UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/841,967	08/20/2007	Olav B. Bergheim	GLAUKO.1C4C10	2690

20995 7590 01/28/2009

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
MARCETICH, ADAM M	

ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
01/28/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	11/841,967	BERGHEIM ET AL.	
	Examiner	Art Unit	
	Adam Marcetich	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 August 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract is objected to for exceeding 150 words, at 157 words in length.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch; Mary G. et al. (US 6450984) in view of Galin M. A. et al. (US 5652014).

6. Regarding claims 1-9, Lynch discloses a method of controlling the flow of aqueous humor in a living eye having an anterior chamber, a Schlemm's canal, and an episcleral venous system (col. 6, lines 50-60, col. 7, lines 44-49);

the method comprising:

[1, 9] introducing into the living eye an indwelling tubular body (col. 7, lines 55-62, shunt device 100 implanted into eye);

[1, 9] which leads from the anterior chamber into Schlemm's canal to provide an aqueous humor directing channel out of the anterior chamber (col. 11, lines 32-36, placement within anterior chamber into Schlemm's canal);

[1, 3] stabilizing and anchoring the tubular body to reduce expulsion thereof from at least one of Schlemm's' s canal or the anterior chamber (col. 9 lines 8-14, providing V-shaped embodiment; Examiner notes that a V-shape implanted within Schlemm's canal substantially stabilizes and anchors the implant); and

[1, 9] conducting aqueous humor through the tubular body to reduce intraocular pressure in the living eye (col. 7, lines 44-49, diverting aqueous humor from the anterior chamber to Schlemm's canal);

[2] wherein the tubular body comprises a V-shape (col. 11, lines 8-14, especially lines 12-14, Fig. 5A, unidirectional embodiment having V-shape);

[4] wherein the tubular body is dimensioned to allow non-linear fluid communication (col. 10, lines 46-52, device 100 having unidirectional valves; it is the Examiner's position that a unidirectional valve dimensions a tubular body to allow non-linear fluid communication);

[5] wherein the tubular body comprises an inlet section and a distal section, wherein the distal section extends at an angle between about 30 degrees to about 150 degrees with reference to the inlet section (Fig. 5A, V-shaped embodiment depicted as having angle between claimed range of about 30-150 degrees);

[6] wherein the tubular body has an outer diameter of between approximately 0.03-0.5 mm (col. 10, lines 64-67, outer diameter of distal portion 25 between 0.1-0.5 mm, overlapping the claimed range of approximately 0.03-0.5 mm);

[7] wherein the tubular body comprises first and second portions that meet at a junction, the first and second portions being oriented transverse to each other (Fig. 5A, V-shaped embodiment depicted as having transversely oriented junction);

[8] wherein the first portion has a first length defined from the junction to a first open end (col. 10, lines 5-9, proximal portion 10 having length of about 0.1-3.0 mm, or about 2.0 mm); and

[8] the second portion has a second length defined between second and third open ends (col. 10, lines 64-67, distal portion 25 having length between about 1.0-20 mm or about 3.0 mm),

[8] with the first length being different from the second length (difference in disclosed optimal ranges)

[8] to clarify, Examiner notes that Lynch defines proximal and distal portions in the same arrangement as Applicant, with a proximal portion being placed within Schlemm's canal and a distal portion being placed within the anterior chamber;

Lynch discloses the invention substantially as claimed, see above. However, Lynch lacks a therapeutic agent as claimed [claims 1 and 9]. Galin discloses an anterior chamber ocular lens implant (col. 1, lines 9-14, col. 4, lines 10-20) further comprising a therapeutic agent coating (col. 4, lines 47-55, polysaccharide medicament). Galin solves the problem of preventing secondary glaucoma (cols. 3-4, lines 65-2). To restate, Galin prevents glaucoma using the same approach as the claimed invention, namely releasing active agent from an implanted device surface into the eye. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Lynch as discussed with the therapeutic agent as taught by Galin in order to prevent or treat glaucoma.

7. Regarding claim 10, Lynch discloses an ocular device comprising:

a solid-walled tubular body for implantation into Schlemm's canal of a living eye (col. 7, lines 55-62, shunt device 100 implanted into eye; lines 27-29, solid construction);

wherein at least a portion of the tubular device comprises a non-linear aqueous humor directing channel (Fig. 5A, V-shaped embodiment depicted as having transversely oriented junction);

wherein said tubular body is configured and dimensioned such that implantation of said tubular body in living tissue of said canal directs dynamic flow of aqueous humor from an anterior chamber of said living eye and through said non-linear aqueous humor directing channel toward episcleral veins (col. 10, lines 46-52, device 100 having unidirectional valves); and

Lynch discloses the invention substantially as claimed, see above. However, Lynch lacks a therapeutic agent as claimed [claim 10]. Galin discloses an anterior chamber ocular lens implant (col. 1, lines 9-14, col. 4, lines 10-20) further comprising a therapeutic agent coating (col. 4, lines 47-55, polysaccharide medicament). Regarding rationale and motivation, see discussion of claim 1 above.

8. Regarding claims 11, 13 and 15, Lynch discloses the structural limitations as discussed for claims 2, 5 and 6 above.

9. Regarding claim 12, Lynch discloses a tubular body comprising first and second elongate lumens (col. 8, lines 40-43, tubular channels having ovoid geometry).

10. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch; Mary G. et al. (US 6450984) in view of Galin M. A. et al. (US 5652014), further in view of Fisher; Bret L. (US 5558630).

11. Regarding claim 14, Lynch in view of Galin discloses the invention substantially as claimed, see above. However, Lynch in view of Galin lacks a stabilizing portion as claimed [claim 14]. Fisher discloses an intraocular pressure regulating device (col. 1, lines 46-52) having a tubular body (col. 2, lines 54-61, Figs. 1-3, tubular body 12) further comprising a stabilizing portion (col. 3, lines 1-9, retention flange 25). Fisher provides the advantage of retaining an implant end within the anterior chamber. Examiner notes that Fisher places the implant between an anterior chamber and the sclera (col. 1, lines 53-62, especially lines 56-58), which is different from Applicant's arrangement of a second end placed within a trabecular meshwork. However, Fisher solves the problem of regulating IOP and retaining one end of an implant within the anterior chamber. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Lynch in view of Galin as discussed with the stabilizing portion as taught by Fisher in order to retain an implant end within the anterior chamber.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-3, 5 and 9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 4, 11, 12 and 19 of Gharib; Morteza et al. (US 6666841). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

14. Gharib claims all limitations of instant claims 1, 3 and 9 in claims 2 and 19, including:

[1, 9] a method of controlling the flow of aqueous humor in a living eye having an anterior chamber, a Schlemm's canal, and an episcleral venous system, the method comprising:

[1, 9] introducing into the living eye an indwelling tubular body (claim 2, ". . . inserting the trabecular shunt into the opening, wherein the trabecular shunt comprises an elongate tubular element. . .");

[1, 9] which leads from the anterior chamber into Schlemm's canal to provide an aqueous humor directing channel out of the anterior chamber (claim 2, ". . . positioning the first and second bifurcatable elements inside a Schlemm's canal of said eye. . .");

[1, 9] wherein the tubular body is at least partially coated with a therapeutic agent (claim 19, ". . .wherein said trabecular shunt comprises a surface coating comprising . . . a therapeutic drug."); and

[1, 3] stabilizing the tubular body to reduce expulsion thereof from at least one of Schlemm's' s canal or the anterior chamber (claim 2, ". . . wherein the outlet section comprises a first bifurcatable element and a second bifurcatable element. . ." Examiner notes that bifurcatable elements reduce expulsion of a tubular body); and

[1, 9] conducting aqueous humor through the tubular body to reduce intraocular pressure in the living eye (claim 2, ". . . elongate tubular element having an inlet section and an outlet section. . ." Examiner notes that an inlet and outlet section on a shunt fairly suggests conducting aqueous humor).

15. Gharib claims all limitations of instant claim 2 in claim 4, including a method wherein the tubular body comprises a V-shape (claim 4, ". . . two bifurcatable elements are attached to said inlet section at a joint.").

16. Gharib claims all limitations of instant claim 5 in claims 11 and 12, including a method wherein the tubular body comprises an inlet section and a distal section, wherein the distal section extends at an angle between about 30 degrees to about 150 degrees with reference to the inlet section (claims 11, 12, ". . . angle is between about 70 degrees and about 110 degrees.").

17. Claims 1-3, 5 and 9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5 and 8 of Bergheim; Olav B. et al. (US 6638239) in view of Galin M. A. et al. (US 5652014).

18. Bergheim claims the limitations of instant claims 1, 3 and 9 in claim 8, including:

[1, 9] a method of controlling the flow of aqueous humor in a living eye having an anterior chamber, a Schlemm's canal, and an episcleral venous system, the method comprising:

[1, 9] introducing into the living eye an indwelling tubular body (claim 8, ". . . implanting a drainage implant in a trabecular meshwork of an eye. . .");

[1, 9] which leads from the anterior chamber into Schlemm's canal to provide an aqueous humor directing channel out of the anterior chamber (claim 8, ". . . such that an inflow portion of the drainage implant is positioned in the anterior chamber and an outflow portion of the drainage implant is positioned in Schlemm's canal.");

[1, 3] stabilizing the tubular body to reduce expulsion thereof from at least one of Schlemm's' s canal or the anterior chamber (claim 5, ". . . outlet portion [having] at least one protrusion configured to exert traction against an inner surface of Schlemm's canal. . .").

[1, 9] conducting aqueous humor through the tubular body to reduce intraocular pressure in the living eye.

Bergheim discloses the invention substantially as claimed, see above. However, Bergheim lacks a therapeutic agent as claimed [claims 1 and 9]. Galin discloses an anterior chamber ocular lens implant (col. 1, lines 9-14, col. 4, lines 10-20) further

comprising a therapeutic agent coating (col. 4, lines 47-55, polysaccharide medicament). Regarding rationale and motivation, see discussion of claim 1 rejected over Lynch in view of Galin above.

Bergheim claims all limitations of instant claims 2 and 5 in claim 8, including said implant being substantially L-shaped (claim 8, ". . . said implant being substantially L-shaped. . ." Examiner notes that an L-shaped implant substantially resembles a V-shaped implant). Additionally, an L-shaped implant approaches a 90-degree angle, which falls within the claimed range of about 30-150 degrees.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Bergheim; Olav B. et al. US 6638239
- Gharib; Morteza et al. US 6666841
- Savage, James A. US 20020026200
- Odrich; Ronald B. US 5041081
- Yaron; Ira et al. US 6203513

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
21 January 2009