PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant’s or agent’s file reference

FOR FURTHER ACTION

See Form PCT/PEA/416

International application No.
PCT/PL2016/000006

International filing date (day/month/year) 21.01.2016

Priority date (day/month/year) 22.01.2015

International Patent Classification (IPC) or national classification and IPC

INV. A61B10/02

Applicant
Sieczkowski, Marcin

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPPOINT consists of a total of 2 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☑ (sent to the applicant and to the International Bureau) a total of 2 sheets, as follows:

      ☑ sheets of the description, claims and drawings which have been amended and/or sheets containing
      rectifications authorized by this Authority, unless those sheets were superseded or cancelled, and any
      accompanying letters (see Rules 46.5, 66.8, 70.16, 91.2, and Section 607 of the Administrative
      Instructions).

      ☐ sheets containing rectifications, where the decision was made by this Authority not to take them into account
      because they were not authorized by or notified to this Authority at the time when this Authority began to
      draw up this report, and any accompanying letters (Rules 66.4bis, 70.2(e), 70.16 and 91.2).

      ☐ superseded sheets and any accompanying letters, where this Authority either considers that the
      superseding sheets contain an amendment that goes beyond the disclosure in the international application
      as filed, or the superseding sheets were not accompanied by a letter indicating the basis for the
      amendments in the application as filed, as indicated in item 4 of Box No. 1 and the Supplemental Box (see
      Rule 70.16(b)).

   b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) copies of
      a sequence listing, in the form of an Annex CST.25 text file, as indicated in the Supplemental Box Relating to
      Sequence Listing (see paragraph 3ter of Annex C of the Administrative Instructions).

4. This report contains indications relating to the following items:

   ☑ Box No. I Basis of the report
   ☐ 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 Article 35(2) with regard to novelty, inventive step or 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

Date of submission of the demand
17.11.2016

Date of completion of this report
26.04.2017

Name and mailing address of the international preliminary examining authority:
European Patent Office
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Tel. +49 89 2399 - 0
Fax: +49 89 2399 - 4465

Authorized officer
Hochrein, Marion
Telephone No. +49 89 2399-5720
Box No. 1  Basis of the report

1. With regard to the language, this report is based on
   ☒ 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 (under Rules 12.3(a) and 23.1(b))
     ☐ publication of the international application (under Rule 12.4(a))
     ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a) and (b))

2. With regard to the elements* of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):

Description, Pages
2-15 as originally filed
1 filed with the letter of 02-02-2017

Claims, Numbers
1-13 filed with the letter of 02-02-2017

Drawings, Sheets
1/15-15/15 as originally filed

☐ a sequence listing - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:
   ☐ the description, pages
   ☐ the claims, Nos.
   ☐ the drawings, sheets/figs
   ☐ the sequence listing (specify):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since either they are considered to go beyond the disclosure as filed, or they were not accompanied by a letter indicating the basis for the amendments in the application as filed, as indicated in the Supplemental Box (Rules 70.2(c) and (c-bis)):
   ☐ the description, pages
   ☐ the claims, Nos.
   ☐ the drawings, sheets/figs
   ☐ the sequence listing (specify):

5. ☐ This report has been established:
   ☐ taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rules 66.1(d-bis) and 70.2(e)).
   ☐ without taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91(Rules 66.4bis and 70.2(e)).

Form PCT/IPEA/409 (January 2015)
6. ☑ With regard to top-up searches (Rules 66.1ter and 70.2(f)):
   ☑ A top-up search was carried out by this Authority on 07.04.2017 (all discovered documents are listed in the Supplemental Box Relating to Top-up Search).
   ☐ Additional relevant documents have been discovered during the top-up search.
   ☐ No top-up search was carried out by this Authority because it would serve no useful purpose.

7. ☐ Supplementary international search report(s) from Authority(ies) has have been received and taken into account in establishing this report (Rule 45bis.8(b) and (c)).

* If item 4 applies, some or all of those sheets may be marked "superseded".

<table>
<thead>
<tr>
<th>Box No. III</th>
<th>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. 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:</td>
<td></td>
</tr>
<tr>
<td>☐ the entire international application,</td>
<td></td>
</tr>
<tr>
<td>☑ claims Nos. 10-13</td>
<td></td>
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<tr>
<td>because:</td>
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<tr>
<td>☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):</td>
<td></td>
</tr>
<tr>
<td>☐ the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify):</td>
<td></td>
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<tr>
<td>☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (specify).</td>
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<tr>
<td>☑ no international search report has been established for the said claims Nos. 10-13</td>
<td></td>
</tr>
<tr>
<td>☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:</td>
<td></td>
</tr>
<tr>
<td>☐ furnish a sequence listing in the form of an Annex CST.25 text file, and such listing was not available to the International Preliminary Examining 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.</td>
<td></td>
</tr>
<tr>
<td>☐ 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 Preliminary Examining 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.</td>
<td></td>
</tr>
<tr>
<td>☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b) and 13ter.2.</td>
<td></td>
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<tr>
<td>☑ See separate sheet for further details</td>
<td></td>
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</tbody>
</table>
Box No. V  Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)  
Yes: Claims  1-10  
No: Claims

Inventive step (IS)  
Yes: Claims  1-10  
No: Claims

Industrial applicability (IA)  
Yes: Claims  1-10  
No: Claims

2. Citations and explanations (Rule 70.7):

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
Re Item III

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

1 The application does not meet the requirements of unity of invention. There are two inventions covered by the claims as follows:

1) Claims 1-9: prostrate biopsy needle with an antibiotic coating of the surface;

2) Claims 10-12: prostrate biopsy needle with a second channel along the cannula.

The reasons for which the inventions are not so linked as to form a single general inventive concept as required by Rule 13.1 PCT are as described in the written opinion of the international searching authority, see Re Item IV.

No further search fee was paid by the applicant, so there will be no examination of the second invention covering claims 10-12.

Re Item V

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

2 Reference is made to the following documents:


3 The present application meets the criteria of Article 33(1) PCT, because the subject-matter of claim 1 involves an inventive step in the sense of Article 33(3) PCT. D6 is regarded as being the prior art closest to the subject-matter of claim 1, and discloses: Prostate biopsy needle comprising a cannula (2); a pointed stylet (2a), which is mounted slidably in the cannula; handles (9a, 9b) for a biopsy gun, which are located on the back side of the needle. The subject-matter of claim 1 therefore differs from this known prostate biopsy needle in that an outer surface of the cannula and/or a surface of the stylet is coated with at least one active layer comprising an antibacterial substance, wherein the active layer forms a biodegradable structure enabling controlled release of the antibacterial substance. The problem to be solved by the present invention may therefore be regarded as how to avoid infection during the biopsy procedure. Some of these features have already been employed for the same purpose in a similar biopsy device (see D2: par. 49; par. 21-25). However, even if the person skilled in the art were to combine D6 with D2, the person would not arrive at the subject-matter of claim 1 since D2 is silent about the exact location of the "release layer" on the biopsy device. Therefore, the solution proposed in claim 1 of the present application is considered to involve an inventive step (Article 33(3) PCT).

4 The claims 2-10 which depend on claim 1 are novel and inventive as well for the same reason as outlined for claim 1.

Re Item VII

Certain defects in the international application

5 The closest prior art next to D6, D2, is not cited in the description (Rule 5.1(a) (ii)PCT).

Re Item VIII
Certain observations on the international application

6 In claim 1, l. 4, the feature "the surface of the stylet" has no precedent and leads to lack of clarity of the claim (Article 6 PCT). It is understood to mean "a surface of the stylet".