PATENT COOPERATION TREATY

PCT

THIRD PARTY OBSERVATION

(PCT Administrative Instructions Part 8)

Applicant's or agent's file reference	
COPA-025/01WO	
International application number	International filing date (day/month/year)
PCT/EP2022/058483	30 Mar 2022 (30/03/2022)
Applicant	
COMPASS PATHFINDER LIMITED	

Third party observation submitted by	Observation submitted on behalf of
Sisi LI	Porta Sophia
Date of submission(day/month/year)	Language of observation
	English

Basis and contents of observation

1. The observation is made on the basis of the claims in the international application as filed.
2. The observation comprises:
   References to documents: 4
   Uploaded copies of documents: 1
3. Further explanations:
   Uploaded copies of documents: 0

Citation # 1(Periodical article) (# uploaded documents:1):

Author:	Title of article:	Title of Periodical:	Publication Date:
Gotvaldová, Klára; Hájková, Kateřina; Borovička, Jan; Jurok , Radek; Cihlářová, Petra; Kuchař, Martin	Stability of psilocybin and its four analogs in the biomass of the psychotropic mushroom Psilocybe cubensis	Drug Testing and Analysis	09 Feb 2021 (09/02/ 2021)

Issue Number of Periodical:	Publisher of Periodical:	Place of publication:
Volume 13 Issue 2		
Page range of article within periodical:	ISBN:	ISSN:

DOI:
10.1002/dta.2950

Most relevant passages or drawings:	Relevant to Claims:
Page 444 Figure 3	1, 40

Brief explanation of relevance:
From page 444 “FIGURE 3 Stability of psilocybin as a major tryptamine in fungal powder after 15 months”; relevant to WO2022207746 claims 1, 40

Citation # 2 (Patent/utility model) (# uploaded documents: 0):

Country code:	Publication number:	Document kind code:
US	20210069170	A1

Patent Applicant/Patent Owner:	Title of invention:
STAMETS; Paul Edward	TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH

Link to document:

Publication Date:	Filing Date:	Priority Date:
11 Mar 2021 (11/03/2021)	18 Nov 2020 (18/11/2020)	23 Jul 2016 (23/07/2016)

Source of Abstract:	Accession number:	Publication Date of Abstract:	Retrieval Date of Abstract:

Most relevant passages or drawings:	Relevant to Claims:
Table 1, Table 2, [0142]-[0143], [0091], [0106], claim 25	2, 3, 5, 6, 7, 13...

Brief explanation of relevance:

From Table 1: “TABLE 1 Exemplary neurotropic or nootropic compositions Component Example Dosage Tryptamine neurotrophics, Psilocybin, baeocystin, norbaeocystin, 10 ng to 10 mg tryptamine derivatives, psilocin, norpsilocin, 4-hydroxytryptamine, esters, or salts thereof … Optional pharmaceutical Fillers, binders, diluents, vehicles, lubricants, quantum sufficit excipients preservatives, flavors, colors, etc.”; relevant to WO2022207746 claims 2, 3, 18, 19, 20, 21, 43, 44

From Table 2: “The percent mass of psilocybin, psilocin and baeocystin in dried psilocybe mushrooms is shown in Table 2.”; relevant to WO2022207746 claims 5, 6, 41

From [0142- 0143]: “Another embodiment is a composition of one or more tryptamines or in pure form or extracts from psilocybin containing mushrooms… tablet and/or capsule diluents (calcium carbonate…, pregelatinized starch, sucrose, compressible sugar, confectioner's sugar); tablet disintegrants (alginic acid, microcrystalline cellulose, croscarmellose sodium, crospovidone, polacrilin potassium, sodium starch glycolate, starch, pregelatinized starch); tablet and/or capsule lubricants (calcium stearate, glyceryl behenate, magnesium stearate, light mineral oil, sodium stearyl fumarate, stearic acid,”; relevant to WO2022207746 claims 7, 14, 30, 36

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.” relevant to WO2022207746 claims 15

From [0106]: “The pharmaceutically acceptable compositions described herein may be orally administered in any orally acceptable dosage form including , but not limited to , capsules , tablets , aqueous suspensions , or solutions .” relevant to WO2022207746 claims 37

From Claim 25: “A method of treating … mood disorders, cognitive enhancement , physical or motor neuron enhancement … or extracts or isolates from psilocybin containing mushrooms … combinations thereof and one or more pharmaceutically acceptable excipients” relevant to WO2022207746 claims 52

Citation # 3 (Patent/utility model) (# uploaded documents: 0):

Country code:	Publication number:	Document kind code:
US	20210015738	A1

Patent Applicant/Patent Owner:	Title of invention:
LaRosa; Tony, Davidson; Robert, Reid; David	ORAL DISSOLVABLE FILM CONTAINING PSYCHEDELIC COMPOUND

Link to document:		
Publication Date: 21 Jan 2021 (21/01/2021)	Filing Date: 14 Jul 2020 (14/07/2020)	Priority Date: 17 Jul 2019 (17/07/2019)

Source of Abstract:	Accession number:	Publication Date of Abstract:	Retrieval Date of Abstract:

Most relevant passages or drawings:	Relevant to Claims:
[0009], [0013], [0075], [0320], [0036], [0097], [0091], [0089], [0088], [0082], [0097], [0146], [0073], [0009]	1, 13, 15, 18, 19...

Brief explanation of relevance:

From [0009]: "…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…" relevant to WO2022207746 claims 1

From [0013]: "…Optional additional excipients (alternatively referred to as "additives") used to manufacture the oral film can include one or more of..." relevant to WO2022207746 claims 1

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..." relevant to WO2022207746 claims 1

From [0135]: "…In specific embodiments, the psychedelic compound has a purity of at least 99.5 wt. % pure...." relevant to WO2022207746 claims 1, 15

From [0320]: "…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..." relevant to WO2022207746 claims 1, 40

From [0036]: "…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..." relevant to WO2022207746 claims 13

From [0097]: "In specific embodiments, the psychedelic compound is present in 1-50 mg" relevant to WO2022207746 claims 18, 42

From [0091]: "In specific embodiments, the psychedelic compound is present in 1 mg" relevant to WO2022207746 claims 19, 42

From [0089]: "In specific embodiments, the psychedelic compound is present in 5 mg" relevant to WO2022207746 claims 20, 42

From [0088]: "In specific embodiments, the psychedelic compound is present in 10 mg" relevant to WO2022207746 claims 21, 42

From [0082]: "In specific embodiments, the psychedelic compound is present in 25 mg" relevant to WO2022207746 claims 22, 42

From [0097]: "In specific embodiments, the psychedelic compound is present in 1-50 mg." relevant

to WO2022207746 claims 23, 42

From [0146]: “In specific embodiments, the oral dissolvable film contains 8±3 wt. % water or moisture.” relevant to WO2022207746 claims 34, 35

From [0073]: “…Enteral medications come in various forms, including, e.g., tablets to swallow, chew or dissolve in water; capsules and...” relevant to WO2022207746 claims 42

From [0185]: “…In specific embodiments, the flowable water-soluble or water swellable film-forming matrix that includes a … glidant, ...” relevant to WO2022207746 claims 45

From [0009]: “…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....” relevant to WO2022207746 claims 52

Citation # 4 (Patent/utility model) (# uploaded documents: 0):

Country code:	Publication number:	Document kind code:
US	20190119310	A1

Patent Applicant/Patent Owner:	Title of invention:
Londesbrough; Derek John, Brown; Christopher...etc	PREPARATION OF PSILOCYBIN, DIFFERENT POLYMORPHIC FORMS, INTERMEDIATES, FORMULATIONS AND THEIR USE

Link to document:

Publication Date:	Filing Date:	Priority Date:
25 Apr 2019 (25/04/2019)	09 Oct 2018 (09/10/2018)	09 Oct 2017 (09/10/2017)

Source of Abstract:	Accession number:	Publication Date of Abstract:	Retrieval Date of Abstract:

Most relevant passages or drawings:	Relevant to Claims:
Table 29, [0026], Table 37, [0108], Table 10, [0115], [0122], [0498]	1, 8, 9, 10, 11 ...

Brief explanation of relevance:

From Table 29: "…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..." relevant to WO2022207746 claims 1

From [0026]: "…It is a first object of this invention to provide psilocybin, of consistent polymorphic form, for administration to human subjects..." relevant to WO2022207746 claims 8, 9

From Table 37: "…TABLE 37 Strength Material flow Blend Content Batch No (mg) (Carrs Index) Uniformity uniformity APL-117- 1.0 19.1 TOP = 127.9 % Label 6085-01 Middle = 106.4 claim = 92.4 Bottom = 104.5 AV = 7.9 Mean = 112.9 % RSD = 10.9 APL-117- 1.0 19.1 TOP = 115.9 % Label 6085-02 Middle = 106.6 claim = 95.2 Bottom = 106.1 AV = 5.9 Mean = 109.6 % RSD = 4.9 APL-117 - 1.0 22.4 TOP = 105.0 % Label 6085-03 Middle = 101.4 claim = 96.3 Bottom = 98.7 AV = 4.6 Mean = 101.7 % RSD = 3.8..." relevant to WO2022207746 claims 8, 9

From [0108]: "…The preferred forms comprises high compactability grades with a particle size range of from about 45 to 150 microns...." relevant to WO2022207746 claims 10, 11

From Table 10: "4. Drug related impurity… No single impurity NMT 1.0% … Typically NLT 99% … Test method… HPLC… NMT = not more than, LT = less than…" relevant to WO2022207746 claims 16, 17

From [0115]: "…The psilocybin would typically be present in a formulated dose in an amount of from 0.01 mg/kg to 1 mg/kg. A typical human dose (for an adult weighing 60-80 kg) would equate to a dose of somewhere between 0.60 mg and 80 mg. In one embodiment, between 2 and 50 mg of crystalline psilocybin, most preferably Polymorph A or Polymorph A′...." relevant to WO2022207746 claims 24, 25, 27

From [0122]: "…Alternatively, and independently, the crystalline psilocybin may take the form of Hydrate A or Polymorph B" relevant to WO2022207746 claims 26, 28

From [0498]: "…From none of the solvents investigated was true Polymorph A or A′ isolated following extended equilibration and thermal maturation of amorphous Psilocybin" relevant to WO2022207746 claims 29