IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Louisiana State University Confirmation No.: 1007

Serial No.: 17/984,011 Group No.: 1626

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Entitled: COMPOSITIONS AND METHODS TO REDUCE PATHOGENESIS

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.

- Int'l Pat. App. Pub. No. WO/2015/120458 "HALOGEN TREATMENT OF HEART ATTACK AND ISCHEMIC INJURY" (Published August 13, 2015)
- 2. MACKOWIAK (2002) "DOI, an agonist of 5-HT2A/2C serotonin receptor, alters the expression of cyclooxygenase-2 in the rat parietal cortex" Journal of Physiological Pharmacology. Vol 53(3):395-407.
- 3. NAU (2015) "Ma" American Journal of Physiology-Lung Cellular and Molecular Physiology. Vol 308 (2):191-198.
- 4. SHARIF (2010) "Serotonin-2 receptor agonists as novel hypotensive agents and their cellular and molecular mechanisms of action" Current Drug Targets. Vol 11 (8):978-993.
- 5. Int'l Pat. App. Pub. No. WO/2006/078610 "DIARYL AND ARYLHETEROARYL UREA DERIVATIVES AS MODULATORS OF THE 5-HT2A SEROTONIN RECEPTOR USEFUL FOR THE PROPHYLAXIS OR TREATMENT OF PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY" (Published July 27, 2006)
- SHACKLETON (2006) "JC Virus Evolution and Its Association with Human Populations" Journal of Virology. Vol 80 (20): 9928-9933.
- 7. PASSIE (2002) "The Pharmacology of Psilocybin" Addiction Biology. 7 (4): 357-364.
- 8. Int'l Pat. App. No. WO/2016/16113 "ANTIVIRAL ACTIVITY FROM MEDICINAL MUSHROOMS AND THEIR ACTIVE CONSTITUENTS" (Published October 6, 2016)

- BURRILL (2013) "Global RNA Structure Analysis of Poliovirus Identifies a Conserved RNA Structure Involved in Viral Replication and Infectivity" Journal of Virology. 87 (21): 11670-11683.
- 10. BRUNO (1991) "Polioencephalitis, Stress, and the Etiology of Post-Polio Sequelae" Orthopedics. 14 (11): 1269-1276.
- 11. WEINSTEIN (1957) "Cardiovascular Disturbances in Poliomyelitis" AHA Journals. 15 (5): 735-756.
- 12. SHULGIN (1990) "PIKHAL 67" Publisher: Transform Press ISBN: 978-0963009609
- 13. GUIO (2014) "White Matter Edema at the Early Stages of Cerebral Autosomal-Dominant Arteriopathy with Subcortical Infarcts and Leukoencephalopathy" Stroke. 2015 (46): 258-261.
- 14. RUCHOUX (1995) "Systemic Vascular Smooth Muscle Cell Impairment in Cerebral Autosomal Dominant Arteriopathy with Subcortical Infarcts and Leukoencephalopathy" Acta Neuropathologica. 89: 500-512.
- 15. Int'l Pat. App. No. WO/2016/055790 "N-PYRIDINYL ACETAMINE DERIVATES AS WNT SIGNALING PATHWAY INHIBITORS" (Published April 14, 2016)
- PASSIE (2008) "The Pharmacology of Lysergic Acid Diethylamide: A Review" CNS Neuroscience & Therapeutics. 1
- 17. Int'l Pat. App. No. WO/2015/195989 "ENTERIC SOFT CAPSULE COMPOSITIONS" (Published December 23, 2015)
- 18. #6 DMT (2011) "N,N-Dimethyltryptamine" Isomer Design. Retrieved from March 7, 2016. URL: https://web.archive.org/web/20160307021701/http://isomerdesign.com/PiHKAL/read.php?id=6&domain=tk
- 19. Int'l Pat. App. No. WO/2015/090583 "SYSTEM FOR THE TRANSDERMAL DELIVERY OF AN ACTIVE INGREDIENT" (Published June 25, 2015)
- 20. SMITH (1998) "Agonist Properties of *N*,*N*-Dimethyltryptamine at Serotonin 5-HT2A and 5-HT2C Receptors" Pharmacology Biochemistry and Behavior. 61 (3): 323-330.
- 21. Int'l Pat. App. No. WO/2014/096873 "BIOMARKERS IN INFLAMMATORY BOWEL DISEASE" (Published June 26, 2014)
- 22. BROWN (2013) "Human Papillomavirus in Older Women: New Infection or Reactivation?" Journal of Infectious Diseases. 207 (2): 211-212.

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.

1. A method of reducing or ameliorating vascularizationassociated pathology in a non-ocular tissue of a subject, the method comprising administering to the subject afflicted with a disease associated with tissue vascularizationassociated pathology a therapeutically effective amount of a composition comprising a serotonin receptor agonist.

From the application of interest 17/984,011 paragraph [0010] "In embodiments, vascularization-associated pathologies comprise neovascularization; angiogenesis, for example that of blood vessels or that of lymphatics; vasoconstriction or vasodialation, for example that of blood vessels or that of lymphatics; vascular leakage, vascular permeability, edema, hypertension; ischemia; vascular occlusions; haemmoraghing, and increased hypersensitivity reactions or disorders."

1.Int'l Pat. App. Pub. No. WO/2015/120458 "HALOGEN TREATMENT OF HEART ATTACK AND ISCHEMIC INJURY" (Published August 13, 2015)

From page 1, paragraph 1: This invention relates to compositions comprising halogen and/or chalcogenide compounds, including those comprising a halogen and/or a chalcogen compound in a reduced form, e.g. halides and/or chalcogenides, and methods for treating or preventing injuries and diseases, including diseases and injuries associated with hypoxia, ischemia or reperfusion injury and/or the formation of reactive oxygen species, e.g., heart attack, chronic heart failure, diseases and injuries associated with excessive metabolic rate, e.g., epilepsy, and diseases and injuries associated with an undesired immune or inflammatory response, e.g., graft versus host disease (GVHD) or organ transplant. The present invention also relates to methods for reducing or inhibiting an immune response, using a composition comprising a halide and/or a chalcogenide compound.

From page 36, paragraph 3: In some embodiments, said halogen compound is an organoiodide comprising of one or more compounds...2,5-Dimethoxy-4-iodoamphetamine.

2.MACKOWIAK (2002) "DOI, an agonist of 5-HT2A/2C serotonin receptor, alters the expression of cyclooxygenase-2 in the rat parietal cortex" Journal of Physiological Pharmacology. Vol 53(3):395-407.

From **abstract**: "The hallucinogenic effect of **DOI**, **a serotonin 5-HT2A/2C receptor agonist**, is known to be associated with the activation of cortical 5-HT2 receptors."

2. The method of claim 1, wherein the tissue comprises an immunologically-restricted tissue.

From the application of interest 17/984,011 paragraph [0012] "In embodiments, the tissue comprises an immunologically-restricted tissue. Non-limiting examples of immunologically-restricted tissues comprise tissues of the lung, skin, brain, eyes, gut or combination thereof."

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species, e.g., heart attack, chronic heart failure, diseases and injuries associated with excessive metabolic rate, e.g., **epilepsy**, and diseases and injuries associated with an undesired immune or inflammatory response, e.g., graft versus host disease (GVHD) or organ transplant. The present invention also relates to methods for reducing or inhibiting an immune response, using a composition comprising a halide and/or a chalcogenide compound.

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From abstract: "The hallucinogenic effect of **DOI**, a serotonin 5-HT2A/2C receptor agonist, is known to be associated with the activation of cortical 5-HT2 receptors."

3. A method of reducing or ameliorating a hypersensitivity or a hypersensitivityassociated disease process in an immunologicallyrestricted tissue of a subject, the method comprising administering to a subject afflicted with a hypersensitivity or a hypersensitivityassociated disease process in an immunologicallyrestricted tissue a therapeutically effective amount of a composition comprising a serotonin receptor agonist.

From the application of interest 17/984,011 paragraph [0240] "Hypersensitivity refers to a set of undesirable reactions produced by a subject's normal immune system. For example, hypersensitivity can refer to an over-reaction of the immune system of a subject, and such over reaction can be damaging or uncomfortable."

From the application of interest 17/984,011 paragraph [0246] "Other embodiments can comprise **Type I hypersensitivities**."

From the application of interest 17/984,011 paragraph [0012] "In embodiments, the tissue comprises an immunologically-restricted tissue. Non-limiting examples of **immunologically-restricted tissues comprise** tissues of the **lung**, skin, brain, eyes, gut or combination thereof."

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3.NAU (2015) "Serotonin 5-HT2 receptor activation prevents allergic asthma in a mouse model" American Journal of Physiology-Lung Cellular and Molecular Physiology. Vol 308 (2):191-198.

From page 16, paragraph 3: "We have identified an important and new functional role of 5-HT2A receptors in the lung. (R)-DOI activation of serotonin 5-HT2 receptors potentially prevents the development of a clinically relevant mouse model of allergic asthma at drug levels far below those necessary to invoke adverse cardiovascular or behavioral effects."

4. A method of treating a vascularization-associated non-ocular disease in a subject, the method comprising administering to a subject afflicted with a vascularization-associated disease a therapeutically effective amount of a composition comprising a serotonin receptor agonist.

From the application of interest 17/984,011 paragraph [0010] "In embodiments, vascularization-associated pathologies comprise neovascularization; angiogenesis, for example that of blood vessels or that of lymphatics; vasoconstriction or vasodialation, for example that of blood vessels or that of lymphatics; vascular leakage, vascular permeability, edema, hypertension; ischemia; vascular occlusions; haemmoraghing, and increased hypersensitivity reactions or disorders."

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From page 34: In some embodiments, said halogen compound is an organoiodide comprising of one or more compounds...2,5-Dimethoxy-4-iodoamphetamine.

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5. A method of treating a hypersensitivity-associated ocular disease in a subject, the method comprising administering to a subject afflicted with a hypersensitivity-associated ocular disease a therapeutically effective amount of a composition

From the application of interest 17/984,011 paragraph [0249] "Non-limiting examples of hypersensitivity processes that contribute to disease of the eye comprise ... increased intraocular pressure..."

2.MACKOWIAK (2002) "DOI, an agonist of 5-HT2A/2C serotonin receptor, alters the expression of cyclooxygenase-2 in the rat parietal cortex" Journal of Physiological Pharmacology. Vol 53(3):395-407.

From **abstract**: "The hallucinogenic effect of **DOI**, a **serotonin 5-HT2A/2C receptor agonist**, is known to be associated with the activation of cortical 5-HT2 receptors."

4.SHARIF (2010) "Serotonin-2 receptor agonists as novel hypotensive agents and their cellular and molecular mechanisms of action" Current Drug Targets. Vol 11 (8):978-993.

comprising a serotonin receptor agonist.	From abstract: "In an effort to delineate the role of the serotonergic system in modulating intraocular pressure (IOP) Functional 5HT(2A) receptors are present in human ocular cells involved in IOP reduction and this correlates with the ability of 5HT(2A) agonists to lower IOP in Cynomolgus monkeys, a surrogate for human subjects."
6. The method of claim 2, wherein the immunologically-restricted tissue comprises a tissue of the lung, skin, brain, or a combination thereof.	1.Int'l Pat. App. Pub. No. WO/2015/120458 "HALOGEN TREATMENT OF HEART ATTACK AND ISCHEMIC INJURY" (Published August 13, 2015)
	From page 1, paragraph 1: This invention relates to compositions comprising halogen and/or chalcogenide compounds, including those comprising a halogen and/or a chalcogen compound in a reduced form, e.g. halides and/or chalcogenides, and methods for treating or preventing injuries and diseases, including diseases and injuries associated with hypoxia, ischemia or reperfusion injury and/or the formation of reactive oxygen species, e.g., heart attack, chronic heart failure, diseases and injuries associated with excessive metabolic rate, e.g., epilepsy, and diseases and injuries associated with an undesired immune or inflammatory response, e.g., graft versus host disease (GVHD) or organ transplant. The present invention also relates to methods for reducing or inhibiting an immune response, using a composition comprising a halide and/or a chalcogenide compound.
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	From page 16, paragraph 3: "We have identified an important and new functional role of 5-HT2A receptors in the lung. (R)-DOI activation of serotonin 5-HT2 receptors potentially prevents the development of a clinically relevant mouse model of allergic asthma at drug levels far below those necessary to invoke adverse cardiovascular or behavioral effects."
7. The mostle of a Color	Every the application of interest 17/004 011 1 500127
7. The method of claim 2 or 3, wherein an immunologically-	From the application of interest 17/984,011 paragraph [0012] "In embodiments, the tissue comprises an immunologically-restricted tissue. Non-limiting examples of immunologically-restricted tissues comprise tissues of the lung, skin, brain , eyes, gut or combination thereof."

restricted tissue is					
infected.	From the application of interest 17/984,011 paragraph [0026]				
	"Non-limiting examples of pathogenesis of the brain comprise				
	demyelination, neural inflammation, encephalitis, meningitis, viral				
	reactivation from latent neurons, or a combination thereof."				
	5.Int'l Pat. App. Pub. No. WO/2006/078610 "DIARYL AND				
	ARYLHETEROARYL UREA DERIVATIVES AS MODULATORS OF				
	THE 5-HT2A SEROTONIN RECEPTOR USEFUL FOR THE				
	PROPHYLAXIS OR TREATMENT OF PROGRESSIVE MULTIFOCAL				
	LEUKOENCEPHALOPATHY" (Published July 27, 2006)				
	From field of the invention: "Formula J and pharmaceutical				
	compositions thereof modulate the activity of the 5-HT _{2A} serotonin				
	receptor. Compounds and pharmaceutical compositions thereof are				
	directed to methods useful for the prophylaxis or treatment of				
	progressive multifocal leukoencephalopathy."				
	progressive materioear reakoencepharopathy.				
8. The method of claim	From the application of interest 17/984,011 paragraph [0012]				
7, wherein the infection	"In embodiments, the tissue comprises an immunologically-restricted tissue.				
	Non-limiting examples of immunologically-restricted tissues comprise				
comprises a viral	tissues of the lung, skin, brain , eyes, gut or combination thereof."				
infection, a bacterial	tissues of the tung, skin, bruin, eyes, gut or combination thereof.				
infection, a fungal	From the application of interest 17/984,011 paragraph [0026]				
infection, a protozoan	"Non-limiting examples of pathogenesis of the brain comprise				
infection, or a	demyelination, neural inflammation, encephalitis, meningitis, viral				
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	progressive management to an open and parties				
9. The method of claim	From the application of interest 17/984,011 paragraph [0012]				
7 or 38, wherein a DNA					
virus causes infection.	Non-limiting examples of immunologically-restricted tissues comprise				
virus causes infection.	tissues of the lung, skin, brain , eyes, gut or combination thereof."				
	, , , , , , , , , , , , , , , , , , , ,				
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	6.SHACKLETON (2006) "JC Virus Evolution and Its Association with				
	Human Populations" Journal of Virology. Vol 80 (20): 9928-9933.				

From abstract: "The ubiquitous human polyomavirus JC (JCV) is a small double-stranded DNA virus that establishes a persistent infection... While 20 to 80% of adults continuously excrete JCV in their urine, almost all infections are benign, only causing the demyelating neurological disease progressive multifocal leukoencephalopathy in immunocompromised patients."

5.Int'l Pat. App. Pub. No. WO/2006/078610 "DIARYL AND ARYLHETEROARYL UREA DERIVATIVES AS MODULATORS OF THE 5-HT2A SEROTONIN RECEPTOR USEFUL FOR THE PROPHYLAXIS OR TREATMENT OF PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY" (Published July 27, 2006)

From field of the invention: "Formula J and pharmaceutical compositions thereof modulate the activity of the 5-HT_{2A} serotonin receptor. Compounds and pharmaceutical compositions thereof are directed to methods useful for the prophylaxis or treatment of progressive multifocal leukoencephalopathy."

10. The method of claim 7 or 38, wherein a RNA virus causes infection.

From the application of interest 17/984,011 paragraph [0012] "In embodiments, the tissue comprises an immunologically-restricted tissue. Non-limiting examples of immunologically-restricted tissues comprise tissues of the lung, skin, **brain**, eyes, gut or combination thereof."

From the application of interest 17/984,011 paragraph [0026] "Non-limiting examples of pathogenesis of the brain comprise demyelination, neural inflammation, **encephalitis**, meningitis, viral reactivation from latent neurons, or a combination thereof."

7.PASSIE (2002) "The Pharmacology of Psilocybin" Addiction Biology. 7 (4): 357-364.

From page 362: "The effects of psilocybin are mediated mainly via activation of presynaptic 5HT2A receptors."

8.Int'l Pat. App. No. WO/2016/161138 "ANTIVIRAL ACTIVITY FROM MEDICINAL MUSHROOMS AND THEIR ACTIVE CONSTITUENTS" (Published October 6, 2016)

From Claim 59: "A pharmaceutical composition produced by the method of claim 57 wherein the composition additionally comprises psilocybin, psilocin, 4-acetoxy dimethyltryptamine, baeocystin, or norbaeocystin."

From **Claim 57**: "A pharmaceutical composition produced by the means of claim 56."

From Claim 56: "A means for preparing a composition comprising one or more of ethyl 7-chloro- 2-oxo-4-phenyl-2H-chromen-3-carboxylate, vanillic acid, chrysin, quercetin hydrate, rutin hydrate, syringic acid, transcinnamic acid, trans-ferulic acid, salts thereof, esters thereof, or

combinations thereof comprising isolating, purifying, synthesizing or manufacturing the molecules and combining in various ratios from 1 : 1 to 99: 1 by weight percentage, including all integers within the specified ratio range, or combining any FDA approved ingredients."

From [0019]: "One embodiment described herein is a method for treating a pathogenic virus infection comprising: administering a therapeutically effective amount of a composition to a patient (a patient may be human or animal) suffering from the pathogenic virus infection, wherein the composition comprises one or more of ethyl 7-chloro-2-oxo-4-phenyl-2H-chromen-3-carboxylate, vanillic acid..."

9.BURRILL (2013) "Global RNA Structure Analysis of Poliovirus Identifies a Conserved RNA Structure Involved in Viral Replication and Infectivity" Journal of Virology. 87 (21): 11670-11683.

From Introduction: "Poliovirus, the prototypical picornavirus and causative agent of poliomyelitis, is a nonenveloped virus with a single-stranded RNA genome of positive polarity."

10.BRUNO (1991) "Polioencephalitis, Stress, and the Etiology of Post-Polio Sequelae" Orthopedics. 14 (11): 1269-1276.

From Abstract: "Post-mortem neurohistopathologies that document polio virus-induced lesions in reticular formation and hypothalamic, thalamic, peptidergic, and monoaminergic neurons in the brain are reviewed from 158 individuals who contracted polio before 1950. This polioencephalitis was found to occur in every case of poliomyelitis, even those without evidence of damage to spinal motor neurons."

11.WEINSTEIN (1957) "Cardiovascular Disturbances in Poliomyelitis" AHA Journals. 15 (5): 735-756.

From Page 735: "Dysfunction of organs other than the nervous system is relatively common; in many instances it is secondary to damage of neural structures, in some it may result from direct viral invasion or secondary bacterial infection, and in others more than one mechanism may be responsible. The situations that threaten life in poliomyelitis most seriously and are the most difficult to control arise not infrequently from such involvement. Thus, secondary bacterial invasion of the broncho- pulmonary tissues in the "respirator patient," acute ulcerations of the gastrointestinal tract with hemorrhage or perforation, infection of the urinary tract, or a variety of cardiovascular abnormalities..."

11. The method of claim 1, 3, 4, 5, or 38 wherein the serotonin receptor agonist comprises a compound of formula (II), formula (III)

From the application of interest 17/984,011, Claim 11 formula (II)

$$R^3$$
 R^4
 R^5
 R^6
 R^6
 R^6

12.SHULGIN (1990) "PIKHAL - 67" Publisher: Transform Press ISBN: 978-0963009609

From **Chapter 67**:

From the application of interest 17/984,011 paragraph [0010] "In embodiments, vascularization-associated pathologies comprise neovascularization; angiogenesis, for example that of blood vessels or that of lymphatics; vasoconstriction or vasodilation, for example that of blood vessels or that of lymphatics; vascular leakage, vascular permeability, edema, hypertension; ischemia; vascular occlusions; haemmoraghing, and increased hypersensitivity reactions or disorders."

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From page 1, paragraph 1: This invention relates to compositions comprising halogen and/or chalcogenide compounds, including those comprising a halogen and/or a chalcogen compound in a reduced form, e.g. halides and/or chalcogenides, and methods for treating or preventing injuries and diseases, including diseases and injuries associated with hypoxia, ischemia or reperfusion injury and/or the formation of reactive oxygen species, e.g., heart attack, chronic heart failure, diseases and injuries associated with excessive metabolic rate, e.g., epilepsy, and diseases and injuries associated with an undesired immune or inflammatory response, e.g., graft versus host disease (GVHD) or organ transplant. The present invention also relates to methods for reducing or inhibiting an immune response, using a composition comprising a halide and/or a chalcogenide compound.

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From **abstract**: "The hallucinogenic effect of **DOI**, a **serotonin 5-HT2A/2C receptor agonist**, is known to be associated with the activation of cortical 5-HT2 receptors."

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13. The method of claim 1, 3, 4, 5, or 38 wherein the method comprises a low dose of the serotonin receptor agonist.

From the application of interest 17/984,011 paragraph [0010] "In embodiments, vascularization-associated pathologies comprise neovascularization; angiogenesis, for example that of blood vessels or that of lymphatics; vasoconstriction or vasodilation, for example that of blood vessels or that of lymphatics; vascular leakage, vascular permeability, edema, hypertension; **ischemia**; vascular occlusions; haemmoraghing, and increased hypersensitivity reactions or disorders."

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	and injuries associated with excessive metabolic rate, e.g., epilepsy, and diseases and injuries associated with an undesired immune or inflammatory response, e.g., graft versus host disease (GVHD) or organ transplant. The present invention also relates to methods for reducing or inhibiting an immune response, using a composition comprising a halide and/or a chalcogenide compound. From page 36, paragraph 3: In some embodiments, said halogen compound is an organoiodide comprising of one or more compounds2,5-Dimethoxy-4-iodoamphetamine. 2.MACKOWIAK (2002) "DOI, an agonist of 5-HT2A/2C serotonin receptor, alters the expression of cyclooxygenase-2 in the rat parietal cortex" Journal of Physiological Pharmacology. Vol 53(3):395-407. From abstract: "The hallucinogenic effect of DOI, a serotonin 5-HT2A/2C receptor agonist, is known to be associated with the activation
	of cortical 5-HT2 receptors."
14. The method of claim 1, 3, 4, 5, or 38 wherein the composition further comprises at least one antimicrobial agent, at least one antipathogenic agent, at least one drug, or a combination thereof.	1.Int'l Pat. App. Pub. No. WO/2015/120458 "HALOGEN TREATMENT OF HEART ATTACK AND ISCHEMIC INJURY" (Published August 13, 2015) From page 1: This invention relates to compositions comprising halogen and/or chalcogenide compounds, including those comprising a halogen and/or a chalcogen compound in a reduced form, e.g. halides and/or chalcogenides, and methods for treating or preventing injuries and diseases, including diseases and injuries associated with hypoxia, ischemia or reperfusion injury and/or the formation of reactive oxygen species, e.g., heart attack, chronic heart failure, diseases and injuries associated with excessive metabolic rate, e.g., epilepsy, and diseases and injuries associated with an undesired immune or inflammatory response, e.g., graft versus host disease (GVHD) or organ transplant. The present invention also relates to methods for reducing or inhibiting an immune response, using a composition comprising a halide and/or a chalcogenide compound. From page 36, paragraph 3: In some embodiments, said halogen compound is an organoiodide comprising of one or more compounds2,5-Dimethoxy-4-iodoamphetamine. 2.MACKOWIAK (2002) "DOI, an agonist of 5-HT2A/2C serotonin receptor, alters the expression of cyclooxygenase-2 in the rat parietal cortex"
	Journal of Physiological Pharmacology. Vol 53(3):395-407. From abstract: "The hallucinogenic effect of DOI, a serotonin 5-HT2A/2C receptor agonist, is known to be associated with the activation of cortical 5-HT2 receptors."
15. The method of claim 14, wherein the antimicrobial agent	7.PASSIE (2002) "The Pharmacology of Psilocybin" Addiction Biology. 7 (4): 357-364.

comprises an antiviral agent, an antibacterial agent, an antifungal agent, an antiprotozoal agent, or a combination thereof.

From page 362: "The effects of psilocybin are mediated mainly via activation of presynaptic 5HT2A receptors."

8.Int'l Pat. App. No. WO/2016/161138 "ANTIVIRAL ACTIVITY FROM MEDICINAL MUSHROOMS AND THEIR ACTIVE CONSTITUENTS" (Published October 6, 2016)

From Claim 59: "A pharmaceutical composition produced by the method of claim 57 wherein the composition additionally comprises psilocybin, psilocin, 4-acetoxy dimethyltryptamine, baeocystin, or norbaeocystin."

From **Claim 57**: "A pharmaceutical composition produced by the means of claim 56."

From Claim 56: "A means for preparing a composition comprising one or more of ethyl 7-chloro- 2-oxo-4-phenyl-2H-chromen-3-carboxylate, vanillic acid, chrysin, quercetin hydrate, rutin hydrate, syringic acid, transcinnamic acid, trans-ferulic acid, salts thereof, esters thereof, or combinations thereof comprising isolating, purifying, synthesizing or manufacturing the molecules and combining in various ratios from 1:1 to 99:1 by weight percentage, including all integers within the specified ratio range, or combining any FDA approved ingredients."

From [0019]: "One embodiment described herein is a method for treating a pathogenic virus infection comprising: administering a therapeutically effective amount of a composition to a patient (a patient may be human or animal) suffering from the pathogenic virus infection, wherein the composition comprises one or more of ethyl 7-chloro-2-oxo-4-phenyl-2H-chromen-3-carboxylate, vanillic acid..."

16. The method of claim 1, 3, 4, 5, or 38, wherein the serotonin receptor comprises the 5-HT2A serotonin receptor.

From the application of interest 17/984,011 paragraph [0010] "In embodiments, vascularization-associated pathologies comprise neovascularization; angiogenesis, for example that of blood vessels or that of lymphatics; vasoconstriction or vasodilation, for example that of blood vessels or that of lymphatics; vascular leakage, vascular permeability, edema, hypertension; **ischemia**; vascular occlusions; haemmoraghing, and increased hypersensitivity reactions or disorders."

1.Int'l Pat. App. Pub. No. WO/2015/120458 "HALOGEN TREATMENT OF HEART ATTACK AND ISCHEMIC INJURY" (Published August 13, 2015)

From page 1, paragraph 1: This invention relates to compositions comprising halogen and/or chalcogenide compounds, including those comprising a halogen and/or a chalcogen compound in a reduced form, e.g. halides and/or chalcogenides, and methods for treating or preventing injuries and diseases, including diseases and injuries associated with hypoxia, ischemia or reperfusion injury and/or the formation of reactive oxygen species, e.g., heart attack, chronic heart failure, diseases and injuries associated with excessive metabolic rate, e.g., epilepsy, and diseases and injuries associated with an undesired immune or inflammatory response, e.g., graft versus host disease (GVHD) or organ transplant. The

	present invention also relates to methods for reducing or inhibiting an
	immune response, using a composition comprising a halide and/or a chalcogenide compound.
	From page 36, paragraph 3: In some embodiments, said halogen compound is an organoiodide comprising of one or more compounds2,5-Dimethoxy-4-iodoamphetamine.
	2.MACKOWIAK (2002) "DOI, an agonist of 5-HT2A/2C serotonin receptor, alters the expression of cyclooxygenase-2 in the rat parietal cortex" Journal of Physiological Pharmacology. Vol 53(3):395-407.
	From abstract : "The hallucinogenic effect of DOI , a serotonin 5-HT2A/2C receptor agonist , is known to be associated with the activation of cortical 5-HT2 receptors."
17. The method of claim 7, wherein the infection causes pathogenesis in at least one tissue of the subject.	From the application of interest 17/984,011 paragraph [0012] "In embodiments, the tissue comprises an immunologically-restricted tissue. Non-limiting examples of immunologically-restricted tissues comprise tissues of the lung, skin, brain, eyes, gut or combination thereof."
	2.MACKOWIAK (2002) "DOI, an agonist of 5-HT2A/2C serotonin receptor, alters the expression of cyclooxygenase-2 in the rat parietal cortex" Journal of Physiological Pharmacology. Vol 53(3):395-407. From abstract: "The hallucinogenic effect of DOI , a serotonin 5-HT2A/2C receptor agonist, is known to be associated with the activation of cortical 5-HT2 receptors."
	5.Int'l Pat. App. Pub. No. WO/2006/078610 "DIARYL AND ARYLHETEROARYL UREA DERIVATIVES AS MODULATORS OF THE 5-HT2A SEROTONIN RECEPTOR USEFUL FOR THE PROPHYLAXIS OR TREATMENT OF PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY" (Published July 27, 2006)
	From field of the invention: "Formula J and pharmaceutical compositions thereof modulate the activity of the 5-HT _{2A} serotonin receptor. Compounds and pharmaceutical compositions thereof are directed to methods useful for the prophylaxis or treatment of progressive multifocal leukoencephalopathy."
18. The method of claim 17, wherein the pathogenesis comprises angiogenesis,	From the application of interest 17/984,011 paragraph [0012] "In embodiments, the tissue comprises an immunologically-restricted tissue. Non-limiting examples of immunologically-restricted tissues comprise tissues of the lung, skin, brain, eyes, gut or combination thereof."
neovascularization, hypersensitivity, vascular leakage, vascular permeability, edema,	2.MACKOWIAK (2002) "DOI, an agonist of 5-HT2A/2C serotonin receptor, alters the expression of cyclooxygenase-2 in the rat parietal cortex" Journal of Physiological Pharmacology. Vol 53(3):395-407.
lymphangiogenesis,	

hypertension, or a combination thereof	From abstract : "The hallucinogenic effect of DOI , a serotonin 5-HT2A/2C receptor agonist , is known to be associated with the activation of cortical 5-HT2 receptors."		
	5.Int'l Pat. App. Pub. No. WO/2006/078610 "DIARYL AND ARYLHETEROARYL UREA DERIVATIVES AS MODULATORS OF THE 5-HT2A SEROTONIN RECEPTOR USEFUL FOR THE PROPHYLAXIS OR TREATMENT OF PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY" (Published July 27, 2006)		
	From field of the invention: "Formula J and pharmaceutical compositions thereof modulate the activity of the 5-HT _{2A} serotonin receptor. Compounds and pharmaceutical compositions thereof are directed to methods useful for the prophylaxis or treatment of progressive multifocal leukoencephalopathy."		
	13.GUIO (2014) "White Matter Edema at the Early Stages of Cerebral Autosomal-Dominant Arteriopathy With Subcortical Infarcts and Leukoencephalopathy" Stroke. 2015 (46): 258-261.		
	From Background and Purpose: "Recently, in a mouse model of cerebral autosomal-dominant arteriopathy with subcortical infarcts and leukoencephalopathy, a monogenic cerebral small vessel disease, intramyelinic edema was detected in the white matter"		
19. The method of claim 17, wherein the pathogenesis affects a tissue of the eye, lung, skin, brain, or a combination thereof.	From the application of interest 17/984,011 paragraph [0012] In embodiments, the tissue comprises an immunologically-restricted tissue. Non-limiting examples of immunologically-restricted tissues comprise tissues of the lung, skin, brain , eyes, gut or combination thereof."		
	2.MACKOWIAK (2002) "DOI, an agonist of 5-HT2A/2C serotonin receptor, alters the expression of cyclooxygenase-2 in the rat parietal cortex' Journal of Physiological Pharmacology. Vol 53(3):395-407.		
	From abstract : "The hallucinogenic effect of DOI , a serotonin 5-HT2A/2C receptor agonist , is known to be associated with the activation of cortical 5-HT2 receptors."		
	5.Int'l Pat. App. Pub. No. WO/2006/078610 "DIARYL AND ARYLHETEROARYL UREA DERIVATIVES AS MODULATORS OF THE 5-HT2A SEROTONIN RECEPTOR USEFUL FOR THE PROPHYLAXIS OR TREATMENT OF PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY" (Published July 27, 2006)		

From field of the invention: "Formula J and pharmaceutical compositions thereof modulate the activity of the 5-HT_{2A} serotonin receptor. Compounds and pharmaceutical compositions thereof are directed to methods useful for the prophylaxis or treatment of progressive multifocal leukoencephalopathy."

14.RUCHOUX (1995) "Systemic Vascular Smooth Muscle Cell Impairment in Cerebral Autosomal Dominant Arteriopathy with Subcortical Infarcts and Leukoencephalopathy" Acta Neuropathologica. 89: 500-512. From Abstract: "Cerebral autosomal dominant arteriopathy with subcortical infarcts and leukoencephalopathy (CADASIL) is characterized by a cerebral non-atherosclerotic, non-amyloid angiopathy mainly affecting the small arteries penetrating the white matter." 20. The method of 1.Int'l Pat. App. Pub. No. WO/2015/120458 "HALOGEN TREATMENT claim 1 or 4, wherein OF HEART ATTACK AND ISCHEMIC INJURY" (Published August 13, vascularization-2015) associated pathologies comprises angiogenesis From page 1, paragraph 1: "This invention relates to compositions of blood vessels, comprising halogen and/or chalcogenide compounds, including those angiogenesis of comprising a halogen and/or a chalcogen compound in a reduced form, e.g. lymphatic vessels, halides and/or chalcogenides, and methods for treating or preventing vascular leakage. injuries and diseases, including diseases and injuries associated with vascular permeability, hypoxia, ischemia or reperfusion injury and/or the formation of vasoconstriction, reactive oxygen species, e.g., heart attack, chronic heart failure, diseases vasodilation, vascular and injuries associated with excessive metabolic rate, e.g., epilepsy, and occlusions, diseases and injuries associated with an undesired immune or inflammatory hypertension, edema, response, e.g., graft versus host disease (GVHD) or organ transplant. The ischemia, or a present invention also relates to methods for reducing or inhibiting an combination thereof. immune response, using a composition comprising a halide and/or a chalcogenide compound." From page 36, paragraph 3: "In some embodiments, said halogen compound is an organoiodide comprising of one or more compounds...2,5-Dimethoxy-4-iodoamphetamine." 2.MACKOWIAK (2002) "DOI, an agonist of 5-HT2A/2C serotonin receptor, alters the expression of cyclooxygenase-2 in the rat parietal cortex" Journal of Physiological Pharmacology. Vol 53(3):395-407. From abstract: "The hallucinogenic effect of DOI, a serotonin 5-HT2A/2C receptor agonist, is known to be associated with the activation of cortical 5-HT2 receptors." 21. A composition 1.Int'l Pat. App. Pub. No. WO/2015/120458 "HALOGEN TREATMENT comprising at least one OF HEART ATTACK AND ISCHEMIC INJURY" (Published August 13, serotonin receptor 2015) agonist and at least one antimicrobial agent From page 1, paragraph 1: "This invention relates to compositions selected from an comprising halogen and/or chalcogenide compounds, including those antibacterial agent, an comprising a halogen and/or a chalcogen compound in a reduced form, e.g. antifungal agent, and an halides and/or chalcogenides, and methods for treating or preventing antiprotozoal agent. injuries and diseases, including diseases and injuries associated with hypoxia, ischemia or reperfusion injury and/or the formation of reactive oxygen species, e.g., heart attack, chronic heart failure, diseases and injuries associated with excessive metabolic rate, e.g., epilepsy, and

diseases and injuries associated with an undesired immune or inflammatory response, e.g., graft versus host disease (GVHD) or organ transplant. The present invention also relates to methods for reducing or inhibiting an immune response, using a composition comprising a halide and/or a chalcogenide compound."

From page 36, paragraph 3: "In some embodiments, said halogen compound is an organoiodide comprising of one or more compounds...2,5-Dimethoxy-4-iodoamphetamine."

From page 7, paragraph 4: "In certain embodiments of methods and compositions of the present invention, the composition comprising the halogen compound and/or the composition comprising the additional active agent comprises one or more of a reducing agent, a tonicity agent, a stabilizer, a surfactant, a lycoprotectant, a polyol, an antioxidant, or a preservative."

From page 28, paragraph 5: "A "preservative" is a natural or synthetic chemical that is added to products such as foods, pharmaceutical compositions, paints, biological samples, wood, etc. to prevent decomposition by microbial growth or by undesirable chemical changes. Preservative additives can be used alone or in conjunction with other methods of preservation. Preservatives may be antimicrobial preservatives, which inhibit the growth of bacteria and fungi, or antioxidants such as oxygen absorbers, which inhibit the oxidation of constituents."

2.MACKOWIAK (2002) "DOI, an agonist of 5-HT2A/2C serotonin receptor, alters the expression of cyclooxygenase-2 in the rat parietal cortex" Journal of Physiological Pharmacology. Vol 53(3):395-407.

From **abstract**: "The hallucinogenic effect of **DOI**, **a serotonin 5-HT2A/2C receptor agonist**, is known to be associated with the activation of cortical 5-HT2 receptors."

22. The method of claim 21, wherein the composition further comprises at least one antiviral agent.

1.Int'l Pat. App. No. WO/2016/055790 "N-PYRIDINYL ACETAMINE DERIVATES AS WNT SIGNALING PATHWAY INHIBITORS" (Published April 14, 2016)

From [00141]: "One or more compounds of the invention may be combined with <u>one or more</u> pharmaceutical agents, for example antiviral agents, chemotherapeutics, anti-cancer agents, immune enhancers, immunosuppressants, anti-tumour vaccines, anti-viral vaccines, cytokine therapy, or tyrosine kinase inhibitors, for the treatment of conditions modulated by the inhibition of Porcn, for example cancer, sarcoma, melanoma, skin cancer, haematological tumors, lymphoma, carcinoma, leukemia, central nervous system disorders, inflammation and immunological diseases"

From [00144]: "The method of treatment or the compound for use in the treatment of inflammation and immunological diseases may involve, in addition to the compound of the invention, additional active agents...

TNF inhibitors for example etanercept; monoclonal antibodies (e.g. infliximab (Remicade), adalimumab (Humira), certolizumab pegol (Cimzia), golimumab (Simponi)); fusion proteins (e.g. etanercept (Enbrel)); and 5-HT2A agonists (e.g. 2,5-dimethoxy-4-iodoamphetamine, TCB-2, lysergic acid diethylamide (LSD), lysergic acid dimethylazetidide);"

7.PASSIE (2002) "The Pharmacology of Psilocybin" Addiction Biology. 7 (4): 357-364.

From page 362: "The effects of psilocybin are mediated mainly via activation of presynaptic 5HT2A receptors."

8.Int'l Pat. App. No. WO/2016/161138 "ANTIVIRAL ACTIVITY FROM MEDICINAL MUSHROOMS AND THEIR ACTIVE CONSTITUENTS" (Published October 6, 2016)

From Claim 59: "A pharmaceutical composition produced by the method of claim 57 wherein the composition additionally comprises psilocybin, psilocin, 4-acetoxy dimethyltryptamine, baeocystin, or norbaeocystin."

From **Claim 57**: "A pharmaceutical composition produced by the means of claim 56."

From Claim 56: "A means for preparing a composition comprising one or more of ethyl 7-chloro- 2-oxo-4-phenyl-2H-chromen-3-carboxylate, vanillic acid, chrysin, quercetin hydrate, rutin hydrate, syringic acid, transcinnamic acid, trans-ferulic acid, salts thereof, esters thereof, or combinations thereof comprising isolating, purifying, synthesizing or manufacturing the molecules and combining in various ratios from 1:1 to 99:1 by weight percentage, including all integers within the specified ratio range, or combining any FDA approved ingredients."

From [0019]: "One embodiment described herein is a method for treating a pathogenic virus infection comprising: administering a therapeutically effective amount of a composition to a patient (a patient may be human or animal) suffering from the pathogenic virus infection, wherein the composition comprises one or more of ethyl 7-chloro-2-oxo-4-phenyl-2H-chromen-3-carboxylate, vanillic acid"

23. The composition of claim 21, wherein the composition further comprises at least one antipathogenic agent.

1.Int'l Pat. App. Pub. No. WO/2015/120458 "HALOGEN TREATMENT OF HEART ATTACK AND ISCHEMIC INJURY" (Published August 13, 2015)

From [0121]: "In some embodiments, said halogen compound is an organoiodide comprising one or more compounds from the non-limiting list of .sup.25I—NBF, .sup.25I—NBMD, .sup.25I—NBOH, .sup.25I—NBOMe, 2C—I, 5, 5-I—R91150, Acetrizoic acid, Adipiodone, Adosterol, Altropane, AM-1241, AM-2233, AM-630, AM-679 (cannabinoid), AM-694, AM251, Amiodarone, Benziodarone, Bromoiodomethane, Budiodarone, Butyl iodide, Carbon tetraiodide, Chiniofon, Chloroiodomethane, Clioquinol, Diatrizoic acid, Diiodohydroxypropane,

Diiodohydroxyquinoline, Diiodomethane, **2,5-Dimethoxy-4-iodoamphetamine**, Domiodol, ..."

From [0086]: "A "preservative" is a natural or synthetic chemical that is added to products such as foods, pharmaceutical compositions, paints, biological samples, wood, etc. to prevent decomposition by microbial growth or by undesirable chemical changes. Preservative additives can be used alone or in conjunction with other methods of preservation.

Preservatives may be antimicrobial preservatives, which inhibit the growth of bacteria and fungi, or antioxidants such as oxygen absorbers, which inhibit the oxidation of constituents. Examples of antimicrobial preservatives include benzalkonium chloride, benzoic acid, chlorohexidine, glycerin, phenol, potassium sorbate, thimerosal, sulfites (sulfur dioxide, sodium bisulfite, potassium hydrogen sulfite, etc.) and disodium EDTA. Other preservatives include those commonly used in parenteral protein compositions such as benzyl alcohol, phenol, m-cresol, chlorobutanol or methylparaben."

2.MACKOWIAK (2002) "DOI, an agonist of 5-HT2A/2C serotonin receptor, alters the expression of cyclooxygenase-2 in the rat parietal cortex" Journal of Physiological Pharmacology. Vol 53(3):395-407.

From abstract: "The hallucinogenic effect of **DOI**, a serotonin 5-HT2A/2C receptor agonist, is known to be associated with the activation of cortical 5-HT2 receptors."

7.PASSIE (2002) "The Pharmacology of Psilocybin" Addiction Biology. 7 (4): 357-364.

From page 362: "The effects of psilocybin are mediated mainly via activation of presynaptic 5HT2A receptors."

8.Int'l Pat. App. No. WO/2016/161138 "ANTIVIRAL ACTIVITY FROM MEDICINAL MUSHROOMS AND THEIR ACTIVE CONSTITUENTS" (Published October 6, 2016)

From Claim 59: "A pharmaceutical composition produced by the method of claim 57 wherein the composition additionally comprises psilocybin, psilocin, 4-acetoxy dimethyltryptamine, baeocystin, or norbaeocystin."

From **Claim 57**: "A pharmaceutical composition produced by the means of claim 56."

From Claim 56: "A means for preparing a composition comprising one or more of ethyl 7-chloro- 2-oxo-4-phenyl-2H-chromen-3-carboxylate, vanillic acid, chrysin, quercetin hydrate, rutin hydrate, syringic acid, transcinnamic acid, trans-ferulic acid, salts thereof, esters thereof, or combinations thereof comprising isolating, purifying, synthesizing or manufacturing the molecules and combining in various ratios from 1:1 to 99:1 by weight percentage, including all integers within the specified ratio range, or combining any FDA approved ingredients."

	From [0019]: "One embodiment described herein is a method for treating a pathogenic virus infection comprising: administering a therapeutically effective amount of a composition to a patient (a patient may be human or animal) suffering from the pathogenic virus infection, wherein the composition comprises one or more of ethyl 7-chloro-2-oxo-4-phenyl-2H-chromen-3-carboxylate, vanillic acid"			
24. The composition of claim 21, wherein the composition comprises a low-dose of the	1.Int'l Pat. App. Pub. No. WO/2015/120458 "HALOGEN TREATMENT OF HEART ATTACK AND ISCHEMIC INJURY" (Published August 13, 2015)			
serotonin receptor agonist.	From [0121]: "In some embodiments, said halogen compound is an organoiodide comprising one or more compounds from the non-limiting list of .sup.25I—NBF, .sup.25I—NBMD, .sup.25I—NBOH, .sup.25I—NBOMe, 2C—I, 5, 5-I—R91150, Acetrizoic acid, Adipiodone, Adosterol, Altropane, AM-1241, AM-2233, AM-630, AM-679 (cannabinoid), AM-694, AM251, Amiodarone, Benziodarone, Bromoiodomethane, Budiodarone, Butyl iodide, Carbon tetraiodide, Chiniofon, Chloroiodomethane, Clioquinol, Diatrizoic acid, Diiodohydroxypropane, Diiodohydroxyquinoline, Diiodomethane, 2,5-Dimethoxy-4-iodoamphetamine, Domiodol,"			
	From [0021]: "In related embodiments, the present invention includes a unit dosage form of a composition of the invention, wherein said unit dosage form is formulated for oral administration. In particular embodiments, the unit dosage form is a pill, tablet, caplet or capsule. In certain embodiments, the unit dosage form comprises less than or equal to 150 mg, less than or equal to 125 mg, less than or equal to 100 mg, less than or equal to 75 mg, less than or equal to 50 mg, less than or equal to 25 mg, or less than or equal to 10 mg of the halogen compound. In certain embodiments, the unit dosage form comprises between about 1 mg and about 150 mg (including any interval in this range), between about 1 mg and about 75 mg, between about 1 mg and about 100 mg, between about 1 mg and about 25 mg or between about 1 mg and about 10 mg of the halogen compound."			
25. The composition of claim 21, wherein the serotonin receptor agonist comprises a compound of formula (I), formula (II), or formula (III).	From the application of interest 17/984,011, Claim 11: formula (II) $R^{3} \longrightarrow R^{2} \longrightarrow R^{\beta} \longrightarrow R^{\alpha}$ $R^{4} \longrightarrow R^{5}$			
	12.SHULGIN (1990) "PIKHAL - 67" Publisher: Transform Press ISBN: 978-0963009609			
	From Chapter 67:			

1.Int'l Pat. App. Pub. No. WO/2015/120458 "HALOGEN TREATMENT OF HEART ATTACK AND ISCHEMIC INJURY" (Published August 13, 2015)

From [0072]: "A "composition" can comprise an active agent, e.g., a halogen compound and/or a chalcogenide, and a carrier, inert or active, e.g., a pharmaceutically acceptable carrier, diluent or excipient.

From [0073] "Pharmaceutically acceptable carrier, diluent or excipient" includes without limitation any adjuvant, carrier, excipient, glidant, sweetening agent, diluent, preservative, dye/colorant, flavor enhancer, surfactant, wetting agent, dispersing agent, suspending agent, stabilizer, isotonic agent, solvent or emulsifier which has been approved by the United States Food and Drug Administration as being acceptable for use in humans or domestic animals."

From [0121]: "In some embodiments, said halogen compound is an organoiodide comprising one or more compounds from the non-limiting list of .sup.25I—NBF, .sup.25I—NBMD, .sup.25I—NBOH, .sup.25I—NBOMe, 2C—I, 5, 5-I—R91150, Acetrizoic acid, Adipiodone, Adosterol, Altropane, AM-1241, AM-2233, AM-630, AM-679 (cannabinoid), AM-694, AM251, Amiodarone, Benziodarone, Bromoiodomethane, Budiodarone, Butyl iodide, Carbon tetraiodide, Chiniofon, Chloroiodomethane, Clioquinol, Diatrizoic acid, Diiodohydroxypropane, Diiodohydroxyquinoline, Diiodomethane, 2,5-Dimethoxy-4-iodoamphetamine, Domiodol, ..."

From [0086]: "A "preservative" is a natural or synthetic chemical that is added to products such as foods, pharmaceutical compositions, paints, biological samples, wood, etc. to prevent decomposition by microbial growth or by undesirable chemical changes. Preservative additives can be used alone or in conjunction with other methods of preservation.

Preservatives may be antimicrobial preservatives, which inhibit the growth of bacteria and fungi, or antioxidants such as oxygen absorbers, which inhibit the oxidation of constituents. Examples of Antimicrobial preservatives include benzalkonium chloride, benzoic acid, chlorohexidine, glycerin, phenol, potassium sorbate, thimerosal, sulfites (sulfur dioxide, sodium bisulfite, potassium hydrogen sulfite, etc.) and disodium EDTA. Other preservatives include those commonly used in parenteral protein compositions such as benzyl alcohol, phenol, m-cresol, chlorobutanol or methylparaben."

2.MACKOWIAK (2002) "DOI, an agonist of 5-HT2A/2C serotonin receptor, alters the expression of cyclooxygenase-2 in the rat parietal cortex" Journal of Physiological Pharmacology. Vol 53(3):395-407.

	From abstract: "The hallucinogenic effect of DOI, a serotonin 5-HT2A/2C receptor agonist, is known to be associated with the activation of cortical 5-HT2 receptors."
26. The composition of claim 21, wherein the serotonin receptor	1.Int'l Pat. App. Pub. No. WO/2015/120458 "HALOGEN TREATMENT OF HEART ATTACK AND ISCHEMIC INJURY" (Published August 13, 2015)
agonist comprises 2,5- Dimethoxy-4- iodoamphetamine (DOI).	From [0072]: "A "composition" can comprise an active agent, e.g., a halogen compound and/or a chalcogenide, and a carrier, inert or active, e.g., a pharmaceutically acceptable carrier, diluent or excipient."
	From [0073] "Pharmaceutically acceptable carrier, diluent or excipient" includes without limitation any adjuvant, carrier, excipient, glidant, sweetening agent, diluent, preservative, dye/colorant, flavor enhancer, surfactant, wetting agent, dispersing agent, suspending agent, stabilizer, isotonic agent, solvent or emulsifier which has been approved by the United States Food and Drug Administration as being acceptable for use in humans or domestic animals."
	From [0121]: "In some embodiments, said halogen compound is an organoiodide comprising one or more compounds from the non-limiting list of .sup.25I—NBF, .sup.25I—NBMD, .sup.25I—NBOH, .sup.25I—NBOMe, 2C—I, 5, 5-I—R91150, Acetrizoic acid, Adipiodone, Adosterol, Altropane, AM-1241, AM-2233, AM-630, AM-679 (cannabinoid), AM-694, AM251, Amiodarone, Benziodarone, Bromoiodomethane, Budiodarone, Butyl iodide, Carbon tetraiodide, Chiniofon, Chloroiodomethane, Clioquinol, Diatrizoic acid, Diiodohydroxypropane, Diiodohydroxyquinoline, Diiodomethane, 2,5-Dimethoxy-4-iodoamphetamine, Domiodol,"
	From [0086]: "A "preservative" is a natural or synthetic chemical that is added to products such as foods, pharmaceutical compositions, paints, biological samples, wood, etc. to prevent decomposition by microbial growth or by undesirable chemical changes. Preservative additives can be used alone or in conjunction with other methods of preservation. Preservatives may be antimicrobial preservatives, which inhibit the growth of bacteria and fungi, or antioxidants such as oxygen absorbers, which inhibit the oxidation of constituents."
	2.MACKOWIAK (2002) "DOI, an agonist of 5-HT2A/2C serotonin receptor, alters the expression of cyclooxygenase-2 in the rat parietal cortex" Journal of Physiological Pharmacology. Vol 53(3):395-407.
	From abstract : "The hallucinogenic effect of DOI , a serotonin 5-HT2A/2C receptor agonist , is known to be associated with the activation of cortical 5-HT2 receptors."
27. The composition of claim 21, wherein the composition comprises an ocular drop, dermal	1.Int'l Pat. App. Pub. No. WO/2015/120458 "HALOGEN TREATMENT OF HEART ATTACK AND ISCHEMIC INJURY" (Published August 13, 2015)

patch, ocular gel, topical gel, systemic delivery system, enteric capsule, nebulized inhalant, inhalant, intrathecal composition, or an injectable. From [0072]: "A "composition" can comprise an active agent, e.g., a halogen compound and/or a chalcogenide, and a carrier, inert or active, e.g., a pharmaceutically acceptable carrier, diluent or excipient.

From [0073] "Pharmaceutically acceptable carrier, diluent or excipient" includes without limitation any adjuvant, carrier, excipient, glidant, sweetening agent, diluent, preservative, dye/colorant, flavor enhancer, surfactant, wetting agent, dispersing agent, suspending agent, stabilizer, isotonic agent, solvent or emulsifier which has been approved by the United States Food and Drug Administration as being acceptable for use in humans or domestic animals."

From [0121]: "In some embodiments, said halogen compound is an organoiodide comprising one or more compounds from the non-limiting list of .sup.25I—NBF, .sup.25I—NBMD, .sup.25I—NBOH, .sup.25I—NBOMe, 2C—I, 5, 5-I—R91150, Acetrizoic acid, Adipiodone, Adosterol, Altropane, AM-1241, AM-2233, AM-630, AM-679 (cannabinoid), AM-694, AM251, Amiodarone, Benziodarone, Bromoiodomethane, Budiodarone, Butyl iodide, Carbon tetraiodide, Chiniofon, Chloroiodomethane, Clioquinol, Diatrizoic acid, Diiodohydroxypropane, Diiodohydroxyquinoline, Diiodomethane, 2,5-Dimethoxy-4-iodoamphetamine, Domiodol, ..."

From [0086]: "A "preservative" is a natural or synthetic chemical that is added to products such as foods, pharmaceutical compositions, paints, biological samples, wood, etc. to prevent decomposition by microbial growth or by undesirable chemical changes. Preservative additives can be used alone or in conjunction with other methods of preservation.

Preservatives may be antimicrobial preservatives, which inhibit the growth of bacteria and fungi, or antioxidants such as oxygen absorbers, which inhibit the oxidation of constituents."

From [0335]: "According to various embodiments of the methods of the present invention, a biological material is provided with a composition of the invention, e.g., intravenously, intradermally, intraarterially, intraperitoneally, intralesionally, intracranially, intraarticularly, intraprostaticaly, intrapleurally, intratracheally, intranasally, intravitreally, intravaginally, intrarectally, topically, intratumorally, intramuscularly, intraperitoneally, intraocularly, subcutaneously, subconjunctival, intravesicularly, mucosally, intrapericardially, intraumbilically, intraocularally, orally, topically, locally, by injection, by infusion, by continuous infusion, by absorption, by adsorption, by immersion, by localized perfusion, via a catheter, or via a lavage. In particular embodiments, it is provided parenterally, e.g., intravenously, or by inhalation."

28. The composition of claim 21, wherein the serotonin receptor comprises the 5-HT2A serotonin receptor.

1.Int'l Pat. App. Pub. No. WO/2015/120458 "HALOGEN TREATMENT OF HEART ATTACK AND ISCHEMIC INJURY" (Published August 13, 2015)

From [0072]: "A "composition" can comprise an active agent, e.g., a halogen compound and/or a chalcogenide, and a carrier, inert or active, e.g., a pharmaceutically acceptable carrier, diluent or excipient.

From [0073] "Pharmaceutically acceptable carrier, diluent or excipient" includes without limitation any adjuvant, carrier, excipient, glidant, sweetening agent, diluent, preservative, dye/colorant, flavor enhancer, surfactant, wetting agent, dispersing agent, suspending agent, stabilizer, isotonic agent, solvent or emulsifier which has been approved by the United States Food and Drug Administration as being acceptable for use in humans or domestic animals."

From [0121]: In some embodiments, said halogen compound is an organoiodide comprising one or more compounds from the non-limiting list of .sup.25I—NBF, .sup.25I—NBMD, .sup.25I—NBOH, .sup.25I—NBOH, .sup.25I—NBOMe, 2C—I, 5, 5-I—R91150, Acetrizoic acid, Adipiodone, Adosterol, Altropane, AM-1241, AM-2233, AM-630, AM-679 (cannabinoid), AM-694, AM251, Amiodarone, Benziodarone, Bromoiodomethane, Budiodarone, Butyl iodide, Carbon tetraiodide, Chiniofon, Chloroiodomethane, Clioquinol, Diatrizoic acid, Diiodohydroxypropane, Diiodohydroxyquinoline, Diiodomethane, 2,5-Dimethoxy-4-iodoamphetamine, Domiodol,

From [0086]: A "preservative" is a natural or synthetic chemical that is added to products such as foods, pharmaceutical compositions, paints, biological samples, wood, etc. to prevent decomposition by microbial growth or by undesirable chemical changes. Preservative additives can be used alone or in conjunction with other methods of preservation.

Preservatives may be antimicrobial preservatives, which inhibit the growth of bacteria and fungi, or antioxidants such as oxygen absorbers, which inhibit the oxidation of constituents. Examples of

Antimicrobial preservatives include benzalkonium chloride, benzoic acid, chlorohexidine, glycerin, phenol, potassium sorbate, thimerosal, sulfites (sulfur dioxide, sodium bisulfite, potassium hydrogen sulfite, etc.) and disodium EDTA. Other preservatives include those commonly used in parenteral protein compositions such as benzyl alcohol, phenol, m-cresol, chlorobutanol or methylparaben.

2.MACKOWIAK (2002) "DOI, an agonist of 5-HT2A/2C serotonin receptor, alters the expression of cyclooxygenase-2 in the rat parietal cortex" Journal of Physiological Pharmacology. Vol 53(3):395-407.

From **abstract**: "The hallucinogenic effect of **DOI**, a **serotonin 5-HT2A/2C** receptor **agonist**, is known to be associated with the activation of cortical 5-HT2 receptors."

29. The composition of claim 21, wherein the serotonin receptor agonist comprises a chemical having the following formula: wherein R1, R2, and R3 are selected from the group comprising CH2CH3,

From the application of interest 17/984,011, Claim 29:

CH(CH3)CH2CH3, CH(CH3)CH2CH2CH3 , C2H5, CH2CH2CH3, CH(CH3)2 and H.	R ² N CH ₃ H R ¹
	16.PASSIE (2008) "The Pharmacology of Lysergic Acid Diethylamide: A Review" CNS Neuroscience & Therapeutics.
	O H C—N(C ₂ H ₅) ₂ N—CH ₃
	N _H
	LSD-25
	From Figure 1: Lysergic Acid Diethylamide
	17.Int'l Pat. App. No. WO/2015/195989 "ENTERIC SOFT CAPSULE COMPOSITIONS" (Published December 23, 2015)
	From [0077]: "Suitable active ingredients can include, for example, active pharmaceutical ingredients (e.g., therapeutic agents, prophylactic agents, and diagnostic agents), nutraceuticals, vitamins, minerals, and combinations thereof."
	From [0123]: "In another embodiment, the active pharmaceutical ingredient may be a substance with abuse potential that presents a safety risk. Such active drug substance may include: lysergic acid diethylamide
	From [0101]: "Examples of active pharmaceutical ingredients that can be included comprise agents classified as, for example, antiviral"
30. The composition of claim 21, wherein the serotonin receptor agonist comprises a chemical having the following formula:	From the application of interest 17/984,011, Claim 30:

wherein Rα, Rβ, R2, R3, R4, R5, R6 and RN are selected from the group comprising OCH3, CH3, SCH3, Br, I, CH2CH(CH3)2, and H.

$$R^3$$
 R^4
 R^5
 R^6
 R^6

12.SHULGIN (1990) "PIKHAL - 67" Publisher: Transform Press ISBN: 978-0963009609

From Chapter 67:

1.Int'l Pat. App. Pub. No. WO/2015/120458 "HALOGEN TREATMENT OF HEART ATTACK AND ISCHEMIC INJURY" (Published August 13, 2015)

From [0121]: "In some embodiments, said halogen compound is an organoiodide comprising one or more compounds from the non-limiting list of .sup.25I—NBF, .sup.25I—NBMD, .sup.25I—NBOH, .sup.25I—NBOH, .sup.25I—NBOMe, 2C—I, 5, 5-I—R91150, Acetrizoic acid, Adipiodone, Adosterol, Altropane, AM-1241, AM-2233, AM-630, AM-679 (cannabinoid), AM-694, AM251, Amiodarone, Benziodarone, Bromoiodomethane, Budiodarone, Butyl iodide, Carbon tetraiodide, Chiniofon, Chloroiodomethane, Clioquinol, Diatrizoic acid, Diiodohydroxypropane, Diiodohydroxyquinoline, Diiodomethane, 2,5-Dimethoxy-4-iodoamphetamine, Domiodol, ..."

From [0086]: "A "preservative" is a natural or synthetic chemical that is added to products such as foods, pharmaceutical compositions, paints, biological samples, wood, etc. to prevent decomposition by microbial growth or by undesirable chemical changes. Preservative additives can be used alone or in conjunction with other methods of preservation.

Preservatives may be antimicrobial preservatives, which inhibit the growth of bacteria and fungi, or antioxidants such as oxygen absorbers, which inhibit the oxidation of constituents. Examples of

Antimicrobial preservatives include benzalkonium chloride, benzoic acid, chlorohexidine, glycerin, phenol, potassium sorbate, thimerosal, sulfites (sulfur dioxide, sodium bisulfite, potassium hydrogen sulfite, etc.) and disodium EDTA. Other preservatives include those commonly used in parenteral protein compositions such as benzyl alcohol, phenol, m-cresol, chlorobutanol or methylparaben."

2.MACKOWIAK (2002) "DOI, an agonist of 5-HT2A/2C serotonin receptor, alters the expression of cyclooxygenase-2 in the rat parietal cortex" Journal of Physiological Pharmacology. Vol 53(3):395-407.

From abstract: "The hallucinogenic effect of DOI, a serotonin 5-HT2A/2C receptor agonist, is known to be associated with the activation of cortical 5-HT2 receptors."

31. The composition of claim 21, wherein the serotonin receptor agonist comprises a chemical having the following formula: wherein Ra, RN 1, RN 2, R4 and R5 are selected from the group comprising C, CH3, OH, F, OCH3 and H.

From the application of interest 17/984,011, Claim 30:

$$\mathbb{R}^{5}$$
 \mathbb{R}^{4}
 $\mathbb{R}^{N_{1}}$
 $\mathbb{R}^{N_{2}}$

18.#6 DMT (2011) "N,N-Dimethyltryptamine" Isomer Design. Retrieved from March 7, 2016. URL:

https://web.archive.org/web/20160307021701/http://isomerdesign.com/PiHKAL/read.php?id=6&domain=tk

From **Figure 1**:

N,N-Dimethyltryptamine

19.Int'l Pat. App. No. WO/2015/090583 "SYSTEM FOR THE TRANSDERMAL DELIVERY OF AN ACTIVE INGREDIENT" (Published June 25, 2015)

From [0060]: "In a preferred embodiment, the active ingredient is selected from the group of cationic indole compounds, in particular from the group of cationic indole compounds, N-dimethyltryptamine and psilocin, the group also encompassing the pharmaceutically suitable salts of these cationically active indole compounds."

From [0072]: "The liquid-soaked carrier material may optionally contain further additives, wherein the additives may be selected from the group of solubilizers, skin penetration enhancers, preservatives and antimicrobial agents."

20.SMITH (1998) "Agonist Properties of *N,N*-Dimethyltryptamine at Serotonin 5-HT2A and 5-HT2C Receptors" Pharmacology Biochemistry and Behavior. 61 (3): 323-330.

From abstract: "Thus, we conclude that DMT behaves as an agonist at both 5-HT2A and 5-HT2C receptors."

32. The method of claim 3, wherein the immunologically-restricted tissue comprises a tissue of the lung, skin, brain, eye or a combination thereof.

From the application of interest 17/984,011 paragraph [0012] "In embodiments, the tissue comprises an immunologically-restricted tissue. Non-limiting examples of immunologically-restricted tissues comprise tissues of the **lung**, skin, brain, eyes, gut or combination thereof."

2.MACKOWIAK (2002) "DOI, an **agonist of 5-HT2A/2C serotonin receptor**, alters the expression of cyclooxygenase-2 in the rat parietal cortex" Journal of Physiological Pharmacology. Vol 53(3):395-407.

From **abstract**: "The hallucinogenic effect of **DOI**, **a serotonin 5-HT2A/2C receptor agonist**, is known to be associated with the activation of cortical 5-HT2 receptors."

3.NAU (2015) "Serotonin 5-HT2 receptor activation prevents allergic asthma in a mouse model" American Journal of Physiology-Lung Cellular and Molecular Physiology. Vol 308 (2):191-198.

From page 16, paragraph 3: "We have identified an important and new functional role of 5-HT2A receptors in the lung. (R)-DOI activation of serotonin 5-HT2 receptors potentially prevents the development of a clinically relevant mouse model of allergic asthma at drug levels far below those necessary to invoke adverse cardiovascular or behavioral effects."

33. The method of claims 1, 17, and 20, wherein the pathogenesis comprises hypersensitivity, a hypersensitivityassociated disease process, vascularization, vascular leakage, vascular permeability, angiogenesis, lymphangiogenesis, neovascularization. vasodialation. vasoconstriction. vascular occlusions, edema, corneal epithelial defects, increased intraocular pressure, increased oxygen saturation, ischemia, haemorrhage, necrotizing inflammation, epithelial hyperproliferation, epithelial thickening, fibrosis, or a combination thereof.

1.Int'l Pat. App. Pub. No. WO/2015/120458 "HALOGEN TREATMENT OF HEART ATTACK AND ISCHEMIC INJURY" (Published August 13, 2015)

From page 1, paragraph 1: This invention relates to compositions comprising halogen and/or chalcogenide compounds, including those comprising a halogen and/or a chalcogen compound in a reduced form, e.g. halides and/or chalcogenides, and methods for treating or preventing injuries and diseases, including diseases and injuries associated with hypoxia, ischemia or reperfusion injury and/or the formation of reactive oxygen species, e.g., heart attack, chronic heart failure, diseases and injuries associated with excessive metabolic rate, e.g., epilepsy, and diseases and injuries associated with an undesired immune or inflammatory response, e.g., graft versus host disease (GVHD) or organ transplant. The present invention also relates to methods for reducing or inhibiting an immune response, using a composition comprising a halide and/or a chalcogenide compound.

From page 36, paragraph 3: In some embodiments, said halogen compound is an organoiodide comprising of one or more compounds...2,5-Dimethoxy-4-iodoamphetamine.

2.MACKOWIAK (2002) "DOI, an agonist of 5-HT2A/2C serotonin receptor, alters the expression of cyclooxygenase-2 in the rat parietal cortex" Journal of Physiological Pharmacology. Vol 53(3):395-407.

From **abstract**: "The hallucinogenic effect of **DOI**, **a serotonin 5-HT2A/2C receptor agonist**, is known to be associated with the activation of cortical 5-HT2 receptors."

34. The method of claim 7, wherein the infection comprises a viral infection.	From the application of interest 17/984,011 paragraph [0012] "In embodiments, the tissue comprises an immunologically-restricted tissue. Non-limiting examples of immunologically-restricted tissues comprise tissues of the lung, skin, brain, eyes, gut or combination thereof."
	2.MACKOWIAK (2002) " DOI , an agonist of 5-HT2A/2C serotonin receptor, alters the expression of cyclooxygenase-2 in the rat parietal cortex" Journal of Physiological Pharmacology. Vol 53(3):395-407.
	From abstract : "The hallucinogenic effect of DOI , a serotonin 5-HT2A/2C receptor agonist , is known to be associated with the activation of cortical 5-HT2 receptors."
	5.Int'l Pat. App. Pub. No. WO/2006/078610 "DIARYL AND ARYLHETEROARYL UREA DERIVATIVES AS MODULATORS OF THE 5-HT2A SEROTONIN RECEPTOR USEFUL FOR THE PROPHYLAXIS OR TREATMENT OF PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY" (Published July 27, 2006)
	From field of the invention: "Formula J and pharmaceutical compositions thereof modulate the activity of the 5-HT _{2A} serotonin receptor. Compounds and pharmaceutical compositions thereof are directed to methods useful for the prophylaxis or treatment of progressive multifocal leukoencephalopathy."
35. The method of claim 33, wherein the	21.Int'l Pat. App. No. WO/2014/096873 "BIOMARKERS IN INFLAMMATORY BOWEL DISEASE" (Published June 26, 2014)
viral infection comprises herpetic keratitis, stromal keratitis, herpetic uveitis, herpetic iritis, viral keratoconjunctivitis, viral retinitis, adenoviral conjunctivitis.	From [0064]: "Weighting Clinical or laboratory variable factor Number of liquid or soft stools each day for ×2 seven days Abdominal pain (graded from 0-3 on severity) ×5 each day for seven days General well being, subjectively assessed from ×7 0 (well) to 4 (terrible) each day for seven days Presence of complications* ×20 Taking Lomotil or opiates for diarrhea ×30 Presence of an abdominal mass (0 as none, ×10 2 as questionable, 5 as definite) Hematocrit of <0.47 in mrn snf <0.42 in women ×6 Percentage deviation from standard weight ×1 *One point each is added for each set of complications: the presence of joint pains (arthralgia) or frank arthritis; inflammation of the iris or uveitis; presence of erythema nodosum, pyoderma gangrenosum, or aphthous ulcers; anal fissures, fistulae or abscesses; other fistulae; fever during the previous week."
	From [0052]: "The invention relates to identifying the status of IR in patients who have been treated with anti TNF α therapy. By anti TNF α therapy it is meant any therapy that inhibits or antagonises TNF α . This could include inhibiting the production of TNF α or its receptor, e.g. by inhibiting its transcription or translation, or inhibiting its activity, directly or indirectly. Various methods for achieving this are known in the art. Inhibitors and antagonists or TNF α thus include antisense molecules, RNAi molecules, ribozymes, antibodies (e.g. a monoclonal antibody) or other

	binding proteins and small molecules. Any of these may be directed against TNF α or its receptor."		
	From [0053]: "Several 5-HT2A agonist hallucinogens including (R)-DOI (2,5-Dimethoxy-4-iodoamphetamine), TCB-2 (1-[(7R)-3-bromo-2,5-dimethoxybicyclo[4.2.0]octa-1,3,5-trien-7-yl]methanamine), LSD (Lysergic acid diethylamide) and LA-SS-Az (Lysergic acid 2,4-dimethylazetidide) have unexpectedly also been found to act as potent inhibitors of the TNFα receptor."		
36. The method of claim 5 wherein the ocular disease	1.Int'l Pat. App. Pub. No. WO/2015/120458 "HALOGEN TREATMENT OF HEART ATTACK AND ISCHEMIC INJURY" (Published August 13, 2015)		
comprises AMD, choroidal vascularization, diabetic retinopathies, viral retinopathies, glaucoma, corneal allograft transplant rejection, ocular hypertension, corneal neovascularization, keratoconjunctivitis, viral conjunctivitis, allergic conjunctivitis, uveitis, iritis, or keratitis.	From page 1, paragraph 1: "This invention relates to compositions comprising halogen and/or chalcogenide compounds, including those comprising a halogen and/or a chalcogen compound in a reduced form, e.g. halides and/or chalcogenides, and methods for treating or preventing injuries and diseases, including diseases and injuries associated with hypoxia, ischemia or reperfusion injury and/or the formation of reactive oxygen species, e.g., heart attack, chronic heart failure, diseases and injuries associated with excessive metabolic rate, e.g., epilepsy, and diseases and injuries associated with an undesired immune or inflammatory response, e.g., graft versus host disease (GVHD) or organ transplant. The present invention also relates to methods for reducing or inhibiting an immune response, using a composition comprising a halide and/or a chalcogenide compound."		
kerattus.	From page 36, paragraph 3: "In some embodiments, said halogen compound is an organoiodide comprising of one or more compounds2,5-Dimethoxy-4-iodoamphetamine."		
	2.MACKOWIAK (2002) "DOI, an agonist of 5-HT2A/2C serotonin receptor, alters the expression of cyclooxygenase-2 in the rat parietal cortex" Journal of Physiological Pharmacology. Vol 53(3):395-407.		
	From abstract : "The hallucinogenic effect of DOI , a serotonin 5-HT2A/2C receptor agonist , is known to be associated with the activation of cortical 5-HT2 receptors."		
37. The method of claim 33, wherein the viral infection is	21.Int'l Pat. App. No. WO/2014/096873 "BIOMARKERS IN INFLAMMATORY BOWEL DISEASE" (Published June 26, 2014)		
associated with ulceration, keratoconjunctivitis, blepharitis, neovascularization, edema, endophthalmitis, haemorrhage, photophobia, glaucoma,	From [0064]: "Weighting Clinical or laboratory variable factor Number of liquid or soft stools each day for ×2 seven days Abdominal pain (graded from 0-3 on severity) ×5 each day for seven days General well being, subjectively assessed from ×7 0 (well) to 4 (terrible) each day for seven days Presence of complications* ×20 Taking Lomotil or opiates for diarrhea ×30 Presence of an abdominal mass (0 as none, ×10 2 as questionable, 5 as definite) Hematocrit of <0.47 in mrn snf <0.42 in women ×6 Percentage deviation from standard weight ×1 *One point each is added for each set of complications: the presence of joint pains (arthralgia) or frank arthritis;		

necrotizing
inflammation, loss of
vision, reduced vision,
uveitis, iritis, ocular
redness, scleral
injection, retinitis,
fibrosis, epithelial
thickening, blepharitis,
endophthalmitis,
photophobia, glaucoma,
loss of vision, or a
combination thereof.

inflammation of the iris or uveitis; presence of erythema nodosum, pyoderma gangrenosum, or aphthous ulcers; anal fissures, fistulae or abscesses; other fistulae; fever during the previous week."

From [0052]: "The invention relates to identifying the status of IR in patients who have been treated with anti TNF α therapy. By anti TNF α therapy it is meant any therapy that inhibits or antagonises TNF α . This could include inhibiting the production of TNF α or its receptor, e.g. by inhibiting its transcription or translation, or inhibiting its activity, directly or indirectly. Various methods for achieving this are known in the art. Inhibitors and antagonists or TNF α thus include antisense molecules, RNAi molecules, ribozymes, antibodies (e.g. a monoclonal antibody) or other binding proteins and small molecules. Any of these may be directed against TNF α or its receptor."

From [0053]: "...Several 5-HT2A agonist hallucinogens including (R)-DOI (2,5-Dimethoxy-4-iodoamphetamine), TCB-2 (1-[(7R)-3-bromo-2,5-dimethoxybicyclo[4.2.0]octa-1,3,5-trien-7-yl]methanamine), LSD (Lysergic acid diethylamide) and LA-SS-Az (Lysergic acid 2,4-dimethylazetidide) have unexpectedly also been found to act as potent inhibitors of the TNF α receptor."

38. A method of delaying or preventing viral reactivation in a tissue of a subject, the method comprising administering to the subject afflicted with a persistent viral infection a therapeutically effective amount of a composition comprising a serotonin receptor agonist.

8.Int'l Pat. App. No. WO/2016/161138 "ANTIVIRAL ACTIVITY FROM MEDICINAL MUSHROOMS AND THEIR ACTIVE CONSTITUENTS" (Published October 6, 2016)

From Claim 59: "A pharmaceutical composition produced by the method of claim 57 wherein the composition additionally comprises psilocybin, psilocin, 4-acetoxy dimethyltryptamine, baeocystin, or norbaeocystin."

From **Claim 57**: "A pharmaceutical composition produced by the means of claim 56."

From Claim 56: "A means for preparing a composition comprising one or more of ethyl 7-chloro- 2-oxo-4-phenyl-2H-chromen-3-carboxylate, vanillic acid, chrysin, quercetin hydrate, rutin hydrate, syringic acid, transcinnamic acid, trans-ferulic acid, salts thereof, esters thereof, or combinations thereof comprising isolating, purifying, synthesizing or manufacturing the molecules and combining in various ratios from 1:1 to 99:1 by weight percentage, including all integers within the specified ratio range, or combining any FDA approved ingredients."

From [0019]: "One embodiment described herein is a method for treating a pathogenic virus infection comprising: administering a therapeutically effective amount of a composition to a patient (a patient may be human or animal) suffering from the pathogenic virus infection, wherein the composition comprises one or more of ethyl 7-chloro-2-oxo-4-phenyl-2H-chromen-3-carboxylate, vanillic acid..."

From Claim 1: A method for treating a pathogenic virus infection comprising: administering a therapeutically effective amount of a composition to a patient suffering from the pathogenic virus infection,

wherein the composition comprises one or more of ethyl 7-chloro-2-oxo-4-phenyl-2H-chromen-3-carboxylate, vanillic acid, chrysin, quercetin hydrate, rutin hydrate, syringic acid, trans-cinnamic acid, trans-ferulic acid, salts thereof, esters thereof, or combinations thereof, wherein the composition has an antiviral effect against the pathogenic virus and wherein the pathogenic virus comprises one or more of herpes Varicella zoster virus, Epstein-Barr virus, herpes simplex I and II viruses, human Papillomavirus (HPV), influenza viruses, hepatitis viruses, poliovirus, or norovirus.

BROWN (2013) "Human Papillomavirus in Older Women: New Infection or Reactivation?" Journal of Infectious Diseases. 207 (2): 211-212.

From Page 112: "...HPV can exist in a low-level persistent state and can reactivate later in life and cause disease."





ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION # **17/984,011**

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Title of Invention

Application Information

APPLICATION TYPE PATENT #

CONFIRMATION # FILED BY Jeremy Rolquin

PATENT CENTER # 64363257 FILING DATE 11/09/2022

CUSTOMER # - FIRST NAMED INVENTOR

CORRESPONDENCE - AUTHORIZED BY

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Documents

TOTAL DOCUMENTS: 23

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
Third-party-notification- request.pdf		1	Request for Notification of Non-compliant Third-Party Submission	13 KB
Concise-description- generated.pdf		2	Concise Description of Relevance	36 KB
third-party-preissuance- submission.pdf		3	Third-Party Submission Under 37 CFR 1.290	75 KB
LSU 3PS FINAL.pdf		32	-	517 KB
LSU 3PS FINAL- 3P.RELEVANCE.pdf	(1-32)	32	Concise Description of Relevance	520 KB
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8_WO2016161138.pdf		85	-	4431 KB
8_WO2016161138- FOR.pdf	(1-85)	85	Foreign Reference	4415 KB
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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



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APPLICATION # **17/984,011**

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ATTORNEY DOCKET #

Title of Invention

Application Information

APPLICATION TYPE PATENT #

CONFIRMATION # FILED BY Jeremy Rolquin

PATENT CENTER # 64363257 AUTHORIZED BY -

CUSTOMER # - FILING DATE 11/09/2022

CORRESPONDENCE - FIRST NAMED ADDRESS INVENTOR

Payment Information

PAYMENT METHOD PAYMENT TRANSACTION ID PAYMENT AUTHORIZED BY CARD / 6701 E20242IA37359208 Jeremy Rolquin

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

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

New International Application Filed with the USPTO as a Receiving Office





ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION # **17/984,011**

RECEIPT DATE / TIME

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ATTORNEY DOCKET #

Title of Invention

Application Information

APPLICATION TYPE PATENT #

CONFIRMATION # FILED BY Jeremy Rolquin

PATENT CENTER # 64365580 FILING DATE 11/09/2022

CUSTOMER # - FIRST NAMED INVENTOR

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	74 KB
Concise-description- generated.pdf		2	Concise Description of Relevance	36 KB
Third-party-notification- request.pdf		1	Request for Notification of Non-compliant Third-Party Submission	13 KB
LSU 3PS FINAL.pdf		32	-	517 KB
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LSU 3PS FINAL- 3P.RELEVANCE.pdf	(1-32)	32	Concise Description of Relevance	520 KB

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Digest

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

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ELECTRONIC PAYMENT RECEIPT

17/984,011

RECEIPT DATE / TIME

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ATTORNEY DOCKET #

Title of Invention

Application Information

APPLICATION TYPE PATENT #

CONFIRMATION # FILED BY Jeremy Rolquin

PATENT CENTER # 64365580 AUTHORIZED BY -

CUSTOMER # - FILING DATE 11/09/2022

CORRESPONDENCE - FIRST NAMED ADDRESS INVENTOR

Payment Information

PAYMENT METHOD PAYMENT TRANSACTION ID PAYMENT AUTHORIZED BY CARD / 6701 E20242IE32549105 Payment Authorized By Jeremy Rolquin

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

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described in MPEP 503.

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION # **17/984,011**

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ATTORNEY DOCKET #

Title of Invention

Application Information

APPLICATION TYPE PATENT #

CONFIRMATION # FILED BY Jeremy Rolquin

PATENT CENTER # 64366266 FILING DATE 11/09/2022

CUSTOMER # - FIRST NAMED INVENTOR

CORRESPONDENCE - AUTHORIZED BY - ADDRESS

Documents

TOTAL DOCUMENTS: 7

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
Concise-description- generated.pdf		2	Concise Description of Relevance	25 KB
Third-party-notification- request.pdf		1	Request for Notification of Non-compliant Third-Party Submission	13 KB
third-party-preissuance- submission.pdf		2	Third-Party Submission Under 37 CFR 1.290	45 KB
LSU 3PS FINAL.pdf		32	-	517 KB
LSU 3PS FINAL- 3P.RELEVANCE.pdf	(1-32)	32	Concise Description of Relevance	520 KB
LSU 3PS FINAL- 3P.RELEVANCE.pdf	(1-32)	32	Concise Description of Relevance	520 KB
21_WO2014096873.pdf		63	-	2546 KB

				Page 2 of 3
21_WO2014096873- FOR.pdf	(1-63)	63	Foreign Reference	2534 KB
22_BROWN.pdf		2	-	49 KB
22_BROWN-NPL.pdf	(1-2)	2	Non Patent Literature	46 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
Concise-description- generated.pdf	66883BF4408A9ACB195EC03E982C47DF81326F3C2CCBAABB 8C57F14448D7856B41585A8EDFB181E6C2C8D41EFC0667EF4 06723BC5A6A344383E3D791EA6D37AD
Third-party-notification- request.pdf	FB6E166AFF4B31D44597055498D0189C34110FDDEECB43E2 C6D0874F3A00551DB7181B46D914E26E2B1AEBBD0A803369F 688575837867D9DDB8A0C96DEBAB702
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LSU 3PS FINAL- 3P.RELEVANCE.pdf	4563B9EF27C3F0C807CD41CB2B7CBA8D6C2D27DB7ABD32A 77593DD1E805AF3759D4DD347D6961047B2D75CF4634D772D 51C358524ABE7893D48F18A3798336FE
LSU 3PS FINAL- 3P.RELEVANCE.pdf	79A9F1CEA34B1A86E022A47AF3B09A15D7D36457E826E0135 6EF02F19E7EF64713D1DF862F09320F1DAF2CB05FC7DCD48 6134A661933B8544D5AFD6649B06915
21_WO2014096873.pdf	9323CFF6155F01C818174F2F431670B2129B06AB56CAD5648B 6431B31D030DD1830609FEA27AFB4BA55186C9A3195FA2B5C 39313899F8255E4DFD34C226DC7BD
21_WO2014096873-FOR.pdf	B73E809FFB5A832F2AF734430F9AA8C03584E5E392E7EFEBC 613F038F7BBEBA2C5597785EA94D4B427F8A866BEA0AAA18 AF1806BF29F364E5BE5E79B2E768AAA
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New Applications Under 35 U.S.C. 111

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Title of Invention

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CONFIRMATION # FILED BY Jeremy Rolquin

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CORRESPONDENCE - FIRST NAMED ADDRESS INVENTOR

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