

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference RCHP-212WO	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2015/029888	International filing date (<i>day/month/year</i>) 08 May 2015 (08.05.2015)	Priority date (<i>day/month/year</i>) 09 May 2014 (09.05.2014)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant THE CHILDREN'S HOSPITAL OF PHILADELPHIA		

<p>1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.</p>																								
<p>3. This report contains indications relating to the following items:</p> <table border="0"> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> <p>4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).</p>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input checked="" 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 type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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	Date of issuance of this report 15 November 2016 (15.11.2016)
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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: STEPHEN J. WEED
RATNERPRESTIA
P.O. BOX 980
VALLEY FORGE, PA 19482

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **07 OCT 2015**

Applicant's or agent's file reference RCHP-212WO		FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/US 15/29888	International filing date (day/month/year) 08 May 2015 (08.05.2015)	Priority date (day/month/year) 09 May 2014 (09.05.2014)	
International Patent Classification (IPC) or both national classification and IPC IPC(8) - A61B 19/02 (2015.01) CPC - A61B 19/5212			
Applicant NAZARETH, GODFREY			

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 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

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 Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Date of completion of this opinion 11 September 2015 (11.09.2015)	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

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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. IV Lack of unity of invention

1. In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- paid additional fees.
- paid additional fees under protest and, where applicable, the protest fee.
- paid additional fees under protest but the applicable protest fee was not paid.
- not paid additional fees.
2. This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

complied with.

not complied with for the following reasons:

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 1-18 directed to a portable surgical system

Group II: Claims 19-22 directed to a method for utilizing a portable surgical system

The inventions listed as Groups I-II 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:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical features of a battery and a light source coupled to the battery, not required by the claims of Group II.

The invention of Group II includes specific method steps such as assembling the retrieved surgical components into a surgical system; positioning a patient within the surgical system for surgery; configuring the surgical system; and performing the surgery with the surgical system, not required by the claims of Group I.

SHARED TECHNICAL FEATURES

Groups I-II are related as an apparatus (Group I) and a method for use thereof (Group II) and thus share the technical features of a portable surgical visualization kit comprising: a camera, viewing equipment, a processor, a stand, and a case. However, these shared technical features fail to make a contribution over prior art as being obvious over US 8,599,097 B2 to Intravotola (hereinafter Intravotola) in view of US 2006/0119701 A1 to King (hereinafter King). Intravotola teaches a portable kit (abstract, fig 1) comprising: a camera (cameras - col 17, ln 64); viewing equipment (output screen - col 17, lns 65-66); a processor (microprocessor - col 18, ln 2); a stand (100, fig 1; col 2, lns 1-5); and a case (200, fig 1), but does not specifically teach wherein the kit is a surgical visualization kit. However, King teaches a portable surgical visualization kit (para [0011], [0015]) comprising a camera (12, fig 1; para [0030]); and viewing equipment (30, figs 1, 4). It would have been obvious to one of ordinary skill in the art to have used the portable kit of Intravotola for surgical visualization as taught by King so that the surgical visualization kit would be as claimed, in order to have provided surgical imaging in remote locations for education, consulting, and diagnostics.

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

4. Consequently, this opinion has been established in respect of the following parts of the international application:
- all parts.
- the parts relating to claims Nos. 1-18

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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

I. Statement

Novelty (N)	Claims	<u>1-18</u>	YES
	Claims	<u>None</u>	NO
Inventive step (IS)	Claims	<u>18</u>	YES
	Claims	<u>1-17</u>	NO
Industrial applicability (IA)	Claims	<u>1-18</u>	YES
	Claims	<u>None</u>	NO

2. Citations and explanations:

Claims 1-8, 11-17 lack an inventive step under PCT Article 33(3) as being obvious over US 8,599,097 B2 to Intravotola (hereinafter Intravotola) in view of US 2006/0119701 A1 to King (hereinafter King).

Regarding claim 1, Intravotola teaches a portable kit (abstract, fig 1) comprising: a camera (cameras - col 17, ln 64) configured to capture images (note: intended use, camera of Intravotola is capable of capturing images); viewing equipment (output screen - col 17, lns 65-66) configured to receive and display the capture images (note: intended use, output screen of Intravotola is capable of displaying images); a processor (microprocessor - col 18, ln 2) coupled to the camera and the viewing equipment (microprocessor of Intravotola is operatively connected to the mast as discussed in col 18, ln 2-5, and the mast is coupled to the camera and viewing equipment); a stand (100, fig 1; col 2, lns 1-5) configured to support the camera and the processor (note: intended use, stand of Intravotola supports entire kit and thus is capable of supporting the camera and the processor); and a case (200, fig 1) configured to house the camera, the viewing equipment, the processor, and the stand (case volume - col 2, lns 13-17), but does not specifically teach wherein the kit is a surgical visualization kit. However, King teaches a portable surgical visualization kit (para [0011], [0015]) comprising a camera (12, fig 1; para [0030]) configured to capture images (note: intended use, camera of King is capable of capturing images); and viewing equipment (30, figs 1, 4) configured to receive and display the captured images (para [0038]). It would have been obvious to one of ordinary skill in the art to have used the portable kit of Intravotola for surgical visualization as taught by King so that the surgical visualization kit would be as claimed, in order to have provided surgical imaging in remote locations for education, consulting, and diagnostics.

Regarding claim 2, Intravotola and King teach the kit of claim 1, but neither specifically teach wherein the processor is configured to couple to the viewing equipment via a wireless connection. However, King teaches wireless control coupling of elements (wireless remote - para [0035]). It would have been obvious to one of ordinary skill in the art to have modified the kit of Intravotola and King with the wireless communication method of King so that the kit would be as claimed in order to have eliminated wires and provided a more compact system, because such wireless connection methods are commonly known in the art.

Regarding claim 3, Intravotola and King teach the kit of claim 1, but neither specifically teaches wherein the processor is configured to couple to the viewing equipment via a wired connection. However, Intravotola teaches power and control signals via a cable (power/control cable - col 11, ln 63). It would have been obvious to one of ordinary skill in the art that the connection from the processor to the viewing equipment would be wired as claimed in order to have provided a stable and reliable connection, because such wired connections are commonly known in the art.

Regarding claim 4, Intravotola and King teach the kit of claim 1, and Intravotola further teaches a kit further comprising: a battery (battery - col 17, ln 26); and a light source (lights - col 17, ln 64); wherein the case is further configured to house the battery (battery included inside the case - col 17, lns 26-27) and the light source (case has sufficient volume to store dual LED lamp heads - col 17, lns 24-26); and wherein the stand is further configured to support the battery and the light source (stand 100, fig 1 supports entire kit and thus supports battery and light source).

Regarding claim 5, Intravotola and King teach the kit of claim 4, and Intravotola further teaches wherein the light source is a high luminosity light source (bright stable light output - col 15, lns 23-26) configured to deliver at least one of coaxial light or collimated light (note: intended use, LEDs of Intravotola are capable of delivering coaxial or collimated light).

Regarding claim 6, Intravotola and King teach the kit of claim 1, and Intravotola further teaches wherein the stand is configured to position the camera along three orthogonal axes and to rotate the camera about the three orthogonal axes (multiple degrees of freedom of motion for adjusting functional attachments - col 13, ln 62 - col 14, ln 8).

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:
Box V, Part 2: Citations and Explanations

Regarding claim 7, Intravatola and King teach the kit of claim 6, and Intravatola further teaches wherein the stand comprises: a base (510, fig 43); a first arm (2002, fig 43) configured for attachment to the base (note: intended use, first arm of Intravatola is capable of being attached to the base); wherein the first arm is a telescoping arm (telescoping mast 2002, col 13, ln 36), but does not specifically teach a second arm configured for attachment to the camera; and a rotatable elbow joint coupled between the first and second arms. However, King teaches a stand having a base (6, fig 3) and a first arm (42, fig 3) configured for attachment to the base (arms 24 are attached to 6); a second arm (44, fig 3) configured for attachment to the camera (camera attached to joint 44 - para [0037]); and a rotatable elbow joint coupled between first and second arms (universal joint 44 pivotably attached to distal end of 42 - para [0037]). It would have been obvious to one of ordinary skill in the art to have combined the kit of Intravatola and King with the second arm of King so that the kit would be as claimed in order to have enabled further adjustability of the device.

Regarding claim 8, Intravatola and King teach the kit of claim 7, and the combination of Intravatola and King further teaches wherein the base, the first arm, the second arm, and the rotatable elbow joint are each configured for releasable assembly (note: intended use, this claim fails to further limit the structure of the kit of claim 7, the base, arms, and joint of Intravatola and King are capable of releasable assembly).

Regarding claim 11, Intravatola and King teach the kit of claim 1, and Intravatola further teaches wherein the case is dimensioned to comply with commercial airline carry-on luggage requirement (8" deep, 22" in height, 14" width as discussed in col 17, ln 21-23 complies with airline requirements).

Regarding claim 12, Intravatola and King teach the kit of claim 11, and Intravatola further teaches wherein the dimensions are 22 inches or less x 14 inches or less x 9 inches or less (col 17, ln 21-23).

Regarding claim 13, Intravatola teaches a portable system (abstract, fig 1) comprising: a battery (battery - col 17, ln 26); a light source (lights - col 17, ln 64) coupled to the battery (deliver electrical power to electrical devices - col 12, lns 60-62); a camera (cameras - col 17, ln 64) coupled to the battery (camera is mounted on mast and batter is coupled to devices on mast as discussed in col 12, lns 60-62), the camera configured to capture images (note: intended use, camera of Intravatola is capable of capturing images); viewing equipment (output screen - col 17, lns 65-66) configured to receive and display the captured images (note: intended use, output screen of Intravatola is capable of displaying images); a processor (microprocessor - col 17, ln 2) coupled to the battery, the camera and the viewing equipment (col 18, lns 2-5); and a stand (100, fig 1; col 2, lns 1-5) supporting the battery, the light source, the camera and the processor (stand supports entire kit and thus supports the batter, light source, camera, and processor); wherein the battery, the light source, the camera, the viewing equipment, the processor, and the stand are configured to be housed in a case (200, fig 1; case volume - col 2, lns 13-17), but does not specifically teach wherein the system is a surgical system. However, King teaches a portable surgical system (para [0011], [0015]) comprising a camera (12, fig 1; para [0030]) configured to capture images (note: intended use, camera of King is capable of capturing images); and viewing equipment (30, figs 1, 4) configured to receive and display the captured images (para [0038]). It would have been obvious to one of ordinary skill in the art to have used the portable system of Intravatola for surgical visualization as taught by King so that the surgical system would be as claimed, in order to have provided surgical imaging in remote locations for education, consulting, and diagnostics.

Regarding claim 14, Intravatola and King teach the system of claim 13, but neither specifically teach wherein the processor is configured to couple to the viewing equipment via a wireless connection. However, King teaches wireless control coupling of elements (wireless remote - para [0035]). It would have been obvious to one of ordinary skill in the art to have modified the kit of Intravola and King with the wireless communication method of King so that the system would be as claimed in order to have eliminated wires and provided a more compact system, because such wireless connection methods are commonly known in the art.

Regarding claim 15, Intravatola and King teach the system of claim 13, and Intravatola further teaches wherein the light source is a high luminosity light source (bright stable light output - col 15, lns 23-26) configured to deliver at least one of coaxial light or collimated light (note: intended use, LEDs of Intravatola are capable of delivery coaxial or collimated light).

Regarding claim 16, Intravatola and King teach the system of claim 13, and Intravatola further teaches wherein the stand is configured to position the camera along three orthogonal axes and to rotate the camera about the three orthogonal axes (multiple degrees of freedom of motion for adjusting functional attachments - col 13, ln 62 - col 14, ln 8).

Regarding claim 17, Intravatola and King teach the system of claim 16, and Intravatola further teaches wherein the stand comprises: a base (510, fig 43); a first arm (2002, fig 43) configured for attachment to the base (note: intended use, first arm of Intravatola is capable of being attached to the base); wherein the first arm is a telescoping arm (telescoping mast 2002, col 13, ln 36), but does not specifically teach a second arm configured for attachment to the camera; and a rotatable elbow joint coupled between the first and second arms. However, King teaches a stand having a base (6, fig 3) and a first arm (42, fig 3) configured for attachment to the base (arms 24 are attached to 6); a second arm (44, fig 3) configured for attachment to the camera (camera attached to joint 44 - para [0037]); and a rotatable elbow joint coupled between first and second arms (universal joint 44 pivotably attached to distal end of 42 - para [0037]). It would have been obvious to one of ordinary skill in the art to have combined the system of Intravatola and King with the second arm of King so that the system would be as claimed in order to have enabled further adjustability of the device.

---Continued on Supplemental Page---

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITYInternational application No.
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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:
Box V, Part 3: Citations and Explanations

Claim 9 lacks an inventive step under PCT Article 33(3) as being obvious over Intravatola and King in view of US 2005/0052527 A1 to Remy et al. (hereinafter Remy).

Regarding claim 9, Intravatola and King teach the kit of claim 1, but neither specifically teach the kit further comprising an endoscope. However, Remy teaches a portable surgical visualization kit (abstract) that uses an endoscope (endoscopes - para [0027]). It would have been obvious to one of ordinary skill in the art to have modified the kit of Intravatola and King to have included the endoscope of Remy so that the kit would be as claimed in order to have completely captured a neurological surgical procedure.

Claim 10 lacks an inventive step under PCT Article 33(3) as being obvious over Intravatola and King in view of US 6,591,239 B1 to McCall et al. (hereinafter McCall).

Regarding claim 10, Intravatola and King teach the kit of claim 1, but neither specifically teach wherein the camera is a three-dimensional camera with voice activated zoom and positioning. However, McCall teaches a surgical camera with voice activated zoom and positioning (col 5, lns 9-17). It would have been obvious to one of ordinary skill in the art to have modified the kit of Intravatola and King with the camera of McCall so that the kit would be as claimed in order to have provided hands free control of the camera.

Claim 18 meets the criteria as set forth by PCT Articles 33(2)-33(3) because the prior art fails to teach or fairly suggest the claimed subject matter.

The prior art is exemplified by Intravatola, King, and US 2011/0145978 A1 to Harbin (hereinafter Harbin).

Regarding claim 18, Intravatola and King teach the system of claim 13, but neither specifically teach wherein the viewing equipment includes: a headset; and a visor coupled to the headset, the visor including optical loupes, digital loupes, and a light source. Further, Harbin teaches an article of surgical headgear (abstract) that has loupes (para [0018]) and a light source (para [0012]) but does not specifically teach a visor coupled to the headset, or wherein the visor includes optical and digital loupes. It would not have been obvious to one of ordinary skill in the art to have combined the teachings of Intravatola, King, and Harbin to have created the system as claimed. Therefore, the prior art does not teach or fairly suggest the portable surgical system as claimed.

Claims 1-18 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.