PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing *(day/month/year)* **29 March 2018 (29.03.2018)**

Applicant's or agent's file reference
ISRG09000PCT

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2017/065162	**07 December 2017 (07.12.2017)**	08 December 2016 (08.12.2016)

International Patent Classification (IPC) or both national classification and IPC
A61B 34/20(2016.01)i, A61B 6/03(2006.01)i, A61B 90/00(2016.01)i

Applicant
INTUITIVE SURGICAL OPERATIONS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ 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 Rule 43bis.1(a)(i) with regard to novelty, inventive step and 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

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.
For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/KR	Date of completion of this opinion	Authorized officer
International Application Division Korean Intellectual Property Office 189 Cheongsa-ro, Seo-gu, Daejeon, 35208, Republic of Korea Facsimile No. +82-42-481-8578	29 March 2018 (29.03.2018)	JANG, Gijeong Telephone No. +82-42-481-8364

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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of :

   ☒ 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 (Rules 12.3(a) and 23.1(b))

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:
      ☐ in the form of an Annex C/ST.25 text file.
      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:
      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).
      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

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

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. 16

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international search *(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 said claims Nos. 16

☐ 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 Searching 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 Searching 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 Rule 13*ter*.1(a) or (b).

☐ See Supplemental Box for further details.

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-15,17-38	YES
	Claims	NONE	NO
Inventive step (IS)	Claims	NONE	YES
	Claims	1-15,17-38	NO
Industrial applicability (IA)	Claims	1-15,17-38	YES
	Claims	NONE	NO

2. Citations and explanations :

2.1 Reference is made to the following documents:

D1: US 2014-0282216 A1 (COVIDIEN LP) 18 September 2014

D2: US 2016-0000302 A1 (COVIDIEN LP) 07 January 2016

2.2 Novelty and Inventive Step

*NOTE:

(1) the phrase, "The method of claim 20 wherein" in claims 21 and 22, is considered to be "The method of claim 20, wherein".

(2) the phrase, "The method of claim 20 determining" in claim 23, is considered to be "The method of claim 20, further comprising: determining".

(3) the phrase, "The system of claim 28 or 29 wherein" in claim 31, is considered to be "The system of claim 28 or 29, wherein".

(4) the phrase, "generating a display a portion" in claim 28, is considered to be "displaying a portion".

(5) the phrase, "the generated pathway" in claim 37, is considered to be "a generated pathway".

The subject-matter of claim 1 relates to a method comprising: receiving, by a medical imaging system having at least one processing device, three-dimensional image data of a patient anatomy; filtering the three-dimensional data to display a portion of the three-dimensional image data that is associated with the patient anatomy; receiving, at the processing device, input from an operator input device, the input comprising navigational directions for virtual movement within a space defined by the three-dimensional image data; tracking the virtual movement; and generating a first model of the patient anatomy based to the tracked virtual movement. D1, which is considered to be the closest prior art to the subject-matter of claim 1, discloses a method for planning a pathway through an anatomical luminal network of a patient, the method

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claim 16 does not comply with PCT Rule 6.4(a) because multiple dependent claims should not serve as a basis for any other multiple dependent claim.

Supplemental Box

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comprising the steps of: importing CT image data of a patient selected by a user input; generating a three-dimensional CT volume from the CT image data; receiving an input from a user indicating a location for a new waypoint in an airway of a rotated slice; and setting a first waypoint in the identified airway and generating a first pathway from the target to the first waypoint (see claim 13). The subject-matter of claim 1 differs from D1 in tracking the virtual movement; and generating the first model of the patient anatomy based to the tracked virtual movement. However, this feature would be easily modified or optimized from the disclosure of D1 considering that an user interface generates a line in virtual window which represents the created pathway, wherein the clinician follows the line from an entry point through a trachea and through an airways of a patient's bronchial tree until the line reaches the target (see paragraph [0087]). Accordingly, claim 1 would have been obvious over D1. Therefore, claim 1 is novel under PCT Article 33(2) but does not involve an inventive step under PCT Article 33(3).

The additional features of claims 2-4, relating to the first model of the patient anatomy, are not disclosed in D1. However, these features would be easily conceived from the user interface which generates a line in virtual window which represents the created pathway of D1 (see paragraph [0087]; figure 13). Accordingly, claims 2-4 would have been obvious over D1. Therefore, claims 2-4 are novel under PCT Article 33(2) but do not involve an inventive step under PCT Article 33(3).

The additional features of claims 5-9, relating to filtering the CT image data, are not disclosed in D1. However, these features would be easily conceived from the at least one processor which is configured to generate a three-dimensional model of the patient's bronchial tree from the CT image data selected by the user for displaying on the display of D1 (see claim 4). Accordingly, claims 5-9 would have been obvious over D1. Therefore, claims 5-9 are novel under PCT Article 33(2) but do not involve an inventive step under PCT Article 33(3).

The additional feature of claim 10, relating to receiving input from the operator input device to filter the three-dimensional image data based on a radiodensity value associated with each voxel in the three-dimensional image data, is not disclosed in D1. However, the feature would be merely a design option when the general knowledge in relevant field of the art is used. Accordingly, claim 10 would have been obvious over D1. Therefore, claim 10 is novel under PCT Article 33(2) but does not involve an inventive step under PCT Article 33(3).

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The additional feature of claim 11 relates to the method comprising identifying a target in the three-dimensional image data. However, D1 discloses a target selection element configured to select the target from a displayed slice of CT image data in response to a user input (see claim 5). Accordingly, claim 11 would have been obvious over D1. Therefore, claim 11 is novel under PCT Article 33(2) but does not involve an inventive step under PCT Article 33(3).

The additional feature of claim 12, relating to determining a vector extending between a viewpoint of the three-dimensional image data in space and the target; and rendering a user interface element representing the vector on a display displaying a rendering of the three-dimensional image data to provide navigational guidance, is not disclosed in D1. However, the feature would be merely a design option when the general knowledge in relevant field of the art is used. Accordingly, claim 12 would have been obvious over D1. Therefore, claim 12 is novel under PCT Article 33(2) but does not involve an inventive step under PCT Article 33(3).

The additional features of claims 13 and 14, relating to determining and indicating of a first subset of modeled passageways, are not disclosed in D1. However, these features would be easily conceived from receiving an input from a user indicating a location for a new waypoint in an airway of the rotated slice; setting a first waypoint in the identified airway; and generating a first pathway from the target to the first waypoint of D1 (see claim 13). Accordingly, claims 13 and 14 would have been obvious over D1. Therefore, claims 13 and 14 are novel under PCT Article 33(2) but do not involve an inventive step under PCT Article 33(3).

The additional feature of claim 15, relating to blocking virtual navigation beyond a location in the three-dimensional image data associated with the rendered first user interface element, is not disclosed in D1. However, this feature would be easily modified or optimized from the disclosure of D1 considering determining if the first waypoint is located in a known airway of the three-dimensional CT volume; and automatically completing a pathway from the first waypoint to the entry point if the first waypoint is located in a known airway (see claim 14). Accordingly, claim 15 would have been obvious over D1. Therefore, claim 15 is novel under PCT Article 33(2) but does not involve an inventive step under PCT Article 33(3).

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The additional feature of claim 17 relates to the method comprising segmenting the three-dimensional image data to generate a second model of a first portion of an anatomical passageway, wherein generating the first model is further based on the tracked virtual movement within a second portion of the anatomical passageway; and combining the first model with the second model to generate a combined model that includes the first and second portions of the anatomical passageway. However, D1 discloses receiving an input from a user indicating a location for a new waypoint in an airway of the rotated slice; setting a second waypoint in the identified airway; and generating a second pathway from the first waypoint to the second waypoint (see claim 15). Accordingly, claim 17 would have been obvious over D1. Therefore, claim 17 is novel under PCT Article 33(2) but does not involve an inventive step under PCT Article 33(3).

The additional feature of claim 18, relating to the first model and the second model comprising a surface model or a line model, is not disclosed in D1. However, this feature would be easily conceived from the user interface which generates a line in virtual window which represents the created pathway of D1 (see paragraph [0087]; figure 13). Accordingly, claim 18 would have been obvious over D1. Therefore, claim 18 is novel under PCT Article 33(2) but does not involve an inventive step under PCT Article 33(3).

The additional feature of claim 19, relating to selectively rendering in a display the first model; a filtered portion of the three-dimensional image data; or both the first model and the portion of the three-dimensional image data, is not disclosed in D1. However, the feature would be merely a design option when the general knowledge in relevant field of the art is used. Accordingly, claim 19 would have been obvious over D1. Therefore, claim 19 is novel under PCT Article 33(2) but does not involve an inventive step under PCT Article 33(3).

The subject-matter of claim 20 relates to a method comprising: receiving, by a medical imaging system having at least one processing device, three-dimensional image data of a patient anatomy; segmenting the three-dimension image data to generate an anatomical model from the three-dimensional image data; receiving, at the processing device, input from an operator input device, the input defining a pathway model within an image space defined by the three-dimension image data and associated with an anatomical passageway of the patient anatomy; and generating a hybrid model of the patient anatomy from the pathway model and from the anatomical model. But it has the same technical features as those of claim 1. Thus,

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the same reasoning as in claim 1 applies to claim 20. Accordingly, claim 20 would have been obvious over D1. Therefore, claim 20 is novel under PCT Article 33(2) but does not involve an inventive step under PCT Article 33(3).

The additional features of claims 21 and 22, relating to the anatomical model which is a line model or a surface model, are not disclosed in D1. However, the features would be merely design options when the general knowledge in relevant field of the art is used. Accordingly, claims 21 and 22 would have been obvious over D1. Therefore, claims 21 and 22 are novel under PCT Article 33(2) but do not involve an inventive step under PCT Article 33(3).

The additional feature of claim 23 relates to determining a termination point of the anatomical model wherein the pathway model is defined beginning from the termination point. However, D1 discloses generating a first pathway from the target to the first waypoint (see claim 13). Accordingly, claim 23 would have been obvious over D1. Therefore, claim 23 is novel under PCT Article 33(2) but does not involve an inventive step under PCT Article 33(3).

The subject-matter of claim 24 relates to a method of facilitating an image-guided medical procedure, the method comprising: receiving, by a teleoperational medical system having at least one processing device, three-dimensional image data of at least a portion of patient anatomy; registering a medical instrument coupled to the teleoperational medical system with the three dimensional data by registering the medical instrument to a surgical environment and registering the three-dimensional image data with the surgical environment; applying a radiodensity filter to the three-dimensional image data to alter a rendering of one or more voxels of the three-dimension image data; and rendering the three-dimensional image data in a display from a perspective associated with the medical instrument. But it has the same technical features as those of claim 1 except for rendering the three-dimensional image data in a display from a perspective associated with the medical instrument (difference 1). Thus, the same reasoning as in claim 1 applies to claim 24. Also, difference 1 would be easily modified or optimized from the disclosure of D2 considering that at least one of the 3D map dynamic view or the local view includes a virtual representation of the distal tip of the probe, the virtual representation configured to provide the user with an indication of an orientation of the distal tip of the probe (see claim 8). Although D1 and D2 do not individually disclose the difference, when they are combined, it is easily derived by a person skilled in the art. Accordingly, the additional feature of claim 24 would be obvious over D1 in view of D2. Therefore, claim 24

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is novel under PCT Article 33(2) but does not involve an inventive step under PCT Article 33(3).

The additional features of claims 25-27, relating to applying the radiodensity filter (claim 25), assigning voxels in the three-dimensional image data (claim 26), and applying the transparent setting to the voxels assigned to the selected tissue type (claim 27), are not disclosed in D1 and D2. However, the features would be merely design options when the general knowledge in relevant field of the art is used. Accordingly, claims 25-27 would have been obvious over D1 in view of D2. Therefore, claims 25-27 are novel under PCT Article 33(2) but do not involve an inventive step under PCT Article 33(3).

The subject-matter of claim 28 relates to a system for processing medical images, the system comprising: a memory storing a set of three-dimensional image data of at least a portion of patient anatomy; a processing device in communication with the memory, the processing device configured to execute instructions to perform operations comprising: receiving three-dimensional image data of a patient anatomy; filtering the three-dimensional image data; displaying a portion of the three-dimensional image data associated with the patient anatomy; receiving input from an operator input device, the input comprising navigational directions for virtual movement within an image space defined by the portion of the three-dimensional image data; tracking the virtual movement; and generating a model of the patient anatomy based on the tracked virtual movement. But it has the same technical features as those of claim 1. Thus, the same reasoning as in claim 1 applies to claim 28. Accordingly, claim 28 would have been obvious over D1. Therefore, claim 28 is novel under PCT Article 33(2) but does not involve an inventive step under PCT Article 33(3).

The additional feature of claim 29 relates to receiving the input from the operator input device comprising receiving a first input associated with virtual movement in a first perspective of the three-dimensional image data; receiving a second input associated with virtual movement in a second perspective of the three-dimensional image data; and combining the first and second inputs associated with the first and second perspectives to generate the model. However, D1 discloses receiving an input from a user indicating a location for a new waypoint in an airway of the rotated slice; setting a second waypoint in the identified airway; and generating a second pathway from the first waypoint to the second waypoint (see claim 19). Accordingly, claim 29 would have been obvious over D1. Therefore, claim 29 is novel under PCT Article 33(2) but

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does not involve an inventive step under PCT Article 33(3).

The additional feature of claim 30, relating to a three-dimensional input device, is not disclosed in D1. However, the feature would be merely a design option when the general knowledge in relevant field of the art is used. Accordingly, claim 30 would have been obvious over D1. Therefore, claim 30 is novel under PCT Article 33(2) but does not involve an inventive step under PCT Article 33(3).

The additional feature of claim 31 relates to the processing device which is configured to execute instructions to perform rendering of a graphical user interface in a display in communication with the processing device. However, D1 discloses that a pathway planning module communicates with a user interface module for displaying visual interactive features to a clinician on the display and for receiving clinician input (see paragraph [0062]). Accordingly, claim 31 would have been obvious over D1. Therefore, claim 31 is novel under PCT Article 33(2) but does not involve an inventive step under PCT Article 33(3).

The additional feature of claim 32, relating to rendering the filtered three-dimensional image data from a perspective internal to the three-dimensional image data or from a perspective external to the three-dimensional image data, is not disclosed in D1. However, the feature would be merely a design option when the general knowledge in relevant field of the art is used. Accordingly, claim 32 would have been obvious over D1. Therefore, claim 32 is novel under PCT Article 33(2) but does not involve an inventive step under PCT Article 33(3).

The additional feature of claim 33, relating to tendering the filtered three-dimensional image data from a perspective external to the three-dimensional image data, is not disclosed in D1. However, the feature would be merely a design option when the general knowledge in relevant field of the art is used. Accordingly, claim 33 would have been obvious over D1. Therefore, claim 33 is novel under PCT Article 33(2) but does not involve an inventive step under PCT Article 33(3).

The additional feature of claim 34, relating to one or more drawing inputs from the operator input device, is not disclosed in D1. However, the feature would be merely a design option when the general knowledge in relevant field of the art is used. Accordingly, claim 34 would have been obvious over D1. Therefore, claim 34 is novel under PCT Article 33(2) but does

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not involve an inventive step under PCT Article 33(3).

The additional feature of claim 35, relating to displaying a plurality of filter selections and receiving a selection of at least one of the plurality of filter selections, is not disclosed in D1. However, the feature would be merely a design option when the general knowledge in relevant field of the art is used. Accordingly, claim 35 would have been obvious over D1. Therefore, claim 35 is novel under PCT Article 33(2) but does not involve an inventive step under PCT Article 33(3).

The additional feature of claim 36, relating to the selection indicating a virtual navigation input mode or a drawing input mode, is not disclosed in D1. However, the feature would be merely a design option when the general knowledge in relevant field of the art is used. Accordingly, claim 36 would have been obvious over D1. Therefore, claim 36 is novel under PCT Article 33(2) but does not involve an inventive step under PCT Article 33(3).

The additional feature of claim 37 relates to the operations comprising displaying the generated pathway and the three-dimensional image data in the display. However, D1 discloses generating a first pathway from the target to the first waypoint (see claim 13). Accordingly, claim 37 would have been obvious over D1. Therefore, claim 37 is novel under PCT Article 33(2) but does not involve an inventive step under PCT Article 33(3).

The additional feature of claim 38 relates to the generated pathway and the three-dimensional image data which are displayed simultaneously. However, D1 discloses generating a first pathway from the target to the first waypoint (see claim 13). Accordingly, claim 38 would have been obvious over D1. Therefore, claim 38 is novel under PCT Article 33(2) but does not involve an inventive step under PCT Article 33(3).

2.3 Industrial Applicability
Claims 1-15, 17-38 are industrially applicable under PCT Article 33(4).