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[Continued on next page]

(54) Title: HEAD WORN BRAIN STIMULATION DEVICE AND METHOD

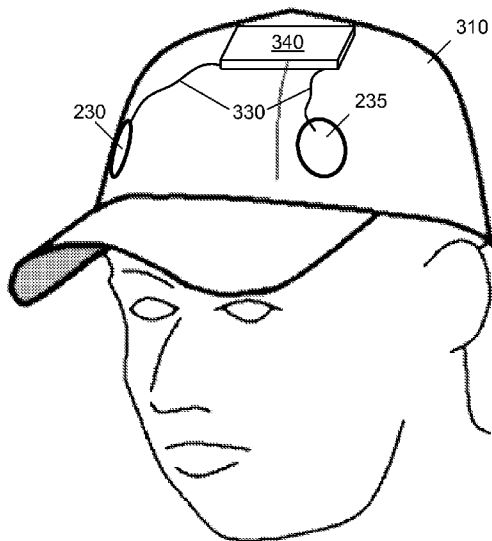


FIG. 3

(57) Abstract: A self-contained portable head worn device and methods to stimulate a portion of the brain of a wearer are presented. A first electrode is held by the head worn device against the scalp of the wearer in a first location and a second electrode is held against the scalp of the wearer in a second location. A pulse generator generates a first electric signal received by the first electrode and a second electric signal received by the second electrode. A power source is connected to the pulse generator.





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).

— *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))*

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6 November 2014

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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 14/21689

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61N 1/00 (2014.01)

USPC - 607/2

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)  
USPC: 607/2Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
USPC: 607/45, 46 (keyword limited; terms below)Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
PatBase; Google Patents; Google  
Search Terms Used: head, cranial, transcranial, electrode%, bend\*, flex\*, conductive, hydrogel, cover\*, coat\*, wrap\*, headband, headwear, headgear, hat, helmet, cap, constant, current, stimulator, pulse generator, steel, disc

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- Y	US 2011/0288610 A1 (BROCKE et al) 24 November 2011 (24.11.2011) fig 2, 3, 5, para [0010], [0058], [0081], [0088]-[0090], [0102], [0128]	1-5, 7, 11, 23 ----- 6, 8-10, 20
X ----- Y	US 2011/0046540 A1 (ALTERMAN et al) 24 February 2011 (24.02.2011) fig 3, para [0012], [0056], [0059], [0081]	1-2, 21-22 ----- 8-9
Y	US 2011/0118806 A1 (PASCUAL-LEONE et al) 19 May 2011 (19.05.2011) para [0033]	6, 10
Y	WO 2012/140629 A1 (MAGALHAES DUQUE DA FONSECA et al) 18 October 2012 (18.10.2012) pg 5, para 1	20

 Further documents are listed in the continuation of Box C.

## \* 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

"&amp;" document member of the same patent family

Date of the actual completion of the international search

11 August 2014 (11.08.2014)

Date of mailing of the international search report

28 AUG 2014

Name and mailing address of the ISA/US

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**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.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
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:  
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-11 and 20-23 directed to a portable head worn device.

Group II: Claims 12-19 directed to a method for stimulating portions of a brain of a wearer of a wearable portable head worn therapeutic device

---See Supplemental Sheet---

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 additional fees, this Authority did not invite payment of 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.:  
1-11 and 20-23

**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.

Continuation of Box III: Observations where unity of invention is lacking

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group II includes the special technical feature of a method for stimulating portions of a brain of a wearer of a wearable portable head worn therapeutic device, comprising the steps of: positioning a first electrode against the skin of the wearer in the vicinity of one of either the left or the right dorsal lateral prefrontal cortex; positioning a second electrode against the skin of the wearer; applying a first stimulation current to the first electrode; and applying a second stimulation current to the second electrode; and limiting said first stimulation current and/or said second stimulation to induce a resulting current to a portion of the brain of the wearer below a current level sufficient to activate a neuron receiving said resulting current, not required in Group I.

The inventions of Groups I-II are related as an apparatus (Group I) and methods for using the apparatus (Group II), and thus share the technical features of the apparatus of a portable head worn device comprising: a first electrode configured to be held against the scalp of the wearer in a first location and a second electrode configured to be held against the scalp of the wearer in a second location; a pulse generator configured to generate a first electric signal received by said first electrode and a second electric signal received by said second electrode; a head worn housing configured to contain said first electrode, said second electrode, and said pulse generator, and to maintain contact between the scalp of said wearer and both the first electrode and said second electrode; and a power source connected to said pulse generator. However, this apparatus was known in prior art as shown in US 2011/0288610 A1 to Brocke, et al. (hereinafter Brocke). Therefore, Groups I and II lack unity since the shared technical features do not represent a contribution over Brocke:

With respect to claim 1, Brocke discloses a portable head worn device configured to stimulate a portion of the brain of a wearer comprising:

a first electrode (3) configured to be held against the scalp of the wearer in a first location and a second electrode (3) configured to be held against the scalp of the wearer in a second location (fig 5, para [0102]);  
a pulse generator (16) configured to generate a first electric signal received by said first electrode and a second electric signal received by said second electrode (fig 5, para [0102]);  
a head worn housing (14) configured to contain said first electrode, said second electrode, and said pulse generator, and to maintain contact between the scalp of said wearer and both the first electrode and said second electrode (fig 5, para [0102]); and  
a power source connected to said pulse generator (para [0128]), wherein said first electric signal and said second electric signal induce an electric current between said first electrode and said second electrode through the scalp of the wearer and the portion of the brain of the wearer, and said induced electric current is limited below a current level sufficient to activate a neuron receiving said induced electric current (intended use - see para [0058]).

With respect to claim 23, Brocke discloses a system for preventing cognitive decline (intended use) in a wearer of a portable head worn device comprising:

a head worn housing (14) of said head worn device configured to hold a first electrode (3) against a first portion of the scalp of the wearer and to hold a second electrode (3) against a second portion of the scalp of the wearer and maintain contact between the scalp of said wearer and both said first electrode and said second electrode (fig 3, para [0081]); and  
a pulse generator (electric signal generator) in electrical communication with said first electrode and said second electrode (para [0128]), said pulse generator configured to induce an electric current between said first electrode and said second electrode through the scalp of the wearer and at least a portion of the brain of the wearer, wherein said induced electric current induced through the at least a portion of the brain of the wearer by said pulse generator is limited below a current level sufficient to activate a neuron receiving said induced electric current (intended use - see para [0058]).

As the common features were known in the art at the time of the invention, they cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.