



(51) International Patent Classification:

A61N 1/05 (2006.01) *A61N 1/08* (2006.01)
A61N 1/36 (2006.01) *A61B 5/00* (2006.01)
A61N 1/04 (2006.01) *A61B 5/0478* (2006.01)

(21) International Application Number:

PCT/US2016/065937

(22) International Filing Date:

9 December 2016 (09.12.2016)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/265,259 9 December 2015 (09.12.2015) US

(71) Applicant: LAWRENCE LIVERMORE NATIONAL SECURITY, LLC [US/US]; 2300 First Street, Suite 204, Livermore, California 94550 (US).

(72) Inventors: PANNU, Satinderpall S.; 7672 Hillsdale Court, Pleasanton, California 94588 (US). SHAH, Kedar G.; 74 Landers Street, San Francisco, California 94114 (US). CHEN, Supin; 407 Daybreak CT, San Ramon, California 94583 (US). CROSETTI, Marissa; c/o LAWRENCE LIVERMORE NATIONAL SECURITY, LLC, 2300 First Street, Suite 204, Livermore, California

94550 (US). DATTA-CHAUDHURI, Timir B.; c/o LAWRENCE LIVERMORE NATIONAL SECURITY, LLC, 2300 First Street, Suite 204, Livermore, California 94550 (US). FELIX, Sarah H.; 872 Warfield Avenue, Apt. 3, Oakland, California 94610 (US). IVAN-OVSKAYA, Anna N.; c/o LAWRENCE LIVERMORE NATIONAL SECURITY, LLC, 2300 First Street, Suite 204, Livermore, California 94550 (US). JONES, Jason; c/o LAWRENCE LIVERMORE NATIONAL SECURITY, LLC, 2300 First Street, Suite 204, Livermore, California 94550 (US). LEE, Kye; c/o LAWRENCE LIVERMORE NATIONAL SECURITY, LLC, 2300 First Street, Suite 204, Livermore, California 94550 (US). PATRA, Susant; 1418 Charisma Way, Brentwood, California 94513 (US). TOLOSA, Vanessa; 4395 Piedmont Avenue, Oakland, California 94611 (US). TOOKER, Angela C.; 6549 Cotton Wood Circle, Apt. H, Dublin, California 94568 (US).

(74) Agents: ELCHUK, Mark D. et al.; HARNESS, DICKEY & PIERCE, P.L.C., P.O. Box 828, Bloomfield Hills, Michigan 48303 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,

[Continued on next page]

(54) Title: IMPLANTABLE NEUROMODULATION SYSTEM FOR CLOSED-LOOP STIMULATION AND RECORDING SIMULTANEOUSLY AT MULTIPLE BRAIN SETS

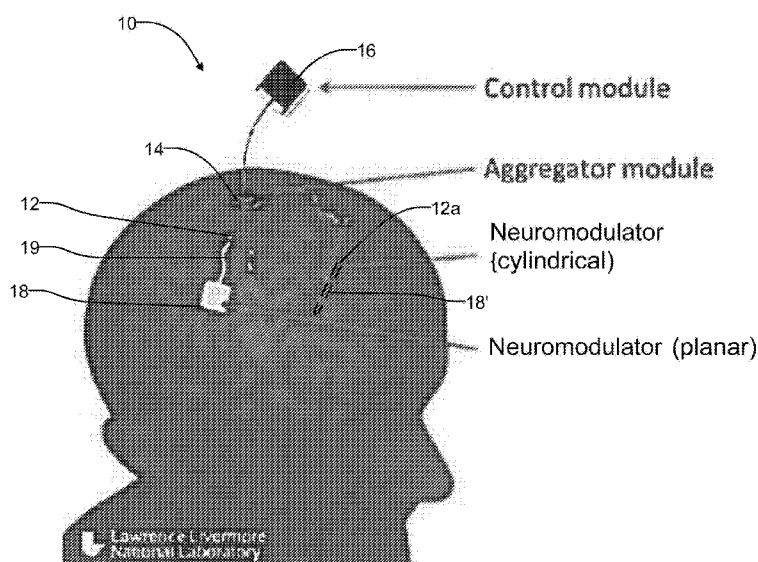


FIGURE 1

(57) Abstract: The present disclosure relates to a modular system for deep brain stimulation (DBS) and electrocorticography (ECoG). The system may have an implantable neuromodulator for generating electrical stimulation signals adapted to be applied to a desired region of a brain via an attached electrode array. An aggregator module may be used for collecting and aggregating electrical signals and transmitting the electrical signals to the neuromodulator. A control module may be used which is in communication with the aggregator module for controlling generation of the electrical signals and transmitting the electrical signals to the aggregator.



HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE,

DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

IMPLANTABLE NEUROMODULATION SYSTEM FOR CLOSED-LOOP
STIMULATION AND RECORDING SIMULTANEOUSLY AT
MULTIPLE BRAIN SETS

5 CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of United States Provisional Application No. 62/265,259, filed on December 9, 2015. The entire disclosure of the above application is incorporated herein by reference.

10 STATEMENT OF GOVERNMENT RIGHTS

[0002] The United States Government has rights in this invention pursuant to Contract No. DE-AC52-07NA27344 between the U.S. Department of Energy and Lawrence Livermore National Security, LLC, for the operation of Lawrence Livermore National Laboratory.

15

FIELD

[0003] The present disclosure relates to systems and methods for Deep Brain Stimulation and electrocorticography arrays, and more particularly to a system and method for performing closed loop neuromodulation and stimulation on a plurality of areas of a brain simultaneously.

20

BACKGROUND

[0004] This section provides background information related to the present disclosure which is not necessarily prior art.

25 **[0005]** Deep brain stimulation (“DBS”) is an established treatment for movement disorders such as Parkinson's disease, essential tremor, and dystonia. Although there are many on-going investigations into other potential uses of DBS, such as psychiatry, studies have been limited by available technology due to large electrode size, a low number of simultaneous recording and stimulation sites, and component size restrictions on anatomical target sites.

30

[0006] Multiple target sites are especially important for studying and treating the brain as a “network” because multiple regions can be associated with a neural disorder. An example is Parkinson's disease where therapeutic effects from

deep brain stimulation can be confirmed with recordings from the brain surface from electrocorticography ("ECoG").

[0007] Another potential example where DBS can be therapeutic is in treating depression. Depression is often associated with several brain regions such as the ventral capsule/ventral, striatum, Brodmann area 25, nucleus accumbens, lateral habenula, and medial forebrain bundle. However, previous clinical trials for treating depression (e.g., Medtronic RECLAIM study, St. Jude BROADEN study) failed to show a significant difference in response rates between the DBS administered group and the control group.

[0008] Commercially available systems for simultaneous recording and stimulation of the brain, such as the Medtronic Activa PC+S and NeuroPace RNS, are not capable of more than two target sites. Furthermore, they also only have four to eight channels per target site which restricts high resolution spatial coverage. To improve understanding and treatment, new technologies with the ability to record and stimulate simultaneously from a greater number of channels from multiple regions of the brain are required.

SUMMARY

[0009] This section provides a general summary of the disclosure, and is not a comprehensive disclosure of its full scope or all of its features.

[0010] In one aspect the present disclosure relates to a modular system for deep brain stimulation (DBS) and electrocorticography. The system may comprise an implantable neuromodulator for generating electrical stimulation signals adapted to be applied to a desired region of a brain via an electrically coupled electrode array. An aggregator module may be included for collecting and aggregating electrical signals and transmitting the electrical signals to the neuromodulator. A control module may be included which is in communication with the aggregator module for controlling generation of the electrical signals and transmitting the electrical signals to the aggregator.

[0011] In another aspect the present disclosure relates to a modular system for deep brain stimulation (DBS) and electrocorticography. The system may comprise an implantable neuromodulator array for applying electrical stimulation signals to a desired region of a brain via an electrically coupled electrode array, and

for transmitting electrical signals representing brain activity. An aggregator module may be included for collecting and aggregating electrical signals and transmitting the electrical signals to the neuromodulator, and for receiving the electrical signals representing brain activity and recording information representing the brain activity.

- 5 A control module may be included in communication with the aggregator module for controlling generation of the electrical signals and transmitting the electrical signals to the aggregator, and for receiving the information representing brain activity.

[0012] In still another aspect the present disclosure provides a method for deep brain stimulation (DBS) and electrocorticography. The method may comprise
10 using a neuromodulator adapted to be implanted in a brain, and configured to generate electrical stimulation signals adapted to be applied to a desired region of the brain via an electrically coupled electrode array. An aggregator module may be used to communicate with the neuromodulator and to collect and aggregate electrical signals, and to transmit the electrical signals to the neuromodulator for use
15 by the neuromodulator in generating the electrical stimulation signals. A control module may be used which is configured to be carried on a person, to communicate with the aggregator module and to generate the electrical signals used by the aggregator module.

[0013] Further areas of applicability will become apparent from the
20 description provided herein. The description and specific examples in this summary are intended for purposes of illustration only and are not intended to limit the scope of the present disclosure.

DRAWINGS

[0014] The drawings described herein are for illustrative purposes only of selected embodiments and not all possible implementations, and are not intended to limit the scope of the present disclosure.

5 **[0015]** Figure 1 is a high level illustration of one embodiment of a system in accordance with the present invention being used on a human brain;

[0016] Figure 2 is a high level exploded perspective illustration of a plurality of components which may be used to form one embodiment of the neuromodulator shown in Figure 1, and where the neuromodulator is electrically
10 coupled to a remotely located electrode array via an electrical connection assembly;

[0017] Figure 3 is a simplified side cross sectional view of the ceramic component of the neuromodulator of Figure 2, further illustrating the conductive feedthroughs and electrically connected bond pads that enable electrical attachment to the individual electrodes of the electrode array;

15 **[0018]** Figure 4 shows an exploded perspective view of the aggregator module and its various components and subsystems;

[0019] Figure 5 shows a plane view of the assembled aggregator module with dimensions which give one example of the form factor of the aggregator module;

20 **[0020]** Figure 6 is a side view of the assembled aggregator module further illustrating one example of the form factor thereof; and

[0021] Figure 7 is a high level perspective view of the control module juxtaposed next to a coin to help illustrate the form factor of the control module.

[0022] Corresponding reference numerals indicate corresponding parts
25 throughout the several views of the drawings.

DETAILED DESCRIPTION

[0023] Example embodiments will now be described more fully with reference to the accompanying drawings.

30 **[0024]** The present disclosure is directed to a system and method which provides closed-loop neuromodulation across multiple brain sites. The system of the present disclosure makes this possible in part by using low profile implantation packages, together with high-density interconnections and direct integration of bare

die. The system provides the additional significant benefit of being both modular and scalable. This enables the system to be easily configured for use with a selected number of implants at a selected number of locations, and using a selected number of channels. This significant flexibility enables personalized treatment and easy
5 access to many physically distinct brain regions. The architecture of the system also reduces the amount of electrical conductors required for providing power and data transfer between various electronic components and the sensors at various sites of the brain. The electronics provided by the system allows for processing and storage of data, as well as autonomous closed-loop operation. Data obtained by the system
10 is available for real time processing.

[0025] Referring to Figure 1, a high level diagram of one embodiment of a system 10 in accordance with the present disclosure is illustrated. The system 10 in this embodiment may include a first neuromodulator 12, a second neuromodulator 12a, an aggregator module 14 and a control module 16. The neuromodulator 12
15 may be implanted in the brain along with another electrical connection device in the form of an electrode array 18 which is electrically and mechanically coupled to the neuromodulator 12 through an electrical connection assembly 20' (not shown) and an electrically conductive cable 19. One example of the electrode array 18 is provided in co-pending PCT application PCT/US16/36775 filed on June 9, 2016, the
20 entire disclosure of which is hereby incorporated by reference into the present disclosure. It will be appreciated then that the electrode array 18 and the electrical connection assembly 20' may both be termed "electrical connection devices."

[0026] The neuromodulator 12a, which in this example is connected to a cylindrical electrode array 18', is especially well adapted for DBS. Neuromodulator
25 12 in this example is connected to a planar electrode array which is especially well adapted for electrocorticography ("ECoG"). Neuromodulator 12 provides a highly compact, implantable package for providing DBS or ECoG stimulation and is shown in Figure 1 implanted within a human brain. The aggregator module 14 may be in bidirectional communication with the neuromodulator 12a and the control module 16.
30 The aggregator module 14 operates to route and distribute data and control information between the neuromodulator 12a and the control module 16. While the following discussion will focus on the system 10 having one neuromodulator 12 connected to the planar electrode array 18, it will be appreciated that in many

applications two or more neuromodulators 12 and/or 12a and their attached electrode arrays will be included, and implementations which include different numbers and combinations of the neuromodulators 12 and/or 12a, using the teachings presented herein, are anticipated. Thus, the system 10 is not limited to only one configuration for the neuromodulator(s) 12 employed.

[0027] Referring to Figure 2, the neuromodulator 12 is shown in greater detail. The neuromodulator 12 forms a highly compact electronics package for recording electrical signals and for providing electrical stimulation signals for DBS purposes. The neuromodulator 12, in one embodiment, may form a 64 channel device that is connected to the electrode array 18 through electrical cable 19 and through the electrical connection assembly 20'. The electrical connection assembly 20' of the neuromodulator 12 may have a ceramic portion 20 (shown simply in diagrammatic form) populated with a plurality of electrical feedthroughs 20a which are in communication with a corresponding plurality of conductive bond pads 20b. The neuromodulator 12 may also include a multiplexer chip 22, a lid 24 (e.g., plastic), an interposer 26, and a housing 28 for encapsulating the electrical connection assembly 20', the multiplexer chip 22 and the interposer 26. Although the exact number of bond pads 20b and electrical feedthroughs 20a used to form the electrical connection assembly 20' may vary widely to meet specific applications, in one example the electrical connection assembly 20' may have 32 to 40 independent bond pads 20b, but as noted above greater or lesser quantities of bond pads may be used. Each electrode of the electrode array 18 may also range widely in size to suit a specific application and to meet the needs for stimulation of neural tissue and/or recording of electrical signals generated within neural tissue. Some electrode arrays 18 may also have a counter electrode which forms a return current path for a stimulating current being applied to the neural tissue, and a reference electrode for differential recording. Both cylindrical electrode arrays for DBS and planar arrays for ECoG may be used to cover a full range of brain regions.

[0028] With specific reference to Figure 3, the ceramic portion 20 of the neuromodulator 12 is shown in highly simplified form. The ceramic portion 20 may be manufactured with the electrical feedthroughs 20a that terminate on the conductive bond pads 20b. In this example the bond pads 20b form electrical contact or connection points that can be electrically connected to the individual

electrodes of an electrode array (not shown) through electrical traces in a connection cable, such as cable 19 in Figures 1 and 2.

[0029] The neuromodulators 12 and 12a each form compact electronics packages having embedded electronics for simultaneous low-noise recording and stimulation. The neuromodulators 12 and 12a may each also monitor electrode impedance to ensure system reliability and stimulation safety, and check that electrical stimulation pulses are within compliance (e.g., with predetermined voltage and/or current ranges). The entire neuromodulator 12 and/or 12a may be formed with a form factor that is less than about 5mm x 8mm x 3mm for chronic subcutaneous implantation.

[0030] Referring to Figures 4-6, one embodiment of the aggregator module 14 is shown. The aggregator module 14 routes and distributes electrical signals in the form of data and control information between one or more neuromodulators 12 and/or 12a and the control module 16. The aggregator module 14 may also receive electrical signals from the neuromodulators 12 and/or 12a, which represent real time brain wave activity, if the neuromodulator 12 or 12a is/are configured to obtain such signals. The aggregator module 14 also distributes power to each neuromodulator 12 and/or 12a and enables a flexible connection of varying numbers of neuromodulators 12 and/or 12a to the single control module 16. In one embodiment data and power may be transmitted between the aggregator module 14 and the control module 16, and/or to and from the neuromodulator 12 and/or 12a, with a 6-wire interface (for example, component 48 illustrates five slots with a 6-wire interface). The aggregator module 14 may be a component which is carried on the person of an individual or it may be mounted in the skull of an individual, or possibly implanted at other locations on the individual's body. The aggregator module 14 may use the SYGNUS[•] implantable contact system and it may be laser welded to provide for hermetic sealing.

[0031] In the example shown in Figures 4-6, the aggregator module 14 includes a lid 42, a printed circuit board (PCB) 44 having a short range wireless transceiver 45 and an on-board microprocessor 47, a housing 46, implantable electrical connections 48, and an overmold 52. The implantable electrical connections 48 are made from only biocompatible materials which helps to ensure that body materials do not damage any portion of the aggregator module 14, and the

body is only exposed to biocompatible materials. The assembled aggregator module 14, in one preferred embodiment, may have a length of about 30-35mm, a width of about 30mm and a thickness of about 4-5mm, although it will be appreciated that these dimensions may vary considerably to suit specific applications.

5 **[0032]** Referring to Figure 7, a high level perspective view of one embodiment of the control module 16 is shown. In this example the control module 16 includes a housing 54, a lid 56, a printed circuit board 58 having its own on-board microprocessor 59 and a short range, wireless transceiver 61, and memory 61a, which are all adapted to on the PCB 58 within the housing. An on-board battery 60,
10 which in one implementation is positioned below the PCB 58, and therefore indicated by dashed lines in Figure 7, may be included for powering the electrical components on the PCB 58 and providing electrical stimulation signals to the electrode array 18. The battery 60 may be a rechargeable battery or it may be a non-rechargeable battery. An Input/Output interface component 62 may also be included that enables
15 electrical coupling to the aggregator module 14. The control module 16 is shown in comparison to a U.S. quarter to provide a sense of its extremely small scale. The control module 16 may communicate wirelessly with both an external device (e.g., smartphone, laptop, desktop, tablet, etc.) and with the aggregator module 14, via its wireless transceiver 61.

20 **[0033]** The control module 16 handles computation and command generation, data acquisition and storage, and power management to enable the system 10 to run independently over extended periods of time. The control module 16 also supports advanced data processing of recorded signals for closed-loop control of stimulation rate, amplitude and timing. Power is stored in the battery 60
25 and the battery can be replaced or wirelessly recharged. The module 16 also can communicate data wirelessly with an external electronic device (e.g., personal digital assistant, laptop, desktop computer, tablet, smartphone, etc.). The control module 16 can be in the form of an external module which is carried on the person, such as on a belt, or even implanted in the chest. The housing 54 is preferably made of plastic,
30 and is therefore transparent to RF signals and chemically resistant to fluids, humidity, sweat, etc. The control module 16 receives the aggregated data stream from the aggregator module 14, which is the data stream combined from the electrode array 18 of the neuromodulator 12. The neural recordings may then be

processed by one or more algorithms stored in memory associated with the on-board microprocessor 59 of the control module 16, and the appropriate stimulation patterns are determined by the microprocessor and then communicated to the aggregator module 14. These signals may be sent wirelessly by the control module 16 using its short range wireless transceiver 61 or they may be sent via a wired connection with the aggregator module 14. The signals are used by the electrode array 18 of the neuromodulator 12 to apply the appropriate neural stimulation. The wireless transceiver 61 of the control module 16 also enables a wireless link to an external device for data transfer that allows custom algorithms to be uploaded to the microprocessor 59 of the control module 16, as well as the wireless downloading of recorded data.

[0034] The system 10 provides both high spatial density cortical and subcortical electrode arrays with embedded electronics which enables simultaneous recording and stimulation from multiple sites on both hemispheres of the brain. The system 10 further provides for flexible and modular data aggregation to integrate and control the data stream from the neural interfaces, and includes sufficient computation, storage and energy to enable the system to run independently over extended periods without recharging by the control module 16. This novel platform will enable clinicians to develop and implement real-time, closed-loop neuromodulation based on neural stimuli with temporal and spatial resolution not possible before.

[0035] The cylindrical electrode array associated with neuromodulator 12a may be surgically implanted via stereotactic placement. The system 10 enables recording from both hemispheres and multiple cortical areas. Each neuromodulator 12 and/or 12a has the capability to record and stimulate from each electrode included in the array. The modular approach of the system 10, together with wireless communications between the neuromodulator 12 (and/or the neuromodulator 12a) and the aggregator module 14, enables the neurosurgeon to flexibly select brain areas for implantation depending on the individual targets for each neuropsychiatric disorder without the constraints of tethered wires.

[0036] The aggregator module 14, with its embedded processor, enables the deployment of closed-loop algorithms which can be wirelessly reprogrammed. This technology enables the capability to "read-out" spatiotemporal patterns of

neural activity in each recording area of the brain, across multiple areas simultaneously, and conversely, to “read-in” information to neural targets by patterned electrical stimulation. The system 10 introduces a highly-scalable approach, allowing for simultaneous stimulation and recording from large numbers of channels in multiple cortical and subcortical areas. The combination of modularity and the highly-miniaturized electronics eliminates the complicated interconnects, thus enabling a practical and translatable method of interfacing simultaneously with many cortical regions. This represents a significant technical advance over current neural stimulation systems with their highly constrained and fixed stimulation settings. The system 10 is expected to enable innovative treatment strategies for guiding rehabilitative neural plasticity.

[0037] Still another benefit of the system 10 is that it is reconfigurable based on the specific neuropsychiatric disorder and the patient-specific therapy. The low-power, integrated circuit technology employed by the various modules of the system 10, combined with the modularity of the system and wireless communications capability, ensures that the system can be adapted, reconfigured as needed (e.g., software updates), and contains sufficient computational power to process information in real time.

[0038] The present system and method is expected to find utility in a wide variety of current studies and treatments involving DBS such as with movement disorders (e.g., Parkinson's Disease, dystonia, essential tremors), epilepsy, neuropsychiatric disorders (e.g., addiction, major depression, chronic pain, etc.), and obsessive compulsive disorder (OCD). The system 10 has the potential to improve neuromodulation for diagnostics and therapeutics by enabling closed-loop stimulation based on sensing from multiple brain sites, which is an important function when most relevant stimulation and recording sites are within different brain regions. The system 10 also enables the study of brain plasticity (altering physiology and anatomy over time) as a response to DBS.

[0039] The foregoing description of the embodiments has been provided for purposes of illustration and description. It is not intended to be exhaustive or to limit the disclosure. Individual elements or features of a particular embodiment are generally not limited to that particular embodiment, but, where applicable, are interchangeable and can be used in a selected embodiment, even if not specifically

shown or described. The same may also be varied in many ways. Such variations are not to be regarded as a departure from the disclosure, and all such modifications are intended to be included within the scope of the disclosure.

CLAIMS

What is claimed is:

1. A modular system for deep brain stimulation (DBS) and
5 electrocorticography, comprising:
an implantable neuromodulator configured to generate electrical stimulation signals adapted to be applied to a desired region of a brain via an electrically coupled electrode array;
an aggregator module for collecting and aggregating electrical signals and
10 transmitting the electrical signals to the neuromodulator; and
a control module in communication with the aggregator module for controlling generation of the electrical signals and transmitting the electrical signals to the aggregator.
- 15 2. The system of claim 1, wherein the neuromodulator is connected to the electrode array via an electrical cable, and wherein the electrode array forms a planar configuration electrode array.
3. The system of claim 1, wherein the neuromodulator is connected to the
20 electrode array via an electrical cable, and wherein the electrode array comprises a cylindrical configuration electrode array.
4. The system of claim 1, wherein the neuromodulator includes a multiplexer
for distributing electrical signals to and from various units of the electrodes.
25
5. The system of claim 1, wherein the aggregator module includes:
a processor and a wireless transceiver for wirelessly communication with the control module; and wherein the control module includes a processor.
- 30 6. The system of claim 1, wherein the control module includes a wireless transceiver for communicating wirelessly with the aggregator module.
7. The system of claim 1, wherein the control module includes a battery.

8. The system of claim 1, wherein the electrical connection package of the neuromodulator is also configured to provide electrical signals back to the aggregator module.

5

9. The system of claim 8, wherein the control module includes a memory for storing data related to the electrical signals received by the aggregator module.

10. The system of claim 1, wherein the control module includes an interface.

10

11. The system of claim 1, wherein the control module includes a battery for powering the system.

12. The system of claim 11, wherein the battery is rechargeable.

15

13. The system of claim 1, wherein the neuromodulator forms a hermetically sealed component.

14. The system of claim 1, wherein the aggregator module forms a hermetically sealed component.

20

15. A modular system for deep brain stimulation (DBS) and electrocorticography, comprising:

an implantable neuromodulator array configured to communicate with an electrically coupled electrode array to apply electrical stimulation signals to a desired region of a brain, and for transmitting electrical signals representing brain activity;

25

an aggregator module for collecting and aggregating electrical signals and transmitting the electrical signals to the neuromodulator, and for receiving the electrical signals representing brain activity and recording information representing the brain activity; and

30

a control module in communication with the aggregator module for controlling generation of the electrical signals and transmitting the electrical signals to the aggregator, and for receiving the information representing brain activity.

16. The system of claim 15, wherein the wherein the aggregator module includes:

a processor; and

a wireless transceiver for wirelessly communicating wirelessly with the control
5 module.

17. The system of claim 15, wherein the control module includes a wireless transceiver for communicating wirelessly with the aggregator module.

10 18. The system of claim 15, wherein the control module includes a memory for storing data related to the electrical signals received by the aggregator module.

19. A method for performing deep brain stimulation (DBS) and electrocorticography, comprising:

15 using a neuromodulator adapted to be implanted in a brain, and configured to generate electrical stimulation signals adapted to be applied to a desired region of the brain via an electrically coupled electrode array;

using an aggregator module to communicate with the neuromodulator and collect and aggregate electrical signals, and transmit the electrical signals to the
20 neuromodulator for use by the neuromodulator in generating the electrical stimulation signals; and

using a control module, configured to be carried on a person, to communicate with the aggregator module and to generate the electrical signals used by the aggregator module.

25 20. The method of claim 19, further comprising using the neuromodulator to receive electrical brain activity signals generated within the brain, and to transmit information corresponding to the electrical brain activity signals to the aggregator module.

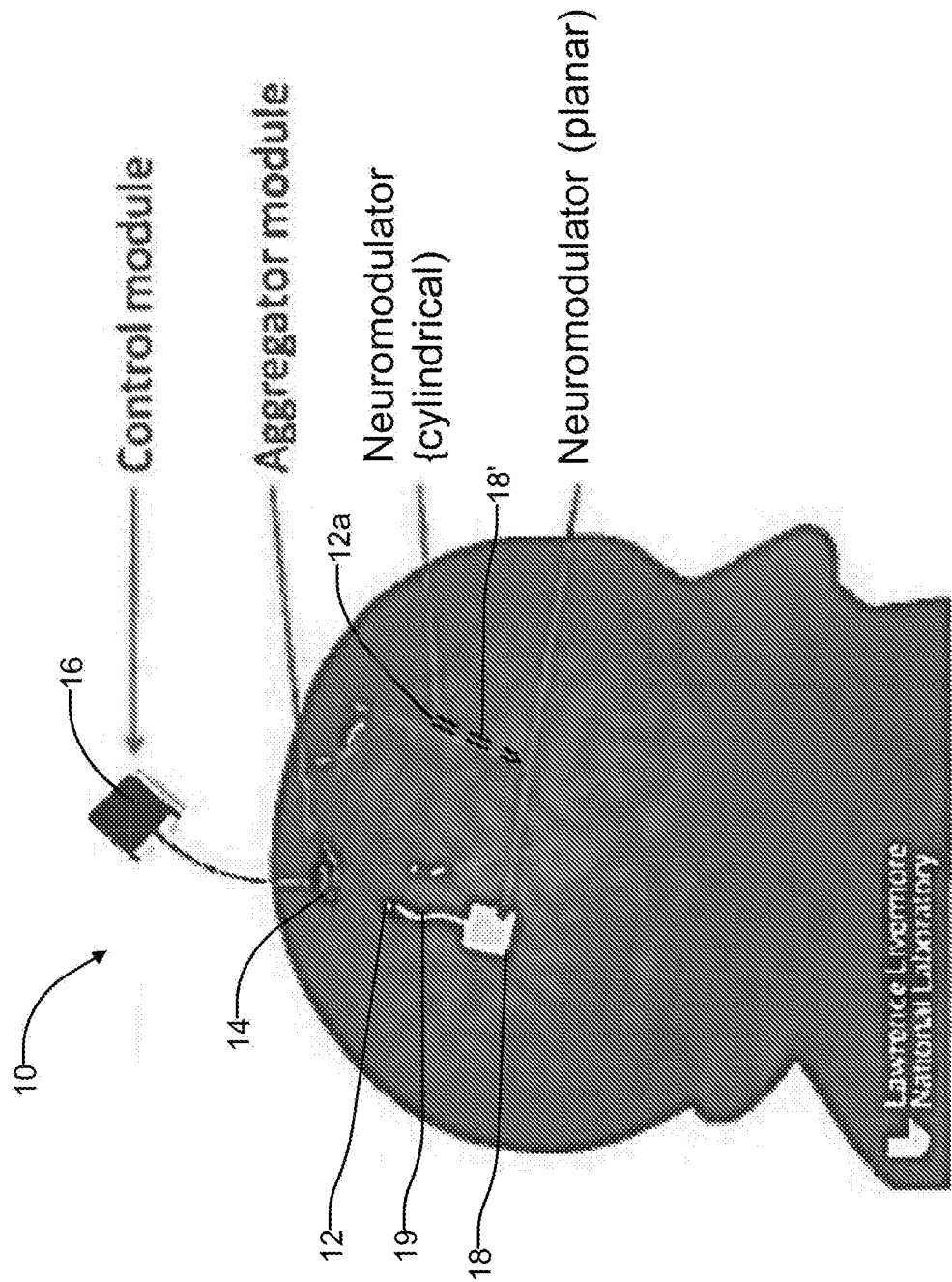


FIGURE 1

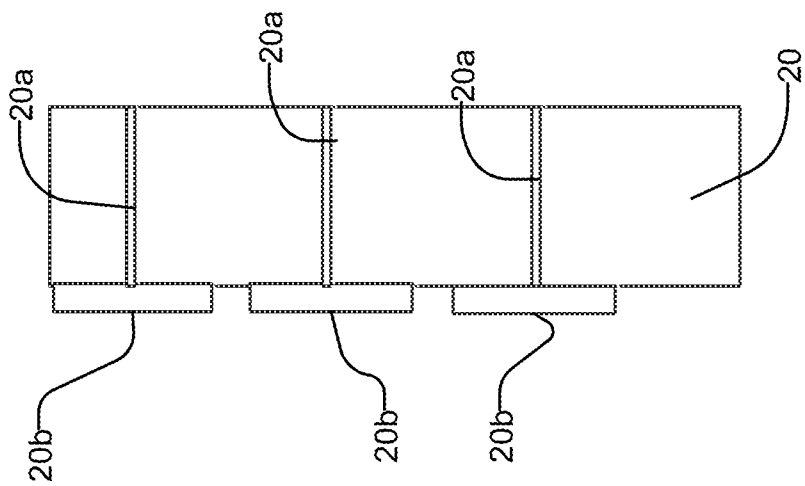
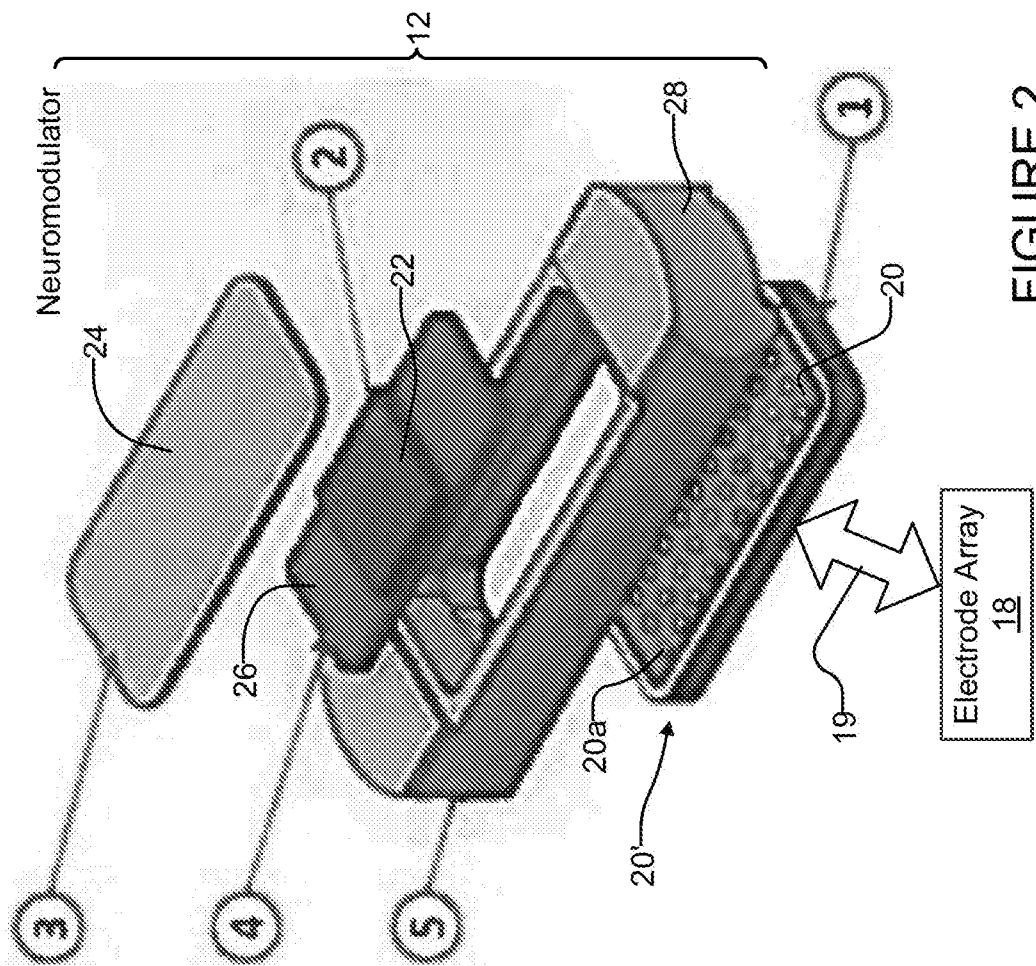


FIGURE 2

FIGURE 3

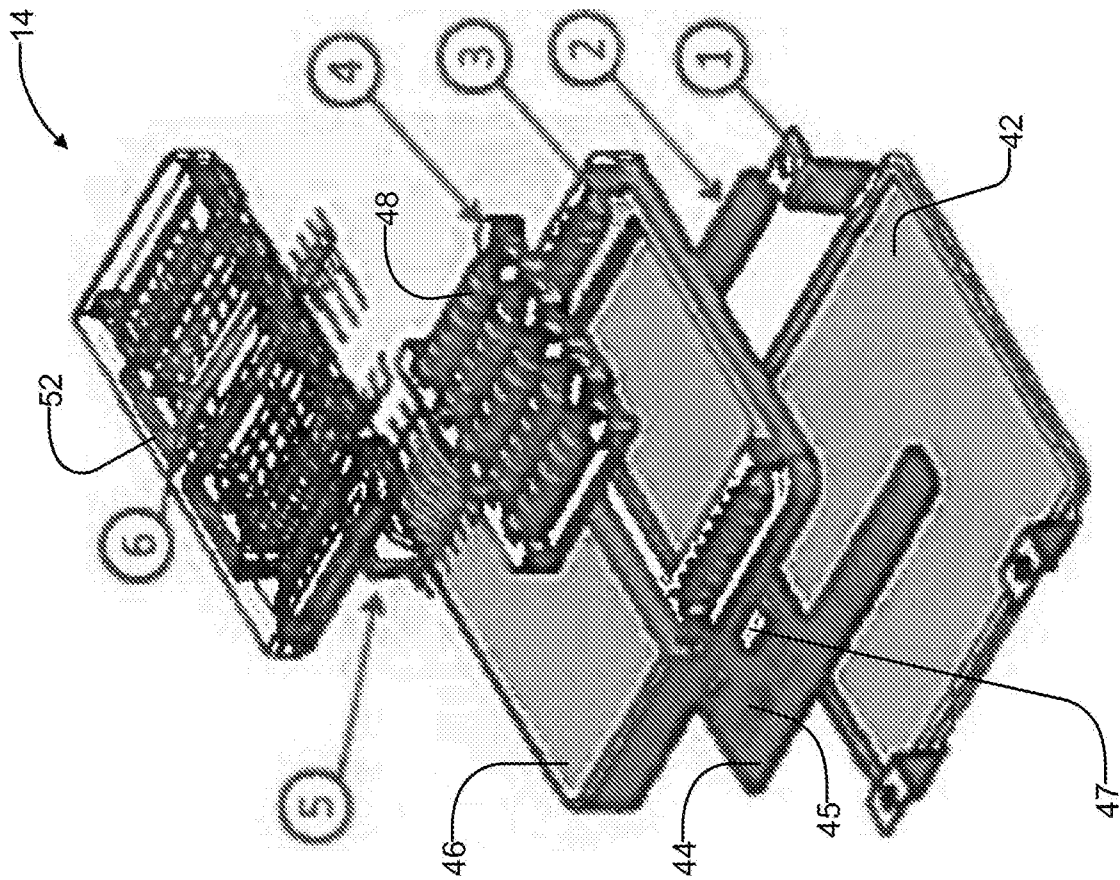


FIGURE 4

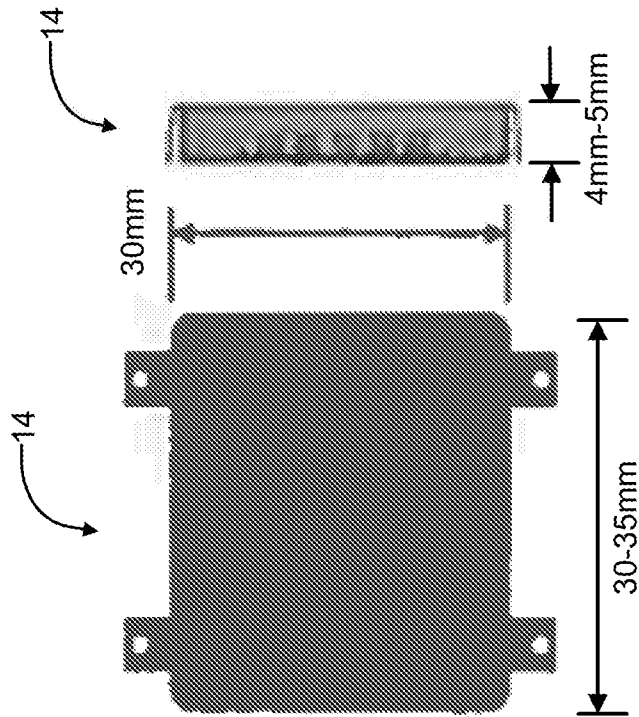


FIGURE 6

FIGURE 5

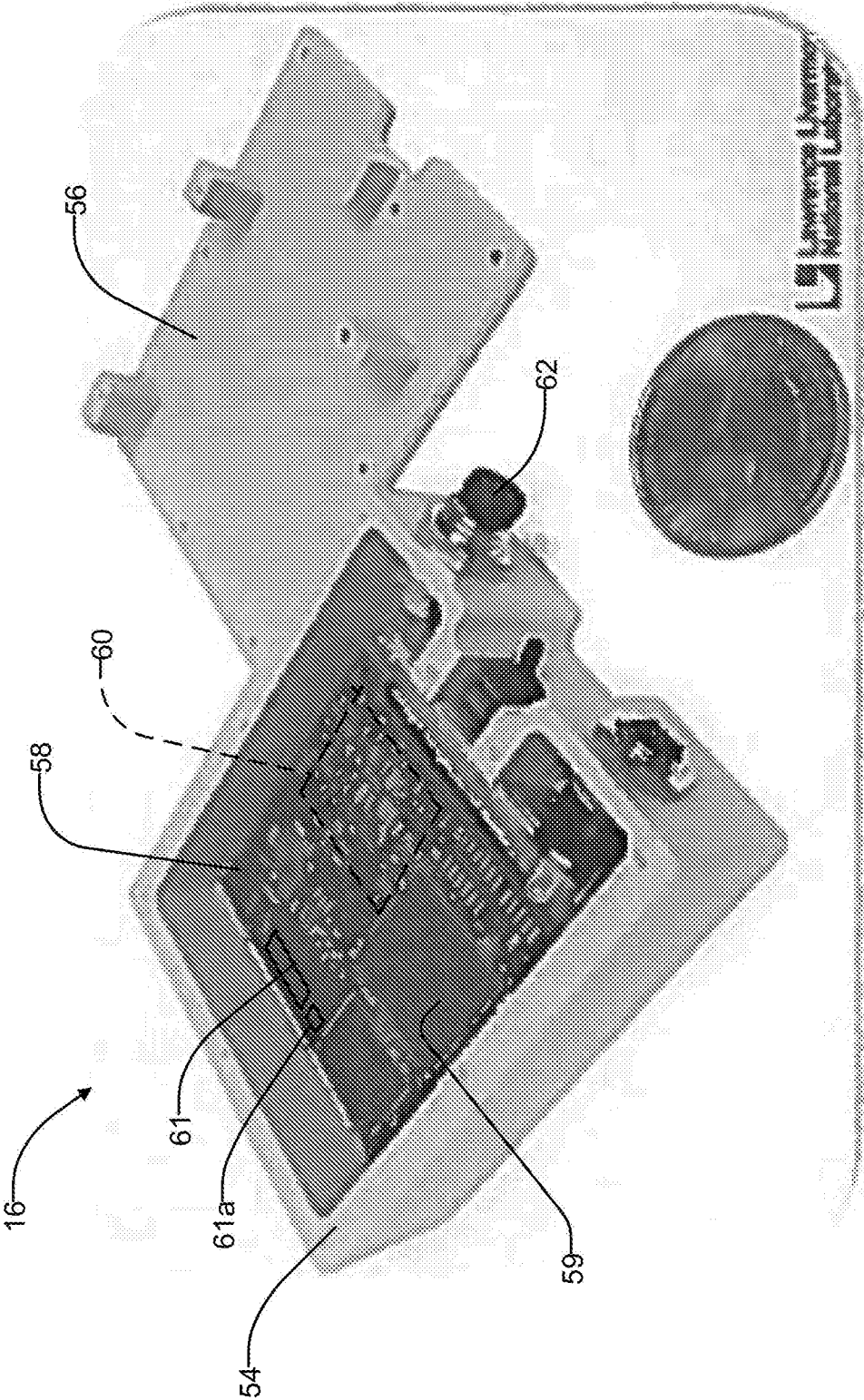


FIGURE 7

INTERNATIONAL SEARCH REPORTInternational application No.
PCT/US2016/065937**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 19-20
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 19-20 pertain to methods for treatment of the human body and thus relate to a subject-matter which this International Searching Authority is not required, under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv), to search.
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/065937**A. CLASSIFICATION OF SUBJECT MATTER****A61N 1/05(2006.01)i, A61N 1/36(2006.01)i, A61N 1/04(2006.01)i, A61N 1/08(2006.01)i, A61B 5/00(2006.01)i, A61B 5/0478(2006.01)i**

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61N 1/05; A61B 5/05; A61N 1/36; A61B 05/00; A61N 136; A61N 1/04; A61N 1/08; A61B 5/00; A61B 5/0478

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal) & keywords: brain, stimulation, electrocorticography, ECoG, aggregator, wireless, transceiver

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6480743 B1 (KIRKPATRICK et al.) 12 November 2002 See column 8, line 55-column 18, line 54; and claims 1-23; and figures 1-11.	1-18
X	US 2015-0157862 A1 (SECOND SIGHT MEDICAL PRODUCTS, INC.) 11 June 2015 See paragraphs [0011]-[0234]; claims 1-13; and figures 1-24.	1-18
X	US 6230049 B1 (FISCHELL et al.) 8 May 2001 See column 3, line 24-column 9, line 1; claims 1-42.	1-3, 5-18
A		4
A	WO 2014-190167 A2 (DEEP BRAIN INNOVATIONS LLC) 27 November 2014 See the whole document.	1-18
A	US 2014-0277257 A1 (MICRON DEVICES, LLC) 18 September 2014 See the whole document.	1-18
A	US 2009-0292336 A1 (NISHIDA et al.) 26 November 2009 See the whole document.	1-18
A	US 2006-0058627 A1 (FLAHERTY et al.) 16 March 2006 See the whole document.	1-18



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

07 April 2017 (07.04.2017)

Date of mailing of the international search report

07 April 2017 (07.04.2017)

Name and mailing address of the ISA/KR

International Application Division

Korean Intellectual Property Office

189 Cheongsa-ro, Seo-gu, Daejeon, 35208, Republic of Korea



Facsimile No. +82-42-481-8578

Authorized officer

HAN, Inho

Telephone No. +82-42-481-3362



INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2016/065937

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6480743 B1	12/11/2002	US 6466822 B1 US 6944501 B1	15/10/2002 13/09/2005
US 2015-0157862 A1	11/06/2015	None	
US 6230049 B1	08/05/2001	EP 0911061 A2 EP 0911061 A3 EP 0911061 B1 EP 1145735 A2 EP 1145735 A3 EP 1145736 A2 EP 1145736 A3 US 2001-0051819 A1 US 2001-0056290 A1 US 2002-0002390 A1 US 2002-0072770 A1 US 2002-0077670 A1 US 2002-0099412 A1 US 2002-0169485 A1 US 2004-0153129 A1 US 2005-0222641 A1 US 2006-0212093 A1 US 2006-0224216 A1 US 2011-0213442 A1 US 6016449 A US 6061593 A US 6128538 A US 6134474 A US 6354299 B1 US 6360122 B1 US 6427086 B1 US 6459936 B2 US 6466822 B1 US 6480743 B1 US 6597954 B1 US 6647296 B2 US 6690974 B2 US 6944501 B1 US 7174213 B2 US 7966073 B2 US 8073544 B2 US 8412333 B2	28/04/1999 24/11/1999 26/10/2005 17/10/2001 21/04/2004 17/10/2001 14/04/2004 13/12/2001 27/12/2001 03/01/2002 13/06/2002 20/06/2002 25/07/2002 14/11/2002 05/08/2004 06/10/2005 21/09/2006 05/10/2006 01/09/2011 18/01/2000 09/05/2000 03/10/2000 17/10/2000 12/03/2002 19/03/2002 30/07/2002 01/10/2002 15/10/2002 12/11/2002 22/07/2003 11/11/2003 10/02/2004 13/09/2005 06/02/2007 21/06/2011 06/12/2011 02/04/2013
WO 2014-190167 A2	27/11/2014	EP 2999515 A2 US 2014-0350635 A1 WO 2014-190167 A3	30/03/2016 27/11/2014 26/02/2015
US 2014-0277257 A1	18/09/2014	US 9433789 B2 WO 2014-145020 A1	06/09/2016 18/09/2014

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2016/065937

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2009-0292336 A1	26/11/2009	US 8428732 B2	23/04/2013
US 2006-0058627 A1	16/03/2006	US 2006-0049957 A1	09/03/2006
		WO 2006-020794 A2	23/02/2006
		WO 2006-020794 A3	15/06/2006