PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2018/039896	28.06.2018	28.06.2017

International Patent Classification (IPC) or both national classification and IPC
INV. A61N1/36

Applicant
MED-EL ELEKTROMEDIZINISCHE GERAETE GMBH

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ 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 Rule 43*bis*.1(a)(i) 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

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Fax: +49 89 2399 - 4465	see form PCT/ISA/210	Molina Silvestre, A Telephone No. +49 89 2399-0

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ 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)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 8-14

because:

☒ the said international application, or the said claims Nos. 8-14 relate to the following subject matter which does not require an international search *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for the whole application or for said claims Nos. 8-14

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing in the form of an Annex C/ST.25 text file, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.
- ☐ furnish a sequence listing on paper or in the form of an image file complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13*ter*.1(a) or (b).

☒ See Supplemental Box for further details

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-7
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-7
Industrial applicability (IA)	Yes:	Claims	1-7
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

1 **Re Item III**

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1.1 No opinion has been established for claims 8-14 with regard to novelty, inventive step and industrial applicability because the subject-matter of these claims includes methods for treatment of the human or animal body by therapy in the sense of Rule 39.1(iv) PCT. This is because the steps leading up to and including the step of developing electrode stimulation signals have a direct link to the therapeutic stimulation provided by the implant system, as clarified by the description.

2 **Re Item V**

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2.1 Reference is made to the following documents:

D1 EP 2 942 976 A1 (UNIV SALAMANCA [ES]) 11 November 2015 (2015-11-11)

D2 US 2016/375244 A1 (SCHLEICH PETER [AT] ET AL) 29 December 2016 (2016-12-29)

D3 WO 2016/089936 A1 (MED EL ELEKTROMED GERAETE GMBH [US]) 9 June 2016 (2016-06-09)

2.2 The application does not meet the requirements of Article 6 PCT, because claims 1, 2 are not clear.

2.2.1 Claim 1 is not clear because the following technical feature is unclear:

F1: "a channel compression module configured to develop an inhibition-adjusted band pass signal for each band pass signal using a channel-specific dynamic inhibition adjustment based on a channel-normalized medial olivocochlear reflex model reflecting bandwidth energy for a corresponding contralateral band pass signal and bandwidth energy for a selected reference contralateral band pass signal".

In turn, F1 is unclear because the underlined characterization of the adjustment to be made fails to define this adjustment in technical terms suitable for determining the claimed scope. In particular, no generally-acknowledged meaning can be attached to what it would mean for an

"adjustment" to be "based on a channel-normalized medial olivocochlear model" (in other words, no generally-acknowledged way of differentiating such an "adjustment" from one that is "not based on a channel-normalized medial olivocochlear model" is known).

For this reason, and merely for the purposes of the present opinion, F1 has been interpreted as if defining "a channel compression module configured to develop an inhibition-adjusted band pass signal for each band pass signal using a channel-specific dynamic inhibition adjustment".

2.2.2 Claim 2 is not clear because the following technical feature is unclear:

F2: "wherein the medial olivocochlear reflex model is configured to produce equal or larger channel-specific dynamic inhibition adjustments for lower frequency band pass signals"

In turn, F2 is unclear because (a) no definition is known (or given) for the parameter that is to be compared, namely the "adjustments" and (b) because the target of the comparison is also not defined (i.e. with respect to what the "adjustments of the lower frequency signals" are to be equal or larger).

For this reason, and merely for the purposes of the present opinion, F2 has been interpreted as if it did not further restrict the subject-matter of the claim.

2.3 The present application does not meet the criteria of Article 33(3) PCT, because the subject-matter of claim 1 (as far as it can be interpreted, see 2.2) does not involve an inventive step.

D1 may be regarded as being the prior art closest to the subject-matter of claim 1, and discloses a signal processing system (fig. 2) for signal processing in a bilateral hearing implant system having left side and right side hearing implants, the system for each hearing implant comprising: at least one sensing microphone (see citations below) configured for sensing a sound environment to develop a corresponding microphone signal output (fig. 2 ("left ear...", "right ear...") signals); a filter bank (fig. 2 ($BPF_{j,k}$)) configured for processing the microphone signal to generate a plurality of band pass signals (output of fig. 2 ($BPF_{j,k}$)), wherein each band pass signal represents an associated band of audio frequencies; a channel compression module (fig. 2 ("Rect/LPF" + "NonLin Map")) configured to develop an inhibition-adjusted band pass signal (output of fig. 2 ("NonLin Map")) for each band pass signal using a channel-specific dynamic inhibition adjustment based on a channel-normalized medial olivocochlear reflex model reflecting bandwidth energy for a corresponding contralateral band pass signal and bandwidth energy for a

selected reference contralateral band pass signal; and a module (transforming the output of fig. 2 ("NonLin Map") into the electrode signals fig. 2 ("Elec. j/k")) configured for processing the inhibition-adjusted band-pass signals to develop electrode stimulation signals for the hearing implant for perception as sound (D1, abstract; figures 1-4B; paragraph [0001] - paragraph [0002]; paragraph [0014] - paragraph [0018]; paragraph [0026] - paragraph [0046]).

The subject-matter of claim 1 therefore differs from this known system in that the module configured for processing the inhibition-adjusted band-pass signals to develop electrode stimulation signals comprises

- a pulse timing and coding module configured for processing the inhibition-adjusted band pass signals to develop stimulation timing signals; and
- a pulse generation module configured for processing the stimulation timing signals to develop the electrode stimulation signals.

In respect of the development of the electrode stimulation signals, D1 only provides a very schematic representation. In fact, fig. 2 merely depicts a "multiplier" with no details as to its function. The corresponding description is also silent to this effect. In other words, D1 lacks a detailed disclosure of how the disclosed electrode stimulation signals are created. The problem to be solved by the present invention may therefore be regarded as filling this gap in the disclosure of D1.

The solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT). This is because using a two-step structure as claimed is a possibility that would occur to the skilled person facing this problem. In turn, this is because such two-step structures are in wide use in cochlear implant technology. An example can be found in fig. 2 of D2 ("a typical cochlear implant signal processing system", [0008]), which includes this two-step structure (fig. 2 (203, 204)). Another example can be found in D3 (fig. 2 (205, 206)).

2.4 Dependent claims 2-7 (as far as they can be interpreted, see 2.2) do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step.

This is because, for each of these claims, the additional technical features provided in addition to those of claim 1 are already disclosed by D1 as well (see D1 citations above). In respect of claims 3-5, note is made of paragraphs [0037]-[0039] of D1. In respect of claim 6, note is made of paragraph [0041] of D1.

The subject-matter of each of these claims therefore differs from the disclosure of D1 in the two-step electrode stimulation signal development, which is an obvious development of the disclosure of D1 as discussed in 2.3 above.

3 **Re Item VII**

Certain defects in the international application

3.1 The features of claims 1-14 are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).