND" (Published January 21, 2021)

psilocybin.	From [**0088**] "In specific embodiments**, the psychedelic compound is present in up to 10 mg**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof." From [**0132**] "In specific embodiments, the **psychedelic compound** has a **purity of at least 97.5 wt. % pure**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof."
63. The pharmaceutical composition of claim 53, wherein the composition comprises 25 mg of psilocybin.	1. U.S. Pat. App. Pub. No. 2021/0015738A1 "ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND" (Published January 21, 2021) From [**0087**] "In specific embodiments**, the psychedelic compound is present in up to 25 mg**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof." From [**0132**] "In specific embodiments, the **psychedelic compound** has a **purity of at least 97.5 wt. % pure**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof."
64. The pharmaceutical composition of claim 53, wherein the composition comprises 40 mg of psilocybin.	1. U.S. Pat. App. Pub. No. 2021/0015738A1 "ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND" (Published January 21, 2021) From [**0097**] "In specific embodiments, **the psychedelic compound is present in 1-50 mg**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof."

	From [**0132**] "In specific embodiments, the **psychedelic compound** has a **purity of at least 97.5 wt. % pure**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof."
65. A pharmaceutical composition comprising: about 1% to about 10%, by weight, psilocybin; about 85% to about 99%, by weight, partially pregelatinized starch; and about 0.5% to about 2.0%, by weight, sodium stearyl fumarate.	1. U.S. Pat. App. Pub. No. 2021/0015738A1 "ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND" (Published January 21, 2021) From [**0113**] "In specific embodiments, **the psychedelic compound is present in 0.01-10 wt. %** of the oral dissolvable film." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof." From [**0132**] "In specific embodiments, the **psychedelic compound** has a **purity of at least 97.5 wt. % pure**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof." 4. U.S. Pat. App. Pub. No. 2021/0069170A1 "TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH" (Published March 11, 2021) From [**0010**] "Another embodiment described herein is a method of treating or preventing serotonin (5-hydroxytryptamine, 5-HT) receptor disorders, neuronal injuries, neurodegeneration, neurological diseases, congenital or organic cognitive impairment, learning disabilities, autism spectrum disorder, psychiatric and mood disorders, cognitive enhancement, physical or motor neuron enhancement, or general improvement of mental health in a subject in need thereof, **the method comprising administering to the subject a therapeutically effective amount** of a composition comprising norpsilocin, norbaeocystin, baeocystin, or **psilocybin**, combined with one or more erinacines or hericenones in pure form or pharmaceutically acceptable salts, hydrates, solvates, prodrugs, stereoisomers, or tautomer thereof, or combinations thereof, extracts or isolates from Hericium mushroom species,

	combinations thereof and one or more pharmaceutically acceptable excipients." From [**0091**] "… In certain embodiments , the compound is made up of at least about 90 % by weight of a preferred enantiomer . In other embodiments, the compound is made up of at least about **95%, 98 %, or 99% by weight of** a preferred enantiomer. Preferred enantiomers may be isolated from racemic mixtures by any method known to those skilled in the art, including chiral high pressure liquid chromatography (HPLC) and the formation and crystallization of chiral salts or prepared by asymmetric syntheses." From [**0143**] "Pharmaceutical excipients useful for the compositions as described herein comprise: acidifying agents… tablet binders (acacia, alginic acid, sodium carboxymethylcellulose, microcrystalline cellulose, dextrin, ethylcellulose, gelatin, liquid glucose, guar gum, hydroxypropyl methylcellulose, methylcellulose, polyethylene oxide, povidone, **pregelatinized starch**, syrup); tablet and/or capsule diluents (calcium carbonate, dibasic calcium phosphate, tribasic calcium phosphate, calcium sulfate, microcrystalline cellulose, powdered cellulose, dextrates, dextrin…" 2. U.S. Pat. App. Pub. No. 2019/0119310A1 "PREPARATION OF PSILOCYBIN, DIFFERENT POLYMORPHIC FORMS, INTERMEDIATES, FORMULATIONS AND THEIR USE" (Published April 25, 2019) From [**0111**] "The formulation may further comprise or consist of a disintegrant, preferably sodium starch glycolate, a glidant, preferably colloidal silicon dioxide and **a lubricant**, preferably **sodium stearyl fumarate.**" From [**0001**] "This invention relates to the **large-scale production of psilocybin for use in medicine**."
66. The pharmaceutical composition of claim 65, wherein the composition does not contain silicified microcrystalline cellulose.	1. U.S. Pat. App. Pub. No. 2021/0015738A1 "ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND" (Published January 21, 2021) From [**0113**] "In specific embodiments, **the psychedelic compound is present in 0.01-10 wt. %** of the oral dissolvable film." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof."

	From [**0132**] "In specific embodiments, the **psychedelic compound** has a **purity of at least 97.5 wt. % pure**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof." 4. U.S. Pat. App. Pub. No. 2021/0069170A1 "TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH" (Published March 11, 2021) From [**0010**] "Another embodiment described herein is a method of treating or preventing serotonin (5-hydroxytryptamine, 5-HT) receptor disorders, neuronal injuries, neurodegeneration, neurological diseases, congenital or organic cognitive impairment, learning disabilities, autism spectrum disorder, psychiatric and mood disorders, cognitive enhancement, physical or motor neuron enhancement, or general improvement of mental health in a subject in need thereof, **the method comprising administering to the subject a therapeutically effective amount** of a composition comprising norpsilocin, norbaeocystin, baeocystin, or **psilocybin**, combined with one or more erinacines or hericenones in pure form or pharmaceutically acceptable salts, hydrates, solvates, prodrugs, stereoisomers, or tautomer thereof, or combinations thereof, extracts or isolates from Hericium mushroom species, combinations thereof and one or more pharmaceutically acceptable excipients." From [**0091**] "… In certain embodiments , the compound is made up of at least about 90 % by weight of a preferred enantiomer . In other embodiments, the compound is made up of at least about **95%, 98 %, or 99% by weight of** a preferred enantiomer. Preferred enantiomers may be isolated from racemic mixtures by any method known to those skilled in the art, including chiral high pressure liquid chromatography (HPLC) and the formation and crystallization of chiral salts or prepared by asymmetric syntheses." From [**0143**] "Pharmaceutical excipients useful for the compositions as described herein comprise: acidifying agents… tablet binders (acacia, alginic acid, sodium carboxymethylcellulose, microcrystalline cellulose, dextrin, ethylcellulose, gelatin, liquid glucose, guar gum, hydroxypropyl methylcellulose, methylcellulose, polyethylene oxide, povidone, **pregelatinized starch**, syrup); tablet and/or capsule diluents (calcium carbonate, dibasic calcium phosphate, tribasic calcium phosphate, calcium sulfate, microcrystalline cellulose, powdered cellulose, dextrates,

	dextrin…" 2. U.S. Pat. App. Pub. No. 2019/0119310A1 "PREPARATION OF PSILOCYBIN, DIFFERENT POLYMORPHIC FORMS, INTERMEDIATES, FORMULATIONS AND THEIR USE" (Published April 25, 2019) From [**0111**] "The formulation may further comprise or consist of a disintegrant, preferably sodium starch glycolate, a glidant, preferably colloidal silicon dioxide and **a lubricant**, preferably **sodium stearyl fumarate.**" From [**0001**] "This invention relates to the **large-scale production of psilocybin for use in medicine**."
67. The pharmaceutical composition of claim 65, wherein the composition is a capsule.	1. U.S. Pat. App. Pub. No. 2021/0015738A1 "ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND" (Published January 21, 2021) From [**0073**] "The term "enteral administration" refers to a drug administration via the human gastrointestinal tract… Enteral medications come in various forms, including, e.g., tablets to swallow, chew or dissolve in water; **capsules** and chewable **capsules** (with a coating that dissolves in the stomach or bowel to release the medication there), oral soluble films, time-release or sustained-release tablets and **capsules** (which release the medication gradually), osmotic delivery systems, powders or granules, and liquid medications or syrups." From [**0075**] "In specific embodiments, the psychedelic compound selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof." From [**0132**] "In specific embodiments, the **psychedelic compound** has a **purity of at least 97.5 wt. % pure**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof."
68. The pharmaceutical composition of claim 65, wherein the composition comprises 1 mg of psilocybin.	1. U.S. Pat. App. Pub. No. 2021/0015738A1 "ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND" (Published January 21, 2021) From [**0091**] "In specific embodiments, **the psychedelic compound is**

	present in up to 1 mg. From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof." From [**0132**] "In specific embodiments, the **psychedelic compound** has a **purity of at least 97.5 wt. % pure**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof."
69. The pharmaceutical composition of claim 65, wherein the composition comprises 5 mg of psilocybin.	1. U.S. Pat. App. Pub. No. 2021/0015738A1 "ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND" (Published January 21, 2021) From [**0089**] "In specific embodiments**, the psychedelic compound is present in up to 5 mg**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof." From [**0132**] "In specific embodiments, the **psychedelic compound** has a **purity of at least 97.5 wt. % pure**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof."
70. The pharmaceutical composition of claim 65, wherein the composition comprises 10 mg of psilocybin.	1. U.S. Pat. App. Pub. No. 2021/0015738A1 "ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND" (Published January 21, 2021) From [**0088**] "In specific embodiments**, the psychedelic compound is present in up to 10 mg**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof."

	From [**0132**] "In specific embodiments, the **psychedelic compound** has a **purity of at least 97.5 wt. % pure**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof."
71. The pharmaceutical composition of claim 65, wherein the composition comprises 25 mg of psilocybin.	1. U.S. Pat. App. Pub. No. 2021/0015738A1 "ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND" (Published January 21, 2021) From [**0087**] "In specific embodiments**, the psychedelic compound is present in up to 25 mg**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof." From [**0132**] "In specific embodiments, the **psychedelic compound** has a **purity of at least 97.5 wt. % pure**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof."
72. The pharmaceutical composition of claim 65, wherein the composition comprises 40 mg of psilocybin.	1. U.S. Pat. App. Pub. No. 2021/0015738A1 "ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND" (Published January 21, 2021) From [**0097**] "In specific embodiments, **the psychedelic compound is present in 1-50 mg**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof." From [**0132**] "In specific embodiments, the **psychedelic compound** has a **purity of at least 97.5 wt. % pure**." From [**0075**] "In specific embodiments, the **psychedelic compound** selected from the group consisting of **psilocybin**, psilocin, baeocystin, mescaline, LSD, ketamine, salvinorin A, ibotenic acid, muscimol, DMT, MDMA, MDEA, MDA, and combinations thereof."

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/285,109	**10/31/2024 05:06:09 PM Z ET**	

Title of Invention

Application Information

APPLICATION TYPE		PATENT #	
CONFIRMATION #		FILED BY	Sisi Li
PATENT CENTER #	67801555	FILING DATE	09/29/2023
CUSTOMER #	–	FIRST NAMED INVENTOR	
INTL. APPLICATION #	-	INTL. FILING DATE	-
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	-

Documents

TOTAL DOCUMENTS: 8

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
third-party-preissuance-submission.pdf		2	Third-Party Submission Under 37 CFR 1.290	48 KB
Concise-description-generated.pdf		2	Concise Description of Relevance	27 KB
Third-party-notification-request.pdf		1	Request for Notification of Non-compliant Third-Party Submission	13 KB
Claims_Chart.pdf		18	-	422 KB
Claims_Chart-3P.RELEVANCE.pdf	(1-18)	18	Concise Description of Relevance	361 KB
Claims_Chart-3P.RELEVANCE.pdf	(1-18)	18	Concise Description of Relevance	361 KB

Claims_Chart-3P.RELEVANCE.pdf	(1-18)	18	Concise Description of Relevance	361 KB
Claims_Chart-3P.RELEVANCE.pdf	(1-18)	18	Concise Description of Relevance	361 KB
3_GOTVALDOVA.pdf		8	-	903 KB
3_GOTVALDOVA-NPL.pdf	(1-8)	8	Non Patent Literature	905 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
third-party-preissuance-submission.pdf	972F5D18D00FD78BC88B54324DA4A5AB8B7FF3CACE1A18581A805D1E94BBB36A007C905F9D5225E680B4BB6FF202F3ACFFAA83A2F06866AE8154C7B265E6DD66
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Claims_Chart.pdf	08E36565CE2A1355C016FE969DE07220D1FBAFFF6D21DFD01D64A4881769E699D8C0DF936532832EDA91C5F84FCDCBD6B4191328140AE8AB1DBC7EFA1A386FC4
Claims_Chart-3P.RELEVANCE.pdf	7A9875848EBADD6F943F7EF1A535C057640502CC7A7FCDC3E3C63DEE336325C9B5C3A18B080FAFCBAAF7540A14F87911112C2F08E4412C9DE34E2D6A78DBAEF2
Claims_Chart-3P.RELEVANCE.pdf	BE9AB5230AB9641C79ECB9775CF9D2991B2FDCB4BD89E3BE6C66AFB7BE9C4F6678929E8FC1D2C301DE19078AB59FA68A3CD309EA0B0F9DBEACDFC94C641CCBF0
Claims_Chart-3P.RELEVANCE.pdf	9F4F9B34B1052E01ECEEFA2FAD9E4A9545CAA37D4A1976B3CC5DA3C5F18D060B9CAEDD3A4238C18CEB4E56F62AAADEE6B044F29F6D4A8D029BDE827F18A6066F
Claims_Chart-3P.RELEVANCE.pdf	39B2B6E168B0AE4C008493E3BAC5A2A3958592A135CB14D8ADDBE7B67603E49AD590A7893FD203E97EF14B1C7C963523C51338A2DDE56912D9827B26CA7E8EB7
3_GOTVALDOVA.pdf	BC7A1075A2AC28885ED8F695BF5757B3D3D85D679B416808832BC70FEC25C50A677EDA8A7EB43431B1360086C91960E5C06BE5E18DD572E1745514915CFC3E73
3_GOTVALDOVA-NPL.pdf	E3E48B009F36493050F7516096855239611245 6AD9C30639E04D0B56DDE581EC7FED0A145DC0AFF34BB36CD133FCAD19EA

A8D42FD2D924D154616499E54E0F22

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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 #
18/285,109	**10/31/2024 05:06:09 PM Z ET**	

Title of Invention

Application Information

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INTL. APPLICATION #	-	INTL. FILING DATE	-
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 0642	**E20240UH07255227**	**Sisi Li**

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

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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.