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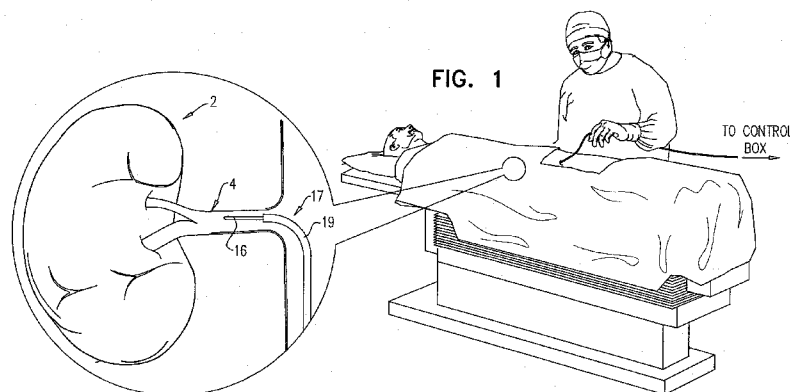
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18 June 2015

(54) Title: TISSUE TREATMENT AND MONITORING BY APPLICATION OF ENERGY



(57) Abstract: Apparatus is provided, which includes at least one ultrasound transducer. The ultrasound transducer is configured to be positioned within a lumen of a subject and to ablate tissue surrounding a wall of the lumen without ablating the wall of the lumen, by focusing ultrasound energy on a focal zone that is outside of the wall of the lumen. A transluminal delivery tool is configured to position the ultrasound transducer in the lumen, and a control unit is configured to drive the ultrasound transducer. Other embodiments are also described.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL2012/000100

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 18/04 (2012.01)

USPC - 606/27

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) - A61B 5/0408, 8/00, 17/39, 18/04; A61H 1/00; A61N 1/05 (2012.01)

USPC - 600/381, 393, 439; 601/2; 606/27, 41; 607/99, 122

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatBase, Google Patents, Google Scholar

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|------------------------------------------------------------------------------------|-----------------------|
| X         | US 2004/0162550 A1 (GOVARI et al) 19 August 2004 (19.08.2004) entire document      | 1, 7-8, 19-23, 27     |
| -         |                                                                                    |                       |
| Y         |                                                                                    | 2-6                   |
| Y         | US 2006/0058711 A1 (HARHEN et al) 16 March 2006 (16.03.2006) entire document       | 2-6                   |
| A         | US 2004/0162507 A1 (GOVARI) 19 August 2004 (19.08.2004) entire document            | 1-67, 71-79, 143, 144 |
| A         | US 2006/0009753 A1 (FJELD et al) 12 January 2006 (12.01.2006) entire document      | 1-67, 71-79, 143, 144 |
| A         | US 2006/0241523 A1 (SINELNIKOV et al) 26 October 2006 (26.10.2006) entire document | 1-67, 71-79, 143, 144 |
| A         | US 6,064,902 A1 (HAISSAGUERRE et al) 16 May 2000 (16.05.2000) entire document      | 1-67, 71-79, 143, 144 |

☐ 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

06 September 2012

Date of mailing of the international search report

17 SEP 2012

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# INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL2012/000100

## 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:

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.:  
claims 1-67, 71-79, 143, and 144

### 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.

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

International application No.

PCT/IL2012/000100

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 1-67, 71-79, 143, and 144 drawn to at least one ultrasound transducer, the ultrasound transducer configured to be positioned within a lumen of a subject and to ablate tissue surrounding a wall of the lumen without ablating the wall of the lumen, by focusing ultrasound energy on a focal zone that is outside of the wall of the lumen.

Group II, claims 68-70, drawn to a treatment device having a longitudinal axis and configured to be positioned within a lumen of a body and transfer energy into or out of tissue that surrounds the lumen.

Group III, claims 80-83, drawn to an ultrasound transducer shaped to define a three-dimensional shape, the ultrasound transducer comprising: an acoustic element comprising a flexible material and configured to apply ultrasound energy, and a layer of acoustic backing coupled to the acoustic element, the acoustic backing comprising a gas and configured to shape the ultrasound transducer into the three-dimensional shape.

Group IV, claims 84-120 and 130-133, drawn to an ultrasound ablation system, which comprises: a reflection-facilitation element, configured to provide a reflective region that is outside a lumen of a subject.

Group V, claims 121 and 134, drawn to at least one ultrasound transducer configured to be advanced through a lumen of a subject, and configured to: during a first time period, apply focused ultrasound energy to a region that is outside the lumen, to generate gas bubbles within the region to provide a reflective region, and during a second time period, apply focused ultrasound energy to tissue, such that at least a portion of the transmitted energy is reflected by the reflective region onto the tissue.

Group VI, claims 122-129, drawn to an inflatable element configured to be inflated within a lumen of a subject; and at least one ultrasound transducer configured to be placed within the inflatable element, and to apply ultrasound energy to tissue of the lumen.

Group VII, claim 135, drawn to at least one ultrasound transducer, the ultrasound transducer configured to be positioned within a lumen of a subject and to heat tissue of a far side of a wall surrounding the lumen while beating to a lesser extent a near side of the wall of the lumen.

Group VIII, claims 136-142, drawn to an intravascular ultrasound transducer, configured to be placed in a renal artery of a subject; and a control unit, configured to: drive the ultrasound transducer to generate a first transmitted signal and to receive a first reflected signal in response thereto, drive the ultrasound transducer to generate a treatment signal, configured to heat a renal nerve of the subject, drive the ultrasound transducer to generate a second transmitted signal and to receive a second reflected signal in response thereto.

The inventions listed as Groups I-VIII 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 special technical feature of the Group I invention: at least one ultrasound transducer, the ultrasound transducer configured to be positioned within a lumen of a subject and to ablate tissue surrounding a wall of the lumen without ablating the wall of the lumen, as claimed therein is not present in the invention of Groups II-VIII. The special technical feature of the Group II invention: a treatment device having a longitudinal axis and configured to be positioned within a lumen of a body and transfer energy into or out of tissue that surrounds the lumen, as claimed therein is not present in the invention of Groups I, III-VIII. The special technical feature of the Group III invention: an ultrasound transducer shaped to define a three-dimensional shape, the ultrasound transducer comprising: an acoustic element comprising a flexible material and configured to apply ultrasound energy, and a layer of acoustic backing coupled to the acoustic element, the acoustic backing comprising a gas and configured to shape the ultrasound transducer into the three-dimensional shape, as claimed therein is not present in the invention of Groups I, II, IV-VIII. The special technical feature of the Group IV invention: an ultrasound ablation system, which comprises: a reflection-facilitation element, configured to provide a reflective region that is outside a lumen of a subject, as claimed therein is not present in the invention of Groups I, II, III or V-VIII. The special technical feature of the Group V invention: at least one ultrasound transducer configured to be advanced through a lumen of a subject, and configured to: during a first time period, apply focused ultrasound energy to a region that is outside the lumen, to generate gas bubbles within the region to provide a reflective region, and during a second time period, apply focused ultrasound energy to tissue, such that at least a portion of the transmitted energy is reflected by the reflective region onto the tissue, as claimed therein is not present in the invention of Groups I-IV, VI-VIII. The special technical feature of the Group VI invention: an inflatable element configured to be inflated within a lumen of a subject; and at least one ultrasound transducer configured to be placed within the inflatable element, and to apply ultrasound energy to tissue of the lumen, as claimed therein is not present in the invention of Groups I-V, VII-VIII. The special technical feature of the Group VII invention: at least one ultrasound transducer, the ultrasound transducer configured to be positioned within a lumen of a subject and to heat tissue of a far side of a wall surrounding the lumen while beating to a lesser extent a near side of the wall of the lumen, as claimed therein is not present in the invention of Groups I-VI or VIII. The special technical feature of the Group VIII invention: an intravascular ultrasound transducer, configured to be placed in a renal artery of a subject; and a control unit, configured to: drive the ultrasound transducer to generate a first transmitted signal and to receive a first reflected signal in response thereto, drive the ultrasound transducer to generate a treatment signal, configured to heat a renal nerve of the subject, drive the ultrasound transducer to generate a second transmitted signal and to receive a second reflected signal in response thereto, as claimed therein is not present in the invention of Groups I-VII.

Since none of the special technical features of the Group I, II, III, IV, V, VI, VII or VIII inventions are found in more than one of the inventions, unity of invention is lacking.