PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 030424-00001	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2007/062922	International filing date *(day/month/year)* 28 February 2007 (28.02.2007)	Priority date *(day/month/year)* 02 March 2006 (02.03.2006)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant SPAIDE, Richard		

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).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   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.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	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 Article 35(2) 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

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.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 44*bis* .2).

	Date of issuance of this report 02 September 2008 (02.09.2008)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Beate Giffo-Schmitt e-mail: pt03.pct@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: Ronald Abramson
Hughes Hubbard & Reed LLP
One Battery Park Plaza
New York, NY 10004

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	21 DEC 2007
Applicant's or agent's file reference 030424-00001	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 07/62922	28 February 2007 (28.02.2007)	02 March 2006 (02.03.2006)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61M 1/00 (2007.10)
USPC - 604/27

Applicant SPAIDE, Richard

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

- [X] 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
- [X] Box No. V Reasoned statement under Rule 43*bis*.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.

3. For further details, see notes to 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. 571-273-3201	22 October 2007 (22.10.2007)	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 07/62922

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. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished subsequently to this Authority for the purposes of search

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

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 07/62922

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

1. Statement

Novelty (N)	Claims	2 - 15 and 17 - 28	YES
	Claims	1 and 16	NO
Inventive step (IS)	Claims	None	YES
	Claims	1 - 28	NO
Industrial applicability (IA)	Claims	1 - 28	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1 and 16 lack novelty under PCT Article 33(2) as being anticipated by US 6,575,989 B1 to Scheller et al. (hereinafter "Scheller").

Regarding Claim 1, Scheller discloses an aspirating cannula (col 4, ln 17-19) comprising a proximal end attachable to a handle (col 6, ln 26-27), a tubular body (col 6, ln 24 - "tip") extending from said proximal end and having a longitudinal internal passage therein (col 6, ln 30 -31), and a tip (col 6, ln 39 - "adaptor") attached to the distal end of said tubular body (col 6, ln 24-34, 39-42), said adaptor comprising an elastic body made of soft material (col 6, ln 49-50) and having an abrasive coating on the distal end thereof (col 7, ln 1-4).

Regarding Claim 16, Scheller discloses an extrusion cannula comprising an extrusion handle and an aspirating cannula (col 6, ln 1-18).

Claims 18, 19 and 24 - 28 lack an inventive step under PCT Article 33(3) as being obvious over Scheller.

Regarding Claim 18, Scheller does not expressly teach a method for performing ophthalmologic surgery, comprising making a sclerotomy incision in the eye, inserting through said incision an aspirating cannul constructed in accordance with Claim 1, using the abrasive distal end of said cannula to apply frictional force to structures within the eye and removing fluid from the eye by aspiration through the longitudinal internal passage of said aspirating cannula, however, this method would have been obvious to one of ordinary skill in the art in view of Scheller. First, Scheller discloses an ophthalmic surgical device that combines the advantages of abrasive membrane scraping with the features of aspiration/infusion (col 3, ln 33-35), such device has the ability to scrape membranes while providing infusion or aspiration to the surgical site (col 4, ln 17-19), and it is common knowledge in the art that the membranes are scraped with frictional forces and aspiration is done through a longitudinal internal passage of an aspirating cannula. Second, Scheller further discloses that the instrument can be introduced into the intraocular cavity through a straight cannul inserted in through an incision in the eye (col 3, col 41-44) and it is common knowledge in the art that a sclerotomy incision is a commonly used incision in the eye.

Regarding Claim 19, Scheller does not expressly teach a method for removing matters from the surface of the retina, further comprising sweeping said surface with the abrasive distal end of said cannula, so as to dislodge said matter and removing said matter by aspiration through the longitudinal internal passage of the said aspirating cannula, however, as discussed above in Claim 18, this would have been obvious to one of ordinary skill in the art in view of Scheller, because Scheller discloses an ophthalmic surgical device that combines the advantages of abrasive membrane scraping with the features of aspiration/infusion (col 3, ln 33-35), such device has the ability to scrape membranes from the surface of the retina while providing infusion or aspiration to the surgical site (col 4, ln 17-19) and it is common knowledge in the art that the membranes are scraped with frictional forces and aspiration is done through a longitudinal internal passage of an aspiring cannula.

Regarding Claim 24, Scheller discloses making an incision in the eye, inserting through said incision an aspirating cannula constructed according to claim 1 (col 3, ln 30-44). Scheller further discloses that such as aspirating cannula can also serve as infusion cannula (col 3, ln 34) that can be used to inject fluid through said cannula (col 2, ln 24-26).
Scheller does not expressly disclose that the incision is a sclerotomy incision, however, this would have been obvious to one of ordinary skill in the art, because a sclerotomy incision is a commonly used incision in an ophthalmologic procedure.

Regarding Claim 25, Scheller disclose that said fluid is injected to clear unwanted material from the cannula (col 2, ln 24-26 - "flush").

Regarding Claim 26, Scheller does not expressly teach that the fluid is injected to disengage from intraocular structures, however, this would have been obvious to one of ordinary skill in the art in view of Scheller that discloses that the aspirating cannula can also serve as an infusion cannula (col 3, ln 34) that can be used to inject fluid through said cannula (col 2, ln 24-26), because it is common practice in the art to inject fluid to disengage from intraocular structures during an ophthalmologic procedure.

Regarding Claim 27, Scheller discloses that said fluid is injected to blow away unwanted material (col 2, ln 24-26 - "flush"). Scheller does not expressly disclose that the unwanted material is blown away from the surface of the retina, however, this would have been obvious to one of ordinary skill in the art, because it is common practice in the art to blow away unwanted material from the surface of the retina during a retinal reattachment procedure.

Continuing on supplemental pages

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 07/62922

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box No. V - Citations and Explanations:

Regarding Claim 28, Scheller does not expressly teach that said fluid comprises a drug, a dye or a marking agent, however, this would have been obvious to one of ordinary skill in the art, because drugs, dyes or marking agents are routinely infused through a cannula intraocularly during an ophthalmologic procedure.

Claim 2 lacks an inventive step under PCT Article 33(3) as being obvious over Scheller in view of US 6,491,670 B1 to Toth et al. (hereinafter "Toth").
Toth discloses a miniaturized surgical instrument for an ophthalmologic procedure with a tip made of medical grade silicone elastomer (col 1, ln 49-59).
It would have been obvious to one of ordinary skill in the art to combine Scheller with Toth to practice the claimed invention, because Toth discloses a commonly used soft, elastic material that can be used for a tip of Scheller's surgical device for eye surgery so that the delicate intraocular tissues that come into contact with the tip will not be harmed.

Claims 3 - 11, 14, 15 and 17 lack an inventive step under PCT Article 33(3) as being obvious over Scheller in view of US 5,921,998 A to Tano et al. (hereinafter "Tano").

Regarding Claim 3, Tano discloses an opthalmological membrane eraser (col 1, ln 47-54) comprising a grip, a rod-shaped body and an elastic body that is placed upon the distal end of the rod-shape body (col 2, ln 45-49). There is an abrasive coating on the distal end of the elastic body, wherein the coating comprises a plurality of hard, fine-grained particles fixed on the elastic body of the tip (col 3, ln 26-33).
It would have been obvious to one of ordinary skill in the art to combine Scheller with Tano, because Tano teaches suitable materials for an abrasive coating for an ophthalmologic surgical tool.

Regarding Claim 4, Tano discloses that the fine-grained particles are diamond particles (col 3, ln 32-33).

Regarding Claim 5, Tano discloses that the fine-grained particles can be marble, silicon carbide, silicon nitride, silica, alumina, crystal, quartz, sapphire or ruby (col 3, ln ln 32-38).

Regarding Claim 6, Tano discloses that the fine-grained particles are fixed to said elastic body by a silicone-based adhesive (col 3, ln 44-48).

Regarding Claims 7 and 8, Tano discloses that the fine-grained particles comprise grains having a range in diameter from about 2 micrometers to about 100 micrometers preferably range between 10 micrometers and 40 micrometers (col 3, ln 39-40).

Regarding Claims 9 and 10, Scheller discloses that the tubular body (col 6, ln 24 - "tip") is made of metal such as stainless steel (col 6, ln 24-26).

Regarding Claim 11, Tano discloses that the tubular body (col 2, ln 51 - "rod-shaped body") is made of titanium (col 2, ln 51-52).

Regarding Claim 14, Scheller discloses an aspirating cannula in accordance with claim 3 (col 4, ln 17-19), wherein said elastic body (col 6,ln 39 - "adaptor") is tubular (fig 1a, part 42A), the distal end of said elastic body has a face that is substantially transverse to the longitudinal axis of the tubular body and elastic body, and at least a portion of the abrasive member is fixed to said face (fig 1B, part 51, 60; col 6, ln 64-65; col 7, ln 1-2).
Tano discloses an ophthalmic membrane eraser (col 1, ln 47-54) comprising a grip, a rod-shaped body and an elastic body that is placed upon the distal end of the rod-shape body (col 2, ln 45-49), wherein the elastic body is tubular (col 2, ln 55-56) and extends the longitudinal passage of the tubular body (fig 1A, part 3; col 2, ln 47 - "rod-shaped body"), the distal tip of the elastic body being covered with fine-grained particles (col 3, ln 26-29).
As discussed above in Claim 3, it would have been obvious to one of ordinary skill in the art to combine Scheller with Tano to practice the claimed invention.

Regarding Claim 15, Scheller discloses that a portion of the abrasive particles are also fixed to the outer surface of the elastic body (col 6, ln 39 - "adaptor") adjacent said face, thereby forming an abrasive-coated tip on said elastic body (fig 1A, part 51, 60; col 7, ln 12-16).
Tano discloses that the fine-grained particle is fixed on the distal tip of the elastic body (col 3, ln 26-29).
As discussed above in Claim 3, it would have been obvious to one of ordinary skill in the art to combine Scheller with Tano to practice the claimed invention.

Regarding Claim 17, Scheller, in combination with Tano, discloses an extrusion cannula comprising an extrusion handle and an aspirating cannula in accordance with claim 11 (col 6, ln 1-18).

Claims 12 and 13 lack an inventive step under PCT Article 33(3) as being obvious over Scheller in view of US 6,800,076 B2 (Humayun).

Regarding Claim 12, Humayun discloses a soft tip cannula for an ophthalmic procedure (col 2, ln 43-46), wherein its proximal end is attachable to a handle by a friction attachment (col 3, ln 56-58).
It would have been obvious to one of ordinary skill in the art to combine Scheller with Humayun to practice the claimed invention, because Humayun discloses a simple fastening means for attaching an ophthalmic surgical device to handle.

Continued in Supplemental Box

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 07/62922

Supplemental Box

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Continuation of:
Previous Page - Citations and Explanations:

Regarding Claim 13, neither Scheller nor Humayun expressly discloses that the proximal end of the cannula is attachable to a handle by a luer-lock, however, this would have been obvious to one of ordinary skill in the art, because Hamayun discloses a soft tip cannula for ophthalmic procedures (col 2, ln 43-46), wherein its proximal end is attachable to a handle by a frictional fit and/or an conventional fastening means (col 3, ln 56-58), and it is common knowledge in the art that a luer-lock is a commonly used conventional fastening means, as evidenced by Scheller that discloses an aspiration cannula comprising a luer-lock that connects the internal passage of a handle and an external aspiration and infusion source (col 6, ln 9-13).

Claim 20 lacks an inventive step under PCT Article 33(3) as being obvious over Scheller in view of US 2006/0030785 A1 to Field et al. (hereinafter "Field"). Neither Scheller nor Field expressly teaches using the suction created by removing fluid from the eye through said cannula to increase the friction provided by said abrasive distal end thereof, without increasing the downward force on said cannula, however, this would have been obvious in view of Field that discloses a biopsy device that utilizes the principle that the sum of suction force and frictional force between a tissue sample and the inner core of the biopsy cannula is the dominating force for retaining the sample in the cannula (para [0008]), because Field teaches that one way of better retaining and grasping a tissue is to use both suction and friction. In addition, it is common knowledge in the art that in an ophthalmalgic procedure, download force on intraocular tissue shall be minimized to avoid injury to the delicate tissues.
It would have been obvious to one of ordinary skill in the art to combine Scheller with Field, because Field teaches a convenient way of better holding a tissue without applying downward force.

Claims 21 and 23 lack an inventive step under PCT Article 33(3) as being obvious over Scheller in view of Field in further view of US 4,578,058 A (Grandon).

Regarding Claim 21, none of Scheller, Field and Grandon expressly teaches using said frictional force, combined with and amplified by said suction to grasp and slide sections of detached retina tissues, however, this would have been obvious to one of ordinary skill in the art in view of Field and Grandon, because first, Field discloses a way of grasping a tissue using the combination of suction and friction, and second, Grandon discloses using an intraorcular catheter apparatus to grasp and move the cortex centrally by suction (col 1, ln 60-63). In addition, it is common practice in the art to grasp and slide sections of detached retina tissues during a surgery for treating retina detachment.
It would have been obvious to one of ordinary skill in the art to add Grandon to the combination of Scheller and Field, because Scheller discloses a useful way of grasping an intraocular tissue by applying suction without using downward force which is harmful to the delicate intraocular tissue.

Regarding Claim 23, none of Scheller, Field and Grandon expressly teaches using the frictional force, combined with and amplified by said suction, and sliding the perifoveal macular tissue centrally to reduce the size of macular holes, however, this would have been obvious to one of ordinary skill in the art in view of Field and Grandon, because first, Field discloses a way of grasping a tissue using the combination of suction and friction (para [0008]), and second, Grandon discloses using an intraorcular catheter apparatus to grasp and move the cortex centrally by suction (col 1, ln 60-63). In addition, it is common practice in the art to slide the perifoveal macular tissue centrally to reduce the size of macular holes.

Claim 22 lacks an inventive step under PCT Article 33(3) as being obvious over Scheller in view of Field in further view of Grandon and still further in view of Humayun.
None of Scheller, Field, Grandon and Humayun expressly discloses using the frictional force, combined with and amplied by the suction, to move structures in the eye during retinal reattachment procedures, however this would have been obvious to one of ordinary skill in the art in view of Field and Grandon, because first, Field discloses a way of grasping a tissue using the combination of suction and friction (para [0008]), and second, Grandon discloses using an intraorcular catheter apparatus to grasp and move the cortex centrally by suction (col 1, ln 60-63). In addition, it is common practice in the art to grasp and slide sections of detached retina tissues during retinal reattachment procedure.
As discussed above, it would have been obvious to one of ordinary skill in the art to add Grandon to the combination of Scheller and Field. Humayun discloses a method to remove subretinal fluid so as to promote retention of the retina by surface tension during a retinal reattachment procedure (col 2, ln 3-9) by an aspirating device using suction (col 4, ln 61-67; col 5, ln 1).
It would have been obvious to one of ordinary skill in the art to add Humayun to the combination of Scheller, Field and Grandon to practice the claimed invention, because Humayun discloses a simple method of removing fluid by aspiration during a retinal reattachment procedure.

Claims 1 - 28 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.