IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Lobe Sciences Ltd Confirmation No.: 2374

Serial No.: 18/009,161 Group No.:

Filing or 371(c) Date: 12 August 2022 Examiner:

Entitled: Methods and Compositions for Treating Mild Traumatic Brain Injury, Post-Traumatic Stress Disorder and Mild Traumatic Brain Injury with Post Traumatic Stress Disorder

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. EAKIN (2014) "Efficacy of N-Acetyl Cysteine in Traumatic Brain Injury" *PLoS One.* Vol. 9(4): e90617.
- 2. BACK (2017) "A Double-Blind Randomized Controlled Pilot Trial of N-Acetylcysteine in Veterans with PTSD and Substance Use Disorders" *Journal of Clinical Psychiatry*. Vol. 77(11): e1439–e1446.
- 3. HOFFER (2013) "Amelioration of Acute Sequelae of Blast Induced Mild Traumatic Brain Injury by N-Acetyl Cysteine: A Double-Blind, Placebo Controlled Study" *PLoS One.* Vol. 8(1): e54163.
- EROWID User Ivan (2018) "Healing From PTSD, Trauma, Rebirth LSD, Oxycodone & MDMA" Retrieved 8 November 2018. URL: https://www.erowid.org/experiences/exp.php?ID=112549
- 5. REDDIT User DryIceAltarGuy (2020) "N-acetyl cysteine (NAC) and MDMA's magic. (pt.5)" Retrieved 12 April 2020. URL:
 - https://www.reddit.com/r/MDMA/comments/fzgb10/nacetyl_cysteine_nac_and_mdmas_magic_p t5/
- 6. CAPELA (2006) "Neurotoxicity of ecstasy metabolites in rat cortical neurons, and influence of hyperthermia" *Toxicology Letters*. Vol. 164: S118.
- 7. FEDUCCIA (2018) "MDMA-assisted psychotherapy for PTSD: Are memory reconsolidation and fear extinction underlying mechanisms?" *Progress in Neuro-Psychopharmacology & Biological Psychiatry*. Vol. 84: 221-228
- 8. EDUT (2014) "A study on the mechanism by which MDMA protects against dopaminergic dysfunction after minimal traumatic brain injury (mTBI) in mice" *Journal of Molecular Neuroscience*. Vol. 54(4): 684-697

- 9. MAYO CLINIC (2017) "Post-traumatic stress disorder (PTSD)" Retrieved from 09 October 2017. URL: https://web.archive.org/web/20171009044608/https://www.mayoclinic.org/diseases-conditions/post-traumatic-stress-disorder/symptoms-causes/syc-20355967
- 10. CISION (2020) "ATAI Life Sciences Partners with Neuronasal Inc. to Develop Novel Treatment for mild Traumatic Brain Injury (mTBI)" Published 6 January 2020. URL: https://web.archive.org/web/20200303215829/https://www.prnewswire.com/news-releases/atai-life-sciences-partners-with-neuronasal-inc-to-develop-novel-treatment-for-mild-traumatic-brain-injury-mtbi-300981591.html
- 11. BLUELIGHT User Cyberius (2014) "MDMA Nasal Dosage #6" Retrieved 14 January 2014. URL: https://bluelight.org/xf/threads/mdma-nasal-dosage.705507/
- 12. LAWS (2007) "Ecstasy (MDMA) and memory function: a meta-analytic update" Human *Psychopharmacology: Clinical and Experimental*. Vol. 22(6): 381-388
- 13. REDDIT User Dowdidik (2020) "N-acetyl cysteine (NAC) and MDMA's magic. (pt.5)"
 Retrieved 11 April 2020. URL:
 https://www.reddit.com/r/MDMA/comments/fzgb10/nacetyl_cysteine_nac_and_mdmas_magic_p
 t5/
- 14. U.S. Pat. App. Doc. No. US 2011/0262442A1 "COMPOSITIONS FOR TREATING CNS DISORDERS" (Published October 27, 2011)

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. 18/009,161 Pending Claims	References
1. A method for	14. U.S. Pat. App. Doc. No. US 2011/0262442A1 "COMPOSITIONS FOR
alleviating one or	TREATING CNS DISORDERS" (Published October 27, 2011)
more symptoms of	
mild traumatic brain	From [0186] "In certain embodiments, the present invention provides for a
injury (mTBI), post-	method of treating post-traumatic stress disorders, comprising
traumatic stress	administering one or more agents that increase BBB permeability in
disorder (PTSD) or	combination with one or more therapeutic agents. Such therapeutic agents
mTBI with PTSD, said	are selected from a group consisting of cycloserine, MDMA, mirtazapine,
method comprising	nepicastat, topiramate and MK 0594."
administering to a	F 12 %12 Th
subject suffering from	From claim 13 "13. The method according to claim 1, wherein the small
mTBI, PTSD or mTBI	molecule therapeutic agent is selected from minocycline, modafinil, morphine, N-acetylcysteine, naproxen, nelfinavir, neurotrin, nitrazepam,
with PTSD a	NSAIDs,"
psychedelic agent in	110/11/20,
combination with N-	From claim 1 "A method for delivering a small molecule therapeutic
acetylcysteine (NAC).	agent to the brain of a subject, comprising administering to said subject:
acetylcysteme (IVAC).	(a) an agent which activates both of A.sub.1 and A.sub.2a adenosine
	receptors; and (b) a small molecule therapeutic agent."
	From [0141] "A therapeutically effective amount of the combination will
	be understood to be an amount which treats, inhibits, prevents or
	ameliorates one or more symptoms of the CNS disorder or episode in
	question . In certain embodiments of the invention, the combination will
	show improved efficacy than that achieved by administration of the
	same amount of the therapeutic agent alone. Furthermore, in certain
	embodiments the effective amount of the combination produces fewer side
	effects than are observed when the therapeutic agent is administered alone at
	a dose that achieves substantially similar therapeutic efficacy. Additionally,
	in certain embodiments, the effective amount of the combination results in
	increased therapeutic efficacy and a reduced effective dose of the therapeutic agent than is observed when the therapeutic agent is administered alone."
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	4. EROWID User Ivan (2018) "Healing From PTSD, Trauma, Rebirth LSD,
	Oxycodone & MDMA" Retrieved 8 November 2018. URL:
	https://www.erowid.org/experiences/exp.php?ID=112549
	maps.//www.crowid.org/experiences/exp.php:1D-112347
	From webpage "I tried this to attempt to overcome PTSD from child
	abuse , family pointing guns at me at age 6, having nightmares of exactly
	this, but my own father doing it.
	I was planning this for like a year. I always thought of the idea of starning
	I was planning this for like a year, I always thought of the idea of stopping
	bad trips before they happen by forcing my brain in a extremely euphoric
	heavenly state as LSD amplifies current mood, so I obtained all the things
	needed for this experiment. I wanted the purest drugs possible and I won't
	mention the source but I am sure purity is a minimum of 90% and is uncut. I

acquired some 10x 165ug tabs and MDMA, Oxycodone from my mom who has cancer.

So woke up at 8am, took a shower, ate breakfast.

10:30am **I Double dosed up on things** to block neurotoxicity, **NAC**, Alpha lipoic acid, Selenium, Vit C, L-Theanine...

2:30pm used my trusty GEMINI-20 and weighed out a single chunk of 120mg of uncut, pure 4-MethylenedioxyMethamphetamine (MDMA) I swallowed it whole, 30 mins It kicked in and peaked in 1 hour, me and my mother who has Stage-4 cancer went to the park who I wanted to spend time with as she is dying but still fully functional for now..."

6. CAPELA (2006) "Neurotoxicity of ecstasy metabolites in rat cortical neurons, and influence of hyperthermia" Toxicology Letters. Vol. 164: S118.

From abstract "3,4-Methylenedioxymethamphetamine (MDMA or "Ecstasy"), is a widely abused, psychoactive recreational drug. Metabolism of MDMA involves N-demethylation to 3,4-methylenedioxyamphetamine (MDA). MDMA and MDA are O-demethylenated to N-methyl-amethyldopamine (N-Me-a-MeDA) and a-methyldopamine (a-MeDA), respectively, both of which are catechols that can undergo oxidation to the corresponding ortho-quinones. In the presence of glutathione (GSH), orthoquinones may be conjugated with GSH to form a glutathionyl adduct. In this study, we evaluated the neurotoxicity of MDMA and of three of its metabolites, obtained by synthesis, N-Me-a-MeDA, a-MeDA and 5-(GSH)a-MeDA (5-(Glutathion-Syl)-a-methyldopamine) in rat cortical neuronal serum free cultures under normal (36.5 °C) and hyperthermic (40 °C) conditions. Our study shows that these metabolites are more neurotoxic than the parent compound MDMA. They induced programmed cell death in cortical neurons and their neurotoxic effect was potentiated under hyperthermic conditions (40 °C). N-Acetylcystein, an antioxidant and precursor of GSH, protected against MDMA metabolites-induced neurotoxicity, indicating that GSH depletion may render the cells more exposed to the effects of these reactive metabolites. These data suggest that MDMA metabolism and MDMA-induced hyperthermia, leading to the formation of ROS/RNS and/or toxic oxidation"

5. REDDIT User DryIceAltarGuy (2020) "N-acetyl cysteine (NAC) and MDMA's magic. (pt.5)" Retrieved 12 April 2020. URL: https://www.reddit.com/r/MDMA/comments/fzgb10/nacetyl_cysteine_nac_a nd_mdmas_magic_pt5/

From **webpage** "Since I was tagged in this post, I'm gonna plug my post on the case for adding taurine to the pre-load stack.

I also want to elaborate more here on how taurine may work synergistically with NAC, and in particular how taurine may help extend the amount of time that NAC, taken before rolling, may offer a protective effect against MDMA induced neurotoxicity.

Taking NAC increases your body's pool of intracellular cysteine. Cysteine is a precursor to the body's natural antioxidant, glutathione. In times of oxidative stress, such as acetaminophen (paracetamol) poisoning or when taking MDMA, the body is able to draw on this cysteine pool to replenish its supply of glutathione...

As I said in the post that was linked, I'm interested in the idea that there might be someway to get the protective effects of pre-loading with NAC without blunting one's roll, by carefully timing the dosage and timing of the last NAC taken before taking MDMA. I suspect that supplementing taurine with that last NAC, and in between the last NAC and when taking MDMA, could help keep the intracellular cysteine pool elevated longer than is accoplished by taking NAC alone."

1. EAKIN (2014) "Efficacy of N-Acetyl Cysteine in Traumatic Brain Injury" *PLoS One.* Vol. 9(4): e90617.

From Abstract "In this study, using two different injury models in two different species, we found that early post-injury treatment with N-Acetyl Cysteine (NAC) reversed the behavioral deficits associated with the TBL."

2. BACK (2017) "A Double-Blind Randomized Controlled Pilot Trial of N-Acetylcysteine in Veterans with PTSD and Substance Use Disorders" *Journal of Clinical Psychiatry*. Vol. 77(11): e1439–e1446.

From Abstract "Participants treated with NAC, as compared to placebo, evidenced significant improvements in PTSD symptoms, craving, and depression."

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From Abstract "Secondary analysis revealed subjects receiving NAC within 24 hours of blast had an 86% chance of symptom resolution with no reported side effects versus 42% for those seen early who received placebo."

From **Abstract** "This study, conducted in an active theatre of war, demonstrates that **NAC**, a safe pharmaceutical countermeasure, has beneficial effects on the severity and resolution of sequelae of blast induced mTBI. This is the first demonstration of an effective short term countermeasure for mTBI. Further work on long term outcomes and the potential use of NAC in civilian mTBI is warranted."

7. FEDUCCIA (2018) "MDMA-assisted psychotherapy for PTSD: Are memory reconsolidation and fear extinction underlying mechanisms?" *Progress in Neuro-Psychopharmacology & Biological Psychiatry*. Vol. 84: 221-228

From abstract "MDMA-assisted psychotherapy for treatment of PTSD has recently progressed to Phase 3 clinical trials and received Breakthrough Therapy designation by the FDA. MDMA used as an adjunct during psychotherapy sessions has demonstrated effectiveness and acceptable safety in reducing PTSD symptoms in Phase 2 trials, with durable remission of PTSD diagnosis in 68% of participants..."

8. EDUT (2014) "A study on the mechanism by which MDMA protects against dopaminergic dysfunction after minimal traumatic brain injury (mTBI) in mice" *Journal of Molecular Neuroscience*. Vol. 54(4): 684-697

From abstract "... We have previously demonstrated in mice that low MDMA doses prior to mTBI can lead to better performances in **cognitive tests.** The purpose of this study was to assess in mice the changes in the dopamine system that occurs after both MDMA and minimal traumatic brain injury (mTBI). Experimental mTBI was induced using a concussive head trauma device. One hour before injury, animals were subjected to MDMA. Administration of MDMA before injury normalized the alterations in tyrosine hydroxylase (TH) levels that were observed in mTBI mice. This normalization was also able to lower the elevated dopamine receptor type 2 (D2) levels observed after mTBI. Brain-derived neurotrophic factor (BDNF) levels did not change following injury alone, but in mice subjected to MDMA and mTBI, significant elevations were observed. In the behavioral tests, haloperidol reversed the **neuroprotection** seen when MDMA was administered prior to injury. Altered catecholamine synthesis and high D2 receptor levels contribute to cognitive dysfunction, and strategies to normalize TH signaling and D2 levels may provide relief for the deficits observed after injury. Pretreatment with MDMA kept TH and D2 receptor at normal levels, allowing regular dopamine system activity..."

- 2. The method of claim 1 wherein the empathogen is selected from the group
- 4. EROWID User Ivan (2018) "Healing From PTSD, Trauma, Rebirth LSD, Oxycodone & MDMA" Retrieved 8 November 2018. URL: https://www.erowid.org/experiences/exp.php?ID=112549

consisting $\overline{\text{of } 3,4}$ methylenedioxymethamphetamine (MDMA), 3,4methlenedioxyampheta mine (MDA), 3,4methylenedioxy-Nethylamphetamine (MDEA), 3,4methylenedioxy-Nhydroxyamphetamine (MDOH), N-methyl-1.3benzodioxolylbutanami ne (MBDB), 6-(2aminopropyl)benzofura n (6-APB), methylone, mephedron, αNT, αET, and 5,6methylenedioxy-2aminoindane (MDAI).

From webpage "I tried this to attempt to overcome PTSD from child abuse, family pointing guns at me at age 6, having nightmares of exactly this, but my own father doing it.

I was planning this for like a year, I always thought of the idea of stopping bad trips before they happen by forcing my brain in a extremely euphoric heavenly state as LSD amplifies current mood, so I obtained all the things needed for this experiment. I wanted the purest drugs possible and I won't mention the source but I am sure purity is a minimum of 90% and is uncut. I acquired some 10x 165ug tabs and MDMA, Oxycodone from my mom who has cancer.

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3. The method of claim 1 wherein the empathogen is MDMA.

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- 4. The method of claim 1 wherein the one or more symptoms alleviated is selected from intrusive memories, nightmares, a sense of reliving the trauma, or psychological or physiological distress when reminded of the trauma, active avoidance of thoughts, feelings, or reminders of the trauma, inability to recall some aspect of the trauma, withdrawal from others, or emotional numbing, insomnia, irritability, difficulty concentrating, hypervigilance and heightened startle response.
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At the park, there was a school, being age 21, **I felt like I was 8 again** and played with the younger kids and got on the swings. My childhood was destroyed due to abuse and trauma from my dad and bullying in school. **I felt like I was in childhood mentally** before my mind was shattered and scarred. The kids were playing, some running, others just lulling along with

their books and backpacks. I thought about all of these kids and their lives and the twisted world in which they had to learn to function as they matured. I wished there was some type of way for them to grow up into a state of being not unlike one that I was living right now. I'm not wishing children to start using drugs but just to feel as I was. I felt so free and part of, but yet away from, all of these various aged children and assorted parents...

I was just smiling and joking around right back at him and the others. The buzz I had felt like more than a buzz. It felt like I was literally more "alive" than living. I felt as if I could do no wrong and my choice in word usage was the absolute paramount selection of what could be used in my communication. I encountered other adults and although I didn't feel intellectually advanced to anyone, I felt like I was in a superior place where any one of them could go if they wished.

Conclusion, Oxycodone, MDMA and LSD was a life changing experience how amazing it is to be alive and breathing, the gift of life, and that forcing good vibes is totally possible and works..."

7. FEDUCCIA (2018) "MDMA-assisted psychotherapy for PTSD: Are memory reconsolidation and fear extinction underlying mechanisms?" *Progress in Neuro-Psychopharmacology & Biological Psychiatry*. Vol. 84: 221-228

From abstract "MDMA-assisted psychotherapy for treatment of PTSD has recently progressed to Phase 3 clinical trials and received Breakthrough Therapy designation by the FDA. MDMA used as an adjunct during psychotherapy sessions has demonstrated effectiveness and acceptable safety in reducing PTSD symptoms in Phase 2 trials, with durable remission of PTSD diagnosis in 68% of participants..."

From page 223 ". For example, a participant from a MAPS-sponsored MDMA-assisted psychotherapy clinical trial described this by saying, "One thing the MDMA facilitates is thinking about traumatic experiences in a neutral, safe manner. I could objectively think about them and talk about them. Then, it seems those memories are put back in their place in the brain in a different configuration — a configuration that does not cause as many problems, such as bad dreams, intrusive thoughts all the time or having horrible insomnia. This has continued to this day, a year and a half after the last MDMA session."

2. BACK (2017) "A Double-Blind Randomized Controlled Pilot Trial of N-Acetylcysteine in Veterans with PTSD and Substance Use Disorders" *Journal of Clinical Psychiatry*. Vo. 77(11): e1439–e1446.

From Abstract "Participants treated with NAC, as compared to placebo, evidenced significant improvements in PTSD symptoms, craving, and depression."

9. MAYO CLINIC (2017) "Post-traumatic stress disorder (PTSD)" Retrieved from 09 October 2017. URL:

https://web.archive.org/web/20171009044608/https://www.mayoclinic.org/diseases-conditions/post-traumatic-stress-disorder/symptoms-causes/syc-20355967

From page 1

"Symptoms

Post-traumatic stress disorder symptoms may start within one month of a traumatic event, but sometimes symptoms may not appear until years after the event. These symptoms cause significant problems in social or work situations and in relationships. They can also interfere with your ability to go about your normal daily tasks.

PTSD symptoms are generally grouped into four types: intrusive memories, avoidance, negative changes in thinking and mood, and changes in physical and emotional reactions. Symptoms can vary over time or vary from person to person.

Intrusive memories

Symptoms of intrusive memories may include:

Recurrent, unwanted distressing memories of the traumatic event
Reliving the traumatic event as if it were happening again (flashbacks)
Upsetting dreams or nightmares about the traumatic event
Severe emotional distress or physical reactions to something that
reminds you of the traumatic event

Avoidance

Symptoms of avoidance may include:

Trying to avoid thinking or talking about the traumatic event Avoiding places, activities or people that remind you of the traumatic event

Negative changes in thinking and mood

Symptoms of negative changes in thinking and mood may include:

Negative thoughts about yourself, other people or the world Hopelessness about the future

Memory problems, including not remembering important aspects of the traumatic event

Difficulty maintaining close relationships Feeling detached from family and friends

Lack of interest in activities you once enjoyed Difficulty experiencing positive emotions

Feeling emotionally numb

Changes in physical and emotional reactions

Symptoms of changes in physical and emotional reactions (also called arousal symptoms) may include:

Being easily startled or frightened Always being on guard for danger

Self-destructive behavior, such as drinking too much or driving too fast

Trouble sleeping

Trouble concentrating

Irritability, angry outbursts or aggressive behavior

Overwhelming guilt or shame"

5. The method of claim 1 wherein the empathogen and NAC are administered simultaneously.

14. U.S. Pat. App. Doc. No. US 2011/0262442A1 "COMPOSITIONS FOR TREATING CNS DISORDERS" (Published October 27, 2011)

From [0151] "As used herein, the term "combination," "combined," and related terms refers to the simultaneous or sequential administration of therapeutic agents in accordance with this invention. For example, a combination of the present invention may be administered with another therapeutic agent simultaneously or sequentially in separate unit dosage forms or together in a single unit dosage form."

From [0186] "In certain embodiments, the present invention provides for a method of treating post-traumatic stress disorders, comprising administering one or more agents that increase BBB permeability in combination with one or more therapeutic agents. Such therapeutic agents are selected from a group consisting of cycloserine, MDMA, mirtazapine, nepicastat, topiramate and MK 0594."

From claim 13 "13. The method according to claim 1, wherein the small molecule therapeutic agent is selected from ... minocycline, modafinil, morphine, N-acetylcysteine, naproxen, nelfinavir, neurotrin, nitrazepam, NSAIDs, ..."

From claim 1 "A method for delivering a small molecule therapeutic agent to the brain of a subject, comprising administering to said subject:

(a) an agent which activates both of A.sub.1 and A.sub.2a adenosine receptors; and (b) a small molecule therapeutic agent."

From [0141] "A therapeutically effective amount of the combination will be understood to be an amount which treats, inhibits, prevents or ameliorates one or more symptoms of the CNS disorder or episode in question. In certain embodiments of the invention, the combination will show improved efficacy than that achieved by administration of the same amount of the therapeutic agent alone. Furthermore, in certain embodiments the effective amount of the combination produces fewer side effects than are observed when the therapeutic agent is administered alone at a dose that achieves substantially similar therapeutic efficacy. Additionally, in certain embodiments, the effective amount of the combination results in increased therapeutic efficacy and a reduced effective dose of the therapeutic agent than is observed when the therapeutic agent is administered alone."

6. The method of claim 5 wherein the empathogen and NAC are formulated in a solid dosage form and administered to a patient orally.

14. U.S. Pat. App. Doc. No. US 2011/0262442A1 "COMPOSITIONS FOR TREATING CNS DISORDERS" (Published October 27, 2011)

From [0110] "Pharmaceutically acceptable compositions of this invention may be orally administered in any orally acceptable dosage form including, but not limited to, capsules, tablets, aqueous suspensions or solutions. In the case of tablets for oral use, carriers commonly used include lactose and corn starch. Lubricating agents, such as magnesium stearate, are also typically added. For oral administration in a capsule form, useful diluents include lactose and dried cornstarch. When aqueous suspensions are required for oral use, the active ingredient is combined with emulsifying and suspending agents. If desired, certain sweetening, flavoring or coloring agents may also be added."

From [0186] "In certain embodiments, the present invention provides for a method of treating post-traumatic stress disorders, comprising administering one or more agents that increase BBB permeability in combination with one or more therapeutic agents. Such therapeutic agents are selected from a group consisting of cycloserine, MDMA, mirtazapine, nepicastat, topiramate and MK 0594."

From claim 13 "13. The method according to claim 1, wherein the small molecule therapeutic agent is selected from ... minocycline, modafinil, morphine, N-acetylcysteine, naproxen, nelfinavir, neurotrin, nitrazepam, NSAIDs, ..."

From claim 1 "A method for delivering a small molecule therapeutic agent to the brain of a subject, comprising administering to said subject: (a) an agent which activates both of A.sub.1 and A.sub.2a adenosine receptors; and (b) a small molecule therapeutic agent."

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ameliorates one or more symptoms of the CNS disorder or episode in question. In certain embodiments of the invention, the combination will show improved efficacy than that achieved by administration of the same amount of the therapeutic agent alone. Furthermore, in certain embodiments the effective amount of the combination produces fewer side effects than are observed when the therapeutic agent is administered alone at a dose that achieves substantially similar therapeutic efficacy. Additionally, in certain embodiments, the effective amount of the combination results in increased therapeutic efficacy and a reduced effective dose of the therapeutic agent than is observed when the therapeutic agent is administered alone."

4. EROWID User Ivan (2018) "Healing From PTSD, Trauma, Rebirth LSD, Oxycodone & MDMA" Retrieved 8 November 2018. URL: https://www.erowid.org/experiences/exp.php?ID=112549

From webpage "I tried this to attempt to overcome PTSD from child abuse, family pointing guns at me at age 6, having nightmares of exactly this, but my own father doing it.

I was planning this for like a year, I always thought of the idea of stopping bad trips before they happen by forcing my brain in a extremely euphoric heavenly state as LSD amplifies current mood, so I obtained all the things needed for this experiment. I wanted the purest drugs possible and I won't mention the source but I am sure purity is a minimum of 90% and is uncut. I acquired some 10x 165ug tabs and MDMA, Oxycodone from my mom who has cancer.

So woke up at 8am, took a shower, ate breakfast.

10:30am **I Double dosed up on things** to block neurotoxicity, **NAC**, Alpha lipoic acid, Selenium, Vit C, L-Theanine...

2:30pm used my trusty GEMINI-20 and weighed out a single chunk of 120mg of uncut, pure 4-MethylenedioxyMethamphetamine (MDMA) I swallowed it whole, 30 mins It kicked in and peaked in 1 hour, me and my mother who has Stage-4 cancer went to the park who I wanted to spend time with as she is dying but still fully functional for now..."

7. The method of claim 5 wherein the empathogen and NAC are formulated as a solution or a suspension and are delivered to a patient as a nasal spray 14. U.S. Pat. App. Doc. No. US 2011/0262442A1 "COMPOSITIONS FOR TREATING CNS DISORDERS" (Published October 27, 2011)

From [0135] "Formulations suitable for administration by nasal inhalation include, for example, fine dusts or mists which may be generated by means such as metered dose pressurized aerosols, nebulisers or insufflators."

containing a metered dose of each ingredient.

From [0186] "In certain embodiments, the present invention provides for a method of treating post-traumatic stress disorders, comprising administering one or more agents that increase BBB permeability in combination with one or more therapeutic agents. Such therapeutic agents are selected from a group consisting of cycloserine, MDMA, mirtazapine, nepicastat, topiramate and MK 0594."

From claim 13 "13. The method according to claim 1, wherein the small molecule therapeutic agent is selected from ... minocycline, modafinil, morphine, N-acetylcysteine, naproxen, nelfinavir, neurotrin, nitrazepam, NSAIDs, ..."

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10. CISION (2020) "ATAI Life Sciences Partners with Neuronasal Inc. to Develop Novel Treatment for mild Traumatic Brain Injury (mTBI)" Published 6 January 2020. URL:

https://web.archive.org/web/20200303215829/https://www.prnewswire.com/news-releases/atai-life-sciences-partners-with-neuronasal-inc-to-develop-novel-treatment-for-mild-traumatic-brain-injury-mtbi-300981591.html

From page 2 "By contrast, Neuronasal's intranasal approach enables direct nose-to-brain delivery, allowing for significantly lower doses and outpatient treatment. Given its apparent efficacy in disrupting the underlying neurochemical cascade, intranasal NAC has the potential to induce a fundamental shift in the natural course of the condition for hundreds of thousands of people."

11. BLUELIGHT User Cyberius (2014) "MDMA Nasal Dosage #6" Retrieved 14 January 2014. URL: https://bluelight.org/xf/threads/mdmanasal-dosage.705507/

	,
	From webpage post #6 "I'd recommend redosing nasally. If you start off the night with a line of mdma than you're not going to get many euphoric effects, redosing on the otherhand you will launch yourself right back into a full blown high with a nasal dose. I usually do 75-100mg redoses nasally . Smaller doses don't seem to really do much of anything."
8. The method of claim 1 wherein the composition is administered to prevent pathological conversion of short term memory to long term memory (LTM) and promote disengagement of pathological LTM by a chemical agonist/antagonist shock.	12. LAWS (2007) "Ecstasy (MDMA) and memory function: a meta-analytic update" Human <i>Psychopharmacology: Clinical and Experimental</i> . Vol. 22(6): 381-388 From abstract "A meta-analysis was conducted to examine the impact of recreational ecstasy use on short-term memory (STM), long-term memory (LTM) , verbal and visual memory. We located 26 studies containing memory data for ecstasy and non-ecstasy users from which effect sizes could be derived. The analyses provided measures of STM and LTM in 610 and 439 ecstasy users and revealed moderate-to-large effect sizes (Cohen's d) of d = -0.63 and d = 10.87, respectively. The difference between STM versus LTM was non-significant. The effect size for verbal memory was large (d = -1.00) and significantly larger than the small effect size for visual memory (d = -0.27)"
	From page 385 "This meta-analysis corroborates the notion that the recreational use of ecstasy is associated with considerable memory impairment, significantly affecting both short-term and long-term memory. Although the effect size was larger for LTM than STM, this difference did not reach significance. In practical terms, the STM and LTM memory performance in 72 and 81% of ecstasy users (respectively) is exceeded by the mean of the non-ecstasy using controls"
9. The method of claim 1 wherein the empathogen is administered before NAC.	13. REDDIT User Dowdidik (2020) "N-acetyl cysteine (NAC) and MDMA's magic. (pt.5)" Retrieved 11 April 2020. URL: https://www.reddit.com/r/MDMA/comments/fzgb10/nacetyl_cysteine_nac_a nd_mdmas_magic_pt5/ From webpage "Before I began taking NAC, I had taken MDMA about 5-6 times
	Last time before I begin taking NAC and i took MDMA it was a good evening but not as expected, maybe it was a lower dose and I did some mistake, maybe it was the begining of my brain reacting differently to MDMA. The effects were felt less than before, it was intriguing, I didn't even sweat. No other chemicals is taken when I take MDMA.

	I began taking daily NAC, 600mg, evening before eating, since 15 february 2020. I stopped on 5 and 6 march because I went to a concert of DnB the 6 march.
	This evening I took 200mg of MDMA total, 120 (1:15 am) + 80 (3:00 am). Coming up was strong, like the first times, maybe not like the first, difficult to say. It was a good moment and very envoyable, better than last time at the same dosage and same set and settings"
10. The method of claim 1 wherein the empathogen is administered after	4. EROWID User Ivan (2018) "Healing From PTSD, Trauma, Rebirth LSD, Oxycodone & MDMA" Retrieved 8 November 2018. URL: https://www.erowid.org/experiences/exp.php?ID=112549
NAC.	From webpage "I tried this to attempt to overcome PTSD from child abuse, family pointing guns at me at age 6, having nightmares of exactly this, but my own father doing it.
	I was planning this for like a year, I always thought of the idea of stopping bad trips before they happen by forcing my brain in a extremely euphoric heavenly state as LSD amplifies current mood, so I obtained all the things needed for this experiment. I wanted the purest drugs possible and I won't mention the source but I am sure purity is a minimum of 90% and is uncut. I acquired some 10x 165ug tabs and MDMA, Oxycodone from my mom who has cancer.
	So woke up at 8am, took a shower, ate breakfast.
	10:30am I Double dosed up on things to block neurotoxicity, NAC, Alpha lipoic acid, Selenium, Vit C, L-Theanine
	2:30pm used my trusty GEMINI-20 and weighed out a single chunk of 120mg of uncut, pure 4-MethylenedioxyMethamphetamine (MDMA) I swallowed it whole, 30 mins It kicked in and peaked in 1 hour, me and my mother who has Stage-4 cancer went to the park who I wanted to spend time with as she is dying but still fully functional for now"
11. A pharmaceutical composition for alleviating one or more symptoms of mild	4. EROWID User Ivan (2018) "Healing From PTSD, Trauma, Rebirth LSD, Oxycodone & MDMA" Retrieved 8 November 2018. URL: https://www.erowid.org/experiences/exp.php?ID=112549
traumatic brain injury (mTBI), post-traumatic stress disorder (PTSD) or mTBI with PTSD,	From webpage "I tried this to attempt to overcome PTSD from child abuse, family pointing guns at me at age 6, having nightmares of exactly this, but my own father doing it.
said composition comprising an empathogen and N-	I was planning this for like a year, I always thought of the idea of stopping bad trips before they happen by forcing my brain in a extremely euphoric heavenly state as LSD amplifies current mood, so I obtained all the things

acetylcysteine (NAC) and a pharmaceutically acceptable excipient.

needed for this experiment. I wanted the purest drugs possible and I won't mention the source but I am sure purity is a minimum of 90% and is uncut. I acquired some 10x 165ug tabs and MDMA, Oxycodone from my mom who has cancer.

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At the park, there was a school, being age 21, I felt like I was 8 again and played with the younger kids and got on the swings. My childhood was destroyed due to abuse and trauma from my dad and bullying in school. I felt like I was in childhood mentally before my mind was shattered and scarred. The kids were playing, some running, others just lulling along with their books and backpacks. I thought about all of these kids and their lives and the twisted world in which they had to learn to function as they matured. I wished there was some type of way for them to grow up into a state of being not unlike one that I was living right now. I'm not wishing children to start using drugs but just to feel as I was. I felt so free and part of, but yet away from, all of these various aged children and assorted parents...

I was just smiling and joking around right back at him and the others. The buzz I had felt like more than a buzz. It felt like I was literally more "alive" than living. I felt as if I could do no wrong and my choice in word usage was the absolute paramount selection of what could be used in my communication. I encountered other adults and although I didn't feel intellectually advanced to anyone, I felt like I was in a superior place where any one of them could go if they wished.

Conclusion, Oxycodone, MDMA and LSD was a life changing experience how amazing it is to be alive and breathing, the gift of life, and that forcing good vibes is totally possible and works..."

7. FEDUCCIA (2018) "MDMA-assisted psychotherapy for PTSD: Are memory reconsolidation and fear extinction underlying mechanisms?" *Progress in Neuro-Psychopharmacology & Biological Psychiatry*. Vol. 84: 221-228

From abstract "MDMA-assisted psychotherapy for treatment of PTSD has recently progressed to Phase 3 clinical trials and received Breakthrough Therapy designation by the FDA. MDMA used as an adjunct during psychotherapy sessions has demonstrated effectiveness and acceptable safety in reducing PTSD symptoms in Phase 2 trials, with durable remission of PTSD diagnosis in 68% of participants..."

From page 223 ". For example, a participant from a MAPS-sponsored MDMA-assisted psychotherapy clinical trial described this by saying, "One thing the MDMA facilitates is thinking about traumatic experiences in a neutral, safe manner. I could objectively think about them and talk about them. Then, it seems those memories are put back in their place in the brain in a different configuration — a configuration that does not cause as many problems, such as bad dreams, intrusive thoughts all the time or having horrible insomnia. This has continued to this day, a year and a half after the last MDMA session."

2. BACK (2017) "A Double-Blind Randomized Controlled Pilot Trial of N-Acetylcysteine in Veterans with PTSD and Substance Use Disorders" *Journal of Clinical Psychiatry*. Vo. 77(11): e1439–e1446.

From Abstract "Participants treated with NAC, as compared to placebo, evidenced significant improvements in PTSD symptoms, craving, and depression."

9. MAYO CLINIC (2017) "Post-traumatic stress disorder (PTSD)" Retrieved from 09 October 2017. URL:

https://web.archive.org/web/20171009044608/https://www.mayoclinic.org/diseases-conditions/post-traumatic-stress-disorder/symptoms-causes/syc-20355967

From page 1

"Symptoms

Post-traumatic stress disorder symptoms may start within one month of a traumatic event, but sometimes symptoms may not appear until years after the event. These symptoms cause significant problems in social or work situations and in relationships. They can also interfere with your ability to go about your normal daily tasks.

PTSD symptoms are generally grouped into four types: intrusive memories, avoidance, negative changes in thinking and mood, and changes in physical and emotional reactions. Symptoms can vary over time or vary from person to person.

Intrusive memories

Symptoms of intrusive memories may include:

Recurrent, unwanted distressing memories of the traumatic event
Reliving the traumatic event as if it were happening again (flashbacks)
Upsetting dreams or nightmares about the traumatic event
Severe emotional distress or physical reactions to something that
reminds you of the traumatic event

Avoidance

Symptoms of avoidance may include:

Trying to avoid thinking or talking about the traumatic event

Avoiding places, activities or people that remind you of the traumatic event

Negative changes in thinking and mood

Symptoms of negative changes in thinking and mood may include:

Negative thoughts about yourself, other people or the world Hopelessness about the future

Memory problems, including not remembering important aspects of the traumatic event

Difficulty maintaining close relationships Feeling detached from family and friends

Lack of interest in activities you once enjoyed Difficulty experiencing positive emotions

Feeling emotionally numb

Changes in physical and emotional reactions

Symptoms of changes in physical and emotional reactions (also called arousal symptoms) may include:

Being easily startled or frightened

Always being on guard for danger

Self-destructive behavior, such as drinking too much or driving too fast

Trouble sleeping

Trouble concentrating

Irritability, angry outbursts or aggressive behavior

Overwhelming guilt or shame"

12 . The pharmaceutical
composition of claim 11
in solid formulation

4. EROWID User Ivan (2018) "Healing From PTSD, Trauma, Rebirth LSD, Oxycodone & MDMA" Retrieved 8 November 2018. URL: https://www.erowid.org/experiences/exp.php?ID=112549

From webpage "I tried this to attempt to overcome PTSD from child abuse, family pointing guns at me at age 6, having nightmares of exactly this, but my own father doing it.

I was planning this for like a year, I always thought of the idea of stopping bad trips before they happen by forcing my brain in a extremely euphoric heavenly state as LSD amplifies current mood, so I obtained all the things needed for this experiment. I wanted the purest drugs possible and I won't mention the source but I am sure purity is a minimum of 90% and is uncut. I acquired some 10x 165ug tabs and MDMA, Oxycodone from my mom who has cancer.

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13. The pharmaceutical composition of claim 11 in solution or suspension formulation.

14. U.S. Pat. App. Doc. No. US 2011/0262442A1 "COMPOSITIONS FOR TREATING CNS DISORDERS" (Published October 27, 2011)

From [0135] "Formulations suitable for administration by nasal inhalation include, for example, fine dusts or mists which may be generated by means such as metered dose pressurized aerosols, nebulisers or insufflators."

From [0186] "In certain embodiments, the present invention provides for a method of treating post-traumatic stress disorders, comprising administering one or more agents that increase BBB permeability in combination with one or more therapeutic agents. Such therapeutic agents are selected from a group consisting of cycloserine, MDMA, mirtazapine, nepicastat, topiramate and MK 0594."

From claim 13 "13. The method according to claim 1, wherein the small molecule therapeutic agent is selected from ... minocycline, modafinil, morphine, N-acetylcysteine, naproxen, nelfinavir, neurotrin, nitrazepam, NSAIDs, ..."

From claim 1 "A method for delivering a small molecule therapeutic agent to the brain of a subject, comprising administering to said subject: (a) an agent which activates both of A.sub.1 and A.sub.2a adenosine receptors; and (b) a small molecule therapeutic agent."

From [0141] "A therapeutically effective amount of the combination will be understood to be an amount which treats, inhibits, prevents or ameliorates one or more symptoms of the CNS disorder or episode in question. In certain embodiments of the invention, the combination will show improved efficacy than that achieved by administration of the same amount of the therapeutic agent alone. Furthermore, in certain embodiments the effective amount of the combination produces fewer side effects than are observed when the therapeutic agent is administered alone at a dose that achieves substantially similar therapeutic efficacy. Additionally, in certain embodiments, the effective amount of the combination results in increased therapeutic efficacy and a reduced effective dose of the therapeutic agent than is observed when the therapeutic agent is administered alone."

14. The pharmaceutical composition of claim 11 wherein the empathogen is selected from the group consisting of 3,4methylenedioxymethamphetamine (MDMA), 3,4methlenedioxyampheta mine (MDA), 3,4methylenedioxy-Nethylamphetamine (MDEA), 3,4methylenedioxy-Nhydroxyamphetamine (MDOH), N-methyl-1,3benzodioxolylbutanami

ne (MBDB), 6-(2-

methylenedioxy-2-

aminoindane (MDAI).

and 5.6-

aminopropyl)benzofura n (6-APB), methylone,

mephedron, αMT, αET,

4. EROWID User Ivan (2018) "Healing From PTSD, Trauma, Rebirth LSD, Oxycodone & MDMA" Retrieved 8 November 2018. URL: https://www.erowid.org/experiences/exp.php?ID=112549

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At the park, there was a school, being age 21, **I felt like I was 8 again** and played with the younger kids and got on the swings. My childhood was

destroyed due to abuse and trauma from my dad and bullying in school. I felt like I was in childhood mentally before my mind was shattered and scarred. The kids were playing, some running, others just lulling along with their books and backpacks. I thought about all of these kids and their lives and the twisted world in which they had to learn to function as they matured. I wished there was some type of way for them to grow up into a state of being not unlike one that I was living right now. I'm not wishing children to start using drugs but just to feel as I was. I felt so free and part of, but yet away from, all of these various aged children and assorted parents...

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Conclusion, Oxycodone, MDMA and LSD was a life changing experience how amazing it is to be alive and breathing, the gift of life, and that forcing good vibes is totally possible and works..."

15. The pharmaceutical composition of claim 11 wherein the empathogen is MDMA.

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION # **18/009,161**

RECEIPT DATE / TIME 01/08/2024 07:45:28 PM Z ET

ATTORNEY DOCKET #

Title of Invention

Application Information

APPLICATION TYPE PATENT #

CONFIRMATION # FILED BY Sisi Li

PATENT CENTER # 63879886 FILING DATE 12/08/2022

CUSTOMER # - FIRST NAMED INVENTOR

INTL. APPLICATION # - INTL. FILING DATE -

CORRESPONDENCE - AUTHORIZED BY - ADDRESS

Documents

TOTAL DOCUMENTS: 23

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
third-party-preissuance- submission.pdf		3	Third-Party Submission Under 37 CFR 1.290	80 KB
Third-party-notification- request.pdf		1	Request for Notification of Non- compliant Third-Party Submission	14 KB
Concise-description- generated.pdf		3	Concise Description of Relevance	42 KB
Claims_Chart.pdf		25	-	415 KB
Claims_Chart- 3P.RELEVANCE.pdf	(1-25)	25	Concise Description of Relevance	329 KB

				Page 2 of 7
Claims_Chart- 3P.RELEVANCE.pdf	(1-25)	25	Concise Description of Relevance	329 KB
Claims_Chart- 3P.RELEVANCE.pdf	(1-25)	25	Concise Description of Relevance	329 KB
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Claims_Chart- 3P.RELEVANCE.pdf	(1-25)	25	Concise Description of Relevance	329 KB
1-EAKIN.pdf		7	-	561 KB
1-EAKIN-NPL.pdf	(1-7)	7	Non Patent Literature	553 KB
2_BACK.pdf		13	-	1826 KB
2_BACK-NPL.pdf	(1-13)	13	Non Patent Literature	1815 KB
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3-HOFFER-NPL.pdf	(1-10)	10	Non Patent Literature	567 KB
4_EROWID_IVAN.pdf		3	-	458 KB

				Page 3 of 7
4_EROWID_IVAN-NPL.pdf	(1-3)	3	Non Patent Literature	450 KB
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5_REDDIT_DrylceAltarGuy- NPL.pdf	(1-1)	1	Non Patent Literature	147 KB
6_CAPELA.pdf		1	-	71 KB
6_CAPELA-NPL.pdf	(1-1)	1	Non Patent Literature	53 KB
7_FEDUCCIA.pdf		8	-	441 KB
7_FEDUCCIA-NPL.pdf	(1-8)	8	Non Patent Literature	397 KB
8_EDUT.pdf		14	-	1327 KB
8_EDUT-NPL.pdf	(1-14)	14	Non Patent Literature	1297 KB
9_MayoClinic.pdf		6	-	255 KB
9_MayoClinic-NPL.pdf	(1-6)	6	Non Patent Literature	327 KB
10_CISION.pdf		2	-	125 KB
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Digest

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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.





ELECTRONIC PAYMENT RECEIPT

APPLICATION # **18/009,161**

RECEIPT DATE / TIME

01/08/2024 07:45:28 PM Z ET

ATTORNEY DOCKET #

Title of Invention

Application Information

APPLICATION TYPE PATENT #

CONFIRMATION # FILED BY Sisi Li

PATENT CENTER # 63879886 AUTHORIZED BY -

CUSTOMER # - FILING DATE 12/08/2022

INTL. APPLICATION # - INTL. FILING DATE -

CORRESPONDENCE - FIRST NAMED ADDRESS INVENTOR

Payment Information

PAYMENT METHOD PAYMENT TRANSACTION ID PAYMENT AUTHORIZED BY CARD / 0642 E202418J46577526 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	\$72.00

AMOUNT:

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New International Application Filed with the USPTO as a Receiving Office

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION # **18/009,161**

RECEIPT DATE / TIME

01/08/2024 07:51:39 PM Z ET

ATTORNEY DOCKET #

Title of Invention

Application Information

APPLICATION TYPE PATENT #

CONFIRMATION # FILED BY Sisi Li

PATENT CENTER # 63880011 FILING DATE 12/08/2022

CUSTOMER # - FIRST NAMED INVENTOR

INTL. APPLICATION # - INTL. FILING DATE -

CORRESPONDENCE - AUTHORIZED BY - ADDRESS

Documents

TOTAL DOCUMENTS: 10

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
third-party-preissuance- submission.pdf	2	Third-Party Submission Under 37 CFR 1.290	55 KB
Third-party-notification- request.pdf	1	Request for Notification of Non- compliant Third-Party Submission	14 KB
Concise-description- generated.pdf	2	Concise Description of Relevance	30 KB
Claims_Chart.pdf	25	-	415 KB
Claims_Chart- 3P.RELEVANCE.pdf	(1-25) 25	Concise Description of Relevance	329 KB

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Claims_Chart- 3P.RELEVANCE.pdf	(1-25)	25	Concise Description of Relevance	329 KB
Claims_Chart- 3P.RELEVANCE.pdf	(1-25)	25	Concise Description of Relevance	329 KB
Claims_Chart- 3P.RELEVANCE.pdf	(1-25)	25	Concise Description of Relevance	329 KB
11_BLUELIGHT_CYBERIUS. pdf		1	-	64 KB
11_BLUELIGHT_CYBERIU S-NPL.pdf	(1-1)	1	Non Patent Literature	56 KB
12_LAW.pdf		8	-	105 KB
12_LAW-NPL.pdf	(1-8)	8	Non Patent Literature	111 KB
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Digest

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New Applications Under 35 U.S.C. 111

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ELECTRONIC PAYMENT RECEIPT

APPLICATION # 18/009,161

RECEIPT DATE / TIME

01/08/2024 07:51:39 PM Z ET

ATTORNEY DOCKET #

Title of Invention

Application Information

APPLICATION TYPE PATENT #

CONFIRMATION # FILED BY Sisi Li

PATENT CENTER # 63880011 AUTHORIZED BY -

CUSTOMER # - FILING DATE 12/08/2022

INTL. APPLICATION # - INTL. FILING DATE -

CORRESPONDENCE - FIRST NAMED ADDRESS INVENTOR

Payment Information

PAYMENT METHOD PAYMENT TRA CARD / 0642 E202418J5257

PAYMENT TRANSACTION ID E202418J52577933

PAYMENT AUTHORIZED BY

AMOUNT:

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	\$72.00

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