A vapor delivery needle and method is provided that is adapted for treating prostate cancer. The energy delivery probe can apply condensable vapor energy to tissue, such as a peripheral zone tissue in a human prostate. In one method, a needle is introduced into peripheral zone tissue of a human prostate, and vapor media is delivered through the needle to ablate peripheral zone tissue without ablating non-peripheral zone tissue. Systems for treating prostate cancer with vapor therapy are also provided.
INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 14/28985

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8): A61B 8/14; A61F 7/12; A61N 7/00 (2014.01)
USPC: 600/412, 438, 439, 474, 549, 601/2, 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 8/14; A61F 7/12; A61N 7/00 (2014.01)
USPC: 600/412, 438, 439, 474, 549, 601/2, 27; CPC: A61B 5/055, 8/485; A61N 7/00

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)

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 2010/0179416 A1 (HOEY, M et al.) July 15, 2010; figure 1; paragraphs [0031]-[0036], [0045], [0049]</td>
<td>33, 37-38</td>
</tr>
<tr>
<td></td>
<td></td>
<td>34-36, 39</td>
</tr>
<tr>
<td>Y</td>
<td>US 2012/01 16376 A1 (HOEY, M et al.) May 10, 2012; abstract; figure 21; paragraphs [0013], [0027], [0084], [0089], [0091], [0094], [0112], [0117], [0119],[0121] claims 1, 7</td>
<td>1-21, 28-32</td>
</tr>
<tr>
<td>Y</td>
<td>NGUYEN, PL, Updated Results of Magnetic Resonance Imaging Guided Partial Prostate Brachytherapy for Favorable Risk Prostate Cancer: Implications for Focal Therapy. The Journal of Urology. October 2012; vol. 188, page 1511; paragraph 2; page 1152, paragraph 4</td>
<td>1-22, 28-32</td>
</tr>
<tr>
<td>Y</td>
<td>US 2010/0292767 A1 (HOEY, M et al.) November 18, 2010; paragraphs [0049], [0053], [0056], [0060], [0068]</td>
<td>17, 22</td>
</tr>
<tr>
<td>Y</td>
<td>US 5807395 A (MULIER, PMJ et al.) September 15, 1998; column 8, lines 44-64; column 18, lines 25-40</td>
<td>29</td>
</tr>
</tbody>
</table>

[* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"B" 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 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 novel or 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
"*" document member of the same patent family

Date of the actual completion of the international search 05 September 2014 (05.09.2014)

Date of mailing of the international search report 20 OCT 2014

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
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Facsimile No. 571-273-3201

Authorized officer: Shane Thomas
PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

Form PCT/ISA/2 10 (second sheet) (July 2009)
**INTERNATIONAL SEARCH REPORT**

**Box No. 11**  
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 64(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 1-22 and 28-39 are directed toward a method for treating abnormal prostate tissue, comprising: delivering condensable vapor through the needle to ablate peripheral zone tissue without ablating non-peripheral zone tissue.*

*Group II: Claims 23-24 are directed toward a method for treating prostate cancer, comprising: wherein the vapor is configured to deliver between 300 and 1000 calories to the peripheral zone lobe to thereby ablate malignant tissue.*

*Group III: Claims 25-27 are directed toward a method for treating prostate cancer, comprising: delivering vapor into the peripheral zone lobe, wherein the vapor is configured to deliver less than 150 calories to a site.*

"-Continued Within the Next Supplemental Box-***".

1. □ A s all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. □ A s all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. □ A s 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.:  
   1-22, 28-39

**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)) (July 2009)
The inventions listed as Groups I-III 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 features of Group I include delivering vapor through the needle at pressure and flow parameters that result in the condensable vapor being reflected by barrier tissue surrounding the peripheral zone lobe to thereby ablate the peripheral zone lobe without ablating non-peripheral zone tissue, which are not present in Groups II-III; the special technical features of Group II include wherein the vapor is configured to deliver between 300 and 1000 calories to the peripheral zone lobe to thereby ablate malignant tissue, which are not present in Groups I and III; the special technical features of Group III include delivering vapor into the peripheral zone lobe, wherein the vapor is configured to deliver less than 150 calories to a site in the peripheral zone lobe to thereby cause focal ablation of malignant tissue in the peripheral zone lobe, which are not present in Groups I-II.

The common technical features of Groups I-III are a method for treating abnormal prostate tissue / a prostate cancer therapy system, comprising: a vapor delivery needle configured to be inserted into a peripheral zone of a prostate to deliver vapor to the peripheral zone to treat prostate cancer.

These common technical features are disclosed by US 2012/01 16376 A1 to Hoey, et al. (hereinafter ‘Hoey’). Hoey discloses a method for treating abnormal prostate tissue / a prostate cancer therapy system (method for treating benign prostatic hyperplasia of a prostate of a patient; claim 1), comprising: a vapor delivery needle configured to be inserted into a peripheral zone of a prostate to deliver vapor to the peripheral zone to treat prostate cancer (inserting a vapor delivery needle through a urethral wall of the patient in a plurality of locations into a prostate lobe; the prostate glandular structure can be classified into three zones: the peripheral zone, transition zone, and central zone; claim 1).

Since the common technical features are previously disclosed by the Hoey reference, the common features are not special and so Groups I-III lack unity.