

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 112849	FOR FURTHER ACTION		See item 4 below
International application No. PCT/US2015/039105	International filing date (<i>day/month/year</i>) 02 July 2015 (02.07.2015)	Priority date (<i>day/month/year</i>) 02 July 2014 (02.07.2014)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant IDx, LLC			

<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 6 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> <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 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 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 03 January 2017 (03.01.2017)
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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: MATTHEW CORYELL
215 10TH ST SUITE 1300
DES MOINES, IA 50309

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
112849

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US2015/039105

International filing date (day/month/year)

02 July 2015

Priority date (day/month/year)

02 July 2014

International Patent Classification (IPC) or both national classification and IPC

IPC(8) - A61B 3/15 (2015.01)

CPC - A61B 3/152 (2015.09)

Applicant **IDX, LLC**

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/
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

14 September 2015

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US2015/039105

Box No. 1 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 43bis.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 13ter.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 13ter.1(a)).
 - on paper or in the form of an image file (Rule 13ter.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:

**WRITTEN OPINION OF THE
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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

1. Statement

Novelty (N)	Claims	1-8, 11-12, 16-18, 20	YES
	Claims	9, 10, 13-15, 19	NO
Inventive step (IS)	Claims	1-8, 11-12, 16-18, 20	YES
	Claims	9, 10, 13-15, 19	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	None	NO

2. Citations and explanations:

Claims 9, 10, 13-15, and 19 lack novelty under PCT Article 33(2) as being anticipated by Silvestrini et al. (hereinafter Silvestrini).

Regarding claim 9, Silvestrini discloses an ocular alignment system for aligning the optical axis of a subject's eye with an optical axis of an ocular imaging device (Abstract) comprising:

- a. a plurality of guide lights (Para. [0143]-[0152], a plurality of reference lights are displayed to the patient as targets, the targets acting to guide the vision of the user); and
- b. one or more baffle (Fig. 4, mask 34 acts as baffle as it blocks light from entering a portion of the eye of a user, para. [0108]&[0136]) configured to mask the one or more guide light from view of the subject such that the one or more guide light is only visible to the subject when the optical axis of the subject's eye is aligned with the optical axis of an ocular imaging system (Para. [0143]-[0152], as the eye of the user is aligned along the optical axis, the reference lights become visible and align from the patient's point of view).

Regarding claim 10, Silvestrini discloses the system of claim 9, further Silvestrini discloses wherein the one or more baffle further comprises one or more slits (Fig. 4-5, mask 34 has an aperture 38 that is substantially slit like, para. [0109]), configured to allow passage of light along the alignment path (Fig. 4-5; aperture 38 is configured to allow passage of light along the alignment path, para. [0109]).

Regarding claim 13, Silvestrini discloses the system of claim 9, further Silvestrini discloses wherein a set of the plurality of guide light is only visible when the eye is aligned along the x, y and z axes with respect to the optical path of the ocular imaging device (Fig. 4-5, the eye must be aligned along the x,y, and z axes with respect to the optical path in order for the light to reach the retina unimpeded and allow the targets to be aligned, para. [0143]-[0152]).

Regarding claim 14, Silvestrini discloses the system of claim 9, however Silvestrini fails to explicitly disclose where the one or more guide light sources is positioned in the x-y plane at varying z-distance to optimize guide light paths or paths to the subject.

In regards to where the one or more guide light sources is positioned in the x-y plane at varying z-distance to optimize guide light paths or paths to the subject, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art is capable of performing the intended use, it meets the claim. In this case, the light source for the reference target guides is capable of being moved at varying z-distance, which would allow for projecting targets at different depths to better align the eye or eyes of the patient.

Regarding claim 15, Silvestrini discloses the system of claim 14, further Silvestrini discloses wherein the one or more guide light is only visible when the eye is aligned along the theta, eta, and zeta axes with respect to the optical path of the ocular imaging device (Fig. 4-5, the eye must be aligned along three axes with respect to the optical path in order for the light to reach the retina unimpeded and allow the targets to be aligned, para. [0143]-[0152]).

Regarding claim 19, Silvestrini discloses a method of aligning a subject's eye with an optical axis of an ocular imaging device (Abstract) comprising:

- a. providing a first set of guide lights along the optical path between the subject's eye and the ocular imaging device (Para. [0143]-[0152], a plurality of reference lights are displayed along an optical path to the patient as targets, the targets acting to guide the vision of the user); and
- b. providing one or more baffle (Fig. 4, mask 34 acts as baffle as it blocks light from entering a portion of the eye of a user, para. [0108]&[0136]), configured to mask the first set of guide lights from view of the subject such that first set of guide lights is only visible to the subject when the eye of the subject is aligned with the optical axis of an ocular imaging system (Para. [0143]-[0152], as the eye of the user is aligned along the optical axis, the reference lights become visible and align from the patient's point of view).

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Supplemental Box

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

Continuation of:

Claims 1-8, 11, 12, 16-18, and 20 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest:

Regarding claim 1, the prior art of record, individually or in combination does not teach or fairly suggest a device for aligning a subject's eye with an optical axis of an ocular imaging device comprising:

- a. a housing comprising a first end, a second end, an outer surface, and an inner surface, wherein the inner surface defines a luminal space and wherein the luminal space is configured to allow for passage of the optical axis therethrough;
- b. a plurality of guide light assemblies disposed within the housing, each guide light assembly comprising: i. a body comprising a first side and a second side opposite the first side, wherein the second side faces the luminal space;
- ii. a channel defined in the body, wherein the channel extends from the body first side to the body second side, wherein the channel forms an opening in the body second side;
- iii. a guide light disposed within the channel, wherein the guide light is configured to emit light out of the opening; and
- iv. a baffle disposed transversely in the channel between the guide light and the opening and configured to mask light from the guide light, wherein the baffle further comprises a slit configured to allow passage of light along a path of ocular alignment; and
- c. a plurality of secondary baffle assemblies disposed on the housing second end, wherein each of the plurality of secondary baffle assemblies is configured to mask light emitted from one of the plurality of guide light assemblies, wherein each of secondary baffle assemblies further comprises a slit configured to allow passage of light along a second path of ocular alignment, wherein the light from each of the plurality of guide light assemblies is visible to the subject when the subject's eye is in alignment with respect to the optical axis of the ocular imaging device and not visible when the subject's eye is out of alignment with respect to the optical axis of the ocular imaging device.

Claims 2-8 depend from base claim 1 and thus meet the criteria set out in PCT Article 33(3) for at least the same reasons as base claim 1.

Regarding claim 11, the prior art of record, individually or in combination does not teach or fairly suggest the system of claim 9, wherein the plurality of baffles or guide lights are adjustable to control a z-axis focal point to the subject's eye.

Regarding claim 12, the prior art of record, individually or in combination does not teach or fairly suggest the system of claim 9, further comprising a first set of the plurality of guide lights wherein the first set of guide lights is visible to the subject when the optical axis of the subject's eye is in alignment along the x-axis with respect to the optical axis of the ocular imaging system; and a second set of guide lights, visible to the subject when the subject's eye is in alignment along a y-axis with respect to the optical axis of an ocular imaging system, wherein when the first set of guide lights and second set of guide lights are simultaneously visible to the subject, the subject's eye is in alignment with the z-axis.

Regarding claim 16, the prior art of record, individually or in combination does not teach or fairly suggest the system of claim 9, further comprising one or more indicator signals, wherein the one or more indicator signals indicates to the subject a direction of eye movement to achieve alignment.

Claim 17 depends from base claim 16 and thus meets the criteria set out in PCT Article 33(3) for at least the same reasons as base claim 16.

Regarding claim 18, the prior art of record, individually or in combination does not teach or fairly suggest the system of claim 9 further comprising a coaxial light, visible to the subject when coarse alignment is achieved.

Regarding claim 20, the prior art of record, individually or in combination does not teach or fairly suggest the method of claim 19, wherein the first set of guide lights is visible to the subject when the subject's eye is in alignment along a x-axis with respect to the optical axis, the method further comprising: a. providing a second set of guide lights, visible to the subject when the subject's eye is in alignment along a y-axis with respect to the optical axis; and b. wherein when the first set of guide lights and second set of guide lights are simultaneously visible to the subject, the subject's eye is in alignment with the z-axis.

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Supplemental Box

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

Continuation of:

The following prior art is made of record to support and further define the reasons for meeting the criteria set out in PCT Article 33(2)-(3) of base claims 1, 11, 12, 16, 18, 20 :

Regarding claim 1, Weinstein et al. discloses an ocular imaging device (Abstract) comprising:

a housing comprising a first end, a second end, an outer surface, and an inner surface, wherein the inner surface defines a luminal space and wherein the luminal space is configured to allow for passage of the optical axis therethrough (Fig. 1, the device 10 has a housing with a first end, second end, outer and inner surfaces, wherein there is a luminal space in a portion of the housing to allow passage of an optical axis, para. [0028]);

a channel defined in a body, wherein the channel extends from the body first side to the body second side, wherein the channel forms an opening in the body second side (Fig. 1, there is substantially a channel present in the device 10, through which the light traverses, para. [0028]);

a baffle disposed transversely in the channel configured to mask light (Para. [0028]&[0105], there is a baffle array transversely disposed in the channel, wherein the baffle acts to mask the light); and

Weinstein et al. fails to disclose wherein the device is a device for aligning a subject's eye with an optical axis of an ocular imaging device, a plurality of guide light assemblies disposed within the housing, each guide light assembly comprising: i. a body comprising a first side and a second side opposite the first side, wherein the second side faces the luminal space; a guide light disposed within the channel, wherein the guide light is configured to emit light out of the opening; wherein the baffle is disposed between a guide light and an opening, wherein the baffle further comprises a slit configured to allow passage of light along a path of ocular alignment, and a plurality of secondary baffle assemblies disposed on the housing second end, wherein each of the plurality of second baffle assemblies is configured to mask light emitted from one of the plurality of guide light assemblies; wherein each of secondary baffle assemblies further comprises a slit configured to allow passage of light along a second path of ocular alignment, wherein the light from each of the plurality of guide light assemblies is visible to the subject when the subject's eye is in alignment with respect to the optical axis of the ocular imaging device and not visible when the subject's eye is out of alignment with respect to the optical axis of the ocular imaging device.

Regarding claim 11, Silvestrini et al. discloses the system of claim 9, however Silvestrini et al. fails to disclose wherein the plurality of baffles or guide lights are adjustable to control a z-axis focal point to the subject's eye.

Regarding claim 12, Silvestrini et al. discloses the system of claim 9, however Silvestrini et al. fails to disclose a first set of the plurality of guide lights wherein the first set of guide lights is visible to the subject when the optical axis of the subject's eye is in alignment along the x-axis with respect to the optical axis of the ocular imaging system; and a second set of guide lights, visible to the subject when the subject's eye is in alignment along a y-axis with respect to the optical axis of an ocular imaging system, wherein when the first set of guide lights and second set of guide lights are simultaneously visible to the subject, the subject's eye is in alignment with the z-axis.

Regarding claim 16, Silvestrini et al. discloses the system of claim 9, however Silvestrini et al. fails to disclose one or more indicator signals, wherein the one or more indicator signals indicates to the subject a direction of eye movement to achieve alignment.

Regarding claim 18, Silvestrini et al. discloses the system of claim 9, however Silvestrini et al. fails to disclose a coaxial light, visible to the subject when coarse alignment is achieved.

Regarding claim 20, Silvestrini et al. discloses the method of claim 19, however Silvestrini et al. fails to disclose wherein the first set of guide lights is visible to the subject when the subject's eye is in alignment along a x-axis with respect to the optical axis, the method further comprising: a. providing a second set of guide lights, visible to the subject when the subject's eye is in alignment along a y-axis with respect to the optical axis; and b. wherein when the first set of guide lights and second set of guide lights are simultaneously visible to the subject, the subject's eye is in alignment with the z-axis.

Claims 1-20 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.