


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			
<p>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.</p> <p>2. This REPORT consists of a total of <u>7</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>7</u> sheets, as follows:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> sheets of the description, claims and/or 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which have been amended and/or sheets containing rectifications authorized by this Authority, unless those sheets were superseded or cancelled, and any accompanying letters (see Rules 46.5, 66.8, 70.16, 91.2, and Section 607 of the Administrative Instructions). <input type="checkbox"/> 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). <input type="checkbox"/> superseded sheets and any accompanying letters, where this Authority either considers that the superseding sheets contain an amendment that goes beyond the disclosure in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. I and the Supplemental Box (see Rule 70.16(b)). <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing, in the form of an Annex C/ST.25 text file, as indicated in the Supplemental Box Relating to Sequence Listing (see paragraph 3ter of Annex C of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input checked="" type="checkbox"/> Box No. VII Certain defects in the international application <input checked="" type="checkbox"/> 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 D-80298 Munich Tel. +49 89 2399 - 0 Fax: +49 89 2399 - 4465	Authorized officer Hochrein, Marion Telephone No. +49 89 2399-5720		



Box No. I 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
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Drawings, Sheets

1/15-15/15	as originally filed	
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- 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)).

6. With regard to top-up searches (Rules 66.1 *ter* 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".

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

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:
- the entire international application,
 - claims Nos. 10-13
- because:
- the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
 - the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
 - the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*).
 - no international search report has been established for the said claims Nos. 10-13
 - a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
 - furnish a sequence listing in the form of an Annex C/ST.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.
 - 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.
 - pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.
 - See separate sheet for further details

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	<u>1-10</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	<u>1-10</u>
	No: Claims	
Industrial applicability (IA)	Yes: Claims	<u>1-10</u>
	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:

D1 US 2010/130850 A1 (PAKTER ROBERT L [US]) 27 May 2010 (2010-05-27)

D2 US 2003/236513 A1 (SCHWARZ MARLENE C [US] ET AL) 25 December 2003 (2003-12-25)

D3 WO 2014/014336 A1 (UNIVERSITI MALAYA UM [MY]) 23 January 2014 (2014-01-23)

D4 US 2004/022864 A1 (FREYMAN TOBY [US] ET AL) 5 February 2004 (2004-02-05)

D5 US 2012/059247 A1 (SPEEG TREVOR W V [US] ET AL) 8 March 2012 (2012-03-08)

D6 US 5 014 717 A (LOHRMANN GUENTER [DE]) 14 May 1991 (1991-05-14)

- 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".