

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: The Regents of the University of California

Confirmation No.:

Serial No.: 17/915,884

Group No.:

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Examiner:

Entitled: Molecularly-Initiated, Experientially-Delivered Treatments And Systems For Practicing Same

**THIRD-PARTY PRE-ISSUANCE SUBMISSION**

Examiner:

The following documents, which are also identified in the Form PTO/SB/429 filed herewith, are submitted for your consideration as being of potential relevance to the examination of the present application

1. U.S. Pat. App. Pub. No. 2020/0086078 “System and method of improving sleep” (Published March 19, 2020)
2. Int’l Pat. App. Pub. No. WO/2019/161050A1 “COGNITIVE PLATFORM INCLUDING COMPUTERIZED ELEMENTS COUPLED WITH A THERAPY FOR MOOD DISORDER” (Published August 22, 2019)
3. Int’l Pat. App. Pub. No. WO/2015/026988A1 “SYSTEMS AND METHODS FOR ELECTROCORTICOGRAPHY SIGNAL ACQUISITION” (Published February 26, 2015)

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. 17/915,884 Pending Claims	References
<p>I. A method comprising: presenting a sensory environment to an individual experiencing the effects of a psychoactive agent; monitoring the neural status, the physiological status, or both, of the individual; and presenting a modified sensory environment to the individual based on the monitoring.</p>	<p>I. U.S. Pat. App. Pub. No. 2020/0086078 “System and method of improving sleep” (Published March 19, 2020)</p> <p>From [0937]: “A <b>recipient is then prepared for receipt of the mental state</b>. The mental state of the recipient may be assessed. This can include responses to a questionnaire, self-assessment, or other psychological assessment method. Further, the <b>transcutaneous EEG (or other brain activity data) of the recipient may be obtained, to determine the starting state for the recipient, as well as activity during experiencing the desired mental state.</b>”</p> <p>From [0938]: “In addition, a <b>set of stimuli, such as visual patterns, acoustic patterns</b>, vestibular, <b>smell</b>, taste, touch (light touch, deep touch, proprioception, stretch, hot, cold, pain, pleasure, electric stimulation, acupuncture, etc.), vagus nerve (e.g., parasympathetic), <b>are imposed on the subject, optionally over a range of baseline brain states, to acquire data defining the effect of individual and various combinations of sensory stimulation on the brain state of the recipient</b>. Population data may also be used for this aspect.”</p> <p>From [0941]: “During stimulation of the recipient, the EEG pattern may be <b>monitored to determine if the desired state is achieved through the sensory stimulation</b>. A closed loop feedback control system may be <b>implemented to modify the stimulation seeking to achieve the target</b>. An evolving genetic algorithm may be used to develop a user model, which relates the mental state, arousal and valence, <b>sensory stimulation</b>, and brain activity patterns, both <b>to optimize the current session of stimulation and learning, as well as to facilitate future sessions, where the mental states of the recipient have further enhanced</b>, and to permit use of the system for a range of mental states.”</p> <p>From [0196]: “<b>Neurofeedback (NFB), also called neurotherapy or neurobiofeedback</b>, is a type of biofeedback that uses real-time displays of brain activity-most commonly electroencephalography (EEG), to teach self-regulation of brain function. Typically, sensors are placed on the scalp to measure activity, with measurements displayed using video displays or sound. The feedback may be in various other forms as well. <b>Typically, the feedback is sought to be presented through primary sensory inputs</b>, but this is not a limitation on the technique.”</p> <p>From [0876]: “While mental states are typically considered internal to the individual, and subjective, in fact, such states are common across individuals and have <b>determinable</b></p>

	<p><b>physiological and electrophysiological population characteristics.</b> Further, mental states may be externally changed or induced in a manner that bypasses the normal cognitive processes. In some cases, the triggers for the mental state are subjective, and therefore the <b>particular subject-dependent sensory or excitation scheme required to induce a particular state will differ.</b> For example, <b>olfactory stimulation</b> can have different effects on different people, based on differences in history of exposure, social and cultural norms, and the like. On the other hand, some mental state response triggers are normative, for example “tear jerker” media.”</p> <p>From [0877]: “Mental states are represented in brainwave patterns, and in normal humans, the <b>brainwave patterns and metabolic (e.g. blood flow, oxygen consumption, etc.)</b> follow prototypical patterns. Therefore, by <b>monitoring brainwave patterns in an individual,</b> a state or series of mental states in that person may be determined or estimated...etc”</p> <p>From [0943]: “While typically, controlled or “illegal” substances are to be avoided, <b>in some cases, these may be appropriate for use. For example, various drugs may alter the state of the brain to enhance or selectively enhance the effect of the stimulation.</b> Such drugs include stimulants (e.g., cocaine, methylphenidate (Ritalin), ephedrine, phenylpropanolamine, amphetamines), narcotics/opiates (opium, morphine, heroin, methadone, oxymorphone, oxycodone, codeine, fentanyl), <b>hallucinogens (lysergic acid diethylamide (LSD), PCP, MDMA (ecstasy), mescaline, psilocybin, magic mushroom (Psilocybe cubensis), Amanita muscaria mushroom, marijuana/cannabis), Salvia divinorum, diphenhydramine (Benadryl), flexeril, tobacco, nicotine, bupropion (Zyban), opiate antagonists, depressants, gamma aminobutyric acid (GABA) agonists or antagonists, NMDA receptor agonists or antagonists, depressants (e.g., alcohol, Xanax; Valium; Halcion; Librium; other benzodiazepines, Ativan; Klonopin; Amytal; Nembutal; Seconal; Phenobarbital, other barbiturates), psychedelics, disassociatives, and delirians (e.g., a special class of acetylcholine-inhibitor hallucinogen). For example, Carhart-Harris showed using fMRI that LSD and psilocybin caused synchronization of different parts of the brain that normally work separately by making neurons fire simultaneously. This effect can be used to induce synchronization of various regions of the brain to heighten the mental state.”</b></p>
<p>2. The method according to claim 1, wherein the psychoactive agent is a psychedelic agent.</p>	<p>1. U.S. Pat. App. Pub. No. 2020/0086078 “System and method of improving sleep” (Published March 19, 2020)</p> <p>From [0943]: “While typically, controlled or “illegal” substances are to be avoided, <b>in some cases, these may be appropriate for use. For example, various drugs may alter the state of the</b></p>

**brain to enhance or selectively enhance the effect of the stimulation.** Such drugs include stimulants (e.g., cocaine, methylphenidate (Ritalin), ephedrine, phenylpropanolamine, amphetamines), narcotics/opiates (opium, morphine, heroin, methadone, oxymorphone, oxycodone, codeine, fentanyl), **hallucinogens (lysergic acid diethylamide (LSD), PCP, MDMA (ecstasy), mescaline, psilocybin, magic mushroom (Psilocybe cubensis), Amanita muscaria mushroom, marijuana/cannabis), Salvia divinorum, diphenhydramine (Benadryl), flexeril, tobacco, nicotine, bupropion (Zyban), opiate antagonists, depressants, gamma aminobutyric acid (GABA) agonists or antagonists, NMDA receptor agonists or antagonists, depressants (e.g., alcohol, Xanax; Valium; Halcion; Librium; other benzodiazepines, Ativan; Klonopin; Amytal; Nembutal; Seconal; Phenobarbital, other barbiturates), psychedelics, disassociatives, and deliriant (e.g., a special class of acetylcholine-inhibitor hallucinogen). For example, Carhart-Harris showed using fMRI that LSD and psilocybin caused synchronization of different parts of the brain that normally work separately by making neurons fire simultaneously. This effect can be used to induce synchronization of various regions of the brain to heighten the mental state.”**

From [0937]: “A recipient is then prepared for receipt of the **mental state**. The mental state of the recipient **may be assessed**. This can include responses to a questionnaire, self-assessment, or other **psychological assessment method**. Further, the **transcutaneous EEG (or other brain activity data) of the recipient may be obtained, to determine the starting state for the recipient, as well as activity during experiencing the desired mental state.”**

From [0938]: “In addition, a **set of stimuli, such as visual patterns, acoustic patterns, vestibular, smell, taste, touch (light touch, deep touch, proprioception, stretch, hot, cold, pain, pleasure, electric stimulation, acupuncture, etc.), vagus nerve (e.g., parasympathetic), are imposed on the subject, optionally over a range of baseline brain states, to acquire data defining the effect of individual and various combinations of sensory stimulation on the brain state of the recipient**. Population data may also be used for this aspect.”

From [0941]: “During stimulation of the recipient, the EEG pattern may be **monitored to determine if the desired state is achieved through the sensory stimulation**. A closed loop feedback control system may be **implemented to modify the stimulation seeking to achieve the target**. An evolving genetic algorithm may be used to develop a user model, which relates the mental state, arousal and valence, **sensory stimulation, and brain activity patterns, both to optimize the current session of stimulation and learning, as well as to facilitate future**

	<p>sessions, where the mental states of the recipient have further enhanced, and to permit use of the system for a range of mental states.”</p>
<p>3. The method of claim 2, wherein the psychedelic agent is selected from the group consisting of: psilocybin, 3,4-Methylenedioxyamphetamine (MDMA), lysergic acid diethylamide (LSD), N,N-Dimethyltryptamine (DMT), mescaline, peyote, 2,5-dimethoxy-4-bromophenethylamine (2C-B), 2,5-Dimethoxy-4-methylamphetamine (DOM), NBOMes (N-methoxybenzyl), and any combination thereof.</p>	<p>1. U.S. Pat. App. Pub. No. 2020/0086078 “System and method of improving sleep” (Published March 19, 2020)</p> <p>From [0943]: “While typically, controlled or “illegal” substances are to be avoided, <b>in some cases, these may be appropriate for use. For example, various drugs may alter the state of the brain to enhance or selectively enhance the effect of the stimulation.</b> Such drugs include stimulants (e.g., cocaine, methylphenidate (Ritalin), ephedrine, phenylpropanolamine, amphetamines), narcotics/opiates (opium, morphine, heroin, methadone, oxycodone, codeine, fentanyl), <b>hallucinogens (lysergic acid diethylamide (LSD), PCP, MDMA (ecstasy), mescaline, psilocybin, magic mushroom (Psilocybe cubensis), Amanita muscaria mushroom, marijuana/cannabis), Salvia divinorum, diphenhydramine (Benadryl), flexeril, tobacco, nicotine, bupropion (Zyban), opiate antagonists, depressants, gamma aminobutyric acid (GABA) agonists or antagonists, NMDA receptor agonists or antagonists, depressants (e.g., alcohol, Xanax; Valium; Halcion; Librium; other benzodiazepines, Ativan; Klonopin; Amytal; Nembutal; Seconal; Phenobarbital, other barbiturates), psychedelics, disassociatives, and deliriants (e.g., a special class of acetylcholine-inhibitor hallucinogen). For example, Carhart-Harris showed using fMRI that LSD and psilocybin caused synchronization of different parts of the brain that normally work separately by making neurons fire simultaneously. This effect can be used to induce synchronization of various regions of the brain to heighten the mental state.”</b></p> <p>From [0937]: “A recipient is then prepared for receipt of the mental state. The mental state of the recipient may be assessed. This can include responses to a questionnaire, self-assessment, or other <b>psychological assessment method.</b> Further, the <b>transcutaneous EEG (or other brain activity data) of the recipient may be obtained, to determine the starting state for the recipient, as well as activity during experiencing the desired mental state.”</b></p> <p>From [0938]: “In addition, a set of stimuli, such as <b>visual patterns, acoustic patterns, vestibular, smell, taste, touch (light touch, deep touch, proprioception, stretch, hot, cold, pain, pleasure, electric stimulation, acupuncture, etc.), vagus nerve (e.g., parasympathetic), are imposed on the subject, optionally over a range of baseline brain states, to acquire data defining the effect of individual and various combinations of sensory stimulation on the brain state of the recipient.</b> Population data may also be used for this aspect.”</p>

From [0941]: “During stimulation of the recipient, the EEG pattern may be **monitored to determine if the desired state is achieved through the sensory stimulation**. A closed loop feedback control system may be **implemented to modify the stimulation seeking to achieve the target**. An evolving genetic algorithm may be used to develop a user model, which relates the mental state, arousal and valence, **sensory stimulation**, and brain activity patterns, both **to optimize the current session of stimulation and learning, as well as to facilitate future sessions, where the mental states of the recipient have further enhanced**, and to permit use of the system for a range of mental states.”

2. Int’l Pat. App. Pub. No. WO/2019/161050A1 “COGNITIVE PLATFORM INCLUDING COMPUTERIZED ELEMENTS COUPLED WITH A THERAPY FOR MOOD DISORDER” (Published August 22, 2019)

From [0062]: “A benefit of using the cognitive platform described herein may be providing a greater and more durable or maintained improvement **following treatment with a psychedelic and/or dissociative drug**. Accordingly, the present disclosure describes examples using the cognitive platform described herein in conjunction with psychedelic and/or dissociative drugs, other drugs for the mood disorder, and/or cognitive behavioral therapy.”

From [63]: “Non-limiting examples of such drugs include **lysergic acid diethylamide (LSD), psilocybin, ketamine, methylenedioxy-n-methylamphetamine (MDMA) mescaline, or N,N- Dimethyltryptamine (DMT or N,N-DMT)**. The psychedelic drug can be a **tryptamine, a phenethylamine**, or a lysergamide.”

From [0126]: “According to the principles herein, the term “session” refers to a discrete time period, with a clear start and finish, during which a user interacts with a platform product to receive assessment or treatment from the platform product (including in the form of an APP). In examples herein, a session can refer to at least one trial or can include at least one trial and at least one other type of measurement and/or other user interaction. As a non limiting example, a session can include at least one trial and one or more of **a measurement using a physiological or monitoring component and/or a cognitive testing component**. As another non-limiting example, a session can include at least one trial and receipt of data indicative of one or more measures of an individual’s condition, including physiological condition and/or cognitive condition.”

	<p>From [0142]: “An example system, method, and apparatus according to the principles herein includes a platform product (including using an APP) that uses a cognitive platform configured to render <b>at least one computerized element in the interaction sequence, measure user responses, and adjust the CSI accordingly.</b> These measurements may be compared with the user responses to interaction sequences in the platform that do not present computerized elements, in order to determine measures of the user’s emotional reactivity. This measurement, with or without comparison to measurements made during interaction sequences that do not present computerized elements, may be for the purpose of assessing the user’s emotional state. The CSI adjustments might be initiating an emotional regulation strategy to enable better engagement with the platform product or initiating certain interactive elements, such as but not limited to tasks or rewards, only under certain emotional conditions. <b>The user response measurement may employ use of inputs such as touchscreens, keyboards, or accelerometers, or passive external sensors such as video cameras, microphones, eye-tracking software/devices, bio-sensors, and/or neural recording (e.g., electroencephalogram),</b> and may include responses that are not directly related to interactions with the platform product, as well as responses based on user interactions with the platform product. The platform product can present measures of a user’s emotional state that include <b>a measure of specific moods and/or a measure of general state of ego depletion that impacts emotional reactivity.</b>”</p> <p>From [0093]: “As used herein, the term “<b>computerized stimuli or interaction</b>” or “<b>CSI</b>” refers to a <b>computerized element that is presented to a user to facilitate the user’s interaction with a stimulus or other interaction.</b>”</p>
<p>4. The method according to claim 1, wherein presenting a sensory environment to the individual comprises presenting to the individual one or more visual stimuli, one or more auditory stimuli, one or more tactile stimuli, one or more olfactory stimuli, or any combination thereof.</p>	<p>1. U.S. Pat. App. Pub. No. 2020/0086078 “System and method of improving sleep” (Published March 19, 2020)</p> <p>From [0938]: “In addition, <b>a set of stimuli, such as visual patterns, acoustic patterns,</b> vestibular, <b>smell, taste, touch (light touch, deep touch, proprioception, stretch, hot, cold, pain, pleasure, electric stimulation, acupuncture, etc.),</b> vagus nerve (e.g., parasympathetic), <b>are imposed on the subject,</b> optionally over a range of baseline brain states, to acquire data defining the effect of individual and <b>various combinations of sensory stimulation</b> on the brain state of the recipient. Population data may also be used for this aspect.”</p>
<p>5. The method according to claim 1, wherein the monitoring comprises monitoring the neural status of the individual.</p>	<p>1. U.S. Pat. App. Pub. No. 2020/0086078 “System and method of improving sleep” (Published March 19, 2020)</p>

	<p>From [0937]: “A recipient is then prepared for receipt of the mental state. The mental state of the recipient may be assessed. This can include responses to a questionnaire, self-assessment, or other psychological assessment method. Further, the transcutaneous EEG (or other brain activity data) of the recipient may be obtained, to determine the starting state for the recipient, as well as activity during experiencing the desired mental state.”</p> <p>From [0196]: “Neurofeedback (NFB), also called neurotherapy or neurobiofeedback, is a type of biofeedback that uses real-time displays of brain activity-most commonly electroencephalography (EEG), to teach self-regulation of brain function. Typically, sensors are placed on the scalp to measure activity, with measurements displayed using video displays or sound. The feedback may be in various other forms as well. Typically, the feedback is sought to be presented through primary sensory inputs, but this is not a limitation on the technique.”</p> <p>From [0941]: “During stimulation of the recipient, the EEG pattern may be monitored to determine if the desired state is achieved through the sensory stimulation. A closed loop feedback control system may be implemented to modify the stimulation seeking to achieve the target. An evolving genetic algorithm may be used to develop a user model, which relates the mental state, arousal and valence, sensory stimulation, and brain activity patterns, both to optimize the current session of stimulation and learning, as well as to facilitate future sessions, where the mental states of the recipient have further enhanced, and to permit use of the system for a range of mental states.”</p>
<p>6. The method according to claim 5, wherein the neural status of the individual is monitored by electroencephalography (EEG), functional magnetic resonance imaging (fMRI), near-infrared spectroscopy (NIRS), electrocorticography (ECoG), or any combination thereof.</p>	<p>1. U.S. Pat. App. Pub. No. 2020/0086078 “System and method of improving sleep” (Published March 19, 2020)</p> <p>From [0949]: “Every activity, mental or motor, and emotion is associated with unique brainwaves having specific spatial and temporal patterns, i.e., a characteristic frequency or a characteristic distribution of frequencies over time and space. Such waves can be read and recorded by several known techniques, including electroencephalography (EEG), magnetoencephalography (MEG), exact low-resolution brain electromagnetic tomography (eLORETA), sensory evoked potentials (SEP), fMRI, functional near-infrared spectroscopy (fNIRS), etc. The cerebral cortex is composed of neurons that are interconnected in networks. Cortical neurons constantly send and receive nerve impulses-electrical activity-even during sleep. The electrical or magnetic activity measured by an EEG or MEG (or another device) device reflects the intrinsic activity of</p>



	<p>neurons in the cerebral cortex and the information sent to it by subcortical structures and the sense receptors.”</p> <p>From [0930]: “It is noted that <b>EEG is not the only neural or brain activity or state data that may be acquired</b>, and of course any and all such data may be included within the scope of the technology, and therefore EEG is a representative example only of the types of data that may be used. <b>Other types include fMRI, magnetoencephalogram, motor neuron activity, PET, etc.</b>”</p> <p>3. Int’l Pat. App. Pub. No. WO/2015/026988A1 “SYSTEMS AND METHODS FOR ELECTROCORTICOGRAPHY SIGNAL ACQUISITION” (Published February 26, 2015)</p> <p>From [0006]: “This invention pertains generally to signal acquisition, and more particularly to <b>neural signal acquisition.</b>”</p> <p>From <b>abstract</b>: “Systems and methods for <b>biosignal acquisition, and in particular, electrocorticography signal acquisition</b>, are disclosed for small area, low noise recording and digitization of brain signals from electrode arrays.”</p>
<p>7. The method according to claim 1, wherein the monitoring comprises monitoring the physiological status of the individual.</p>	<p>1. U.S. Pat. App. Pub. No. 2020/0086078 “System and method of improving sleep” (Published March 19, 2020)</p> <p>From [0876]: “While mental states are typically considered internal to the individual, and subjective, in fact, such states are common across individuals and have <b>determinable physiological and electrophysiological population characteristics</b>. Further, mental states may be externally changed or induced in a manner that bypasses the normal cognitive processes. In some cases, the triggers for the mental state are subjective, and therefore the particular subject-dependent sensory or excitation scheme required to induce a particular state will differ. For example, olfactory stimulation can have different effects on different people, based on differences in history of exposure, social and cultural norms, and the like. On the other hand, some mental state response triggers are normative, for example “tear jerker” media.”</p> <p>From [1025]: “The technology may be used to modify or alter a mental state (e.g., from sleep to waking and vice versa) in a subject. Typically, the starting mental state, brain state, or brainwave pattern is assessed, such as by EEG, MEG, observation, stimulus-response amplitude and/or delay, or the like. Of particular interest in uncontrolled environments are automated mental state assessments, which do not rely on human observation or EEG signals, and rather may be acquired through MEG (e.g., SQID, optically-pumped magnetometer), EMG,</p>

	<p>MMG (magnetomyogram), mechanical (e.g., accelerometer, gyroscope, etc.), <b>data from physiological sensors</b> (e.g., AKG, <b>heartrate, respiration rate</b>, temperature, <b>galvanic skim potential</b>, etc.), or <b>automated camera sensors.</b>”</p>
<p>8. The method according to claim 7, wherein monitoring the physiological status of the individual comprises monitoring one or more of the individual's heart rate, blood pressure, respiration, electrodermal activity, movement, eye movement, facial expression, and any combination thereof.</p>	<p>1. U.S. Pat. App. Pub. No. 2020/0086078 “System and method of improving sleep” (Published March 19, 2020)</p> <p>From <b>[0876]</b>: “While mental states are typically considered internal to the individual, and subjective, in fact, such states are common across individuals and have <b>determinable physiological and electrophysiological population characteristics</b>. Further, mental states may be externally changed or induced in a manner that bypasses the normal cognitive processes. In some cases, the triggers for the mental state are subjective, and therefore the particular subject-dependent sensory or excitation scheme required to induce a particular state will differ. For example, olfactory stimulation can have different effects on different people, based on differences in history of exposure, social and cultural norms, and the like. On the other hand, some mental state response triggers are normative, for example “tear jerker” media.”</p> <p>From <b>[1025]</b>: “The technology may be used to modify or alter a mental state (e.g., from sleep to waking and vice versa) in a subject. Typically, the starting mental state, brain state, or brainwave pattern is assessed, such as by EEG, MEG, observation, stimulus-response amplitude and/or delay, or the like. Of particular interest in uncontrolled environments are automated mental state assessments, which do not rely on human observation or EEG signals, and rather may be acquired through MEG (e.g., SQID, optically-pumped magnetometer), EMG, MMG (magnetomyogram), mechanical (e.g., accelerometer, gyroscope, etc.), <b>data from physiological sensors</b> (e.g., AKG, <b>heartrate, respiration rate</b>, temperature, <b>galvanic skim potential</b>, etc.), or <b>automated camera sensors.</b>”</p> <p>2. Int’l Pat. App. Pub. No. WO/2019/161050A1 “COGNITIVE PLATFORM INCLUDING COMPUTERIZED ELEMENTS COUPLED WITH A THERAPY FOR MOOD DISORDER” (Published August 22, 2019)</p> <p>From <b>[0062]</b>: “A benefit of using the cognitive platform described herein may be providing a greater and more durable or maintained improvement <b>following treatment with a psychedelic and/or dissociative drug</b>. Accordingly, the present disclosure describes examples using the cognitive platform described herein in conjunction with psychedelic and/or dissociative drugs, other drugs for the mood disorder, and/or cognitive behavioral therapy.”</p>

From [63]: “Non-limiting examples of such drugs include **lysergic acid diethylamide (LSD), psilocybin, ketamine, methylenedioxy-n-methylamphetamine (MDMA) mescaline, or N,N- Dimethyltryptamine (DMT or N,N-DMT)**. The psychedelic drug can be a **tryptamine, a phenethylamine**, or a lysergamide.”

From [0126]: “According to the principles herein, the term “session” refers to a discrete time period, with a clear start and finish, during which a user interacts with a platform product to receive assessment or treatment from the platform product (including in the form of an APP). In examples herein, a session can refer to at least one trial or can include at least one trial and at least one other type of measurement and/or other user interaction. As a non limiting example, a session can include at least one trial and one or more of **a measurement using a physiological or monitoring component and/or a cognitive testing component**. As another non-limiting example, a session can include at least one trial and receipt of data indicative of one or more measures of an individual’s condition, including physiological condition and/or cognitive condition.”

From [0142]: “An example system, method, and apparatus according to the principles herein includes a platform product (including using an APP) that uses a cognitive platform configured to render **at least one computerized element in the interaction sequence, measure user responses**, and adjust the CSI accordingly. These measurements may be compared with the user responses to interaction sequences in the platform that do not present computerized elements, in order to determine measures of the user’s emotional reactivity. This measurement, with or without comparison to measurements made during interaction sequences that do not present computerized elements, may be for the purpose of assessing the user’s emotional state. The CSI adjustments might be initiating an emotional regulation strategy to enable better engagement with the platform product or initiating certain interactive elements, such as but not limited to tasks or rewards, only under certain emotional conditions. **The user response measurement may employ use of inputs such as touchscreens, keyboards, or accelerometers, or passive external sensors such as video cameras, microphones, eye-tracking software/devices, bio-sensors, and/or neural recording (e.g., electroencephalogram)**, and may include responses that are not directly related to interactions with the platform product, as well as responses based on user interactions with the platform product. The platform product can present measures of a user’s emotional state that include **a measure of specific moods and/or a measure of general state of ego depletion that impacts emotional reactivity.**”

	<p>From [0155]: “In any example herein, the <b>one or more physiological components can include any means of measuring physical characteristics</b> of the body and nervous system, including electrical activity, <b>heart rate, blood flow</b>, and oxygenation levels, to provide the measurement data 112. This can include camera-based heart rate detection, <b>measurement of galvanic skin response, blood pressure measurement</b>, electroencephalogram, electrocardiogram, magnetic resonance imaging, near- infrared spectroscopy, and/or pupil dilation measures, to provide the measurement data 112. The one or more physiological components can include one or more sensors for measuring parameter values of the physical characteristics of the body and nervous system, and one or more signal processors for processing signals detected by the one or more sensors.”</p>
<p>9. The method according to claim 1, wherein monitoring the neural status, the physiological status, or both, of the individual is performed continuously for a period of time and is used to monitor the state of the individual in real-time, wherein the state of the individual comprises one or more of stress, mood, attention, arousal, and any combination thereof.</p>	<p>1. U.S. Pat. App. Pub. No. 2020/0086078 “System and method of improving sleep” (Published March 19, 2020)</p> <p>From [0196]: “<b>Neurofeedback (NFB), also called neurotherapy or neurobiofeedback</b>, is a type of biofeedback that uses <b>real-time displays of brain activity-most commonly electroencephalography (EEG)</b>, to teach self-regulation of brain function. Typically, sensors are placed on the scalp to measure activity, with measurements displayed using video displays or sound. The feedback may be in various other forms as well. <b>Typically, the feedback is sought to be presented through primary sensory inputs</b>, but this is not a limitation on the technique.”</p> <p>From [0941]: “During stimulation of the recipient, the EEG pattern may be <b>monitored to determine if the desired state is achieved through the sensory stimulation</b>. A closed loop feedback control system may be <b>implemented to modify the stimulation seeking to achieve the target</b>. An evolving genetic algorithm may be used to develop a user model, which relates the <b>mental state, arousal and valence, sensory stimulation, and brain activity patterns, both to optimize the current session of stimulation and learning, as well as to facilitate future sessions, where the mental states of the recipient have further enhanced</b>, and to permit use of the system for a range of mental states.”</p> <p>From [0045]: “<b>The mental state may be associated with a learning or performing a skill</b>. The skill may comprise a mental skill, e.g., cognitive, alertness, concentration, <b>attention</b>, focusing, memorization, visualization, relaxation, meditation, speedreading, creative skill, “whole-brain-thinking”, analytical, reasoning, problem-solving, critical thinking, intuitive, leadership, learning, speedreading, patience, balancing, perception, linguistic or language, language comprehension,</p>

quantitative, “fluid intelligence”, pain management, skill of maintaining positive attitude, a foreign language, musical, musical composition, writing, poetry composition, mathematical, science, art, visual art, rhetorical, emotional control, empathy, compassion, motivational skill, people, computational, science skill, or an inventorship skill. See, U.S. Patent and Pub. 6,435,878, 5,911,581, and 20090069707. The skill may comprise a motor skill, e.g., fine motor, muscular coordination, walking, running, jumping, swimming, dancing, gymnastics, yoga; an athletic or sports, massage skill, martial arts or fighting, shooting, self-defense; speech, singing, playing a musical instrument, penmanship, calligraphy, drawing, painting, visual, auditory, olfactory, game-playing, gambling, sculptor's, craftsman, massage, or assembly skill. Where a skill is to be enhanced, and an emotion to be achieved (or suppressed), concurrently, the stimulus to the recipient may be combined in such a way as to achieve the result. In some cases, the component is universal, while in others, it is subjective. Therefore, the combination may require adaptation based on the recipient characteristics.

From [0515]: “**Changes in neural oscillations, demonstrable through electroencephalogram (EEG) measurements, are precipitated by listening to music**, which can modulate autonomic arousal ergotropically and trophotropically, **increasing and decreasing arousal respectively**. Musical auditory stimulation has also been demonstrated to improve immune function, facilitate relaxation, **improve mood**, and contribute to the **alleviation of stress**.”

2. Int’l Pat. App. Pub. No. WO/2019/161050A1 “COGNITIVE PLATFORM INCLUDING COMPUTERIZED ELEMENTS COUPLED WITH A THERAPY FOR MOOD DISORDER” (Published August 22, 2019)

From [0142]: “An example system, method, and apparatus according to the principles herein includes a platform product (including using an APP) that uses a cognitive platform configured to render **at least one computerized element in the interaction sequence, measure user responses**, and adjust the CSI accordingly. These measurements may be compared with the user responses to interaction sequences in the platform that do not present computerized elements, in order to determine measures of the user’s emotional reactivity. This measurement, with or without comparison to measurements made during interaction sequences that do not present computerized elements, may be for the purpose of assessing the user’s emotional state. The CSI adjustments might be initiating an emotional regulation strategy to enable better engagement with the platform product or initiating certain interactive

	<p>elements, such as but not limited to tasks or rewards, only under certain emotional conditions. <b>The user response measurement may employ use of inputs such as touchscreens, keyboards, or accelerometers, or passive external sensors such as video cameras, microphones, eye-tracking software/devices, biosensors, and/or neural recording (e.g., electroencephalogram),</b> and may include responses that are not directly related to interactions with the platform product, as well as responses based on user interactions with the platform product. The platform product can present measures of a user’s emotional state that include <b>a measure of specific moods and/or a measure of general state of ego depletion that impacts emotional reactivity.”</b></p>
<p>10. The method according to claim 1, wherein presenting a modified sensory environment to the individual comprises presenting a customized sensory environment to the individual in real-time based on the monitoring.</p>	<p>1. U.S. Pat. App. Pub. No. 2020/0086078 “System and method of improving sleep” (Published March 19, 2020)</p> <p>From [0196]: “<b>Neurofeedback (NFB), also called neurotherapy or neurobiofeedback,</b> is a type of biofeedback that uses <b>real-time displays of brain activity-most commonly electroencephalography (EEG),</b> to teach self-regulation of brain function. Typically, sensors are placed on the scalp to measure activity, with measurements displayed using video displays or sound. The feedback may be in various other forms as well. <b>Typically, the feedback is sought to be presented through primary sensory inputs,</b> but this is not a limitation on the technique.”</p> <p>From [0941]: “During stimulation of the recipient, the EEG pattern may be <b>monitored to determine if the desired state is achieved through the sensory stimulation.</b> A closed loop feedback control system may be <b>implemented to modify the stimulation seeking to achieve the target.</b> An evolving genetic algorithm may be used to develop a user model, which relates the <b>mental state, arousal and valence, sensory stimulation, and brain activity patterns, both to optimize the current session of stimulation and learning, as well as to facilitate future sessions, where the mental states of the recipient have further enhanced,</b> and to permit use of the system for a range of mental states.”</p>
<p>11. The method according to claim 1, wherein the individual is suffering from a mental health condition selected from the group consisting of: depression, anxiety, post-traumatic stress disorder (PTSD), addiction, and any combination thereof.</p>	<p>1. U.S. Pat. App. Pub. No. 2020/0086078 “System and method of improving sleep” (Published March 19, 2020)</p> <p>From [1051]: “<b>According to the present technology, the modulation of stimulation, which is, for example, a transcranial direct current stimulation (tDCS),</b> whose waveform is modulated to correspond to the raw or processed brainwave pattern of the first subject (donor) for the brain region associated with the stimulation electrode.”</p>

From [0343]: “**Transcranial Direct Current Stimulation (tDCS)**: Cranial electrotherapy stimulation (CES) is a form of non-invasive brain stimulation that applies a small, pulsed electric current across a person's head to **treat a variety of conditions such as anxiety, depression** and insomnia. See, [en.wikipedia.org/wiki/Cranial\\_electrotherapy\\_stimulation](http://en.wikipedia.org/wiki/Cranial_electrotherapy_stimulation). Transcranial direct current stimulation (tDCS) is a form of neurostimulation that uses constant, low current delivered to the brain area of interest via electrodes on the scalp. It was originally developed to help patients with brain injuries or psychiatric conditions like major depressive disorder. tDCS appears to have some potential for treating depression.”

2. Int’l Pat. App. Pub. No. WO/2019/161050A1 “**COGNITIVE PLATFORM INCLUDING COMPUTERIZED ELEMENTS COUPLED WITH A THERAPY FOR MOOD DISORDER**” (Published August 22, 2019)

From [0062]: “A benefit of using the cognitive platform described herein may be providing a greater and more durable or maintained improvement **following treatment with a psychedelic and/or dissociative drug**. Accordingly, the present disclosure describes examples using the cognitive platform described herein in conjunction with psychedelic and/or dissociative drugs, other drugs for the mood disorder, and/or cognitive behavioral therapy.”

From **claim 24**: “The method of claim 17, wherein the mood disorder is selected from the group consisting of **depression, anxiety, post- traumatic stress disorder (PTSD)**, and obsessive compulsive disorder (OCD).”

From **claim 17**: “**A computer-implemented method for quantifying cognitive skills in an individual undergoing therapy for a mood disorder**, the method comprising: using one or more processors to execute instructions stored in one or more memory storage devices comprising computer executable instructions to perform operations including: present via a user interface a first instance of a task with an interference at the user interface, requiring a first response from the individual to the first instance of the task in the presence of the interference, wherein the individual at least one of (i) preparing to undergo **a therapy for a mood disorder comprising at least one of ingesting or injecting at least one of a psychedelic or a dissociative drug for treatment of the mood disorder** or (ii) has undergone the therapy; present via the user interface the first instance of the task, requiring a second response from the individual to the first instance of the task in the absence of the interference;

	<p>wherein: at least one of the first instance of the task and the interference comprises a computerized element; measure substantially simultaneously the first response from the individual to the first instance of the task and the response from the individual to the interference; receive data indicative of the first response and the second response; and analyze the data indicative of the first response and the second response to compute at least one performance metric comprising at least one quantified indicator of cognitive abilities of the individual.”</p>
<p>12. The method according to claim 11, wherein the method is effective in treating the mental health condition.</p>	<p>1. US 20200086078 A1 (Published 03/19/2020)</p> <p>From [1051]: “<b>According to the present technology, the modulation of stimulation, which is, for example, a transcranial direct current stimulation (tDCS)</b>, whose waveform is modulated to correspond to the raw or processed brainwave pattern of the first subject (donor) for the brain region associated with the stimulation electrode.”</p> <p>From [0343]: “<b>Transcranial Direct Current Stimulation (tDCS)</b>: Cranial electrotherapy stimulation (CES) is a form of non-invasive brain stimulation that applies a small, pulsed electric current across a person's head to <b>treat a variety of conditions such as anxiety, depression</b> and insomnia. See, <a href="http://en.wikipedia.org/wiki/Cranial_electrotherapy_stimulation">en.wikipedia.org/wiki/Cranial_electrotherapy_stimulation</a>. Transcranial direct current stimulation (tDCS) is a form of neurostimulation that uses constant, low current delivered to the brain area of interest via electrodes on the scalp. It was originally developed to help patients with brain injuries or psychiatric conditions like major depressive disorder. tDCS appears to have some potential for treating depression.”</p> <p>From [0943]: “While typically, controlled or “illegal” substances are to be avoided, <b>in some cases, these may be appropriate for use. For example, various drugs may alter the state of the brain to enhance or selectively enhance the effect of the stimulation.</b> Such drugs include stimulants (e.g., cocaine, methylphenidate (Ritalin), ephedrine, phenylpropanolamine, amphetamines), narcotics/opiates (opium, morphine, heroin, methadone, oxycodone, codeine, fentanyl), <b>hallucinogens (lysergic acid diethylamide (LSD), PCP, MDMA (ecstasy), mescaline, psilocybin, magic mushroom (Psilocybe cubensis), Amanita muscaria mushroom, marijuana/cannabis, Salvia divinorum, diphenhydramine (Benadryl), flexeril, tobacco, nicotine, bupropion (Zyban), opiate antagonists, depressants, gamma aminobutyric acid (GABA) agonists or antagonists, NMDA receptor agonists or antagonists, depressants (e.g., alcohol, Xanax; Valium; Halcion; Librium; other benzodiazepines, Ativan; Klonopin; Amytal; Nembutal; Seconal; Phenobarbital, other barbiturates), psychedelics, disassociatives, and deliriants (e.g., a special class of</b></p>



	<p>acetylcholine-inhibitor hallucinogen). <b>For example, Carhart-Harris showed using fMRI that LSD and psilocybin caused synchronization of different parts of the brain that normally work separately by making neurons fire simultaneously. This effect can be used to induce synchronization of various regions of the brain to heighten the mental state.</b></p>
<p>13. A system for presenting sensory environments to an individual experiencing the effects of a psychoactive agent, comprising: one or more processors; and one or more non-transitory computer-readable media comprising instructions stored thereon that cause the system to: present a sensory environment to an individual experiencing the effects of a psychoactive agent; monitor the neural status, the physiological status, or both, of the individual; and present a modified sensory environment to the individual based on the monitoring.</p>	<p>1. U.S. Pat. App. Pub. No. 2020/0086078 “System and method of improving sleep” (Published March 19, 2020)</p> <p>From [0946]: “The technology may be embodied in apparatuses for acquiring the brain activity information from the source, processing the brain activity information to reveal a target brain activity state and a set of stimuli, which seek to achieve that state in a recipient, and generating stimuli for the recipient to achieve and maintain the target brain activity state over a period of time and potential state transitions. The generated stimuli may be feedback controlled. A general-purpose computer may be used for the processing of the information, a microprocessor, a FPGA, an ASIC, a system-on-a-chip, or a specialized system, which employs a customized configuration to efficiently achieve the information transformations required. Typically, the source and recipient act asynchronously, with the brain activity of the source recorded and later processed. However, real-time processing and brain activity transfer are also possible. <b>In the case of a general purpose programmable processor implementation or portions of the technology, computer instructions may be stored on a nontransient computer readable medium.</b> Typically, the system will have special-purpose components, such as a transcranial stimulator, or a modified audio and/or display system, and therefore the system will not be a general purpose system. Further, even in a general purpose system the operation per se is enhanced according to the present technology.”</p> <p>From [0995]: “<b>A computer apparatus may be provided for creating and maintaining a relational database of mental states and frequencies associated with the mental states,</b> the computer apparatus comprising: a non-volatile memory for <b>storing a relational database of mental states and neural correlates of brain activity associated with the mental states,</b> the <b>database comprising a first table,</b> the first table further comprising a plurality of data records of neural correlates of brain activity associated with the mental states, and a second table, the second table comprising a plurality of mental states, each of the mental states being linked to one or more records in the first table; <b>a processor coupled with the non-volatile memory, configured to process relational database queries,</b> which are then used for searching the database; RAM coupled with the processor and the non-volatile memory for temporary holding database queries and data records retrieved from the</p>

	<p>relational database; and an I/O interface configured <b>to receive database queries and deliver data records retrieved from the relational database. A SQL or noSQL database may also be used to store and retrieve records.</b>”</p> <p>From [0943]: “While typically, controlled or “illegal” substances are to be avoided, <b>in some cases, these may be appropriate for use. For example, various drugs may alter the state of the brain to enhance or selectively enhance the effect of the stimulation.</b> Such drugs include stimulants (e.g., cocaine, methylphenidate (Ritalin), ephedrine, phenylpropanolamine, amphetamines), narcotics/opiates (opium, morphine, heroin, methadone, oxycodone, codeine, fentanyl), <b>hallucinogens (lysergic acid diethylamide (LSD), PCP, MDMA (ecstasy), mescaline, psilocybin, magic mushroom (Psilocybe cubensis), Amanita muscaria mushroom, marijuana/cannabis), Salvia divinorum, diphenhydramine (Benadryl), flexeril, tobacco, nicotine, bupropion (Zyban), opiate antagonists, depressants, gamma aminobutyric acid (GABA) agonists or antagonists, NMDA receptor agonists or antagonists, depressants (e.g., alcohol, Xanax; Valium; Halcion; Librium; other benzodiazepines, Ativan; Klonopin; Amytal; Nembutal; Seconal; Phenobarbital, other barbiturates), psychedelics, disassociatives, and deliriant (e.g., a special class of acetylcholine-inhibitor hallucinogen). For example, Carhart-Harris showed using fMRI that LSD and psilocybin caused synchronization of different parts of the brain that normally work separately by making neurons fire simultaneously. This effect can be used to induce synchronization of various regions of the brain to heighten the mental state.</b>”</p>
<p>14. One or more non-transitory computer-readable media comprising instructions stored thereon that cause a system to: present a sensory environment to an individual experiencing the effects of a psychoactive agent; monitor the neural status, the physiological status, or both, of the individual; and present a modified sensory environment to the individual based on the monitoring.</p>	<p>1. U.S. Pat. App. Pub. No. 2020/0086078 “System and method of improving sleep” (Published March 19, 2020)</p> <p>From [0946]: “The technology may be embodied in apparatuses for acquiring the brain activity information from the source, processing the brain activity information to reveal a target brain activity state and a set of stimuli, which seek to achieve that state in a recipient, and generating stimuli for the recipient to achieve and maintain the target brain activity state over a period of time and potential state transitions. The generated stimuli may be feedback controlled. A general-purpose computer may be used for the processing of the information, a microprocessor, a FPGA, an ASIC, a system-on-a-chip, or a specialized system, which employs a customized configuration to efficiently achieve the information transformations required. Typically, the source and recipient act asynchronously, with the brain activity of the source recorded and later processed. However, real-time processing and brain activity transfer are also possible. <b>In the case of a general purpose programmable processor implementation or portions of the technology, computer</b></p>

**instructions may be stored on a nontransient computer readable medium.** Typically, the system will have special-purpose components, such as a transcranial stimulator, or a modified audio and/or display system, and therefore the system will not be a general purpose system. Further, even in a general purpose system the operation per se is enhanced according to the present technology.”

From [0995]: “**A computer apparatus may be provided for creating and maintaining a relational database of mental states and frequencies associated with the mental states,** the computer apparatus comprising: a non-volatile memory for **storing a relational database of mental states and neural correlates of brain activity associated with the mental states,** the **database comprising a first table,** the first table further comprising a plurality of data records of neural correlates of brain activity associated with the mental states, and a second table, the second table comprising a plurality of mental states, each of the mental states being linked to one or more records in the first table; **a processor coupled with the non-volatile memory, configured to process relational database queries,** which are then used for searching the database; RAM coupled with the processor and the non-volatile memory for temporary holding database queries and data records retrieved from the relational database; and an I/O interface configured **to receive database queries and deliver data records retrieved from the relational database. A SQL or noSQL database may also be used to store and retrieve records.**”

From [0943]: “While typically, controlled or “illegal” substances are to be avoided, **in some cases, these may be appropriate for use. For example, various drugs may alter the state of the brain to enhance or selectively enhance the effect of the stimulation.** Such drugs include stimulants (e.g., cocaine, methylphenidate (Ritalin), ephedrine, phenylpropanolamine, amphetamines), narcotics/opiates (opium, morphine, heroin, methadone, oxycodone, codeine, fentanyl), **hallucinogens (lysergic acid diethylamide (LSD), PCP, MDMA (ecstasy), mescaline, psilocybin, magic mushroom (Psilocybe cubensis), Amanita muscaria mushroom,** marijuana/cannabis), Salvia divinorum, diphenhydramine (Benadryl), flexeril, tobacco, nicotine, bupropion (Zyban), opiate antagonists, depressants, gamma aminobutyric acid (GABA) agonists or antagonists, NMDA receptor agonists or antagonists, depressants (e.g., alcohol, Xanax; Valium; Halcion; Librium; other benzodiazepines, Ativan; Klonopin; Amytal; Nembutal; Seconal; Phenobarbital, other barbiturates), **psychedelics,** disassociatives, and deliriant (e.g., a special class of acetylcholine-inhibitor hallucinogen). **For example, Carhart-Harris showed using fMRI that LSD and psilocybin caused synchronization of different parts of the brain that normally**

	<p><b>work separately by making neurons fire simultaneously. This effect can be used to induce synchronization of various regions of the brain to heighten the mental state.”</b></p> <p>From [0876]: “While mental states are typically considered internal to the individual, and subjective, in fact, such states are common across individuals and have <b>determinable physiological and electrophysiological population characteristics</b>. Further, mental states may be externally changed or induced in a manner that bypasses the normal cognitive processes. In some cases, the triggers for the mental state are subjective, and therefore the particular subject-dependent sensory or excitation scheme required to induce a particular state will differ. For example, olfactory stimulation can have different effects on different people, based on differences in history of exposure, social and cultural norms, and the like. On the other hand, some mental state response triggers are normative, for example “tear jerker” media.”</p> <p>From [1025]: “The technology may be used to modify or alter a mental state (e.g., from sleep to waking and vice versa) in a subject. Typically, the starting <b>mental state, brain state, or brainwave pattern is assessed, such as by EEG, MEG, observation</b>, stimulus-response amplitude and/or delay, or the like. Of particular interest in uncontrolled environments are automated mental state assessments, which do not rely on human observation or EEG signals, and rather may be acquired through MEG (e.g., SQID, optically-pumped magnetometer), EMG, MMG (magnetomyogram), mechanical (e.g., accelerometer, gyroscope, etc.), <b>data from physiological sensors</b> (e.g., AKG, <b>heartrate, respiration rate, temperature, galvanic skim potential</b>, etc.), or <b>automated camera sensors</b>.”</p>
<p>15. The one or more non-transitory computer-readable media of claim 14, comprising instructions stored thereon that cause a system to monitor the neural status of the individual using one or more neural status monitoring devices.</p>	<p>1. U.S. Pat. App. Pub. No. 2020/0086078 “System and method of improving sleep” (Published March 19, 2020)</p> <p>From [0946]: “The technology may be embodied in apparatuses for acquiring the brain activity information from the source, processing the brain activity information to reveal a target brain activity state and a set of stimuli, which seek to achieve that state in a recipient, and generating stimuli for the recipient to achieve and maintain the target brain activity state over a period of time and potential state transitions. The generated stimuli may be feedback controlled. A general-purpose computer may be used for the processing of the information, a microprocessor, a FPGA, an ASIC, a system-on-a-chip, or a specialized system, which employs a customized configuration to efficiently achieve the information transformations required. Typically, the source and recipient act asynchronously, with the brain activity of the source recorded and later processed. However, real-time processing and brain activity transfer are also possible. <b>In the</b></p>

	<p><b>case of a general purpose programmable processor implementation or portions of the technology, computer instructions may be stored on a nontransient computer readable medium.</b> Typically, the system will have special-purpose components, such as a transcranial stimulator, or a modified audio and/or display system, and therefore the system will not be a general purpose system. Further, even in a general purpose system the operation per se is enhanced according to the present technology.”</p> <p>From [0930]: “It is noted that <b>EEG is not the only neural or brain activity or state data that may be acquired</b>, and of course any and all such data may be included within the scope of the technology, and therefore EEG is a representative example only of the types of data that may be used. <b>Other types include fMRI, magnetoencephalogram, motor neuron activity, PET, etc.</b>”</p>
<p>16. The one or more non-transitory computer-readable media of claim 15, wherein the one or more neural status monitoring devices comprises one or more of an electroencephalography (EEG) device, a functional magnetic resonance imaging (fMRI) device, a near-infrared spectroscopy (NIRS) device, an electrocortocography (ECoG) device, or any combination thereof.</p>	<p>1. U.S. Pat. App. Pub. No. 2020/0086078 “System and method of improving sleep” (Published March 19, 2020)</p> <p>From [0946]: “The technology may be embodied in apparatuses for acquiring the brain activity information from the source, processing the brain activity information to reveal a target brain activity state and a set of stimuli, which seek to achieve that state in a recipient, and generating stimuli for the recipient to achieve and maintain the target brain activity state over a period of time and potential state transitions. The generated stimuli may be feedback controlled. A general-purpose computer may be used for the processing of the information, a microprocessor, a FPGA, an ASIC, a system-on-a-chip, or a specialized system, which employs a customized configuration to efficiently achieve the information transformations required. Typically, the source and recipient act asynchronously, with the brain activity of the source recorded and later processed. However, real-time processing and brain activity transfer are also possible. <b>In the case of a general purpose programmable processor implementation or portions of the technology, computer instructions may be stored on a nontransient computer readable medium.</b> Typically, the system will have special-purpose components, such as a transcranial stimulator, or a modified audio and/or display system, and therefore the system will not be a general purpose system. Further, even in a general purpose system the operation per se is enhanced according to the present technology.”</p> <p>From [0949]: “Every activity, mental or motor, and emotion is associated with unique brainwaves having specific spatial and temporal patterns, i.e., a characteristic frequency or a characteristic distribution of frequencies over time and space. Such waves can be read and <b>recorded by several known</b></p>

	<p><b>techniques, including electroencephalography (EEG), magnetoencephalography (MEG), exact low-resolution brain electromagnetic tomography (eLORETA), sensory evoked potentials (SEP), fMRI, functional near-infrared spectroscopy (fNIRS), etc.</b> The cerebral cortex is composed of neurons that are interconnected in networks. Cortical neurons constantly send and receive nerve impulses-electrical activity-even during sleep. The electrical or magnetic activity measured by an EEG or MEG (or another device) device reflects the intrinsic activity of neurons in the cerebral cortex and the information sent to it by subcortical structures and the sense receptors.”</p> <p>From [0930]: “It is noted that <b>EEG is not the only neural or brain activity or state data that may be acquired</b>, and of course any and all such data may be included within the scope of the technology, and therefore EEG is a representative example only of the types of data that may be used. <b>Other types include fMRI, magnetoencephalogram, motor neuron activity, PET, etc.</b>”</p> <p>3. Int’l Pat. App. Pub. No. WO/2015/026988A1 “SYSTEMS AND METHODS FOR ELECTROCORTICOGRAPHY SIGNAL ACQUISITION” (Published February 26, 2015)</p> <p>From [0006]: “This invention pertains generally to signal acquisition, and more particularly to <b>neural signal acquisition.</b>”</p> <p>From <b>abstract</b>: “Systems and methods for <b>biosignal acquisition, and in particular, electrocorticography signal acquisition</b>, are disclosed for small area, low noise recording and digitization of brain signals from electrode arrays.”</p>
<p>17. The one or more non-transitory computer-readable media of claim 14, comprising instructions stored thereon that cause a system to monitor the physiological status of the individual using one or more physiological status monitoring devices.</p>	<p>1. U.S. Pat. App. Pub. No. 2020/0086078 “System and method of improving sleep” (Published March 19, 2020)</p> <p>From [0946]: “The technology may be embodied in apparatuses for acquiring the brain activity information from the source, processing the brain activity information to reveal a target brain activity state and a set of stimuli, which seek to achieve that state in a recipient, and generating stimuli for the recipient to achieve and maintain the target brain activity state over a period of time and potential state transitions. The generated stimuli may be feedback controlled. A general-purpose computer may be used for the processing of the information, a microprocessor, a FPGA, an ASIC, a system-on-a-chip, or a specialized system, which employs a customized configuration to efficiently achieve the information transformations required. Typically, the source and recipient act asynchronously, with the brain activity of the source recorded and later processed. However, real-time processing and brain activity transfer are also possible. <b>In the</b></p>

	<p><b>case of a general purpose programmable processor implementation or portions of the technology, computer instructions may be stored on a nontransient computer readable medium.</b> Typically, the system will have special-purpose components, such as a transcranial stimulator, or a modified audio and/or display system, and therefore the system will not be a general purpose system. Further, even in a general purpose system the operation per se is enhanced according to the present technology.”</p> <p>From [0876]: “While mental states are typically considered internal to the individual, and subjective, in fact, such states are common across individuals and have <b>determinable physiological and electrophysiological population characteristics</b>. Further, mental states may be externally changed or induced in a manner that bypasses the normal cognitive processes. In some cases, the triggers for the mental state are subjective, and therefore the particular subject-dependent sensory or excitation scheme required to induce a particular state will differ. For example, olfactory stimulation can have different effects on different people, based on differences in history of exposure, social and cultural norms, and the like. On the other hand, some mental state response triggers are normative, for example “tear jerker” media.”</p>
<p>18. The one or more non-transitory computer-readable media of claim 17, wherein the one or more physiological status monitoring devices comprises one or more of a heart rate monitor, a blood pressure monitor, an electrodermal activity monitor, a movement tracker, an eye movement tracker, and a facial expression monitor.</p>	<p>1. U.S. Pat. App. Pub. No. 2020/0086078 “System and method of improving sleep” (Published March 19, 2020)</p> <p>From [0946]: “The technology may be embodied in apparatuses for acquiring the brain activity information from the source, processing the brain activity information to reveal a target brain activity state and a set of stimuli, which seek to achieve that state in a recipient, and generating stimuli for the recipient to achieve and maintain the target brain activity state over a period of time and potential state transitions. The generated stimuli may be feedback controlled. A general-purpose computer may be used for the processing of the information, a microprocessor, a FPGA, an ASIC, a system-on-a-chip, or a specialized system, which employs a customized configuration to efficiently achieve the information transformations required. Typically, the source and recipient act asynchronously, with the brain activity of the source recorded and later processed. However, real-time processing and brain activity transfer are also possible. <b>In the case of a general purpose programmable processor implementation or portions of the technology, computer instructions may be stored on a nontransient computer readable medium.</b> Typically, the system will have special-purpose components, such as a transcranial stimulator, or a modified audio and/or display system, and therefore the system will not be a general purpose system. Further, even in a general</p>

purpose system the operation per se is enhanced according to the present technology.”

From [1025]: “The technology may be used to modify or alter a mental state (e.g., from sleep to waking and vice versa) in a subject. Typically, the starting mental state, brain state, or brainwave pattern is assessed, such as by EEG, MEG, observation, stimulus-response amplitude and/or delay, or the like. Of particular interest in uncontrolled environments are automated mental state assessments, which do not rely on human observation or EEG signals, and rather may be acquired through MEG (e.g., SQID, optically-pumped magnetometer), EMG, MMG (magnetomyogram), mechanical (e.g., accelerometer, gyroscope, etc.), **data from physiological sensors** (e.g., AKG, **heartrate, respiration rate, temperature, galvanic skin potential**, etc.), or **automated camera sensors**.”

2. Int’l Pat. App. Pub. No. WO/2019/161050A1 “COGNITIVE PLATFORM INCLUDING COMPUTERIZED ELEMENTS COUPLED WITH A THERAPY FOR MOOD DISORDER” (Published August 22, 2019)

From [0062]: “A benefit of using the cognitive platform described herein may be providing a greater and more durable or maintained improvement **following treatment with a psychedelic and/or dissociative drug**. Accordingly, the present disclosure describes examples using the cognitive platform described herein in conjunction with psychedelic and/or dissociative drugs, other drugs for the mood disorder, and/or cognitive behavioral therapy.”

From [63]: “Non-limiting examples of such drugs include **lysergic acid diethylamide (LSD), psilocybin, ketamine, methylenedioxy-n-methylamphetamine (MDMA) mescaline, or N,N- Dimethyltryptamine (DMT or N,N-DMT)**. The psychedelic drug can be a **tryptamine, a phenethylamine**, or a lysergamide.”

From [0126]: “According to the principles herein, the term “session” refers to a discrete time period, with a clear start and finish, during which a user interacts with a platform product to receive assessment or treatment from the platform product (including in the form of an APP). In examples herein, a session can refer to at least one trial or can include at least one trial and at least one other type of measurement and/or other user interaction. As a non limiting example, a session can include at least one trial and one or more of **a measurement using a physiological or monitoring component and/or a cognitive testing component**. As another non-limiting example, a session can include at least one trial and receipt of data indicative of one



	<p>or more measures of an individual’s condition, including physiological condition and/or cognitive condition.”</p> <p>From [0142]: “An example system, method, and apparatus according to the principles herein includes a platform product (including using an APP) that uses a cognitive platform configured to render <b>at least one computerized element in the interaction sequence, measure user responses</b>, and adjust the CSI accordingly. These measurements may be compared with the user responses to interaction sequences in the platform that do not present computerized elements, in order to determine measures of the user’s emotional reactivity. This measurement, with or without comparison to measurements made during interaction sequences that do not present computerized elements, may be for the purpose of assessing the user’s emotional state. The CSI adjustments might be initiating an emotional regulation strategy to enable better engagement with the platform product or initiating certain interactive elements, such as but not limited to tasks or rewards, only under certain emotional conditions. <b>The user response measurement may employ use of inputs such as touchscreens, keyboards, or accelerometers, or passive external sensors such as video cameras, microphones, eye-tracking software/devices, bio-sensors, and/or neural recording (e.g., electroencephalogram)</b>, and may include responses that are not directly related to interactions with the platform product, as well as responses based on user interactions with the platform product. The platform product can present measures of a user’s emotional state that include <b>a measure of specific moods and/or a measure of general state of ego depletion that impacts emotional reactivity.</b>”</p> <p>From [0155]: “In any example herein, the <b>one or more physiological components can include any means of measuring physical characteristics</b> of the body and nervous system, including electrical activity, <b>heart rate, blood flow</b>, and oxygenation levels, to provide the measurement data 112. This can include camera-based heart rate detection, <b>measurement of galvanic skin response, blood pressure measurement, electroencephalogram, electrocardiogram, magnetic resonance imaging, near- infrared spectroscopy, and/or pupil dilation</b> measures, to provide the measurement data 112. The one or more physiological components can include one or more sensors for measuring parameter values of the physical characteristics of the body and nervous system, and one or more signal processors for processing signals detected by the one or more sensors.”</p>
<p>19. The one or more non-transitory computer-readable media of claim 14, comprising instructions stored thereon that cause a system to</p>	<p>1. U.S. Pat. App. Pub. No. 2020/0086078 “System and method of improving sleep” (Published March 19, 2020)</p>

<p>present sensory stimuli to the individual comprising one or more of a visual stimulus, an auditory stimulus, a tactile stimulus, an olfactory stimulus, or any combination thereof, via one or more output devices.</p>	<p>From [0946]: “The technology may be embodied in apparatuses for acquiring the brain activity information from the source, processing the brain activity information to reveal a target brain activity state and a set of stimuli, which seek to achieve that state in a recipient, and generating stimuli for the recipient to achieve and maintain the target brain activity state over a period of time and potential state transitions. The generated stimuli may be feedback controlled. A general-purpose computer may be used for the processing of the information, a microprocessor, a FPGA, an ASIC, a system-on-a-chip, or a specialized system, which employs a customized configuration to efficiently achieve the information transformations required. Typically, the source and recipient act asynchronously, with the brain activity of the source recorded and later processed. However, real-time processing and brain activity transfer are also possible. <b>In the case of a general purpose programmable processor implementation or portions of the technology, computer instructions may be stored on a nontransient computer readable medium.</b> Typically, the system will have special-purpose components, such as a transcranial stimulator, or a modified audio and/or display system, and therefore the system will not be a general purpose system. Further, even in a general purpose system the operation per se is enhanced according to the present technology.”</p> <p>From [0938]: “In addition, <b>a set of stimuli, such as visual patterns, acoustic patterns, vestibular, smell, taste, touch</b> (light touch, deep touch, proprioception, stretch, hot, cold, pain, pleasure, electric stimulation, acupuncture, etc.), <b>vagus nerve</b> (e.g., parasympathetic), <b>are imposed on the subject, optionally over a range of baseline brain states, to acquire data defining the effect of individual and various combinations of sensory stimulation on the brain state of the recipient.</b> Population data may also be used for this aspect.”</p>
<p>20. The one or more non-transitory computer-readable media of claim 14, comprising instructions stored thereon that cause the system to monitor the neural status, the physiological status, or both, of the individual continuously for a period of time to monitor the state of the individual in real-time, wherein the state of the individual comprises one or more of <b>stress, mood, attention, arousal</b>, and any combination thereof.</p>	<p>1. U.S. Pat. App. Pub. No. 2020/0086078 “System and method of improving sleep” (Published March 19, 2020)</p> <p>From [0946]: “The technology may be embodied in apparatuses for acquiring the brain activity information from the source, processing the brain activity information to reveal a target brain activity state and a set of stimuli, which seek to achieve that state in a recipient, and generating stimuli for the recipient to achieve and maintain the target brain activity state over a period of time and potential state transitions. The generated stimuli may be feedback controlled. A general-purpose computer may be used for the processing of the information, a microprocessor, a FPGA, an ASIC, a system-on-a-chip, or a specialized system, which employs a customized configuration to efficiently achieve the information transformations required. Typically, the source and recipient act asynchronously, with the brain activity of the</p>

source recorded and later processed. However, real-time processing and brain activity transfer are also possible. **In the case of a general purpose programmable processor implementation or portions of the technology, computer instructions may be stored on a nontransient computer readable medium.** Typically, the system will have special-purpose components, such as a transcranial stimulator, or a modified audio and/or display system, and therefore the system will not be a general purpose system. Further, even in a general purpose system the operation per se is enhanced according to the present technology.”

From [0196]: “**Neurofeedback (NFB), also called neurotherapy or neurobiofeedback,** is a type of biofeedback that uses **real-time displays of brain activity-most commonly electroencephalography (EEG),** to teach self-regulation of brain function. Typically, sensors are placed on the scalp to measure activity, with measurements displayed using video displays or sound. The feedback may be in various other forms as well. **Typically, the feedback is sought to be presented through primary sensory inputs,** but this is not a limitation on the technique.”

From [0941]: “During stimulation of the recipient, the EEG pattern may be **monitored to determine if the desired state is achieved through the sensory stimulation.** A closed loop feedback control system may be **implemented to modify the stimulation seeking to achieve the target.** An evolving genetic algorithm may be used to develop a user model, which relates the **mental state, arousal and valence, sensory stimulation, and brain activity patterns, both to optimize the current session of stimulation and learning, as well as to facilitate future sessions, where the mental states of the recipient have further enhanced,** and to permit use of the system for a range of mental states.”

2. Int’l Pat. App. Pub. No. WO/2019/161050A1 “**COGNITIVE PLATFORM INCLUDING COMPUTERIZED ELEMENTS COUPLED WITH A THERAPY FOR MOOD DISORDER**” (Published August 22, 2019)

From [0142]: “An example system, method, and apparatus according to the principles herein includes a platform product (including using an APP) that uses a cognitive platform configured to render **at least one computerized element in the interaction sequence, measure user responses,** and adjust the CSI accordingly. These measurements may be compared with the user responses to interaction sequences in the platform that do not present computerized elements, in order to determine measures of the user’s emotional reactivity. This

	<p>measurement, with or without comparison to measurements made during interaction sequences that do not present computerized elements, may be for the purpose of assessing the user’s emotional state. The CSI adjustments might be initiating an emotional regulation strategy to enable better engagement with the platform product or initiating certain interactive elements, such as but not limited to tasks or rewards, only under certain emotional conditions. <b>The user response measurement may employ use of inputs such as touchscreens, keyboards, or accelerometers, or passive external sensors such as video cameras, microphones, eye-tracking software/devices, bio-sensors, and/or neural recording (e.g., electroencephalogram),</b> and may include responses that are not directly related to interactions with the platform product, as well as responses based on user interactions with the platform product. The platform product can present measures of a user’s emotional state that include <b>a measure of specific moods and/or a measure of general state of ego depletion that impacts emotional reactivity.”</b></p>
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## Electronic Acknowledgement Receipt

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<b>Confirmation Number:</b>	8282
<b>Title of Invention:</b>	Molecularly-Initiated, Experientially-Delivered Treatments and Systems for Practicing Same
<b>First Named Inventor/Applicant Name:</b>	Adam Gazzaley
<b>Customer Number:</b>	24353
<b>Filer:</b>	Sisi Li
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1	Concise Description of Relevance	Concise-description-generated.pdf	33721 c8b26cf96850186eff897183bc8d655143b39bb3	no	3

**Warnings:**

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2	Third-Party Submission Under 37 CFR 1.290	Third-party-preissuance-submission.pdf	55758 1824720708dc91ae0288b8423dee79b2fe84d336	no	2
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3	Request for Notification of Non-compliant Third-Party Submission	Third-party-notification-request.pdf	23616 ffd79c8e6020a163ed807c25cea37790d3d77f9c	no	1
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4	Concise Description of Relevance	Claims_Chart.pdf	358569 96f2f54a49268af86367d9813276f754f4d81a6d	no	28
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5	Evidence of Publication	US20200086078A1.pdf	15303493 11761d28210ca1c8cf5d44bdd479156ce5c079e0	no	104
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6	Evidence of Publication	WO2015026988A1.pdf	2972369 3ead451c483f3b187e7180c65bed7d3c10ae7199	no	61
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7	Evidence of Publication	WO2019161050A1.pdf	7577128	no	105
			cddf48645bd85153a221de86cee127ee00c0e28f		

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8	Fee Worksheet (SB06)	fee-info.pdf	37801	no	2
			5ade89b7656e8ed7c42537fa988c499f1 ca5739f		

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