

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PCTP2019-004	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/IB2019/051005	International filing date (<i>day/month/year</i>) 07 February 2019 (07.02.2019)	Priority date (<i>day/month/year</i>) 07 February 2018 (07.02.2018)
International Patent Classification (IPC) or both national classification and IPC IPC: A61N 1/04, 1/32, 1/36, 2/00, 2/02 CPC: A61N 1/04; A61N 1/323; A61N 1/36; A61N 1/36014; A61N 1/36034; A61N 2/006; A61N 2/02		
Applicant PANACEA QUANTUM LEAP TECHNOLOGY LLC		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:

- a. ☒ (sent to the applicant and to the International Bureau) a total of 24 sheets, as follows:
 - ☒ sheets of the description, claims and/or drawings which have been amended and/or sheets containing rectifications authorized by this Authority, unless those sheets were superseded or cancelled, and any accompanying letters (see Rules 46.5, 66.8, 70.16, 91.2, and Section 607 of the Administrative Instructions).
 - ☐ sheets containing rectifications, where the decision was made by this Authority not to take them into account because they were not authorized by or notified to this Authority at the time when this Authority began to draw up this report, and any accompanying letters (Rules 66.4bis, 70.2(e), 70.16 and 91.2).
 - ☐ superseded sheets and any accompanying letters, where this Authority either considers that the superseding sheets contain an amendment that goes beyond the disclosure in the international application as filed, or the superseding sheets were not accompanied by a letter indicating the basis for the amendments in the application as filed, as indicated in item 4 of Box No. I and the Supplemental Box (see Rule 70.16(b)).
- b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____ containing a sequence listing, in the form of an Annex C/ST.25 text file, as indicated in the Supplemental Box Relating to Sequence Listing (see paragraph 3ter of Annex C of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

Date of submission of the demand 07 December 2019 (07.12.2019)	Date of completion of this report 24 June 2020 (24.06.2020)
Name and mailing address of the IPEA/US COMMISSIONER FOR PATENTS MAIL STOP PCT, ATTN: IPEA/US P.O. BOX 1450 ALEXANDRIA, VA 22313-1450, UNITED STATES OF AMERICA Facsimile No. (571)273-8300	Authorized officer THADDEUS B COX Telephone No. (571)270-5132

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of:
- ☐ international search (Rules 12.3(a) and 23.1(b))
- ☐ publication of the international application (Rule 12.4(a))
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a) and (b))

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☐ the international application as originally filed/furnished, or
- ☒ the description:
pages 1-36 as originally filed/furnished.
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____
- ☒ the claims:
Nos. _____ as originally filed/furnished.
Nos.* _____ as amended (together with any statement) under Article 19
Nos.* 1-19 received by this Authority on 07 December 2019 (07.12.2019)
- ☒ the drawings:
pages 1-11 as originally filed/furnished.
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____
- ☐ a sequence listing - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since either they are considered to go beyond the disclosure as filed, or they were not accompanied by a letter indicating the basis for the amendments in the application as filed, as indicated in the Supplemental Box (Rules 70.2(c) and (c-bis)):

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____

5. ☐ This report has been established:

- ☐ taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rules 66.1(d-bis) and 70.2(e)).
- ☐ without taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rules 66.4bis and 70.2(e)).

6. With regard to top-up searches (Rules 66.1ter and 70.2(f)):

- ☒ A top-up search was carried out by this Authority on 24 June 2020 (24.06.2020)
- ☒ Additional relevant documents have been discovered during the top-up search.
- ☐ No top-up search was carried out by this Authority because it would serve no useful purpose.

7. ☐ Supplementary international search report(s) from Authority(ies) _____ has/ have been received and taken into account in establishing this report (Rule 45bis.8(b) and (c)).

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	7,8,15-19	YES
	Claims	1-6,9-14	NO
Inventive step (IS)	Claims	7,8,16,17	YES
	Claims	1-6,9-15,18,19	NO
Industrial applicability (IA)	Claims	1-19	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

----- NEW CITATIONS -----

US 20180193658 A1 (HONG ET AL) 12 July 2018 (12.07.2018) , Figs. 2, 4, 7, 8, 10. Paragraphs [0006]-[0009], [0045]-[0049], [0066]-[0070], [0087]-[0091], [0103]

US 20110307029 A1 (HARGROVE) 15 December 2011 (15.12.2011) , Paragraph [0170]

US 20180078269 A1 (MEINKE ET AL) 22 March 2018 (22.03.2018) , Paragraphs [0004]-[0005], [0027], [0033], [0042]

----- EXPLANATION -----

Claims 1-6 and 9-14 lack novelty under PCT Article 33(2) as being anticipated by **Hong et al. (U.S. Pub. No. 20180193658 A1; hereinafter known as "Hong")**.

Regarding claim 1, Hong discloses a method for electromagnetic stimulation of a tissue (Abstract), the method comprising the steps of: a) disposing an arrangement of electromagnetic transducers **130** encompassing a volume containing a tissue ([0006]; [0045]) and b) applying an electromagnetic field stimulus to a tissue through the arrangement of electromagnetic transducers according to an activation pattern for a determined period of time, wherein the activation pattern varies the intensity and direction of an electromagnetic field vector produced by the arrangement of electromagnetic transducers in a three-dimensional space ([0007]-[0009]; [0046]; [0049]; [0066]; [0091]; [0103]).

Regarding claim 2, Hong discloses changing the activation pattern and returning to step (b) ([0049]; [0064]-[0070]; [0080]; [0091]).

Regarding claim 3, Hong discloses changing the activation pattern on the basis of a measurement of intensity of the electromagnetic field produced by the arrangement of electromagnetic transducers, on a tissue impedance response feedback, or a combination of these ([0049]; [0064]-[0070]; [0080]; [0091]).

Regarding claim 4, Hong discloses a unitary arrangement of magnetic field transducers ([0070]).

Regarding claim 5, Hong discloses that the active face of each electromagnetic transducer of the arrangement of electromagnetic transducers is spaced apart from the external surface of the tissue (Fig. 4).

Regarding claim 6, Hong discloses that the active face of one of the electromagnetic transducers in the arrangement of electromagnetic transducers is spaced apart from the external surface of the tissue (Fig. 4).

Regarding claim 9, Hong discloses a method for electromagnetic stimulation of a tissue (Abstract), the method comprising the steps of: a) disposing an arrangement of electromagnetic transducers **130** encompassing a volume containing a tissue ([0006]; [0045]) and b) applying an electromagnetic field stimulus to a tissue through the arrangement of electromagnetic transducers according to an activation pattern for a determined period of time, wherein the electromagnetic field stimulus provides an intensity of either a magnetic field or an electrical field on the tissue, or the combination thereof, as follows: ([0007]-[0009]; [0046]; [0049]; [0066]; [0091]; [0103]) the magnetic field generated by the magnetic field transducers is of between about 0.1 mT and 200 mT ([0068]) or the electrical field generated by the electrical field transducers is of between about 2 V/cm and about 5 V/cm.

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
	Regarding claim 10, Hong discloses changing the activation pattern and returning to step (b) ([0049]; [0064]-[0070]; [0080]; [0091]). Regarding claim 11, Hong discloses changing the activation pattern on the basis of a measurement of intensity of the electromagnetic field produced by the arrangement of electromagnetic transducers, on a tissue impedance response feedback, or a combination of these ([0049]; [0064]-[0070]; [0080]; [0091]). Regarding claim 12, Hong discloses a unitary arrangement of magnetic field transducers ([0070]). Regarding claim 13, Hong discloses that the active face of each electromagnetic transducer of the arrangement of electromagnetic transducers is spaced apart from the external surface of the tissue (Fig. 4). Regarding claim 14, Hong discloses that the active face of one of the electromagnetic transducers in the arrangement of electromagnetic transducers is spaced apart from the external surface of the tissue (Fig. 4). Claims 1-6 and 9-14 also lack novelty under PCT Article 33(2) as being anticipated by Meinke et al. (U.S. Pub. No. 20180078269 A1; see cited portions). Claims 15, 18, and 19 lack an inventive step under PCT Article 33(3) as being obvious over Hong in view of Hargrove (U.S. Pub. No. 2011/0307029 A1). Regarding claim 15, Hong discloses a device for stimulating a tissue with electromagnetic fields (Abstract), the device comprising: a computing unit 160 (Figs. 2, 16), an external power source 150 connected to the computing unit ([0028]), an arrangement of electromagnetic transducers 130 connected to the computing unit (Fig. 2), wherein the computing unit implements a method for electromagnetic stimulation of a tissue, the method comprising the steps of: disposing an arrangement of electromagnetic transducers encompassing a volume containing a tissue ([0006]; [0045]) and b) applying an electromagnetic field stimulus to a tissue through the arrangement of electromagnetic transducers according to an activation pattern for a determined period of time, wherein the activation pattern varies the intensity and direction of an electromagnetic field vector produced by the arrangement of electromagnetic transducers in a three-dimensional space ([0007]-[0009]; [0046]; [0049]; [0066]; [0091]; [0103]). Hong fails to disclose a decoupling circuit connected to the external power source and to the computing unit and a switching circuit connected to the external power source, the decoupling circuit, the computing unit, and the arrangement of electromagnetic transducers. Hargrove discloses a similar device for stimulating a tissue (Abstract) that comprises a decoupling circuit and a switching circuit connected to a power source, a computing unit, and a stimulation device, in order to selectively provide power and to electrically decouple the stimulation device when desirable ([0170]). It would have been obvious to one of ordinary skill to modify Hong with a decoupling circuit and a switching circuit, as taught by Hargrove, in order to selectively provide power and to electrically decouple the stimulation device when desirable. Regarding claim 18, the combination of Hong and Hargrove discloses the invention as claimed, and Hong further discloses a special purpose computing unit comprising a CPU connected to a plurality of oscillators each having an activation signal output ([0083]-[0085]). Regarding claim 19, the combination of Hong and Hargrove discloses the invention as claimed, and Hong further discloses that the CPU is also connected to a peripheral device selected among others, from storage devices such as a memory unit, a database and a hard drive, input devices such as a keyboard, a camera, a touchscreen display, and a scanner, output devices such as a display, and a printer ([0084]). Claims 7, 8, 16, and 17 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the recited steps of defining an electrical field transducers index or a magnetic transducers index and a maximum number of pairs of electrical field transducers or of magnetic transducers, selecting a pair of electrical field transducers or a magnetic field transducer in a position defined for the index, activating then deactivating the pair of electrical field transducers or the magnetic field transducer, increasing the index and comparing it with the maximum number, and if the index is greater than the maximum number, making the index equal to the value in step a and returning to step b, and if the index is less than or equal to the maximum number, returning to step b. Claims 1-19 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 5, 6, 13, 14, 18, and 19 are objected to under PCT Article 6 as lacking clarity because claims 5, 6, 13, 14, 18, and 19 are indefinite for the following reason(s):

Claims 5, 6, 13, and 14 each recite "the active face" and "the external surface," which have insufficient antecedent basis in the claims.

Claim 18 includes element number "21a", which should be deleted, and the description of the oscillators is written confusingly so as to be indefinite as to what is intended to be claimed.

Claim 19 recites several "such as" limitations, where it is not clear if the elements following "such as" are positively recited to be part of the claimed invention or not. It is also not clear what is meant by "selected among others."

AMENDED CLAIMS

1. A method for electromagnetic stimulation of a tissue, the method comprising the steps of:

- a) disposing an arrangement of electromagnetic transducers encompassing a volume containing a tissue; and
- b) applying an electromagnetic field stimulus to a tissue through the arrangement of electromagnetic transducers according to an activation pattern for a determined period of time;

wherein the activation pattern varies the intensity and direction of an electromagnetic field vector produced by the arrangement of electromagnetic transducers in a three-dimensional space.

2. The method of Claim 1, wherein, after step (b), there is a step of changing the activation pattern and returning to step (b).

3. The method of Claim 2, wherein, changing the activation pattern is executed on the basis of a measurement of intensity of the electromagnetic field produced by the arrangement of electromagnetic transducers, on a tissue impedance response feedback or a combination of these.

4. The method of Claim 1, wherein, at step (a), the arrangement of electromagnetic transducers is a unitary arrangement of magnetic field transducers.

5. The method of Claim 1, wherein, at step (a), the active face of each electromagnetic transducer of the arrangement of electromagnetic transducers is spaced apart from the external surface of the tissue.

6. The method of Claim 1, wherein, at step (a), the active face of one of the electromagnetic transducers in the arrangement of electromagnetic transducers is spaced apart from the external surface of the tissue.

7. The method of Claim 1, wherein, step (b) is executed in a computing unit and the activation pattern follows the steps of:

- A) defining an electrical field transducers index with an initial value and a maximum number of pairs of electrical field transducers in the computing unit;
- B) selecting a pair of electrical field transducers from the arrangement of electromagnetic transducers simultaneously in a position defined for the electrical field transducers index of step (A);
- C) activating the pair of electrical field transducers selected in step (B) with a determined polarity such that an electrical field transducer of said pair has positive electrical potential in relation to the other electric field transducer of said pair, during a determined period of time;
- E) deactivating the pair of electrical field transducers selected in step (B);
- F) increasing an index for electrical field transducers and comparing the electrical field transducers index with the maximum number of pairs of electrical field transducers,
 - if the electrical field transducers index is greater than the maximum number of pairs of electrical field transducers, making the index for the electrical field transducers equal to the value defined in step (A) and returning to step (B);
 - if the index of the electrical field transducers is less than or equal to the maximum number of pairs of electrical field transducers, return to step (B);

wherein the electrical field transducers index is less than the maximum number of pairs of electrical field transducers, and the arrangement of electromagnetic transducers has “n” pairs of electrical field transducers with “n” being a natural number greater than two.

8. The method of Claim 1, wherein step (b) is executed in a computing unit and the activation pattern follows the steps of:

A) defining a magnetic transducers index and a maximum number of magnetic transducers;

B) selecting a magnetic field transducer from the arrangement of electromagnetic transducers simultaneously in a position defined for the magnetic field transducers index of step (A);

C) activating the magnetic transducer selected in step (B) for a determined period of time and going to step (D);

D) deactivating the magnetic transducer selected in step (B) and going to step (E);

E) increasing a magnetic transducers index and comparing the magnetic transducers index with the maximum number of magnetic transducers,

- if the magnetic transducers index is greater than the maximum number of magnetic transducers, make the magnetic transducers index equal to the value defined in step (A) and returning to step (B);

- if the magnetic transducers index is less than or equal to the maximum number of magnetic transducers, return to step (B);

wherein the magnetic transducers index is less than the maximum number of magnetic transducers.

9. A method for electromagnetic stimulation of a tissue, the method comprising the steps of:

a) disposing an arrangement of electromagnetic transducers encompassing a volume containing a tissue; and

b) applying an electromagnetic field stimulus to the tissue through the arrangement of electromagnetic transducers according to an activation pattern for a determined period of time;

wherein the electromagnetic field stimulus provides an intensity of either a magnetic field or an electrical field on the tissue, or the combination thereof, as follows:

the magnetic field generated by the magnetic field transducers is of between about 0.1 mT and 200 mT; or

the electrical field generated by the electrical field transducers is of between about 2 V/cm and about 5 V/cm.

10. The method of Claim 9, wherein, after step (b), there is a step of changing the activation pattern and returning to step (b).
11. The method of Claim 9, wherein, changing the activation pattern is executed on the basis of a measurement of intensity of the electromagnetic field produced by the arrangement of electromagnetic transducers, on a tissue impedance response feedback or a combination of these.
12. The method of Claim 9, wherein, at step (a), the arrangement of electromagnetic transducers is a unitary arrangement of magnetic field transducers.
13. The method of Claim 9, wherein, at step (a), the active face of each electromagnetic transducer of the arrangement of electromagnetic transducers is spaced apart from the external surface of the tissue.
14. The method of Claim 9, wherein, at step (a), the active face of one of the electromagnetic transducers in the arrangement of electromagnetic transducers is spaced apart from the external surface of the tissue.
15. A device for stimulating a tissue with electromagnetic fields, the device comprising:
 - a computing unit;
 - an external power source connected to the computing unit;
 - a decoupling circuit connected to the external power source and to the computing unit;
 - a switching circuit connected to the external power source, to the decoupling circuit and to the computing unit; and
 - an arrangement of electromagnetic transducers connected to the computing unit and to the switching circuit;

wherein the computing unit implements a method for electromagnetic stimulation of a tissue, the method comprising the steps of: a) disposing an arrangement of electromagnetic transducers encompassing a volume containing a tissue; and b) applying an electromagnetic field stimulus to a tissue through the arrangement of electromagnetic transducers according to an activation pattern for a determined period of time;

wherein the activation pattern varies the intensity and direction of an electromagnetic field vector produced by the arrangement of electromagnetic transducers in a three-dimensional space.

16. The device of Claim 15, wherein step (b) is executed in the computing unit and the activation pattern follows the steps of:

- A) defining an electrical field transducers index with an initial value and a maximum number of pairs of electrical field transducers in the computing unit;
- B) selecting a pair of electrical field transducers from the arrangement of electromagnetic transducers simultaneously in a position defined for the electrical field transducers index of step (A);
- C) activating the pair of electrical field transducers selected in step (B) with a determined polarity such that an electrical field transducer of said pair has positive electrical potential in relation to the other electric field transducer of said pair, during a determined period of time;
- E) deactivating the pair of electrical field transducers selected in step (B);
- F) increasing an index for electrical field transducers and comparing the electrical field transducers index with the maximum number of pairs of electrical field transducers,
 - if the electrical field transducers index is greater than the maximum number of pairs of electrical field transducers, making the index for the electrical field transducers equal to the value defined in step (A) and returning to step (B);
 - if the index of the electrical field transducers is less than or equal to the maximum number of pairs of electrical field transducers, return to step (B);

wherein the electrical field transducers index is less than the maximum number of pairs of electrical field transducers, and the arrangement of electromagnetic transducers has

“n” pairs of electrical field transducers with “n” being a natural number greater than two.

17. The device of Claim 15, wherein step (b) is executed in the computing unit and the activation pattern follows the steps of:

- A) defining a magnetic transducers index and a maximum number of magnetic transducers;
- B) selecting a magnetic field transducer from the arrangement of electromagnetic transducers simultaneously in a position defined for the magnetic field transducers index of step (A);
- C) activating the magnetic transducer selected in step (B) for a determined period of time and going to step (D);
- D) deactivating the magnetic transducer selected in step (B) and going to step (E);
- E) increasing a magnetic transducers index and comparing the magnetic transducers index with the maximum number of magnetic transducers,
 - if the magnetic transducers index is greater than the maximum number of magnetic transducers, make the magnetic transducers index equal to the value defined in step (A) and returning to step (B);
 - if the magnetic transducers index is less than or equal to the maximum number of magnetic transducers, return to step (B);

wherein the magnetic transducers index is less than the maximum number of magnetic transducers.

18. The device of Claim 15, wherein the computing unit is a special purpose computing unit comprising a central processor unit (21a) connected to oscillators from a first oscillator, a second oscillator to an oscillator “n” each oscillator having an activation signal output; wherein “n” is a natural number equal or greater than zero.

19. The device of Claim 15, wherein the central processor unit is also connected to a peripheral device selected among others, from storage devices such as a memory unit, a

database and a hard drive, input devices such as a keyboard, a camera, a touchscreen display, and a scanner, output devices such as a display, and a printer.

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International Application Number PCT/IB2019/051005
Letter accompanying amendments under Article 34
submitted with Demand for IPEA under Article 20(1)

COLOMBIA
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7 December 2019
VIA ELECTRONIC FILING BY E-PCT

The International Preliminary Examining Authority (IPEA/US)
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

INTERNATIONAL BUREAU OF WIPO

Applicants:	PANACEA QUANTUM LEAP TECHNOLOGY LLC
International Application No.	PCT/IB2019/051005
International filing date:	7 February 2019
Title:	"SPATIAL SCANNING"
Agent's Reference No.	PCTP2019/000004

REQUEST FOR PRELIMINARY EXAMINATION UNDER ART. 34

Dear Sirs:

1. After having received the International Search Report (ISR) and Written Opinion, mailed on 9 August 2019 by the International Searching Authority (ISA), the Applicant herewith encloses amendments in the claim chapter in order to overcome the novelty objections raised by the ISA in the ISR, and requests that an International Preliminary Report on Patentability (IPRP) be issued.

A clean and a marked copy of the claims is enclosed to show the amendments. No new matter was added.

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2. Amendments and basis for them (Art. 34 PCT)

The set of claims have been amended to highlight that the present invention focuses on spatial scanning that refers to the variation of the electromagnetic, electrical or magnetic field vector, in a three-dimensional space and also focuses on that the electromagnetic field stimulus provides an intensity of a magnetic field on the tissue generated by the magnetic field transducers of between about 0.1 mT and 200 mT. With the aim of clearly reflecting the differences of the present invention with the prior art, the claims are amended as follows.

Specifically, the following amendments have been introduced:

- i) amended Claim 1 includes the feature that the electromagnetic field vector is produced in a “three-dimensional space.” The support for this amendment can be found in page 8 line 6 of the International Publication WO2019/1554A2;
- ii) new Claim 9 corresponds to a method for electromagnetic stimulation of a tissue, wherein the electromagnetic and an electric field stimulus is provided. The support for this amended can be found in page 7 lines 27 to 29; page 8 lines 1 to 3; page 20 lines 23 to 25 and page 21 lines 28 to 30 of the International Publication WO2019/1554A2;
- iii) new Claims 10 to 14 correspond to old Claims 2 to 4 and old Claims 9 to 10 respectively. New Claims 10 to 14 depend on the new Claim 9;
- iv) amended Claim 15 includes the feature that the electromagnetic field vector is produced in a “three-dimensional space.” The support for this amendment can be found in page 8 line 6 of the International Publication WO2019/1554A2;
- v) amended Claim 18 includes the term “oscillator” and eliminates the reference number “21a;”
- vi) Claims 5 to 8, 11 and 13 have been deleted; and
- vii) all claims have been renumbered.

The amendments to the set of claims are explicit in the enclosures.

3. Clarity objections

a. The ISA objects the clarity of Claims 15 and 18 because the expression “the de switching circuit” in Claim 15 lacks antecedent basis, and Claim 18 includes numbered elements without antecedent basis.

b. In response, the Applicant has amended Claim 15 by deleting the word “de.” Additionally, it has been deleted the expressions “OSC 1,” “OSC 2” from Claim 18.

4. Comments on patentability

The ISA states that document US 2010/0152817 A1 (D1) affects the novelty of the present invention, as follows:

a. The ISA considers Claims 1 to 19 of the patent application are not novel, therefore it does not comply with Article 33(2) of the PCT in accordance with the following:

As for method Claim 1, the ISA states that D1 discloses an array stimulator using an array of electrodes to stimulate a tissue (Figures 1-3, paragraphs [0113, 0115, 0116]). Also, D1 discloses a composite waveform 01 required to affect the behavior of excitable tissue in a transcutaneous nerve stimulation application, the waveform being created by series of component waveforms A-E between pairs of electrode A1, A2, -E2 according to the pattern of fig.1 (Figures 1-3 paragraphs [0114-0116]). Additionally, the voltage applied to opposing electrodes creates a field according to the vector plot of Figure 17 where the direction and magnitude of the field at any point resulting from the magnitude and current provided to each electrode, with resulting field from a combination of pairs being formed from a matrix (Figures 1-3 and 17A-17B, paragraphs [0177-0181]).

Additionally, as for device Claim 15, the ISA states that D1 discloses a stimulator using an array of electrodes to stimulate tissue (Figures 1-3, paragraphs [0113, 0115, 0116]). Also, D1 has a microprocessor 90 (figure 18, paragraph [0187]), a battery 108 that may be charged by an external charging unit and feeds the microprocessor 108 (Figure 18, paragraph [0200]), the charging and battery control 99 (Figure 18, paragraph [0200]). Additionally, D1 discloses that the electrodes are connected to each of the outputs which connect to switching to connect to the power supply, battery, and microprocessor (Figure 18, paragraphs [0187-0191]). Finally, the voltage applied to opposing electrodes creates a field according to the vector plot of Figure 17 where the direction and magnitude of the field at any point resulting from the magnitude and current provided to each electrode, with resulting field from a combination of pairs being formed from a matrix (Figures 1-3 and 17A-17B, paragraphs [0177-0181]).

b. i) As for the present invention, it consists in methods and devices for the electromagnetic stimulation of a tissue by spatial scanning. The method comprising the steps of: a) disposing an arrangement of electromagnetic transducers encompassing a volume containing a tissue; b) applying an electromagnetic field stimulus to a tissue through the arrangement of electromagnetic transducers according to an activation pattern for a determined period of time; wherein the activation pattern makes it possible to vary the intensity and direction of an electromagnetic field vector produced by the arrangement of electromagnetic transducers. Such spatial scanning refers to the variation of either of the

electromagnetic, or electrical or magnetic field vector or the combination thereof, in a three-dimensional space.

ii) Regarding the cited prior art, D1 discloses an array stimulator that has a plurality of electrodes in an array (22), the electrodes forming a plurality of electrode pairs, and a signal generator (18) for generating signals to the electrodes so as to generate electrical pulse in a patient to which the stimulator has been applied either transcutaneously or by implantation. Those electrical pulses form a composite pulse in the patient which stimulates the nervous system of the patient. The composite pulse has duration between 4 μ s and 1500 μ s and a maximum voltage between 2V and 50V when the stimulator is implanted, and 15V to 500V when applied transcutaneously. The electrical pulses themselves are significantly shorter duration than the composite pulse, so they stimulate the nervous system of the patient much less than the composite pulse or not at all (abstract).

iii) Regarding the novelty objection, D1 does not disclose the following characteristics of the new Claim 1:

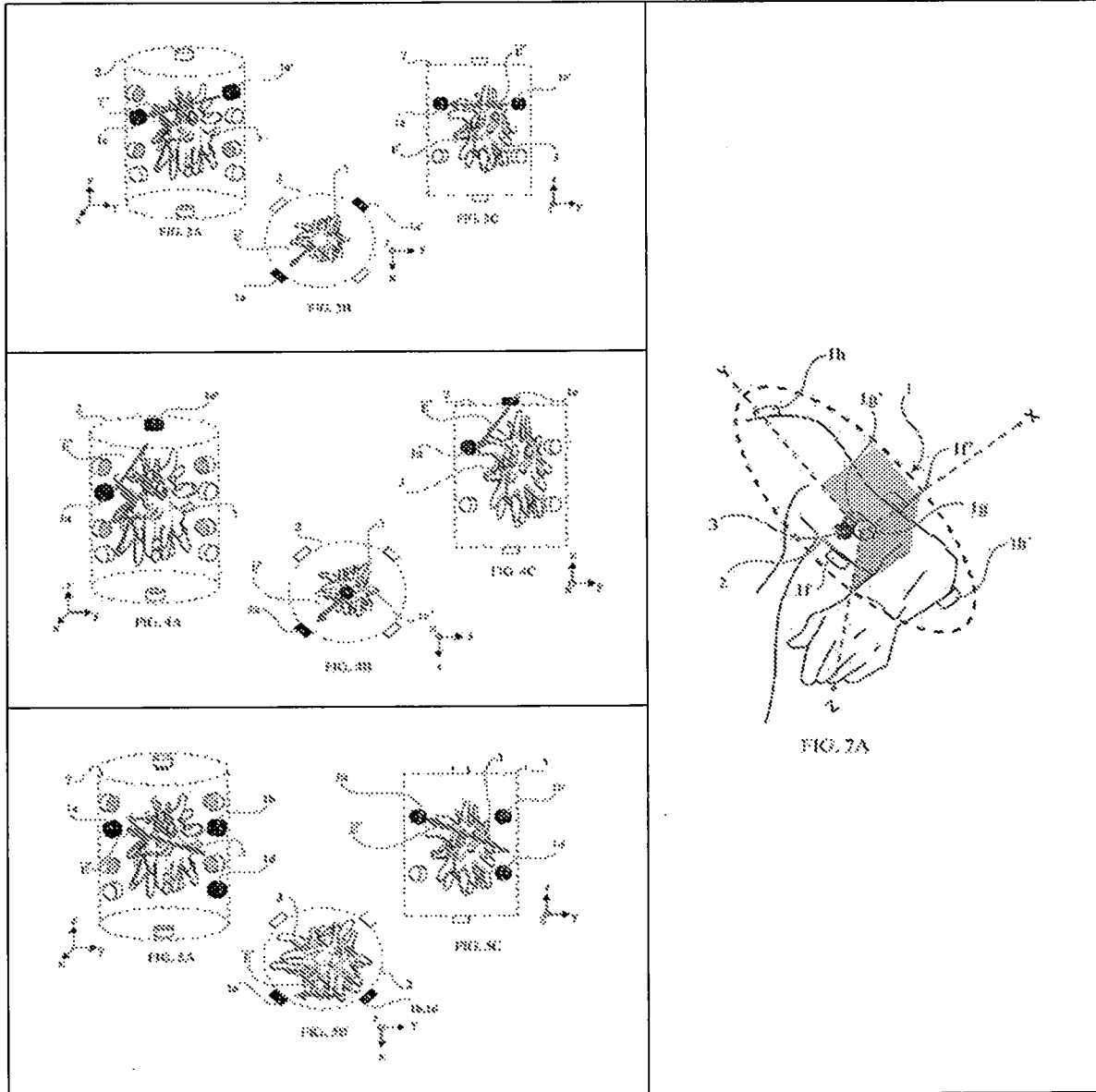
- D1 does not disclose that the activation pattern varies the intensity and direction of an electromagnetic field vector produced by the arrangement of electromagnetic transducers in a three-dimensional space.

The generation of the activation pattern corresponds to signals generated by a computing unit or by a signals generator or combinations of these, sent to the arrangement of electromagnetic transducers, which vary the intensity and direction of the electromagnetic stimulation vector induced in the tissue in a three-dimensional space.

The three-dimensional space corresponds to the Cartesian coordinates representing an electromagnetic field vector of a vector resulting from the variation of the electrical field ($\vec{E}$) and/or magnetic field ($\vec{B}$) with an angle α in relation to the plane created by axes "x" and "y" (page 15 lines 26 to 31), as illustrated in Figures 3A to 5C. Figures 3A to 5C show a generation of different activation patterns having different sequences which varies in a three-dimensional space. For instance, FIG. 3 shows the electric field generated between transducers 1a' and 1a, FIG. 4 shows the electric field generated between transducers 1a and 1e', and FIG. 5 shows the electric field generated between transducers 1b, 1d and 1a.

Additionally, it is shown FIG. 7A of the present invention with the cartesian coordinates in different colors representing the three-dimensional arrangement of electromagnetic transducers.

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On the contrary, D1 discloses a current induced in the tissue, which varies its direction in only one plane. For instance, Figure 8 of D1 shows an array of two linear electrodes side by side which generates a field in the same plane.

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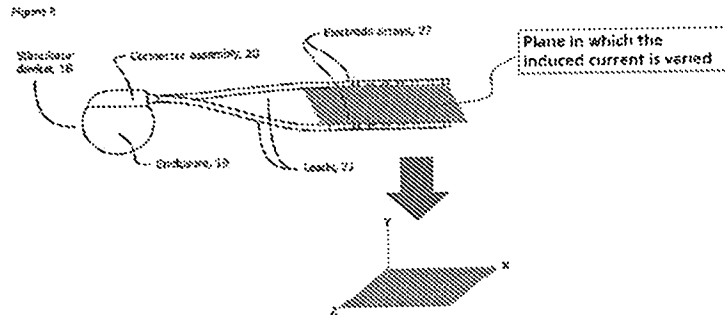


Figure 8 of D1

The current path in D1 spreads out as it transits between the two electrode pairs, with its start and end point defined by the arrangement of the electrode pairs. It is also possible to vary the shape of the region of stimulation and the centre of this region by varying the relative duty cycle of the component waveforms and the pairing of electrodes (Paragraph 118).

Therefore, there is no evidence that D1 varies the intensity and direction of the electromagnetic vectors produced by the arrangement of electromagnetic transducers in a three-dimensional space. On the contrary, D1 discloses that for each pair of electrodes in an array, a nominal current is applied resulting in a two-dimensional current distribution produced by the repeated activation of the electrode pairs.

In D1 the term three-dimensional refers to the fact that it is possible to generate an anatomical model mapping the electrical characteristics of the tissues in three dimensions, which is opposite to changing the direction of the electromagnetic field in a three-dimensional space as claimed in the present invention.

iv) As for device Claim 15, as amended herein, contains features similar to Claim 1 and is allowable for at least the same reasons. Accordingly, it is respectfully submitted that Claim 15 is novel for at least the same reasons as Claim 1.

Claims 2-8, 16-19 variously depend from Claims 1 and 15 are novel for at least the same reasons as Claim 1 and Claim 15.

v) As for new method Claim 9, as amended herein, D1 does not disclose a magnetic field between about 0.1 mT and 200 mT and an electrical field between about 2 V/cm and about 5 V/cm on the tissue. Accordingly, it is respectfully submitted that new Claim 9 is novel.

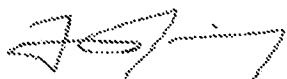
Dependent Claims 10-14 are also novel for at least the reasons explained above.

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4. This is submitted as a full and complete response to the Written Opinion to correct any deficiencies. Every effort to completely comply with the rules and no new matter has been added.

We look forward to receiving the International Preliminary Report on Patentability.

Truly yours,



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Attachments: Amended set of claims (clean and working copy).

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AMENDED CLAIMS

1. A method for electromagnetic stimulation of a tissue, the method comprising the steps of:

- a) disposing an arrangement of electromagnetic transducers encompassing a volume containing a tissue; and
- b) applying an electromagnetic field stimulus to a tissue through the arrangement of electromagnetic transducers according to an activation pattern for a determined period of time;

wherein the activation pattern ~~makes it possible to vary~~ varies the intensity and direction of an electromagnetic field vector produced by the arrangement of electromagnetic transducers ~~in a three-dimensional space~~.

2. The method of Claim 1, wherein, after step (b), ~~there~~ is a step of changing the activation pattern and returning to step (b).

3. The method of Claim 2, wherein, changing the activation pattern is executed on the basis of a measurement of intensity of the electromagnetic field produced by the arrangement of electromagnetic transducers, on a tissue impedance response feedback or a combination of these.

4. The method of Claim 1, wherein, at step (a), the arrangement of electromagnetic transducers is a unitary arrangement of magnetic field transducers.

~~5. The method of Claim 1, wherein, at step (a), the arrangement of electromagnetic transducers has two electrical field transducers.~~

~~6. The method of Claim 1, wherein, at step (a), in the arrangement of electromagnetic transducers, the electromagnetic transducers are selected from a group consisting of: organic electrodes, photoacoustic transducers, induction actuators, resistors, coils that generate magnetic fields for induction, permanent magnets, parallel plate capacitor materials, and combinations of these.~~

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~~7. The method of Claim 1, wherein, at step (a), the arrangement of electromagnetic transducers is spaced apart from a tissue, comprising the steps:~~

~~8. The method of Claim 1, wherein, at step (a), the active face of each electromagnetic transducer of the arrangement of electromagnetic transducers is in contact with the external surface of the tissue.~~

9. The method of Claim 1, wherein, at step (a), the active face of each electromagnetic transducer of the arrangement of electromagnetic transducers is spaced apart from the external surface of the tissue.

10. The method of Claim 1, wherein, at step (a), the active face of one of the electromagnetic transducers in the arrangement of electromagnetic transducers is spaced apart from the external surface of the tissue.

~~11. The method of Claim 1, wherein, at step (a), a portion of an area of the active face of the electromagnetic transducers in the arrangement of electromagnetic transducers is in contact with the external surface of the tissue.~~

12. The method of Claim 1, wherein, step (b) is executed in a computing unit and the activation pattern follows the steps of:

- A) defining an electrical field transducers index with an initial value and a maximum number of pairs of electrical field transducers in the computing unit;
- B) selecting a pair of electrical field transducers from the arrangement of electromagnetic transducers simultaneously in a position defined for the electrical field transducers index of step (A);
- C) activating the pair of electrical field transducers selected in step (B) with a determined polarity such that an electrical field transducer of said pair has positive electrical potential in relation to the other electric field transducer of said pair, during a determined period of time;
- E) deactivating the pair of electrical field transducers selected in step (B);

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F) increasing an index for electrical field transducers and comparing the electrical field transducers index with the maximum number of pairs of electrical field transducers,

- if the electrical field transducers index is greater than the maximum number of pairs of electrical field transducers, making the index for the electrical field transducers equal to the value defined in step (A) and returning to step (B);
- if the index of the electrical field transducers is less than or equal to the maximum number of pairs of electrical field transducers, return to step (B);

wherein the electrical field transducers index is less than the maximum number of pairs of electrical field transducers, and the arrangement of electromagnetic transducers has "n" pairs of electrical field transducers with "n" being a natural number greater than two.

~~4.3. The method of claim 1, wherein, after step (C), there is a step (E) in which the polarity of the pair of electrical field transducers selected in step (B) is inverted in relation to the polarity of step (C).~~

4.4. The method of Claim 1, wherein step (b) is executed in a computing unit and the activation pattern follows the steps of:

- A) defining a magnetic transducers index and a maximum number of magnetic transducers;
- B) selecting a magnetic field transducer from the arrangement of electromagnetic transducers simultaneously in a position defined for the magnetic field transducers index of step (A);
- C) activating the magnetic transducer selected in step (B) for a determined period of time and going to step (D);
- D) deactivating the magnetic transducer selected in step (B) and going to step (E);
- E) increasing a magnetic transducers index and comparing the magnetic transducers index with the maximum number of magnetic transducers,
 - if the magnetic transducers index is greater than the maximum number of magnetic transducers, make the magnetic transducers index equal to the value defined in step (A) and returning to step (B);
 - if the magnetic transducers index is less than or equal to the maximum number of magnetic transducers, return to step (B);

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wherein the magnetic transducers index is less than the maximum number of magnetic transducers.

2. A method for electromagnetic stimulation of a tissue, the method comprising the steps of:

a) disposing an arrangement of electromagnetic transducers encompassing a volume containing a tissue; and

b) applying an electromagnetic field stimulus to the tissue through the arrangement of electromagnetic transducers according to an activation pattern for a determined period of time;

wherein the electromagnetic field stimulus provides an intensity of either a magnetic field or an electrical field on the tissue, or the combination thereof, as follows:

the magnetic field generated by the magnetic field transducers is of between about 0.1 mT and 200 mT; or

the electrical field generated by the electrical field transducers is of between about 2 V/cm and about 5 V/cm.

10. The method of Claim 9, wherein, after step (b), there is a step of changing the activation pattern and returning to step (b).

1211. The method of Claim 9, wherein, changing the activation pattern is executed on the basis of a measurement of intensity of the electromagnetic field produced by the arrangement of electromagnetic transducers, on a tissue impedance response feedback or a combination of these.

1243. The method of Claim 9, wherein, at step (a), the arrangement of electromagnetic transducers is a unitary arrangement of magnetic field transducers.

1344. The method of Claim 9, wherein, at step (a), the active face of each electromagnetic transducer of the arrangement of electromagnetic transducers is spaced apart from the external surface of the tissue.

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~~1445. The method of Claim 9, wherein, at step (a), the active face of one of the electromagnetic transducers in the arrangement of electromagnetic transducers is spaced apart from the external surface of the tissue.~~

15. A device for stimulating a tissue with electromagnetic fields, the device comprising:

- a computing unit;
- an external power source connected to the computing unit;
- a decoupling circuit connected to the external power source and to the computing unit;
- a switching circuit connected to the external power source, to the decoupling circuit and to the computing unit; and
- an arrangement of electromagnetic transducers connected to the computing unit and to the switching circuit;

wherein the computing unit implements a method for electromagnetic stimulation of a tissue, the method comprising the steps of: a) disposing an arrangement of electromagnetic transducers encompassing a volume containing a tissue; and b) applying an electromagnetic field stimulus to a tissue through the arrangement of electromagnetic transducers according to an activation pattern for a determined period of time;

wherein the activation pattern ~~makes it possible to vary~~ varies the intensity and direction of an electromagnetic field vector produced by the arrangement of electromagnetic transducers in a three-dimensional space.

16. The device of Claim 15, wherein step (b) is executed in the computing unit and the activation pattern follows the steps of:

- A) defining an electrical field transducers index with an initial value and a maximum number of pairs of electrical field transducers in the computing unit;
- B) selecting a pair of electrical field transducers from the arrangement of electromagnetic transducers simultaneously in a position defined for the electrical field transducers index of step (A);

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C) activating the pair of electrical field transducers selected in step (B) with a determined polarity such that an electrical field transducer of said pair has positive electrical potential in relation to the other electric field transducer of said pair, during a determined period of time;

E) deactivating the pair of electrical field transducers selected in step (B);

F) increasing an index for electrical field transducers and comparing the electrical field transducers index with the maximum number of pairs of electrical field transducers,

- if the electrical field transducers index is greater than the maximum number of pairs of electrical field transducers, making the index for the electrical field transducers equal to the value defined in step (A) and returning to step (B);

- if the index of the electrical field transducers is less than or equal to the maximum number of pairs of electrical field transducers, return to step (B);

wherein the electrical field transducers index is less than the maximum number of pairs of electrical field transducers, and the arrangement of electromagnetic transducers has "n" pairs of electrical field transducers with "n" being a natural number greater than two.

17. The device of Claim 15, wherein step (b) is executed in the computing unit and the activation pattern follows the steps of:

A) defining a magnetic transducers index and a maximum number of magnetic transducers;

B) selecting a magnetic field transducer from the arrangement of electromagnetic transducers simultaneously in a position defined for the magnetic field transducers index of step (A);

C) activating the magnetic transducer selected in step (B) for a determined period of time and going to step (D);

D) deactivating the magnetic transducer selected in step (B) and going to step (E);

E) increasing a magnetic transducers index and comparing the magnetic transducers index with the maximum number of magnetic transducers,

- if the magnetic transducers index is greater than the maximum number of magnetic transducers, make the magnetic transducers index equal to the value defined in step (A) and returning to step (B);

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- if the magnetic transducers index is less than or equal to the maximum number of magnetic transducers, return to step (B);

wherein the magnetic transducers index is less than the maximum number of magnetic transducers.

18. The device of Claim 15, wherein the computing unit is a special purpose computing unit comprising a central processor unit ~~(CPU)~~ (21a) connected to oscillators from a first ~~oscillator~~ OSC-1, a second oscillator OSC-2 to an oscillator OSC-"n" each oscillator having an activation signal output; wherein "n" is a natural number equal or greater than zero.

19. The device of Claim 15, wherein the central processor unit is also connected to a peripheral device selected among others, from storage devices such as a memory unit, a database and a hard drive, input devices such as a keyboard, a camera, a touchscreen display, and a scanner, output devices such as a display, and a printer.

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