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/US2018/037688	15.06.2018	06.09.2017

International Patent Classification (IPC) or both national classification and IPC
INV. A61B90/14 A61N1/05 A61B90/10

Applicant
MEDTRONIC, INC.

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 P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Fax: +31 70 340 - 3016	see form PCT/ISA/210	Ioanovici, T Telephone No. +31 70 340-0

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2018/037688

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. 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	5, 6, 8, 9, 12, 16-19, 21
	No:	Claims	1-4, 7, 10, 11, 13-15, 20
Inventive step (IS)	Yes:	Claims	5, 6, 16, 17
	No:	Claims	1-4, 7-15, 18-21
Industrial applicability (IA)	Yes:	Claims	1-21
	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

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:

see separate sheet

1 **Re Item V**

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

Reference is made to the following documents:

D1 WO 2006/062892 A2 (IMAGE GUIDED NEUROLOGICS INC [US]; SKAKOON JAMES G [US]; SOLAR MATTHEW) 15 June 2006 (2006-06-15)

D2 US 7 004 948 B1 (PIANCA ANNE M [US] ET AL) 28 February 2006 (2006-02-28)

D3 EP 1 016 432 A2 (MEDTRONIC INC [US]) 5 July 2000 (2000-07-05)

D4 US 2010/161018 A1 (SAUTER-STARACE FABIEN [FR] ET AL) 24 June 2010 (2010-06-24)

D5 US 2005/182425 A1 (SCHULTE GREGORY T [US] ET AL) 18 August 2005 (2005-08-18)

D6 US 9 474 896 B2 (LOPEZ THOMAS P [US]; BOSTON SCIENT NEUROMODULATION CORP [US]) 25 October 2016 (2016-10-25)

1.1 The present application does not meet the criteria of Article 33(2) PCT, because the subject-matter of claims 1 and 13 is not new.

1.2 D1 discloses (abstract; page 12, line 4 - page 22, line 25; figures 17-41):

An implantable medical device (page 7 lines 4-13) comprising:
a burr cap assembly (1700) configured to be positioned at least partially within a burr hole in a cranium of a patient (page 7 lines 9-12), the burr cap assembly defining a cavity (center passage of hoop 1702) and being configured to enable implantation of at least a portion of an implantable medical elongate member (2200) into a brain of the patient through the burr cap assembly (page 13 lines 24-28), the burr cap assembly including a member (insert 1706) positioned within the cavity (fig.17-18) of the burr cap and defining at least one opening (1708) to enable passage of at least a

portion of the implantable medical elongate member into the brain of the patient (fig.18), the member (insert 1706) being configured to move within the cavity relative to the burr cap within at least one dimension of a plane that is substantially perpendicular to a longitudinal axis of at least a portion of the implantable medical elongate member (insert 1706 is rotated with respect to hoop 1702, page 12 lines 16-18; insert 1706 capable of being rotated about the instrument 2200, page 13 lines 28-29; the wording of the claim does not exclude a rotation in a plane perpendicular to the longitudinal axis).

1.3 Moreover also the cover (page 14 lines 9-12) and the implantable medical elongate member (wire electrode or other instrument 2200) claimed in claim 13 are disclosed in D1.

1.4 Furthermore also D2 (cap 58 is rotated relative to cavity 56, fig.8-9), D3 (piece 30 and plate 44 are rotated so that slits line up to permit placement of lead 32, para.[0013], fig.1-3) and D4 (securing part 32 is move by rotation-translation inside principal part, para.[0045],[0049]-[0050],fig.3) disclose all technical features of claim 1, and D2 (fig.9) and D3 (cap 52, fig.5) also disclose all technical features of claim 13.

1.5 Dependent claims 2-4, 7-12, 14-15 and 18-21 do not appear to contain any additional features which, in combination with the features of any claim to which it refers, meet the requirements of the PCT in respect of novelty and/or inventive step. The technical features of these claims are either disclosed in D1-D6 or are minor constructional detail changes. Some examples of the disclosed features can be seen below:

Claims 2,10,11,14,20: D2 fig. 8-9.

Claim 7: D1 fig. 27; D2 fig.8; D3 fig.1-3; D4 fig.1-4.

Claims 8,18: D1 insert 1706 is snap-fitted inside hoop 1702, fig.17-18.

2 **Re Item VII**

Certain defects in the international application

The present application does not meet the requirements of Rule 6.3(b) PCT regarding the use of the two-part form in claims, of Rule 6.2(b) PCT regarding reference signs, nor those of Rule 5.1(a)(ii) PCT regarding mentioning relevant prior art in the description.

3 **Re Item VIII**

Certain observations on the international application

Although claims 1 and 13 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.