PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	17 MAY 2018

Applicant's or agent's file reference	**FOR FURTHER ACTION** See paragraph 2 below
1959185.00037	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US18/21614	08 March 2018 (08.03.2018)	09 March 2017 (09.03.2017)

International Patent Classification (IPC) or both national classification and IPC
IPC - A61B 6/00; G06T 7/00, 7/55, 17/00 (2018.01)
CPC - A61B 6/466, 6/504; G06T 11/003, 17/00, 17/005, 17/005

Applicant CathWorks, 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 43*bis*.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 66.1*bis*(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/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	01 May 2018 (01.05.2018)	Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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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. 5-22, 27-28

because: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

☐ 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. 5-22, 27-28 are so unclear that no meaningful opinion could be formed *(specify)*:

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

☐ 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. 5-22, 27-28

☐ 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 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-4, 23-26	YES
	Claims	NONE	NO
Inventive step (IS)	Claims	1-4, 23-26	YES
	Claims	NONE	NO
Industrial applicability (IA)	Claims	1-4, 23-26	YES
	Claims	NONE	NO

2. Citations and explanations:

Claims 1-4 and 23-26 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the claimed matter.

Claim 1 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method of reconstructing a vascular tree shape from vascular segments imaged in a source 2-D projection image using anchoring segments and reference segments, the method comprising: receiving, by computer circuitry, a structuring shape comprising 3-D spatial positions of reference vascular segments; extending the spatial positions to define a computer-represented surface model representing an anatomical surface along which the reference vascular segments extend; registering, by the computer circuitry, anchoring vascular segments shown in the source 2-D projection image to the spatial positions of the reference vascular segments on the surface model; and assigning, by the computer circuitry, 3-D positions to associated vascular segments shown in the source 2-D projection image, based on their occupation of the surface in common with the anchoring vascular segments.

As per claim 1, US 2015/0339847 A1 to Cathworks Ltd. (hereinafter 'Cathworks') discloses a method of reconstructing a vascular tree shape from vascular segments imaged in a source 2-D projection image using reference segments (a method of constructing a 3-D vascular tree from a 2-D angiogram (projection) image using vascular centerlines 451 (reference segments); paragraphs [0367]-[0375], [0441]), the method comprising: receiving, by computer circuitry, a structuring shape comprising 3-D spatial positions of reference vascular segments (a plurality of images received by a computer are used to construct a 3-D hull (structuring shape) comprising 3-D positions of vascular centerlines 451 (reference vascular segments); figures 18A, 18C; paragraphs [0185], [0379], [0441]); extending the spatial positions to define a computer-represented surface model representing an anatomical surface along which the reference vascular segments extend (the 3-D hull (structuring shape) is dilated (extended) to a volume corresponding to a heart surface to form a cardiac shell (computer-represented surface model representing an anatomical surface) along which the true vascular regions are expected to fall; figures 18B, 18C; paragraphs [0438], [0442]). Cathworks does not disclose a method of reconstructing a vascular tree shape from vascular segments imaged in a source 2-D projection image using anchoring segments and reference segments, the method comprising: registering, by the computer circuitry, anchoring vascular segments shown in the source 2-D projection image to the spatial positions of the reference vascular segments on the surface model; and assigning, by the computer circuitry, 3-D positions to associated vascular segments shown in the source 2-D projection image, based on their occupation of the surface in common with the anchoring vascular segments.

Additionally, US 2004/0066958 A1 to Chen et al. (hereinafter 'Chen') discloses a method of reconstructing a vascular tree shape from vascular segments imaged in a source 2-D projection image (a method of reconstructing a vascular tree using vascular segments from a 2-D angiogram image; paragraphs [0049]-[0051]), the method comprising: receiving, by computer circuitry, a structuring shape comprising 3-D spatial positions of reference vascular segments (a computer system receives an X-ray of vascular segments to serve as the origin of a 3-D coordinate space (structuring shape); paragraphs [0043], [0045], [0053], [0056]); extending the spatial positions to define a computer-represented surface model (after the 3-D vessel centerlines and lumen diameters are obtained, the anatomical morphology of coronary arterial tree can then be generated by a surface based reproduction technique; paragraph [0077]). Chen does not disclose a method of reconstructing a vascular tree shape from vascular segments imaged in a source 2-D projection image using anchoring segments and reference segments, the method comprising: extending the spatial positions to define a computer-represented surface model representing an anatomical surface along which the reference vascular segments extend (Chen discloses extending the vascular centerlines to define a surface of the vascular segments themselves, but does not disclose extending the vascular segments to define an anatomical surface along which the vascular segments extend; paragraph [0077]); registering, by the computer circuitry, anchoring vascular segments shown in the source 2-D projection image to the spatial positions of the reference vascular segments on the surface model; and assigning, by the computer circuitry, 3-D positions to associated vascular segments shown in the source 2-D projection image, based on their occupation of the surface in common with the anchoring vascular segments

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Also, US 2017/0018116 A1 to Siemens Medical Solutions USA, Inc. et al. (hereinafter 'Siemens') discloses a method of reconstructing a vascular tree shape from vascular segments imaged in a source 2-D projection image using reference segments (a method of reconstructing a vascular tree using vascular segments from 2-D images using centerlines; abstract), the method comprising: receiving, by computer circuitry, a structuring shape comprising 3-D spatial positions of reference vascular segments (a computer receives 3-D positons (structuring shape) of a centerline vascular tree (reference segments); claims 1, 19); extending the spatial positions to define a computer-represented surface model (after a 3-D centerline vessel tree skeleton is constructed, an initial 3-D vessel surface is constructed; claim 1). Siemens does not disclose a method of reconstructing a vascular tree shape from vascular segments imaged in a source 2-D projection image using anchoring segments and reference segments, the method comprising: extending the spatial positions to define a computer-represented surface model representing an anatomical surface along which the reference vascular segments extend (Siemens discloses extending the vascular centerlines to define a surface of the vascular segments themselves, but does not disclose extending the vascular segments to define an anatomical surface along which the vascular segments extend; claim 1); registering, by the computer circuitry, anchoring vascular segments shown in the source 2-D projection image to the spatial positions of the reference vascular segments on the surface model; and assigning, by the computer circuitry, 3-D positions to associated vascular segments shown in the source 2-D projection image, based on their occupation of the surface in common with the anchoring vascular segments.

In addition, US 2005/0249327 A1 to Wink et al. (hereinafter 'Wink') discloses a method of reconstructing a vascular tree shape from vascular segments imaged in a source 2-D projection image using reference segments (a method of reconstructing a three dimensional reconstruction of a vascular tree using vascular structures from x-ray images; abstract; paragraph [0027]), the method comprising: receiving, by computer circuitry, a structuring shape comprising 3-D spatial positions of reference vascular segments (a three dimensional modeled segment of a region of interest (structuring shape) in the vascular structure is generated by a computer based system; abstract; paragraphs [0038]-[0039]); extending the spatial positions to define a computer-represented surface model representing an anatomical surface along which the reference vascular segments extend (a three dimensional volumetric reconstruction of a vascular structure is generated that is larger than the modeled segment, wherein the modeled segment of interest (structuring shape) and the volumetric reconstruction of the larger vascular structure are combined and displayed in human readable form (surface model); abstract). Wink does not disclose a method of reconstructing a vascular tree shape from vascular segments imaged in a source 2-D projection image using anchoring segments and reference segments, the method comprising: registering, by the computer circuitry, anchoring vascular segments shown in the source 2-D projection image to the spatial positions of the reference vascular segments on the surface model; and assigning, by the computer circuitry, 3-D positions to associated vascular segments shown in the source 2-D projection image, based on their occupation of the surface in common with the anchoring vascular segments.

Thus, it would not have been obvious to one of ordinary skill in the art at the time of the invention to have modified Cathworks, Chen, Siemens, and Wink, such that a method of reconstructing a vascular tree shape from vascular segments imaged in a source 2-D projection image using anchoring segments and reference segments, the method comprising: receiving, by computer circuitry, a structuring shape comprising 3-D spatial positions of reference vascular segments; extending the spatial positions to define a computer-represented surface model representing an anatomical surface along which the reference vascular segments extend; registering, by the computer circuitry, anchoring vascular segments shown in the source 2-D projection image to the spatial positions of the reference vascular segments on the surface model; and assigning, by the computer circuitry, 3-D positions to associated vascular segments shown in the source 2-D projection image, based on their occupation of the surface in common with the anchoring vascular segments, as described, because the references of record fail to disclose all of the elements of the inventive method. Furthermore, since Cathworks, Chen, Siemens, and Wink employ a strategy of reconstructing 3D models using only reference centerlines, the references teach away from a strategy involving reference segments and anchor segments, and so it would not have been obvious to have modified the methods to include registering, by the computer circuitry, anchoring vascular segments shown in the source 2-D projection image to the spatial positions of the reference vascular segments on the surface model; and assigning, by the computer circuitry, 3-D positions to associated vascular segments shown in the source 2-D projection image, based on their occupation of the surface in common with the anchoring vascular segments, without further complicating the methods of Cathworks, Chen, Siemens, and Wink.

Claims 2-4 meet the criteria set out in PCT Article 33(2)-(3), because of direct and indirect dependencies upon claim 1.

Claim 23 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a system of reconstructing a vascular tree shape from vascular segments imaged in a source 2-D projection image, the system comprising computer circuitry configured to: receive a structuring shape comprising spatial positions of reference vascular segments; define, based on the structuring shape, a surface model representing a surface along which the reference vascular segments extend; register anchoring vascular segments shown in the source 2-D projection Image to the structuring shape; and assign 3-D positions to associated vascular segments shown in the source 2-D projection image, based on their occupation of the surface in common with the anchoring vascular segments.

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As per claim 23, Cathworks discloses a system of reconstructing a vascular tree shape from vascular segments imaged in a source 2-D projection image (a system for constructing a 3-D vascular tree from a 2-D angiogram (projection) image; paragraphs [0367]-[0375], [0441]), the system comprising computer circuitry configured to: receive a structuring shape comprising spatial positions of reference vascular segments (a plurality of images received by a computer are used to construct a 3-D hull (structuring shape) comprising 3-D positions of vascular centerlines 451 (reference vascular segments); figure 18C; paragraphs [0185], [0379], [0441]); define, based on the structuring shape, a surface model representing a surface along which the reference vascular segments extend (the 3-D hull (structuring shape) is dilated (extended) to a volume corresponding to a heart surface to form a cardiac shell (computer-represented surface model representing an anatomical surface) along which the true vascular regions are expected to fall; figure 18C; paragraphs [0438], [0442]). Cathworks does not disclose computer circuitry configured to: register anchoring vascular segments shown in the source 2-D projection Image to the structuring shape; and assign 3-D positions to associated vascular segments shown in the source 2-D projection image, based on their occupation of the surface in common with the anchoring vascular segments.

Additionally, Chen discloses a system of reconstructing a vascular tree shape from vascular segments imaged in a source 2-D projection image (a system of reconstructing a vascular tree using vascular segments from a 2-D angiogram image; paragraphs [0049]-[0051]), the system comprising computer circuitry configured to: receive a structuring shape comprising spatial positions of reference vascular segments (a computer system receives an X-ray of vascular segments to serve as the origin of a 3-D coordinate space (structuring shape); paragraphs [0043], [0045], [0056]); define, based on the structuring shape, a surface model representing a surface (after the 3-D vessel centerlines and lumen diameters are obtained, the anatomical morphology of coronary arterial tree can then be generated by a surface based reproduction technique; paragraph [0077]). Chen does not disclose computer circuitry configured to: define, based on the structuring shape, a surface model representing a surface along which the reference vascular segments extend (Chen discloses extending the vascular centerlines to define a surface of the vascular segments themselves, but does not disclose extending the vascular segments to define an anatomical surface along which the vascular segments extend; paragraph [0077]); register anchoring vascular segments shown in the source 2-D projection Image to the structuring shape; and assign 3-D positions to associated vascular segments shown in the source 2-D projection image, based on their occupation of the surface in common with the anchoring vascular segments.

Also, Siemens discloses a system of reconstructing a vascular tree shape from vascular segments imaged in a source 2-D projection image (a system of reconstructing a vascular tree using vascular segments from 2-D images using centerlines; abstract), the system comprising computer circuitry configured to: receive a structuring shape comprising spatial positions of reference vascular segments (a computer receives 3-D positons (structuring shape) of a centerline vascular tree (reference segments); claims 1, 19); define, based on the structuring shape, a surface model representing a surface (after a 3-D centerline vessel tree skeleton is constructed, an initial 3-D vessel surface is constructed; claim 1). Siemens does not disclose computer circuitry configured to: define, based on the structuring shape, a surface model representing a surface along which the reference vascular segments extend (Siemens discloses extending the vascular centerlines to define a surface of the vascular segments themselves, but does not disclose extending the vascular segments to define an anatomical surface along which the vascular segments extend; claim 1); register anchoring vascular segments shown in the source 2-D projection Image to the structuring shape; and assign 3-D positions to associated vascular segments shown in the source 2-D projection image, based on their occupation of the surface in common with the anchoring vascular segments.

In addition, Wink discloses a system of reconstructing a vascular tree shape from vascular segments imaged in a source 2-D projection image (a system of reconstructing a three dimensional reconstruction of a vascular tree using vascular structures from x-ray images; abstract; paragraph [0027]), the system comprising computer circuitry configured to: receive a structuring shape comprising spatial positions of reference vascular segments (a three dimensional modeled segment (structuring shape) of a region of interest in the vascular structure is received by a computer based system; abstract; paragraph [0039]); define, based on the structuring shape, a surface model representing a surface along which the reference vascular segments extend (a three dimensional volumetric reconstruction of a vascular structure is generated that is larger than the modeled segment, wherein the modeled segment of interest (structuring shape) and the volumetric reconstruction of the larger vascular structure are combined and displayed in human readable form (surface model); abstract). Wink does not disclose computer circuitry configured to: register anchoring vascular segments shown in the source 2-D projection Image to the structuring shape; and assign 3-D positions to associated vascular segments shown in the source 2-D projection image, based on their occupation of the surface in common with the anchoring vascular segments.

Thus, it would not have been obvious to one of ordinary skill in the art at the time of the invention to have modified Cathworks, Chen, Siemens, and Wink, such that a system of reconstructing a vascular tree shape from vascular segments imaged in a source 2-D projection image, the system comprising computer circuitry configured to: receive a structuring shape comprising spatial positions of reference vascular segments; define, based on the structuring shape, a surface model representing a surface along which the reference vascular segments extend; register anchoring vascular segments shown in the source 2-D projection Image to the structuring shape; and assign 3-D positions to associated vascular segments shown in the source 2-D projection image, based on their occupation of the surface in common with the anchoring vascular segments, as described, because the references of record fail to disclose all of the elements of the inventive method. Furthermore, since Cathworks, Chen, Siemens, and Wink employ a strategy of reconstructing 3D models using only reference centerlines, the references teach away from a strategy involving reference segments and anchor segments, and so it would not have been obvious to have modified the methods to include registering, by the computer circuitry, anchoring vascular segments shown in the source 2-D projection image to the spatial positions of the reference vascular segments on the surface model; and assigning, by the computer circuitry, 3-D positions to associated vascular segments shown in the source 2-D projection image, based on their occupation of the surface in common with the anchoring vascular segments, without further complicating the systems of Cathworks, Chen, Siemens, and Wink.

Claims 24-26 meet the criteria set out in PCT Article 33(2)-(3), because of direct and indirect dependencies upon claim 23.

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Claims 1-4 and 23-26 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.