Electrodes and Electrode Positioning Systems for Transvascular Neuromodulation

Abstract: Electrode systems for transvascular stimulation of target nerves include electrode arrays, elements promoting blood flow between electrode surfaces and surrounding vascular walls, electrodes shaped to promote more even current density than electrodes having angular edges, features for retaining the electrode systems with blood vessels, and features for using electrode-carrying elements to asymmetrically distend blood vessel walls towards target nerve structures.
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))

— with international search report (Art. 21(3))
A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61N 1/05 (2016.01)
CPC - A61N 1/05
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)
IPC (8) A61N 1/05 (2016.01)
CPC: A61N 1/05

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC (8) A61N 1/18 (2016.01)
CPC: A61N 1/18

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase; Google (Web, Scholar, Patents); search terms: neuromodulation therapy array plurality row column electrode vessel wall pair first second energize current electricity intravascular combination position bipolar anode cathode vasculature neural modulation electric field orthogonal normal perpendicular blood flow angular multiple stimul

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>US 2010/0036451 A1 (HOFFER); 11 February 2010 (11.02.2010); entire document, especially Abstract, paras. [0073], [0136]-[0137], [0141], [0144], [0146], [0148], Fig 7C-E, Fig. 7H.</td>
<td>1-5</td>
</tr>
<tr>
<td>A</td>
<td>US 2008/0004675 A1 (KING et al.); 3 January 2008 (03.01.2008); entire document.</td>
<td>1-5</td>
</tr>
<tr>
<td>A</td>
<td>US 2014/0124290 A1 (MASSON); 22 May 2014 (22.05.2014); entire document.</td>
<td>1-5</td>
</tr>
<tr>
<td>A</td>
<td>US 2012/0239109 A1 (LEE); 20 September 2012 (20.09.2012); entire document.</td>
<td>1-5</td>
</tr>
</tbody>
</table>

Further documents are listed in the continuation of Box C.

Date of actual completion of the international search:
12 January 2016 (12.01.2016)

Date of mailing of the international search report:
28 JAN 2016

Authorized officer:
Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)
INTERNATIONAL SEARCH REPORT

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.

<table>
<thead>
<tr>
<th>Group</th>
<th>Claims</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>1-5</td>
</tr>
<tr>
<td>II</td>
<td>6-8 and 14-18</td>
</tr>
</tbody>
</table>

- Group I: Claims 1-5 directed to a method of delivering neuromodulation therapy using an electrode array.
- Group II: Claims 6-8 and 14-18 directed to an intravascular electrode system comprising an elongate support or substrate configured for positioning in a target blood vessel and a plurality of electrodes positioned on a face of the support or substrate.
- Group III: Claim 9 directed to an intravascular electrode system, comprising a catheter member having a longitudinal axis, a plurality of longitudinally extending first struts on the catheter, and a rotatable strut having at least one electrode thereon.

---Continued in extra 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.: 1-5

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.

Form PCT/ISA/210 (continuation of first sheet (2)) (January 2015)
-Box No. Ill- Observations where unity of invention is lacking-

Group IV: Claims 10-13 directed to an intravascular electrode system, comprising a catheter member and a support on a distal portion of the catheter member.

Group V: Claims 19-22 directed to an intravascular electrode system comprising an electrode support including a plurality of longitudinally extending struts and electrodes carried on at least one of the struts.

The inventions listed as Groups I-V 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:

Special Technical Features

The invention of Group I includes the special technical feature of an electrode array including first and second columns of electrodes not required by the claims in Groups II-V.

The invention of Group II includes the special technical features of a plurality of electrodes positioned on a face of the support or substrate, not required by the claims of in Groups I and III-V.

The invention of Group III includes the special technical feature of a rotatable strut not required by the claims in Groups I, II, IV, and V.

The invention of Group IV includes the special technical features of a support on a distal portion of a catheter member not required by the claims in Groups I-III and V.

The invention of Group V includes the special technical feature of an electrode support not required by the claims in Groups I-IV.

Common Technical Features

The invention of Group I shares no technical features with Groups II-V.

The invention of Group II shares no technical features with Groups I and III-V.

The inventions of Groups III and IV share the technical features of an intravascular electrode system comprising a catheter member. However, this shared technical feature is known in the prior art as shown in US 2014/0142590 A1 to Masson, which teaches an intravascular electrode system comprising a catheter member (neurocatheter 10 is an intravascular electrode catheter, Fig. 2 and para. [0006]).

The inventions of Groups IV and V share the technical features of an intravascular electrode system comprising a member having a plurality of longitudinally extending struts, and at least one electrode carried on the struts. However, this shared technical feature is known in the prior art as shown in US 2014/0142590 A1 to Masson, which teaches an intravascular electrode system comprising a member having a plurality of longitudinally extending struts (neurocatheter 10 has a plurality of longitudinally extending support elements 18 making up a support structure 12, Fig. 5 and para. [0045]), and at least one electrode carried on the struts (an electrode array is mounted to a subset of the longitudinally-extending support elements 18, para. [0045]).

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-V lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.