UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

New World Medical, Inc.,
Petitioner

v.

MicroSurgical Tech., Inc.,
Patent Owner

Case No. IPR2021-00017
U.S. Patent No. 9,820,885

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,820,885

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EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent 9,820,885 ("the '885 patent")
1002	U.S. Patent 9,820,885 File History ('885 patent file history")
1003	Declaration of Dr. Peter Netland ("Decl.")
1004	Manuel Quintana, *Gonioscopic Trabeculotomy. First Results*, in 43 SECOND EUROPEAN GLAUCOMA SYMPOSIUM, DOCUMENTA OPHTHALMOLOGICA PROCEEDINGS SERIES 265 (E.L. Greve, W. Leydhecker, & C. Raitta ed., 1985) ("Quintana")
1005	M. Johnstone *et al.*, "Microsurgery of SC and the Human Aqueous Outflow System," *Am. J. Ophthalmology* 76(6):906-917 (1973) ("Johnstone")
1006	U.S. Patent 4,900,300 to Lee ("Lee")
1007	Philipp C. Jacobi *et al.*, "Technique of goniocurettage: a potential treatment for advance chronic open angle glaucoma," 81 BRITISH J. OPHTHALMOLOGY 302-307 (1997) ("Jacobi")
1008	Richard S. Snell *et al.*, *Clinical Anatomy of the Eye*, Malden, Massachusetts: Blackwell Science, Inc. (2nd ed., 1998) ("Snell")
1009	Am. Acad. Of Ophthalmology, *Section 8 External Disease and Cornea*, in BASIC AND CLINICAL SCIENCE COURSE 2001-2002 (2001) ("AAO Cornea")
1010	Michael John Hogan, *History of the Human Eye: An Atlas and Textbook.* Philadelphia, Pennsylvania: W. B. Saunders Company (1971) ("Hogan")
1011	M. Bruce Shields, *Textbook of Glaucoma, Fourth Edition*. Baltimore, Maryland: Williams & Wilkins (1998) ("Shields")

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1012	Am. Acad. Of Ophthalmology, *Section 10 Glaucoma*, in BASIC AND CLINICAL SCIENCE COURSE 2000-2001 (2000) ("AAO Glaucoma")
1013	Phillip C. Jacobi *et al.*, "Perspectives in trabecular surgery," *Eye* 2000;14(Pt 3B)(3b):519-530 (2000) ("Jacobi 2000")
1014	F. Skjaerpe, "Selective Trabeculectomy. A Report of a New Surgical Method for Open Angle Glaucoma," *Acta Ophthalmologica* 61:714-727 (1983) ("Skjaerpe 1983")
1015	U.S. Patent Application Publication 2002/0111608 to Baerveldt ("Baerveldt")
1016	U.S. Patent 4,501,274 to Skjaerpe ("Skjaerpe '274")
1017	*Microsurgical Technology, Inc. v. New World Medical, Inc.*, No. 1:20-cv-00754, Doc. 1 (D. Del. June 4, 2020) ("Complaint")
1018	E. Ferrari *et al.*, "Ab-interno trabeculo-canalectomy: surgical approach and histological examination," *European J. Ophthalmology* 12(5):401-05 (2002) ("Ferrari")
1019	U.S. Patent App. 13/159,356 File History ('356 application file history")
1020	T. Shute, "A Novel Technique for Ab Interno Trabeculectomy: Description of Procedure and Preliminary Results," *Am. Glaucoma Society 29th Annual Meeting Poster Abstracts* 34-35 (2019) (*available at*: https://ags.planion.com/Web.User/AbstractDet?ACCOUNT=AGS&CONF=AM19&ABSID=12309) ("Shute")
1021	Arsham Sheybani, *Bent Ab-interno Needle Goniectomy (BANG)*, YouTube (Aug. 24, 2017), https://youtu.be/b5QxWts-Pxs ("BANG Video")
1022	U.S. Patent 9,107,729 File History ('729 patent file history")

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1023	U.S. Patent 9,358,155 File History (‘155 patent file history”)
1024	U.S. Patent Application Publication No. 2006/0241580 to Mittelstein (“Mittelstein”)
1025	U.S. Patent RE38,018 to Anctil (“Anctil”)

PETITIONER'S MANDATORY NOTICES

A. Real Party in Interest (§42.8(b)(1))

New World Medical, Inc. ("NWM" or "Petitioner") is the real party of interest of this Petition. No other entity is a real party of interest or a privy of NWM for this petition.

B. Other Proceedings (§42.8(b)(2))

Microsurgical Tech., Inc. ("MST" or "Patent Owner") and The Regents of the University of California (collectively "Plaintiffs") filed a complaint asserting infringement of U.S. Patent 9,820,885 ("the '885 patent") (Ex.1001) against NWM in the U.S. District Court for the District of Delaware (No. 20-cv-00754) on June 4, 2020. *See* Ex.1017. Plaintiffs also asserted U.S. Patent 9,107,729 ("the '729 patent"), U.S. Patent 9,358,155 ("the '155 patent"), U.S. Patent 9,999,544 ("the '544 patent"), and U.S. Patent 10,123,905 ("the '905 patent), against NWM in that case. NWM was served with the complaint on August 5, 2020.

NWM filed a petition for *inter partes* review ("IPR") regarding the '729 patent on September 4, 2020. *See* IPR No. 2020-01573. NWM also filed a petition for IPR regarding the '155 patent on October 2, 2020. *See* IPR No. 2020-01711.

C. Lead and Backup Counsel (§42.8(b)(3))

Todd R. Tucker (Lead Counsel) Reg. No. 40,850 CALFEE, HALTER & GRISWOLD LLP The Calfee Building 1405 East Sixth Street Cleveland, OH 44114 P: 216-622-8231 / F: 216-214-0816 ttucker@calfee.com	Kyle T. Deighan (Back-up Counsel) Reg. No. 75,525 CALFEE, HALTER & GRISWOLD LLP The Calfee Building 1405 East Sixth Street Cleveland, OH 44114 P: 216-622-8551 / F: 216-214-0816 kdeighan@calfee.com John Reulbach (Back-up Counsel) (*pro hac vice* to be requested) CALFEE, HALTER & GRISWOLD LLP The Calfee Building 1405 East Sixth Street Cleveland, OH 44114 P: 216-622-8263 / F: 216-214-0816 jreulbach@calfee.com

D. Service Information (§42.8(b)(4))

Service on Petitioner may be made by mail or email to: Calfee, Halter & Griswold LLP, 1405 E. 6th Street, Cleveland, Ohio 44114; Telephone: 216-622-8200; Facsimile: 216-241-0816. Petitioner also consents to electronic service by email at the email addresses listed above and ipdocket@calfee.com.

I. INTRODUCTION

The ‘885 patent claims nothing more than using known techniques and devices to treat glaucoma, an eye disease that can lead to blindness. All limitations of the ‘885 patent claims are taught in the prior art. For instance, Quintana (Ex.1004) discloses everything claimed from the device (cutting device with two cutting edges made from a bent needle) to the type of procedure (inserting the device into the anterior chamber (“AC”)) to technique (cutting a “strip” of tissue from the eye’s trabecular meshwork (“TM”) to treat glaucoma). Simply put, there is nothing in the claims of the ‘885 patent that was not known and/or obvious.

For decades, a common method of treating glaucoma has centered on creating openings in the TM, a tissue that regulates fluid outflow from the eye. Fluid build-up in the eye causes elevated intraocular pressure (“IOP”), which is the only modifiable risk factor for glaucoma, and removing sections of TM has long been known to lower IOP. Older surgical approaches to opening the TM created a single, slit-like incision to allow fluid to drain from the eye, but decades before the ‘885 patent’s 2003 filing, surgeons recognized that mere incisions in the TM could close back up and cause subsequent elevation in IOP. Recognizing this shortcoming, doctors such as Quintana, Lee and Jacobi developed techniques and instruments well prior to the ‘885 patent to create more permanent openings by removing strips of TM tissue to facilitate fluid outflow and prevent reclosure.

The ‘885 patent attempts to claim these well-known principles but fails to actually set forth anything inventive. The claims relate to methods for forming an opening in the TM but list steps that the patent itself admits were known and used in surgical procedures decades prior to the patent. The claims merely define a device for performing these well-known methods that includes nothing more than known components commonly used in surgical instruments for treating glaucoma. Tellingly, the patent ***describes the claimed device as nothing more than a needle with a bent tip***. The claims attempt to cover a known technique for removing TM tissue using generic, broadly-claimed, known devices—nothing inventive or novel.

As demonstrated below, the claimed methods and devices are not patentably distinct from the prior art. Even setting aside that the patent admits the very surgical procedure covered by the claims (*i.e.*, goniectomy) was known, the claimed methods and devices were also disclosed in numerous prior art references. Quintana (Ex.1004) describes a surgical technique akin to a traditional goniectomy for removing strips of TM tissue using a needle with a bent tip. Jacobi (Ex.1007) describes a similar technique using a device with dual cutting surfaces separated from each other on a bowl-shaped tip, which “peels” the TM resulting in “strings” of TM tissue. These and many other references make clear that the patent claims simply cover what was already well-known in the art, rendering those claims unpatentable.

Accordingly, Petitioner respectfully requests that trial be instituted and claims 1-11 of the '885 patent (the "Challenged Claims") be cancelled.

II. CERTIFICATIONS; GROUNDS

A. NWM May Contest the Patent (§42.104(a))

NWM certifies that the '885 patent is available for IPR and it is not barred or estopped from requesting IPR. Neither NWM, nor any party in privity with NWM, has filed a civil action challenging the validity of any claim of the '885 patent. The '885 patent has not been the subject of a prior IPR by NWM or a privy of NWM. This petition is timely filed as NWM was served with a complaint alleging infringement of the '885 patent on August 5, 2020. *See* 35 U.S.C. § 315(b).

B. Challenged Claims (§42.104(b))

NWM requests cancellation of the Challenged Claims[1] based on the following prior art and grounds.

Reference	Pub. / Priority Date	Prior Art Status	Exhibit
Quintana	Published 1985	§§102(a) and (b)	1004
Lee	Issued Feb. 13, 1990	§§102(a) and (b)	1006
Jacobi	Published 1997	§§102(a) and (b)	1007

[1] The Challenged Claims are reproduced in the **Claim Appendix** below.

Grounds	Claims Challenged	Basis	Reference(s)
Ground 1	1-3, 6, 9-10	§102	Quintana
Ground 2	4-5, 7-8, 11	§103	Quintana, Knowledge of a POSITA
Ground 3	1-11	§103	Jacobi, Knowledge of a POSITA

C. IPR Fee (§42.15(a))

The Director is authorized to charge the fee in 37 C.F.R. §42.15(a) to Deposit Account 03-0172.

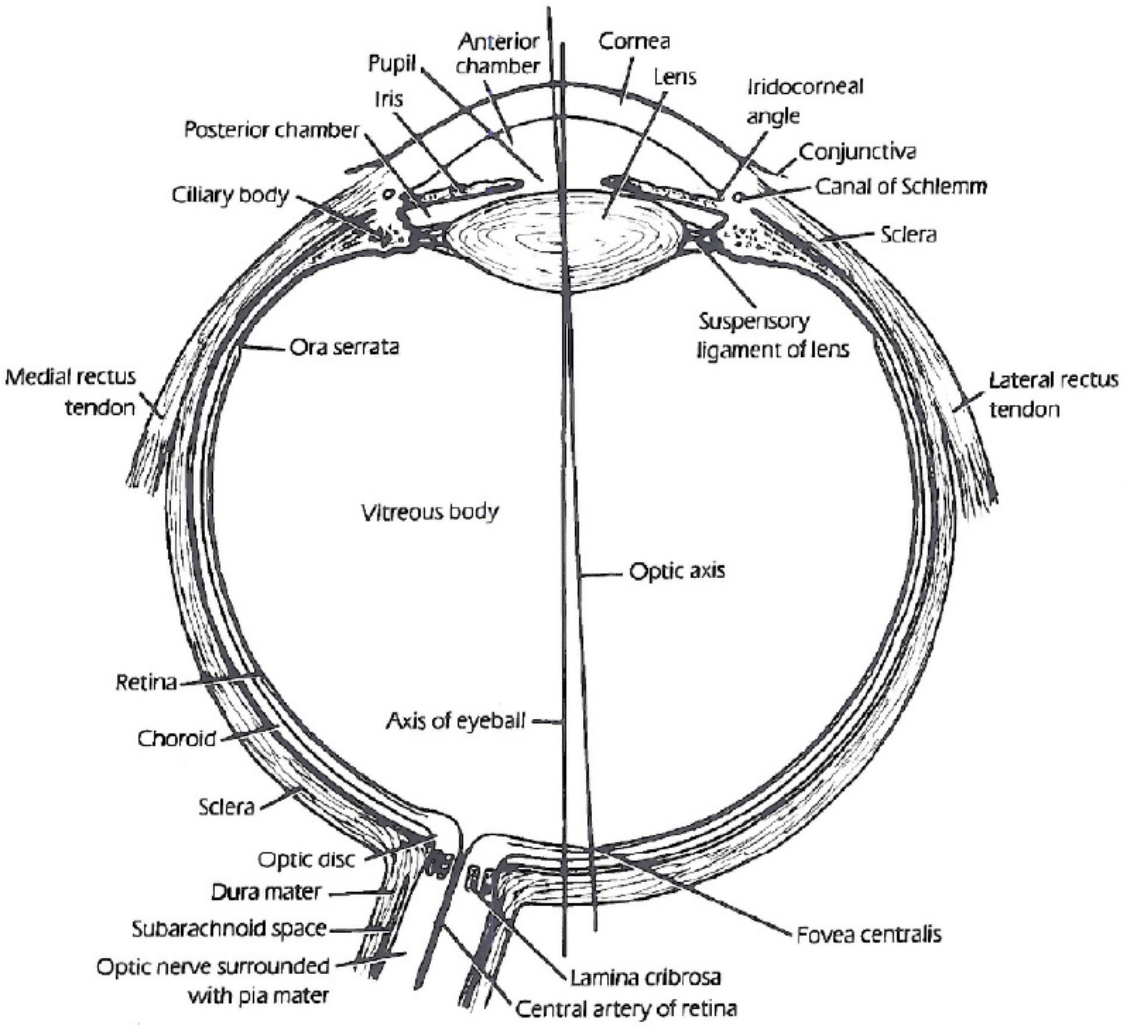
D. Service (§42.105)

Proof of service of this petition is provided below.

III. Background Technology

A. Eye Anatomy

Human eyes take in light and convert it to a neural signal to provide vision. Ex.1008, 8-9, 47. Eyes have three layers: (1) an outer **fibrous layer**; (2) a middle **vascular layer**; and (3) an inner **neural layer**. *Id.*, 11. The schematic diagram below depicts the layers and other structures of the eye.



Ex.1008, 9.

The outer fibrous layer includes the **cornea** (transparent part allowing light to enter) and **sclera** (opaque white part). Ex.1008, 1. The cornea is divided into "zones": (1) central; (2) paracentral; (3) peripheral; and (4) limbal. Ex.1009, 4; Ex.1003, ¶33.

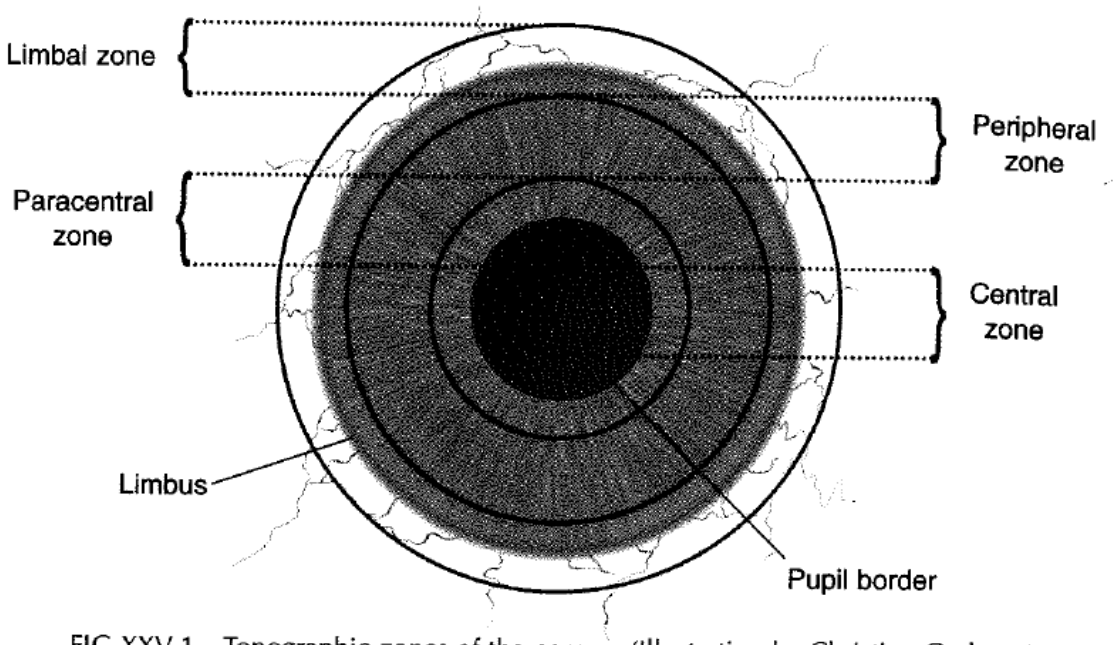


FIG XXV-1—Topographic zones of the cornea. (Illustration by Christine Gralapp.)

Ex.1009, 9. The **limbus** is within the limbal zone of the cornea and is the transition between the cornea and sclera. *Id.*, 9; Ex.1008, 23; Ex.1003, ¶34.

The **uvea** or vascular layer includes: the **iris** (colored portion surrounding the **pupil** that regulates light entry); **ciliary body** (produces aqueous humor or "aqueous"); and the **choroid** (surrounds and nourishes retina). Ex.1008, 29, 31-32, 36, 46. The neural layer includes the **retina**—the light-sensitive lining within the eye. *Id.*, 47.

As shown above, the eye also has three chambers: (1) the **anterior chamber** ("AC"); (2) the **posterior chamber**; and (3) the **vitreous chamber**. *Id.*, 66-68. Within the posterior chamber is the **lens**, which focuses light on the retina. *Id.*, 69.

B. Aqueous Humor Outflow

Aqueous humor, a clear fluid that protects and nourishes the eye, flows from the posterior chamber into the AC via the pupil. Ex.1011, 27. Normally, aqueous drains through the **TM**, a filterlike tissue between the iris and cornea, and into **Schlemm's Canal ("SC")**, a canal running circularly about the eye. *Id.*, 16-17; Ex.1006, 1:9-27; Ex.1003, ¶39. The following shows a cutaway of the TM and SC:

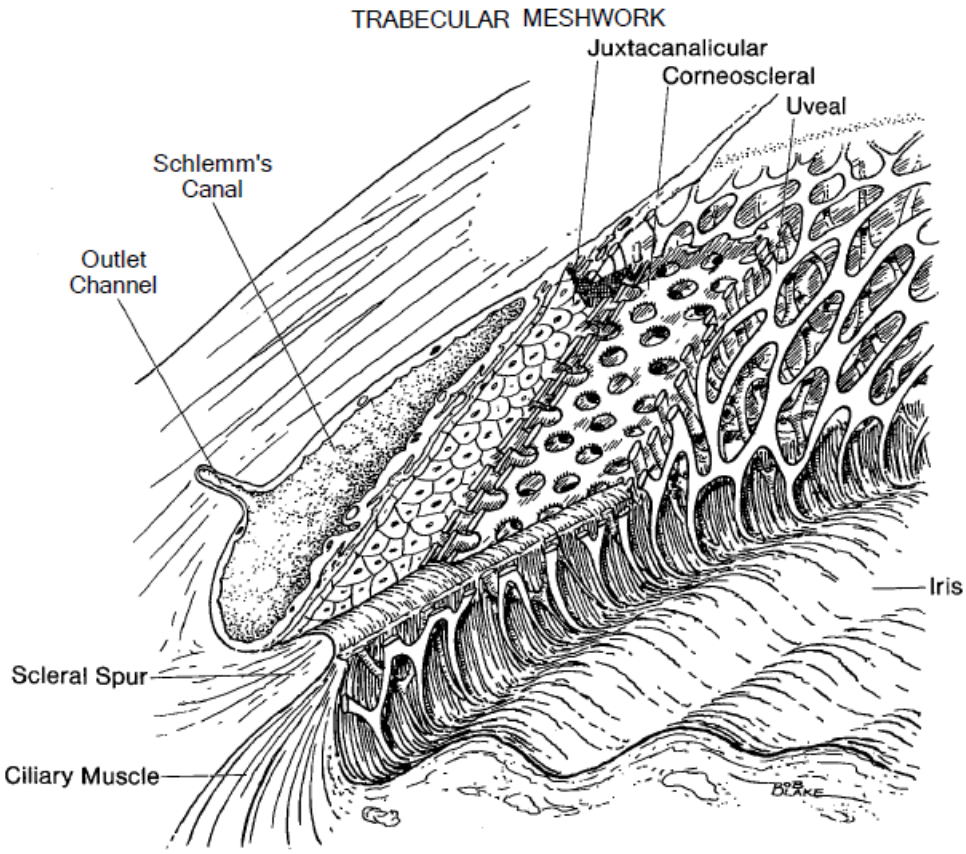


Figure 2.10. Three layers of trabecular meshwork (shown in cutaway views): (1) uveal; (2) corneoscleral; and (3) juxtacanalicular.

Ex.1011, 18.

From SC, aqueous drains from the eye through channels/outlets, as shown schematically below. *Id.*, 16-17. In healthy eyes, aqueous is produced at generally the same rate it drains. *Id.*, 7; Ex.1003, ¶40.

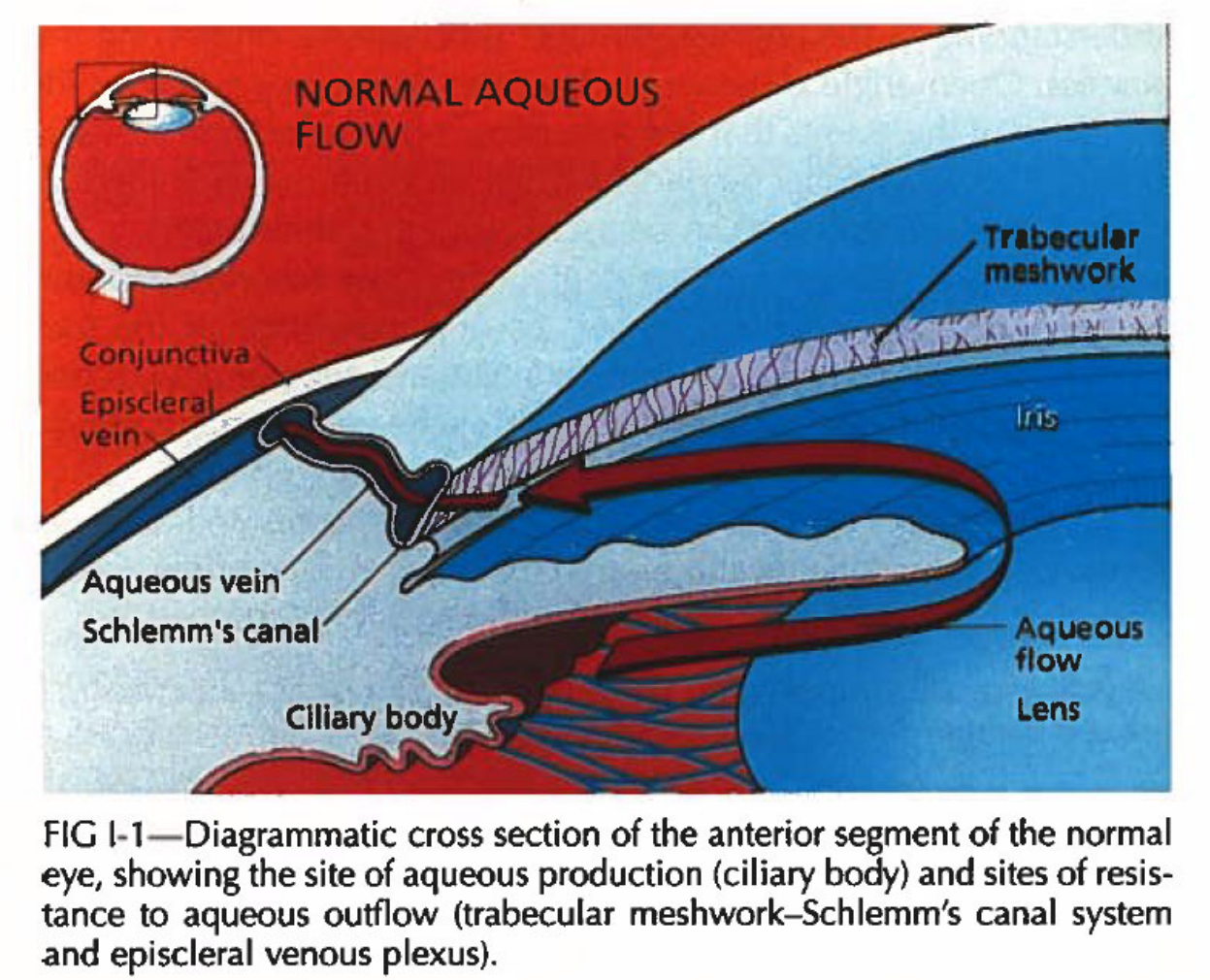


FIG I-1—Diagrammatic cross section of the anterior segment of the normal eye, showing the site of aqueous production (ciliary body) and sites of resistance to aqueous outflow (trabecular meshwork–Schlemm's canal system and episcleral venous plexus).

Ex.1012, 6.

C. Glaucoma

Glaucoma refers to a collection of diseases that can cause irreversible blindness. Ex.1003, ¶41. It was well-known by 2003 that elevated IOP was a primary risk factor for glaucoma. *Id.*; Ex.1006, 1:9-27; Ex.1012, 6. It was also

known that "[i]n most cases increased IOP is caused by increased resistance to aqueous humor outflow" across the TM-SC system. Ex.1012, 6; *see also* Ex.1004, 3; Ex.1007, 4; Ex.1006, 1:13-27; Ex.1003, ¶41.

Two common glaucoma types are open-angle and closed-angle. Ex.1012, 7; Ex.1003, ¶¶42-44. As shown below, in open-angle glaucoma, the TM restricts aqueous outflow from the AC. Ex.1012, 10.

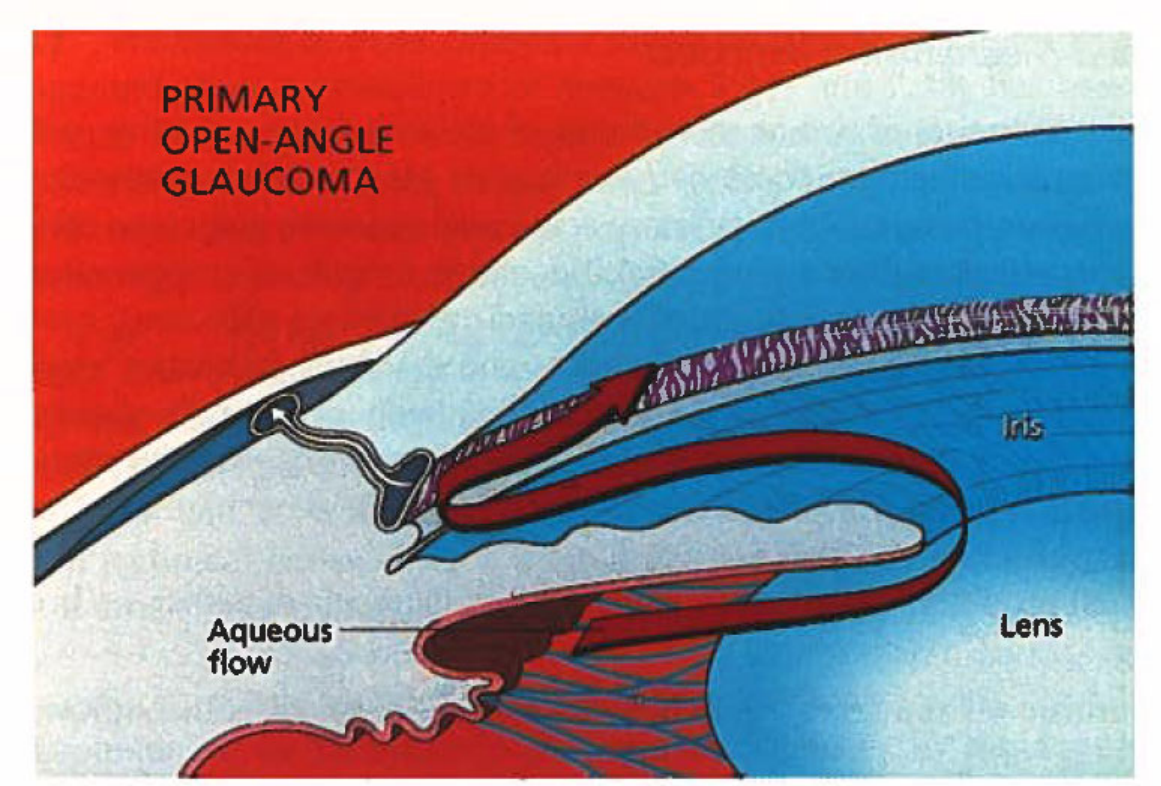


FIG I-2—Schematic of open-angle glaucoma with resistance to aqueous outflow through the trabecular meshwork–Schlemm's canal system in the absence of gross anatomic obstruction. Small white arrow shows normal path of outflow and indicates that resistance in this illustration is relative, not total.

In closed-angle, the anatomical angle between the iris and cornea narrows, blocking aqueous outflow, as shown below. *Id*.

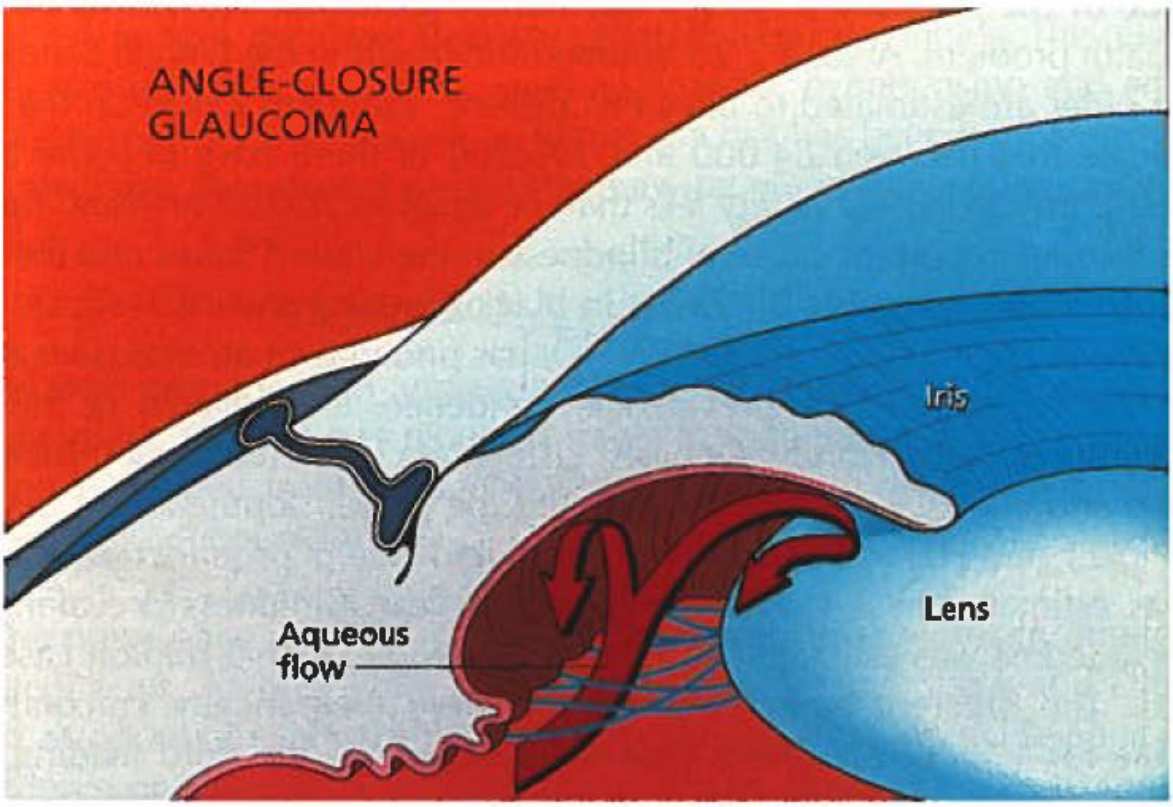


FIG I-3—Schematic of angle-closure glaucoma with pupillary block leading to peripheral iris obstruction of the trabecular meshwork.

These blockages cause increased pressure in the AC due to the continuous production of aqueous, but with limited or no drainage. *Id.*, 6; Ex.1011, 7. This increased pressure ultimately damages the optical nerve and can lead to vision loss. Ex.1011, 4-5; Ex.1003, ¶44.

D. Treatment of Glaucoma

Surgical attempts to treat glaucoma date back centuries and have often sought to decrease IOP by improving fluid drainage from the eye. Ex.1012, 4-5; Ex.1003, ¶45.

By the mid-1900's, Grant found that most resistance to outflow is caused by the TM and 75% of the resistance could be eliminated using an "ab interno"[2] approach to incise the TM. Ex.1007, 4; Ex.1011, 23. These findings spurred development of new surgical procedures and devices that, well before 2003, focused on bypassing, disrupting, incising, and removing strips of TM tissue. Ex.1003, ¶46.

1. Trabeculotomy and Trabeculectomy

Trabeculotomy and trabeculectomy were two common "ab externo" procedures. Trabeculotomy, introduced in the early 1960's, involves creating an opening in the sclera directly into SC and using an instrument to disrupt (*e.g.*, tear) the TM. Ex.1011, 49; Ex.1012, 51-53, Fig.VIII-13 (below); Ex.1003, ¶¶48-49.

[2] Procedures for treating glaucoma can be classified as "ab interno" (from inside the eye) or "ab externo" (from outside of eye). Ex.1003, ¶47. In general, these terms indicate whether target tissue (*e.g.*, TM) is approached from inside the eye ("ab interno") or outside of eye ("ab externo"). *Id.*

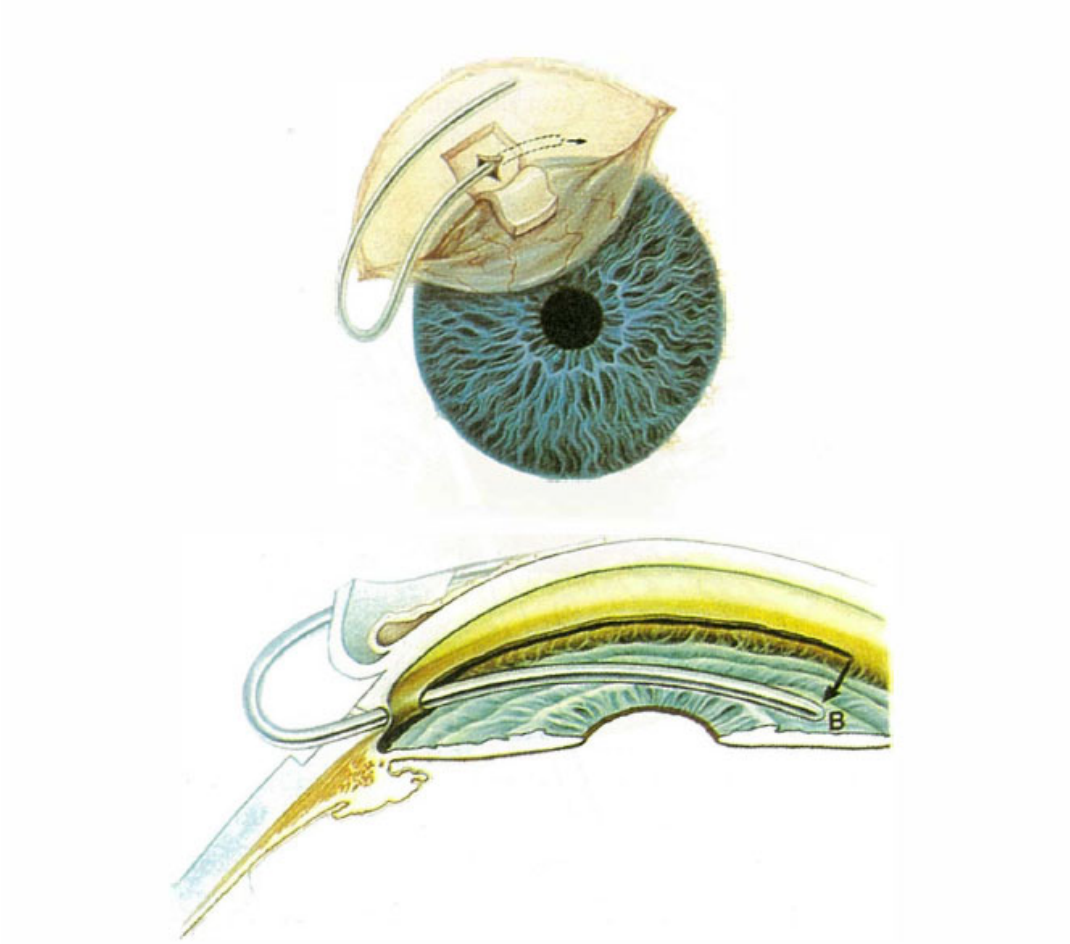


FIG VIII-13-Trabeculotomy. *Top,* Probe is gently passed along Schlemm's canal with little resistance for 6-10 mm. *Bottom,* By rotating the probe internally (8), the surgeon ruptures the trabeculum, and the probe appears in the anterior chamber with minimum bleeding. (Reproduced and modified with permission from Kolker AE, Hetherington J, eds. *Becker-Shaffer's Diagnosis and Therapy of the Glaucomas.* 5th ed. St Louis: Mosby; 1983.)

Trabeculectomy, described in the late 1960's, involves excising the TM. Ex.1011, 61-63. As shown below, trabeculectomy involves creating an exterior flap and ***excising*** (or removing) a portion of the TM, SC, and sclera underneath the flap to increase outflow. *Id.*; Ex.1003, ¶50.

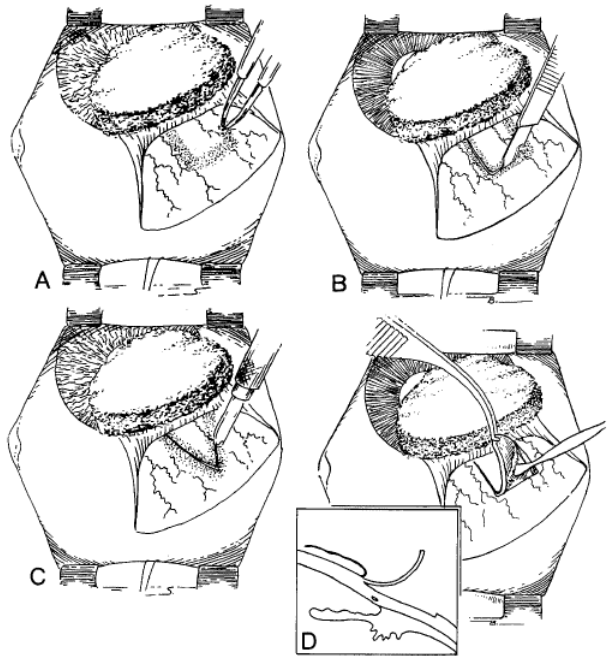


Figure 37.10. Trabeculectomy. A. Cauterization of area intended for margins of scleral flap. B. Margins of scleral flap outlined by partial-thickness incisions. C. Triangular scleral flap as an alternative technique. D. Dissection of scleral flap.

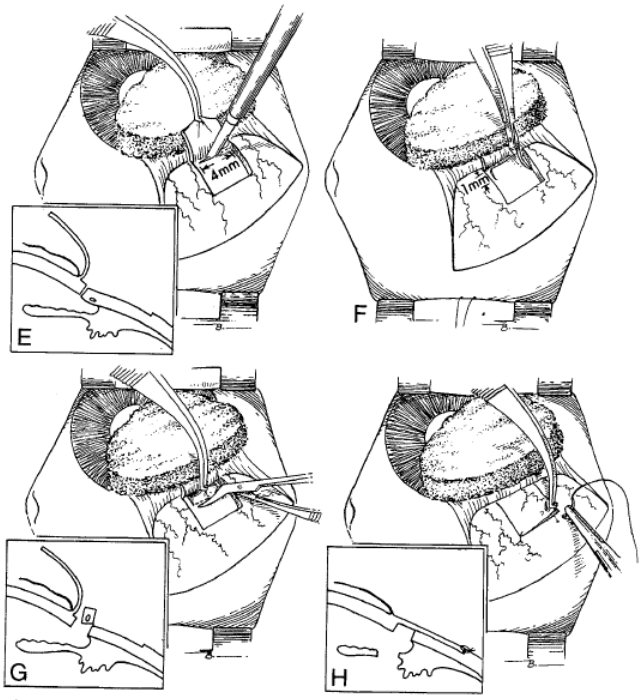


Figure 37.10. (cont'd) E. Anterior chamber entered just behind the hinge of the scleral flap. F. Completion of anterior and lateral margins of deep limbal incision with scissors. G. Flap of deep limbal tissue excised by cutting along scleral spur. H. Approximation of scleral flap. (Portions reprinted by permission from Shields, MB: Trabeculectomy vs. full-thickness filtering operation for control of glaucoma. Ophthalmic Surg 11:498, 1980.)

Ex.1011, 62-63.

2. Goniotomy

Goniotomy was introduced in the late 1930's. *Id.*, 51. As shown below, goniotomy is an "ab interno" procedure that involves penetrating the AC and creating a slit-like incision in the TM. *Id.*; Ex.1012, 51-52. A goniolens placed over the eye allows the surgeon to view the angle. Ex.1003, ¶¶51-53.

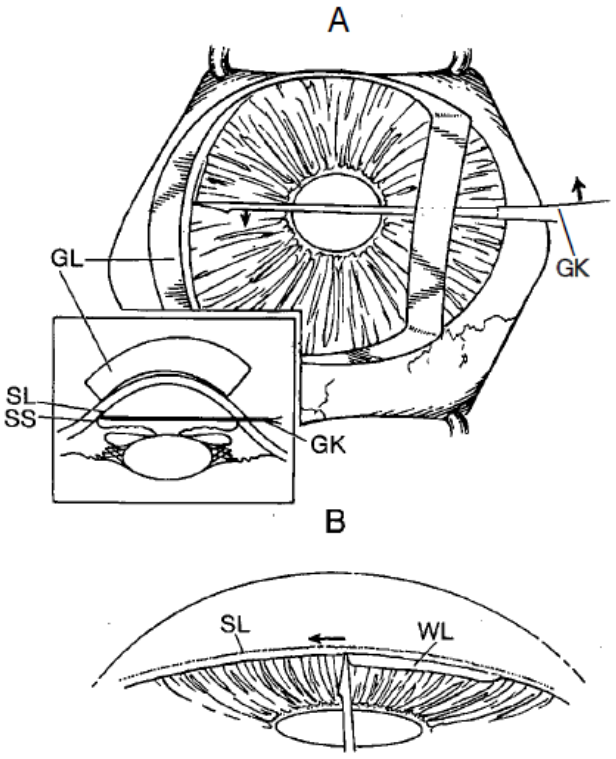


Figure 35.8. Goniotomy. A. With a surgical goniolens *(GL)* positioned on the cornea, a goniotomy knife *(GK)* is inserted through peripheral cornea and passed across the anterior chamber to the angle in the opposite quadrant. B. Under direct gonioscopic visualization, angle tissue is excised between Schwalbe's line *(SL)* and scleral spur *(SS)* for approximately one-third of the chamber angle circumference. This creates a white line *(WL)* as the cut edge of tissue retracts from the incision. *Arrows* indicate the direction of knife movement during incision of angle tissue.

Ex. 1011, 51.

3. "Excisional" Goniotomy

Despite some success, it was recognized well before 2003 that the slit-like opening these procedures create could close or scar over after surgery, blocking aqueous outflow. Ex.1007, 4 (traditional approaches "remove little tissue and allow filling in and scarring to occur with subsequent closure of the trabecular opening."); *see also* Ex.1006, 1:39-47; Ex.1014, 2; Ex.1003, ¶54. Techniques were developed to create larger and more permanent openings by removing strips of tissue to "avoid early reclosure" of the TM. Ex.1007, 4-5; Ex.1003, ¶54. These are referred to as "***excisional goniotomy***" procedures. Ex.1013, 11; Ex.1003, ¶¶54-55.

The '885 patent recognizes goniectomy was a known technique for treating glaucoma. Ex.1001, 1:36-65. Goniectomy is an "ab interno" procedure that involves excising and removing pieces of TM from the eye. *Id.*; Ex.1006, 5:55-6:45; Ex.1003, ¶56. Lee (Ex.1006), issued in 1990, teaches a dual-bladed instrument for goniectomy "to excise a piece of tissue" to improve outflow and to collect tissue for histopathological examination. Ex.1006, 3:50-57, 5:55-6:45. As seen below, Lee's device excises a "strip of angle tissue 40" using dual blades (14) angled from 0-45° "depending on surgical requirements." *Id.*, Fig.5, 4:49-54; Ex.1003, ¶56.

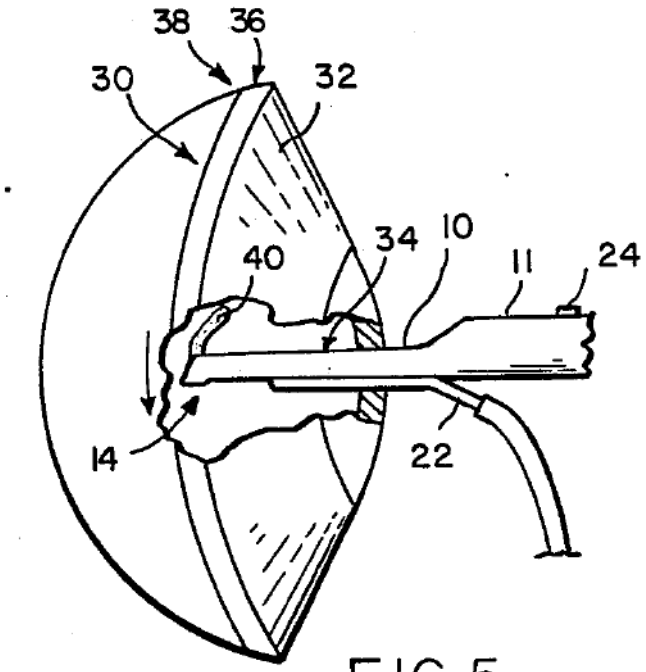


FIG.5

Quintana (Ex.1004) discloses a procedure for "stripping" and "achiev[ing] a section" of TM tissue. Ex.1004, 3, 4. Quintana sought to improve on techniques that incised TM by penetrating the AC with a needle having a tip bent 20-30°; introducing the needle tip into SC from within the AC; and "stripping" a section of TM tissue using the dual cutting edges at the needle tip. *Id*.; Ex.1003, ¶57.

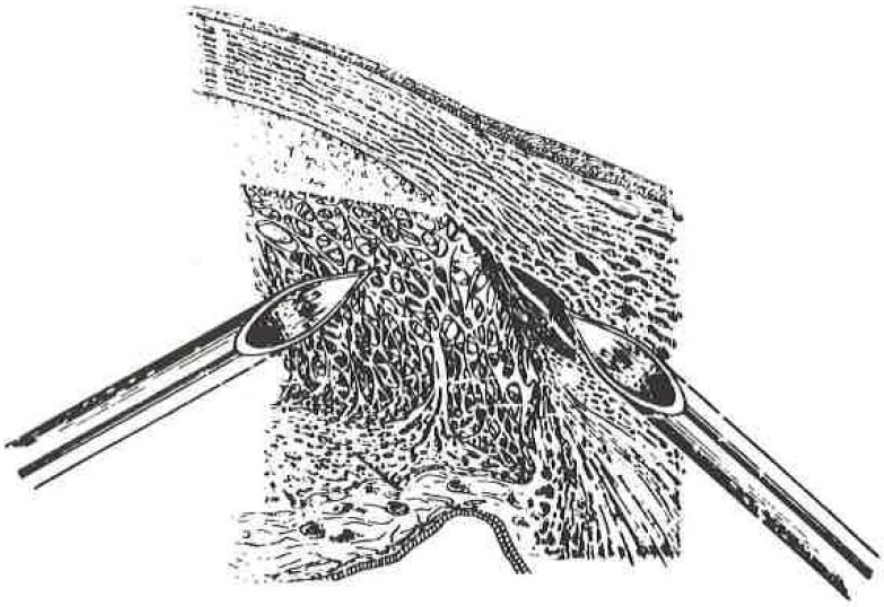


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

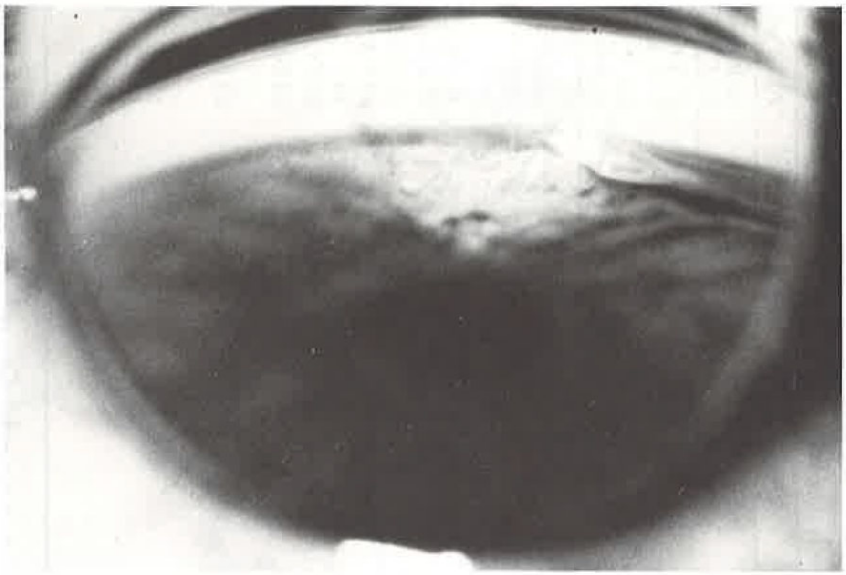


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

Ex.1004, 4. 5.

Jacobi (Ex.1007) disclosed "goniocurettage", another "ab interno" procedure, to excise TM. Ex.1007, 5. Jacobi used a "gonioscraper" with a bowl-shaped tip having spaced-apart, sharpened edges, inserted the device into the AC through a corneal incision, and used the sharpened edges to create parallel incisions in the TM to "peel" tissue resulting in "strings of trabecular tissue." *Id.*, 2; Ex.1003, ¶58.

Techniques were well-known by 2003 that allowed entering the AC from various locations or bending the instruments at different angles to suit the needs of a procedure. Well before 2003, the underlying basis for most glaucoma procedures had long been established—decrease IOP by removing strips of tissue from the TM. Ex.1013, 11; Ex.1003, ¶59.

IV. The '885 Patent

A. Overview

The '885 patent discloses devices and methods for performing the well-known goniectomy procedure. Ex.1001, 1:25-2:40. The patent expressly ***admits*** that goniectomy procedures for removing strips of tissue from the eye and instruments for performing these procedures ***were known***. *Id.*, 1:39-43; Ex.1003, ¶60. Neither the patent's devices nor methods are valid over the prior art.

The patent claims a device that is a needle with a bent tip. Ex.1003, ¶61. As shown in its figures, the patent discloses a "needle cutter device" 10 with a probe-

like shaft 14, distal tip 24, and spaced apart cutting edges 20, 22 on either side of a lumen 27. Ex.1001, 3:6-49.

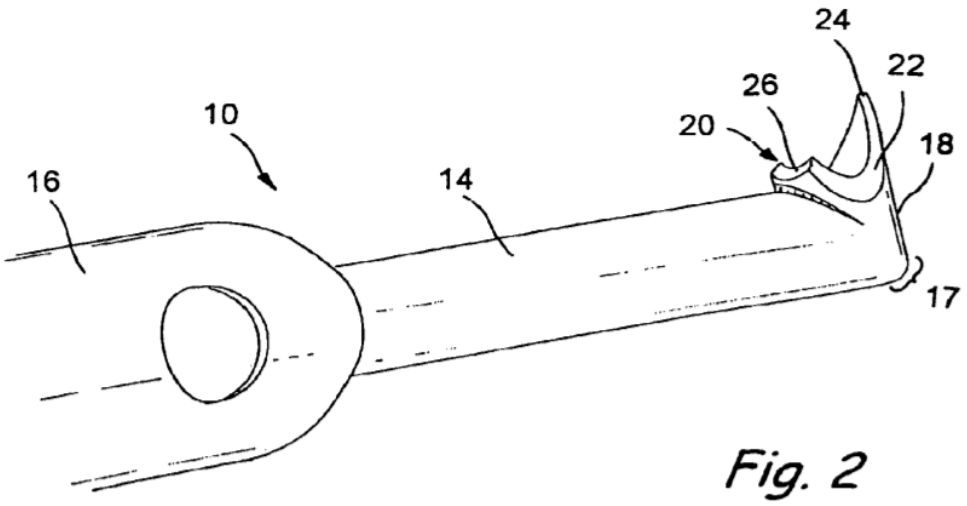


Fig. 2

The device may include well-known "bends or curves" (such as bend 17 above) formed in the cutting tube 14 "to facilitate its use for its intended purpose." *Id.*, 3:30-38. The patent indicates making the device involves nothing more than cutting and bending "standard tubing"—a needle. *Id.*, 4:66-5:18; *see also id.*, Figs.3A-3D (below, showing "standard tubing" cut to form device); Ex.1003, ¶¶62-63.

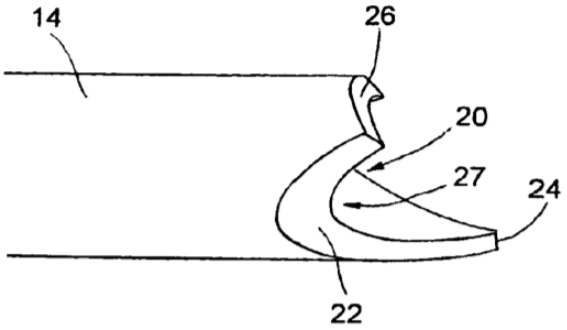


Fig. 3A

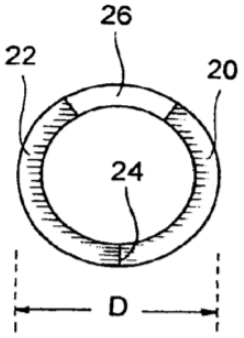


Fig. 3B

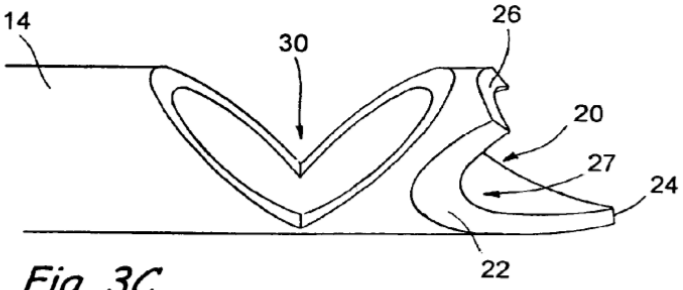


Fig. 3C

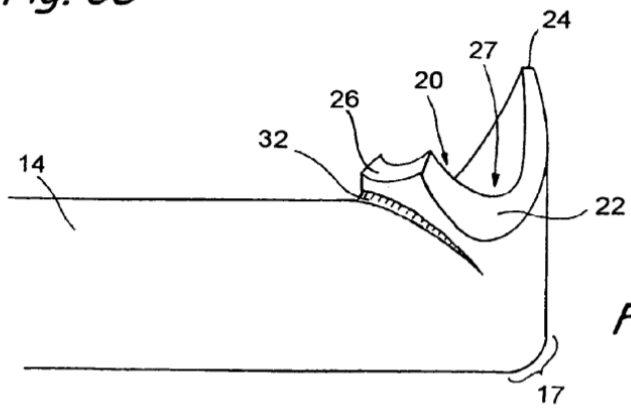


Fig. 3D

The patent also describes performing a goniectomy using the device in the exact same manner that was well-known: inserting the device into the AC, advancing the tip 24 through SC, and cutting a strip of tissue from the TM. Ex.1001, 5:32-6:30, Fig.4.

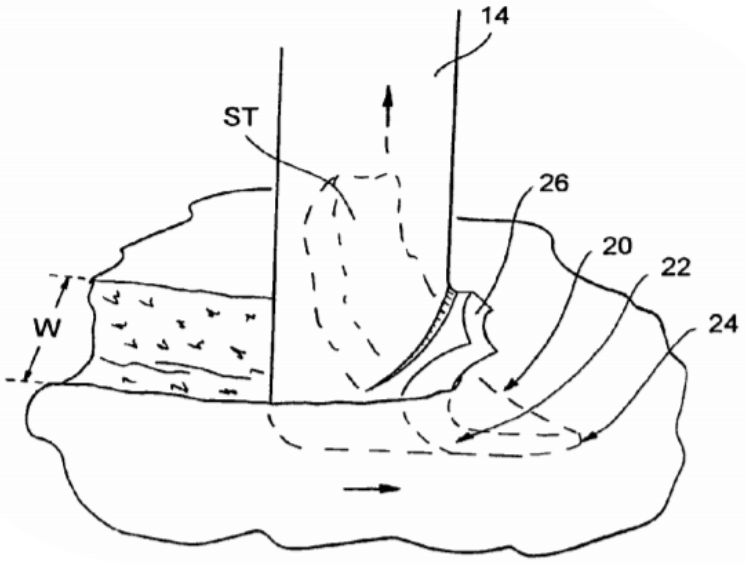


Fig. 4

This procedure had been performed for decades before 2003 to remove strips of TM. Ex.1003, ¶¶64-65. Importantly, the patent does not claim to have invented goniectomy and claim language related to that ***procedure is not a source of patentability***.

B. Prosecution History

The '885 patent issued from U.S. Application 15/076,624 ("the '624 application"), filed on March 21, 2016, which is a continuation of U.S. Application 14/789,632 ("the '632 application"), filed on July 1, 2015 and issued as the '155 patent. The '632 application is a continuation of U.S. Application 14/481,754 ("the '754 application"), filed on September 9, 2014 and issued as the '729 patent. The '754 application is a divisional of U.S. Application 13/159,356 ("the '356 application"), filed on June 13, 2011 and abandoned. The '885 patent claims

priority to U.S. Provisional Application 60/477,258, filed June 10, 2003. The '885 patent belongs to a large family and thus, only select portions of the prosecution histories are discussed.

1. '356 Application

During prosecution of the '356 application, the Examiner rejected certain claims over U.S. Patent 6,419,684 ("Heisler"), which the Examiner found teaches a device for cutting strips of tissue. Ex.1019, 202. Applicant amended the claims to require a "dual blade device usable for performing an ab interno surgical procedure." *Id.*, 225 (emphasis added). After receiving another rejection, applicant argued Heisler's straight tube device could not be "advanced longitudinally along the TM tissue to remove a 'strip' . . . by an ab interno approach." *Id.*, 265. The application was subsequently abandoned.

2. '754 Application

In the notice of allowance for the '754 application (which issued as the '729 patent), the Examiner explained that the closest prior art was Lee, which disclosed a "dual blade" device but not a distal protruding tip extending to "form a bend or curve." Ex.1022, 320-21. Lee's device includes a bowl-like cavity 12 "having a sharpened rim which creates a single, more or less U-shaped cutting edge 14." Ex.1006, 4:38-41, Figs. 2 (bottom view) and 3 (sectional side view).

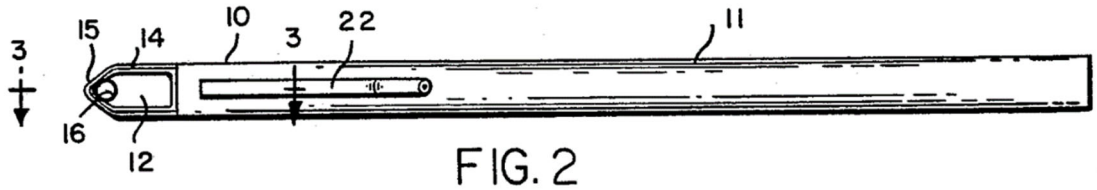


FIG. 2

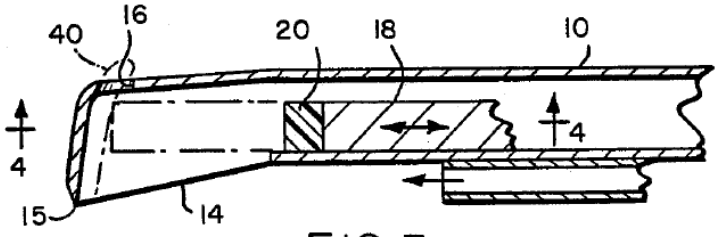
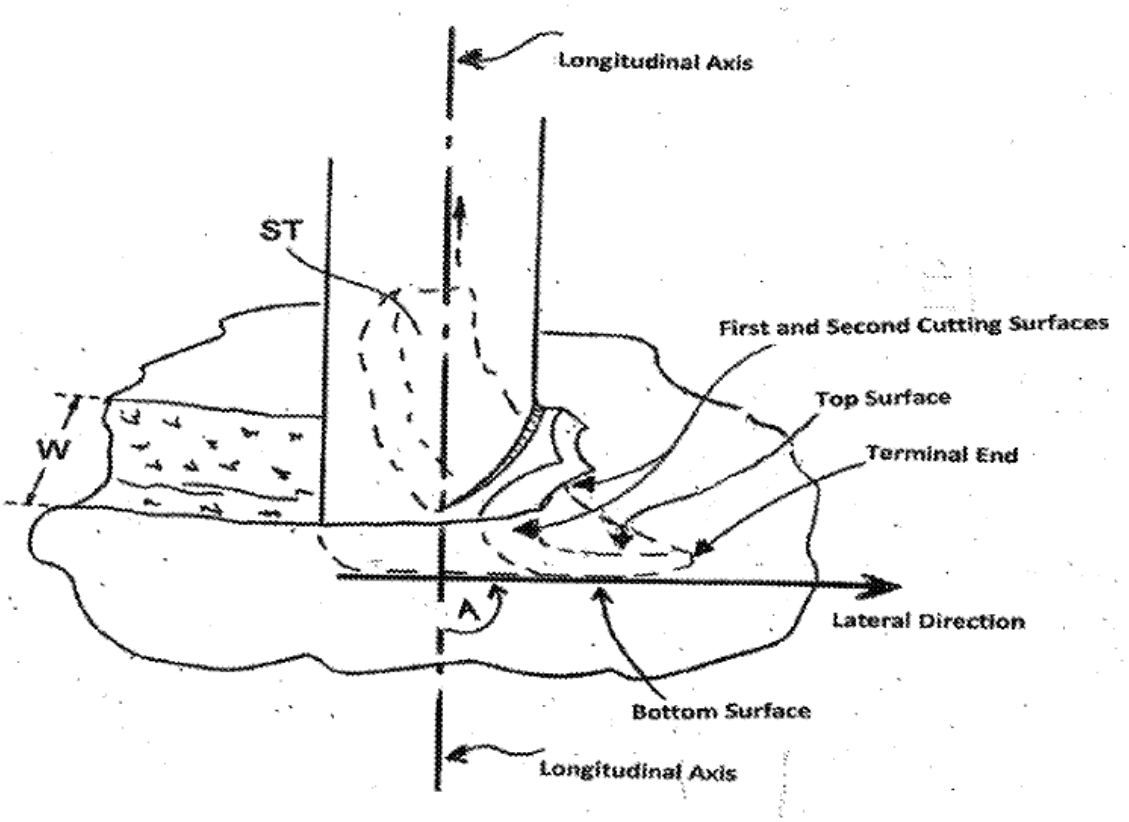


FIG. 3

Given the Examiner's finding that Lee's device has "dual blades corresponding to the U-shape," dual blade devices such as Lee's have two cutting edges, as claimed. Ex.1003, ¶¶69-70.

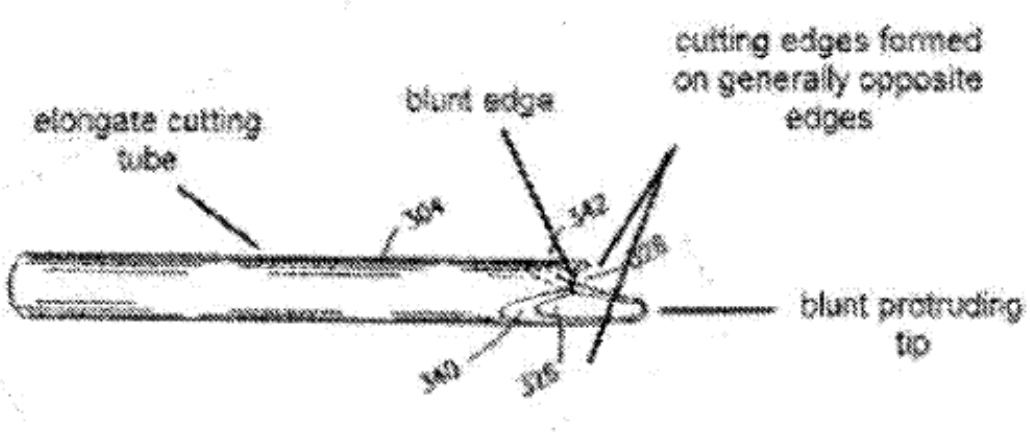
3. '632 Application

During prosecution of the '632 application (which issued as the '155 patent), the applicant included an annotated version of Fig.4 labeling certain claimed elements:



Ex.1023, 199. A standard needle (such as Quintana's discussed below) would have these same components. Ex.1003, ¶72.

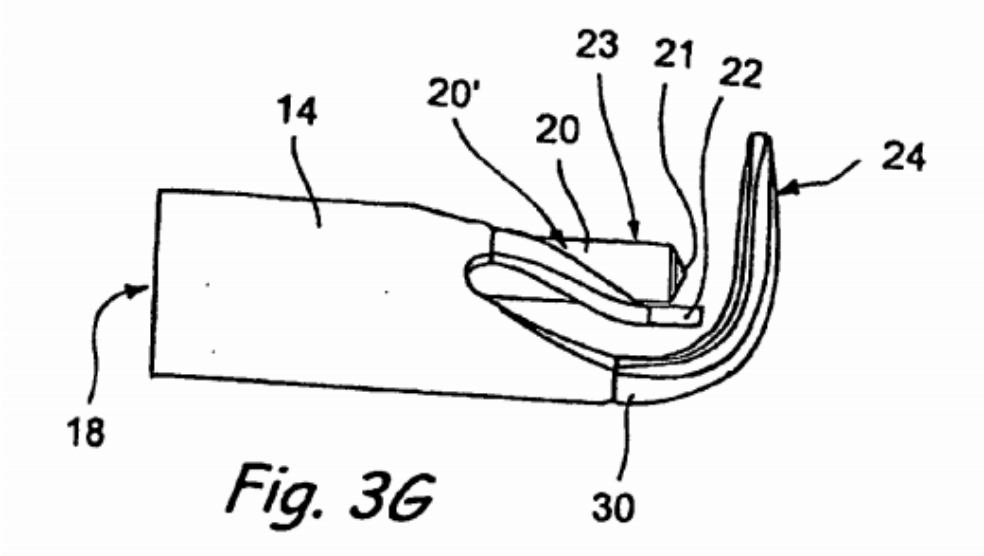
The applicant received a notice of allowance indicating the "closest prior art includes Heisler USP 6,419,684 which teaches two cutting edges, a blunt protruding tip extending beyond the cutting edges, and a blunt top edge." Ex.1023, 232. The Examiner stated, however, Heisler does not teach a "bend or curve" and it would not be obvious to add a bend or curve to the device because it would render the device inoperable. *Id.* As shown in an annotated image of Heisler from the file history, Heisler discloses a needle-like device that the Examiner found meets many claim limitations but does not have a "bend or curve":



Id., 66-68.

4. '624 Application

During prosecution of the '624 application (which issued as the '885 patent), the pending claims were rejected over U.S. Publication No. 2006/0241580 ("Mittelstein"). Ex.1002, 97-100. The Examiner asserted Mittelstein taught the claimed device and procedure, including the claimed "tip" and "platform" of the device. *Id.*; *see* Ex.1024, Fig.3G (below).



The applicant overcame the Mittelstein rejected by arguing that Mittelstein shares the same filing date as the application. Ex.1002, 166. In the notice of allowance, Lee was again identified as the closest prior art. *Id.*, 182. The Examiner noted that although Lee discloses the claimed procedure with a device having two cutting blades, the tip of Lee's device does not have a transverse width narrowest at the terminal end, despite Lee's teaching that the bowl-like cavity of the device has a distal end 15 that protrudes beyond cutting edges 14. *Id.*; Ex.1006, 4:38-48.

C. Person of Ordinary Skill in the Art ("POSITA")

A POSITA would have: (1) a medical degree and at least two years' experience with treating glaucoma and performing glaucoma surgery; or (2) an undergraduate or graduate degree in biomedical or mechanical engineering and at least five years of work experience in the area of ophthalmology, including familiarity with ophthalmic anatomy and glaucoma surgery. Ex.1003, ¶24.

D. Effective Filing Date

The '885 patent claims priority to the '258 provisional filed June 10, 2003. The prior art relied on in this Petition published well before 2003. For this Petition alone NWM will assume a June 10, 2003 effective filing date for the '885 patent claims.

V. Claim Construction

In IPR proceedings filed after November 12, 2018, claims are construed under the standard used in civil actions under 35 U.S.C. §282(b). 37 C.F.R. §42.100(b). Petitioner submits all terms should be given their plain and ordinary meaning, unless otherwise indicated below.[3]

VI. Detailed Explanation of Unpatentability

A. Ground 1: Quintana (Ex.1004) Anticipates Claims 1-3, 6, and 9-10

1. Overview of Quintana

Quintana[4] describes an "ab interno" method of goniotrabeculotomy for treating glaucoma which "achieves a section of the trabecular meshwork without damage to the external wall of Schlemm's canal." Ex.1004, 3. According to Quintana, "[i]ncreased resistance to the outflow of aqueous through the TM is the most accepted pathogenic mechanism in the majority of open-angle glaucomas" and therefore, "the rational treatment of the trabecular glaucomas should consist in opening the TM." *Id.*

[3] Nothing herein is a waiver of challenge, or agreement that the requirements of 35 U.S.C. §112 are met for any claim.

[4] Quintana was not cited during prosecution of the '885 patent.

Quintana's procedure uses a needle having a tip bent 20-30°. Ex.1004, 3. The surgeon is positioned temporally closest to the eye being treated and uses the needle to penetrate the AC. *Id*. If the eye is viewed as a clock and the top of the eye is 12 o'clock, the needle penetrates the right eye at 6 hours and the left eye at 12 hours. *Id.*, 4. After penetrating the AC, the surgeon visualizes the angle through a goniolens and inserts the bent tip of the needle through the TM into the SC. *Id.* The needle tip is oriented such that the convex side faces SC's external wall. The surgeon advances the needle through SC, causing TM tissue to be "stripped" from SC. *Id.* The needle advances 100-120° through SC. *Id.* The technique resulted in an IOP decrease in almost all cases. *Id.*, 3; Ex.1003, ¶78.

Quintana indicates the needle penetrates the AC "through the scleral side of the limbus . . . in order to run parallel to SC." Ex.1004, 4. This causes the needle to be roughly parallel to SC upon entry into the AC, given that SC is beneath the limbus in most patients. Ex.1003, ¶79. Penetrating the AC at or near the limbus would still allow the needle to run parallel to SC upon entry for the same reason. *Id.*

Quintana's needle penetrates the AC on a "tangential approach." Ex.1004, 4. This means the needle tip approaches and enters the TM at a shallow angle to allow each cutting edge at the tip to separately cut the TM. Ex.1003, ¶80. In contrast, the perpendicular approach would have the needle approach and enter the

TM at a roughly 90° angle. *Id.* In that orientation, an unbent needle tip would act as a single blade and create a single, slit-like incision in the TM. *Id.* Fig.1 below shows Quintana's tangential approach (right) and a perpendicular approach (left).

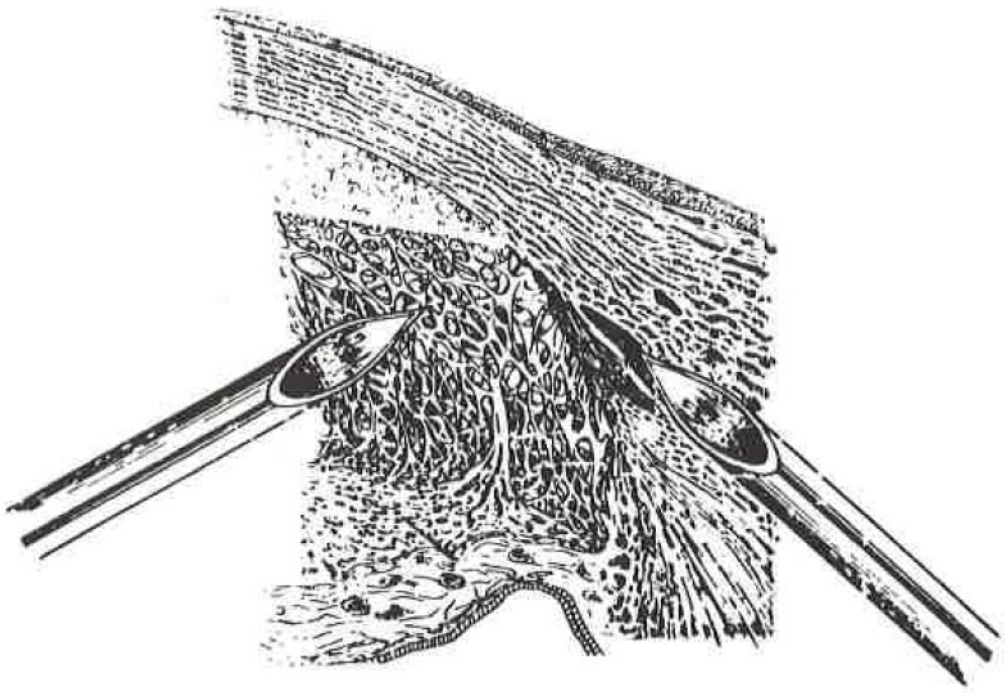
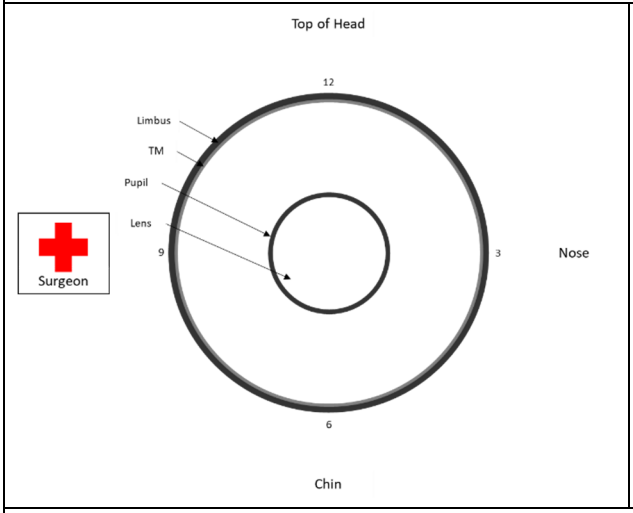
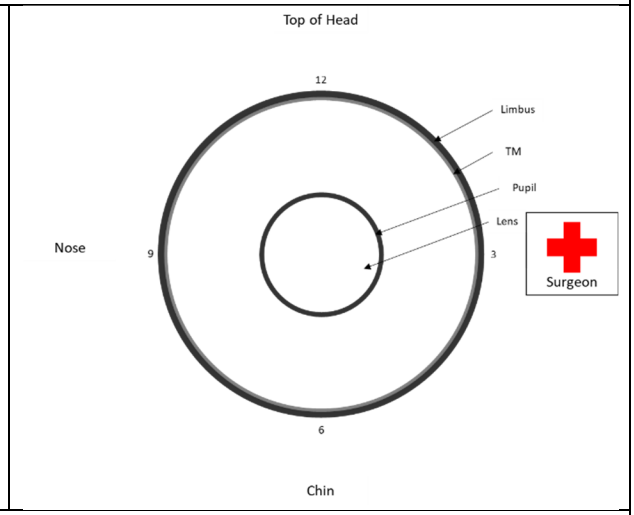
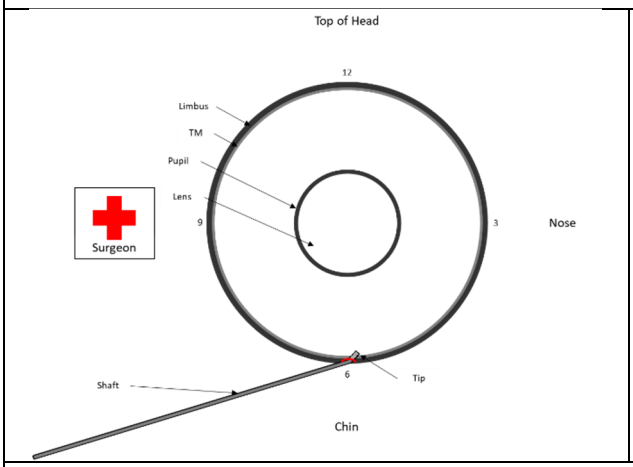
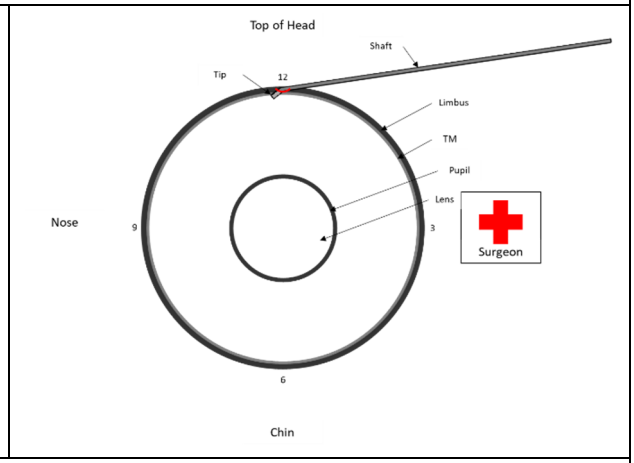
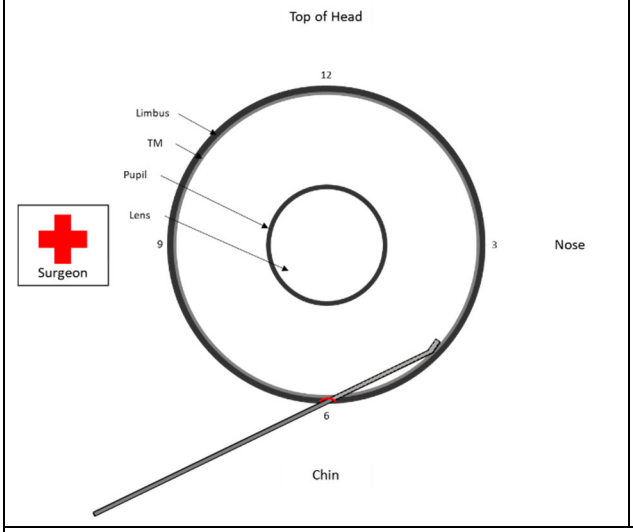
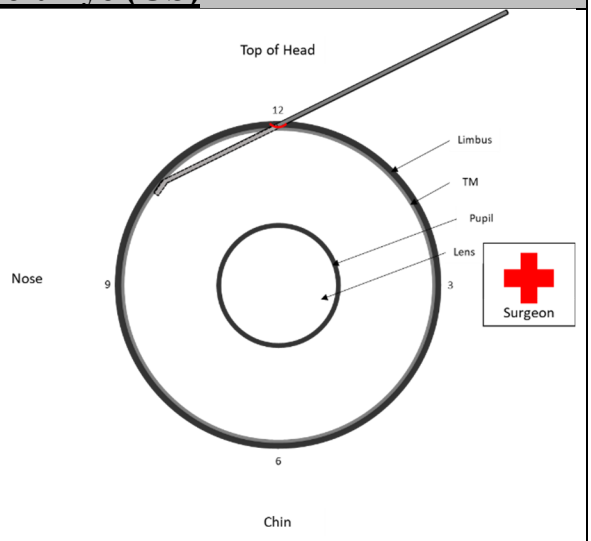


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

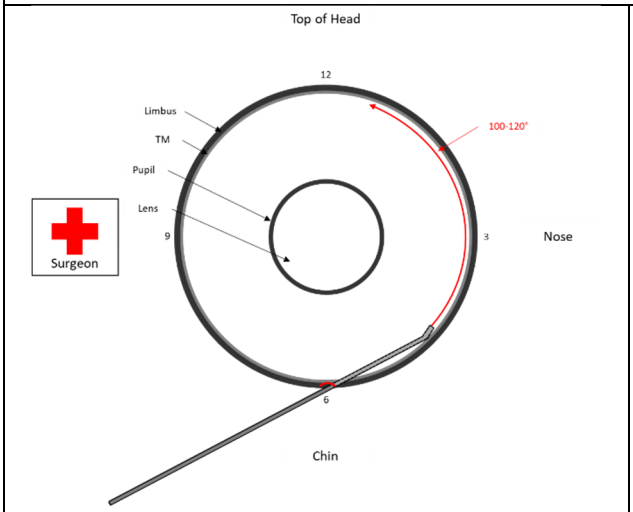
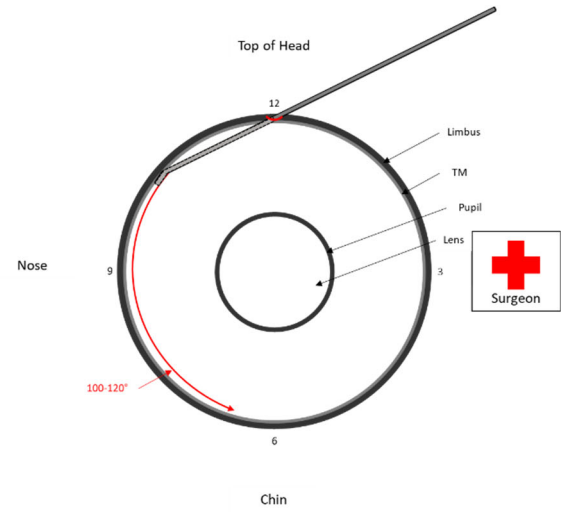
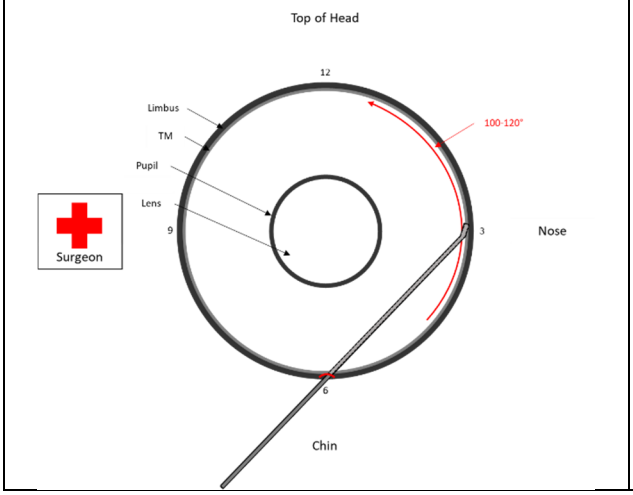
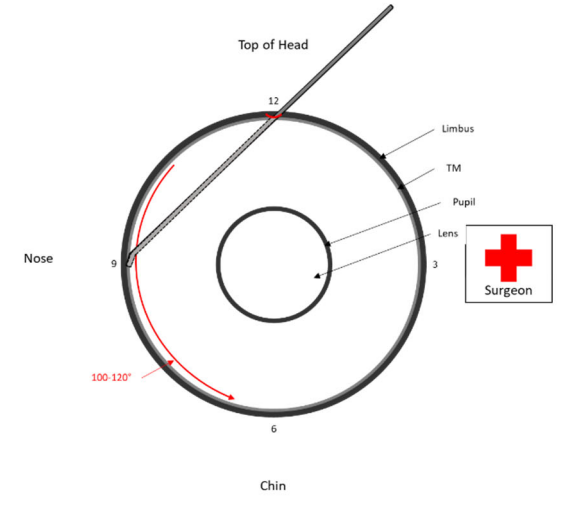
Ex.1004, 4.

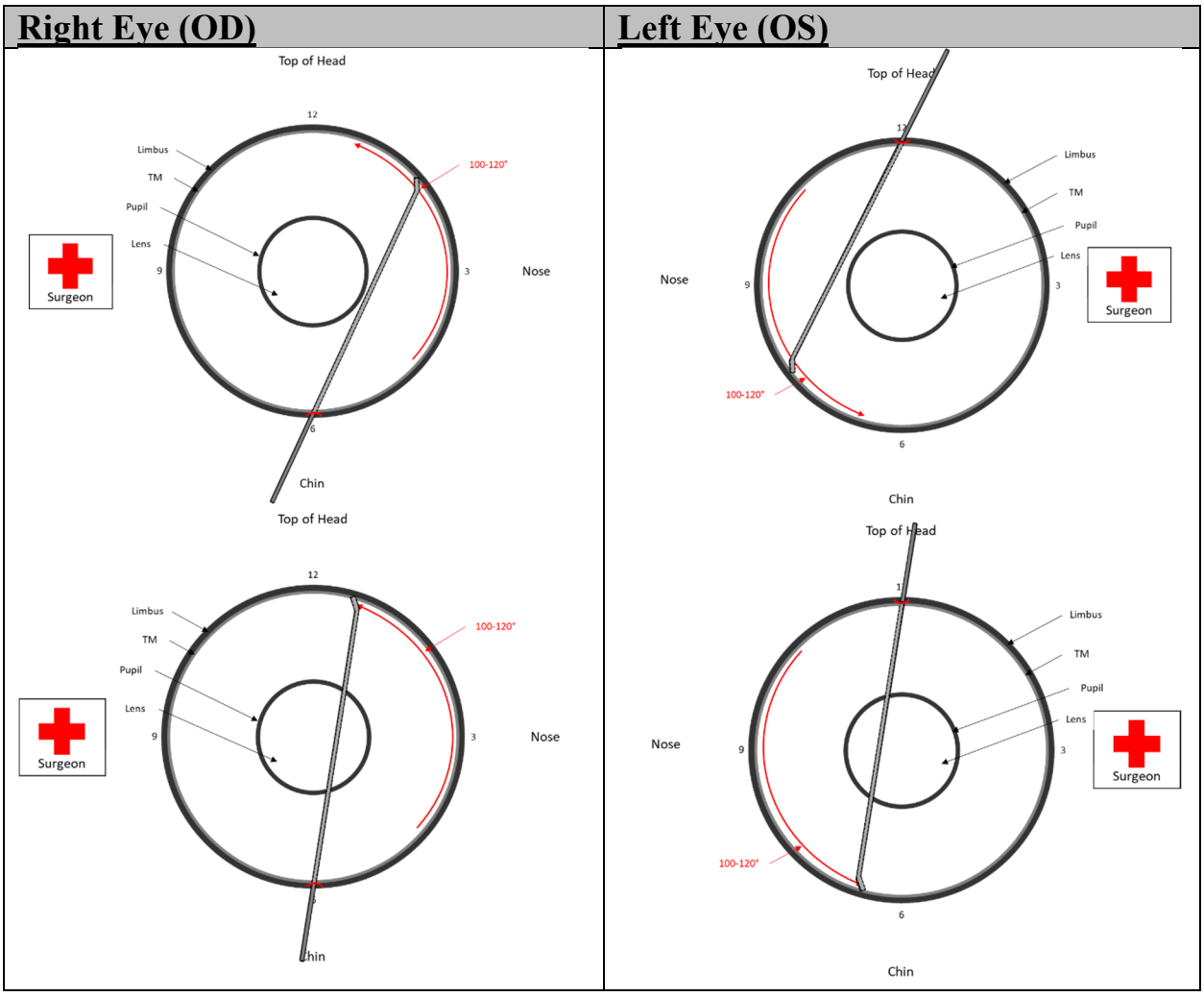
At the direction of NWM's expert, Dr. Peter Netland, illustrations depicting Quintana's procedure were prepared. Ex.1003, ¶81. The illustrations show a patient's right and left eye with the general location and progression of Quintana's needle throughout the procedure. *Id.*

Right Eye (OD)	Left Eye (OS)
Surgeon positioned on temporal side of patient. Ex.1004, 3-4.	
	
"The needle penetrates the anterior chamber at 6 hours (right eye) or 12 hours (left eye) through the scleral side of the limbus." Id., 4.	
	
Needle tip introduced into SC with convexity of tip facing external wall of SC. Id. "[T]he TM is stripped slowly, gently and easily from the canal's lumen towards the anterior chamber as the needle progresses in the angle." Id.	

Right Eye (OD)	Left Eye (OS)
	

"A 100-120° trabeculotomy can be achieved." Id.



Quintana's Fig.2 below is a photograph taken through a goniolens, showing the needle tip "stripping the TM."

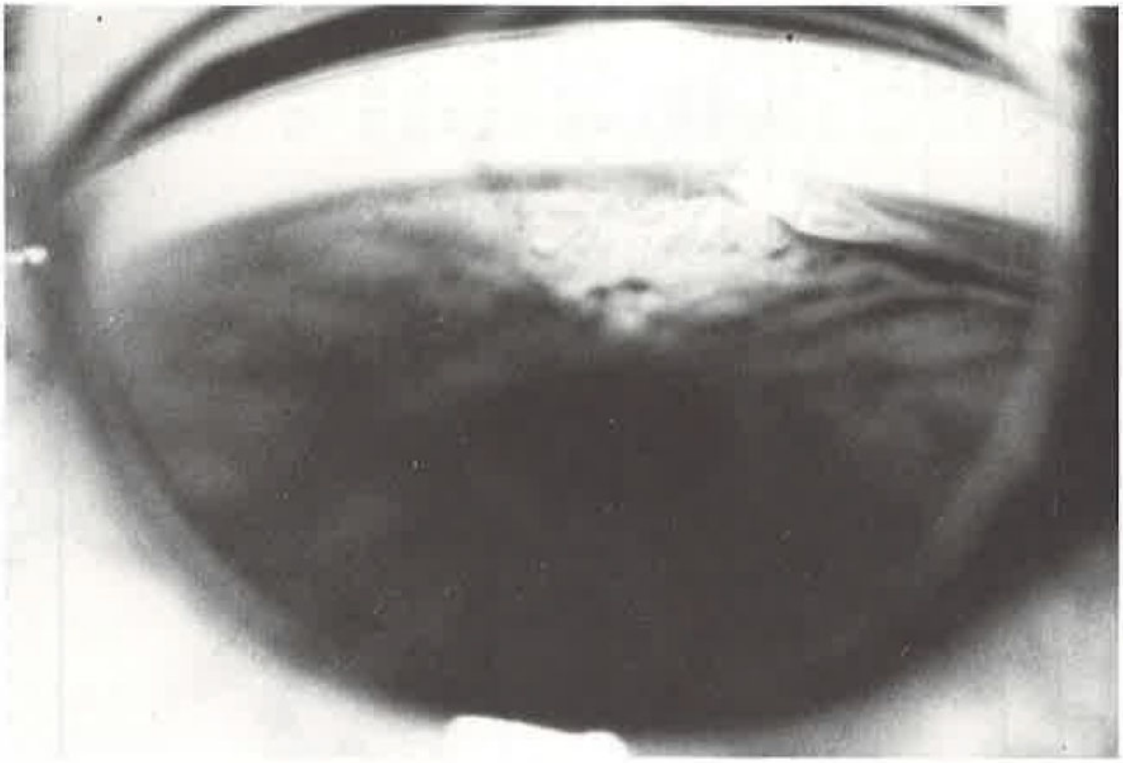
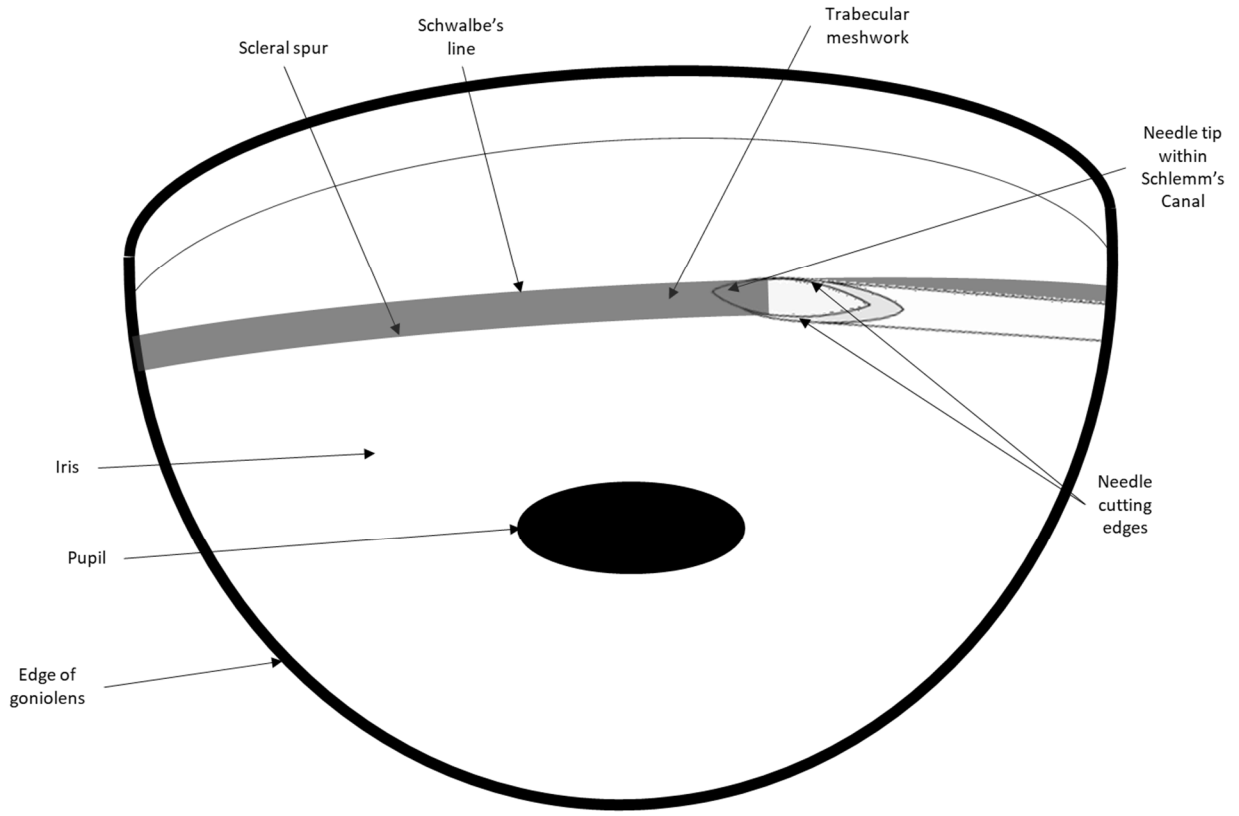


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

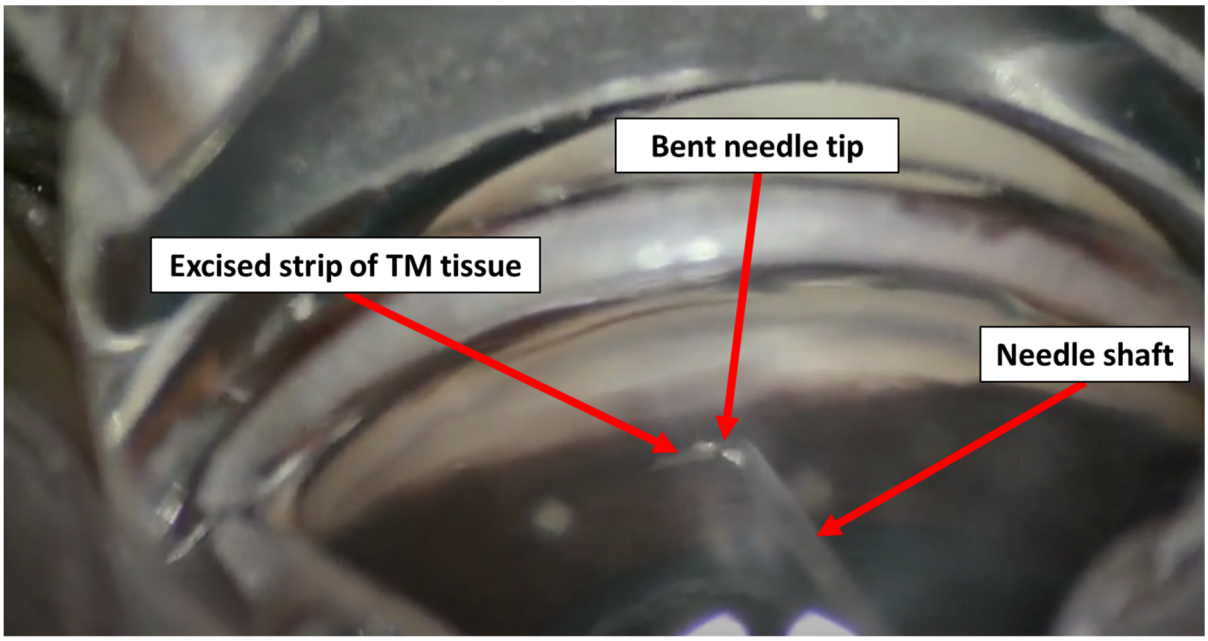
Id., Fig.2. To more clearly visualize Fig.2, the following schematic was prepared at Dr. Netland's direction. Ex.1003, ¶82.



Id. As shown, the needle tip is inserted into and advances through the TM to strip tissue with the needle's dual cutting edges. *Id.*

As confirmed by NWM's expert, Dr. Netland, Quintana's surgical procedure would result in cutting "strips of tissue" from the TM. Ex.1003, ¶¶84-86. Not only is this demonstrated explicitly in the reference, Quintana's basic technique has since been used in similar surgical procedures to remove strips of TM from SC. *Id.* For example, Shute (Ex.1020) describes a procedure called "bent ab interno needle goniectomy" ("BANG") that involves, like Quintana, using a standard needle having a bent tip to "completely excise a segment of TM" and in which the needle's "cutting edges" create a "double blade" "capable of excising tissue en

bloc." Ex.1020, 1; Ex.1003, ¶84. Another surgeon posted a video online showing performance of the BANG procedure on a patient's eye, showing the tip of a standard needle being bent, entering the AC, being introduced through the TM into SC, and advancing through SC. Ex.1021; Ex.1003, ¶¶85-86. As shown in the screen capture from the video below (which includes labels for the needle shaft, bent needle tip, and excised strip of tissue), a strip of TM tissue adhered to the needle tip after being cut from the TM is visible when the needle is removed from SC. Ex.1003, ¶¶85-86.



These recent examples provide further evidence that procedures such as Quintana's that use standard needles having bent tips to excise TM tissue from within the AC result in cutting "strips of tissue" from the TM. *Id.*

2. Claim 1

a. *A method for cutting a strip of trabecular meshwork tissue within an eye of a subject, said eye having an anterior chamber, trabecular meshwork tissue and a Schlemm's canal, said method comprising:*

Quintana's procedure "achieves a ***section of the TM***" and the reference states "***the TM is <u>stripped</u> slowly, gently and easily*** from the canal's lumen towards the anterior chamber as the needle progresses in the angle." Ex.1004, 3, 4 (emphasis added). The figures below depict cutting a strip of TM tissue from a patient's eye and Fig.2's caption indicates the figure shows the "tip of the needle stripping the [TM]." *Id.*, 5; Ex.1003, ¶96.

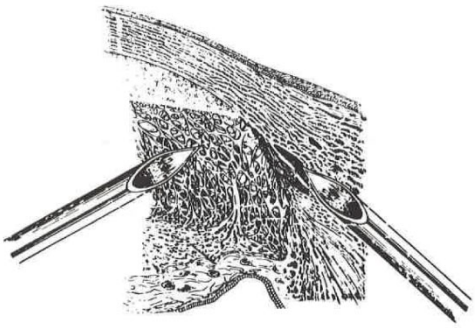


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

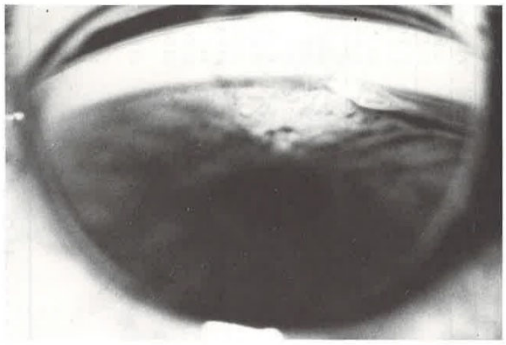


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

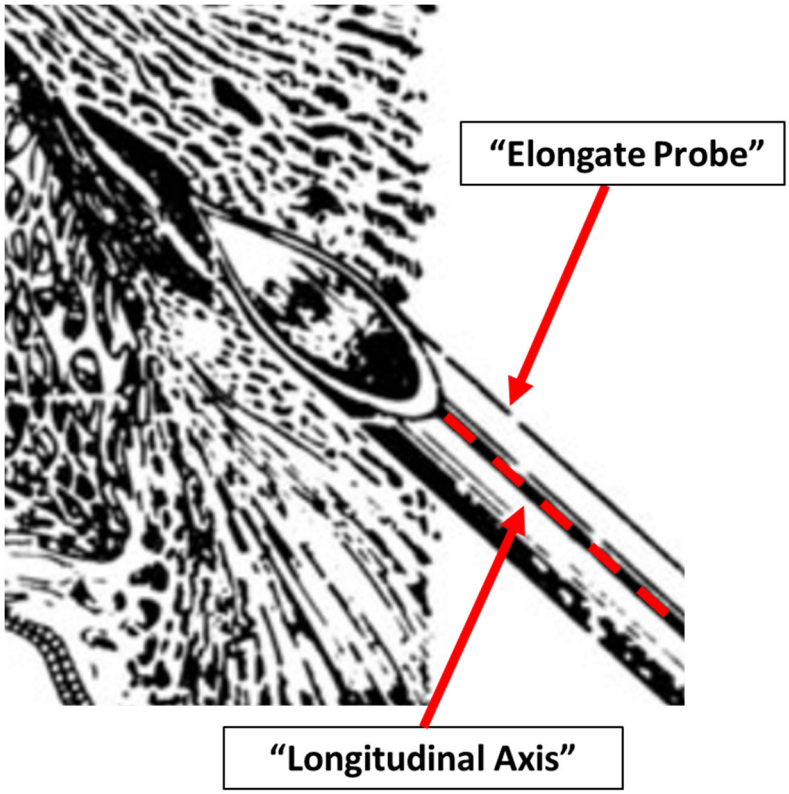
Ex.1004, Figs. 1-2. Quintana's statements that the "TM is stripped" and that the method "achieves a section of the TM" demonstrate that a "strip of [TM] tissue" is cut from the TM. *Id.* Quintana's needle has dual, spaced-apart cutting edges. *See infra,* §VI.A.2.f. Both cutting edges contact the TM and concurrently cut the TM as the tip advances through SC, which necessarily cuts and removes a strip of tissue from the TM. Ex.1003, ¶97. If the cutting edges did not concurrently cut

the TM, Quintana would not have "achieve[d] a section of the TM," but would instead have created a slit-like incision as in traditional approaches. *Id.*; *see also id.*, ¶¶84-86.

A POSITA would understand that the patients' eyes in Quintana would include "an anterior chamber, trabecular meshwork tissue and a Schlemm's canal," as claimed. Human eyes contain an AC, TM, and SC, *see supra*, §III.A, and Quintana explicitly states that the procedure involves penetrating the eye into the AC with the needle, piercing the TM with the needle tip, and advancing the needle tip through SC to "strip[]" TM tissue. Ex. 1004, 4; Ex.1003, ¶98.

b. a) providing or obtaining a device which comprises; an elongate probe that extends along a longitudinal axis

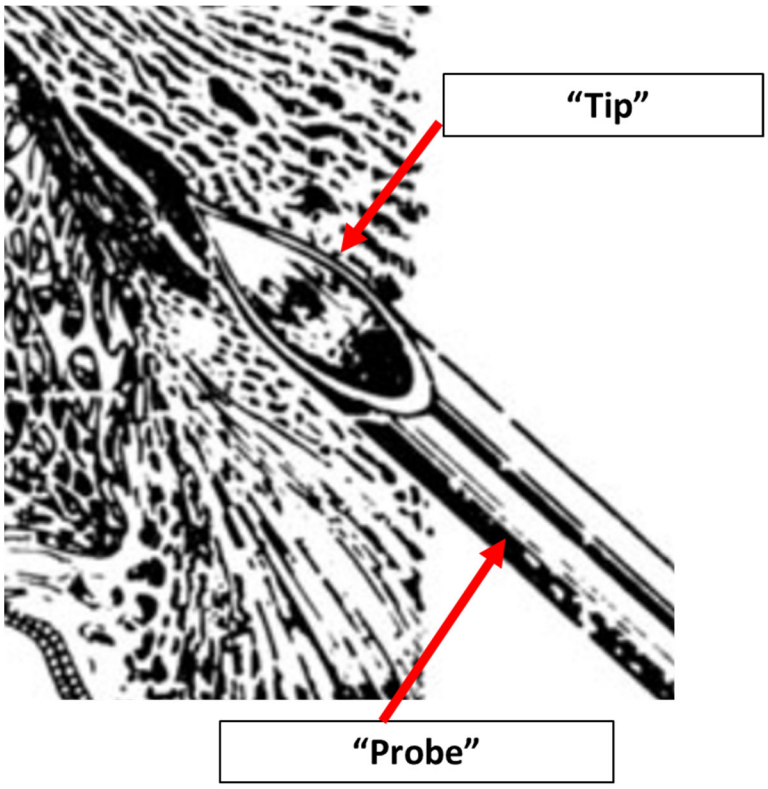
Quintana uses a "trabeculotome [that] is a 0.4 x 15 mm needle, or an insulin-type needle" with the tip bent 20-30°. Ex.1004, 3. Quintana's needle is inserted into a syringe, and thus the needle is an "elongate probe" that extends from the syringe. Ex.1004, 3; Ex.1003, ¶99. As shown below, the needle includes a shaft, *i.e.*, the needle tubing, which extends along a longitudinal axis running along the length of the shaft.



Ex.1004, Fig.1 (annotated); Ex.1003, ¶99.

c. a tip which extends laterally from an end of the probe,

As shown below, the "tip" of Quintana's needle extends from the distal end of the needle shaft and guides Quintana's device through SC. Ex.1004, 4, Fig.1; Ex.1003, ¶101. Moreover, the tip of Quintana's needle is bent 20-30° relative to the plane of the shaft and is explicitly said to point toward the anterior chamber during Quintana's procedure. Ex.1004, 3, 4. As such, the tip extends laterally from the needle shaft, as claimed. Ex.1003, ¶102.



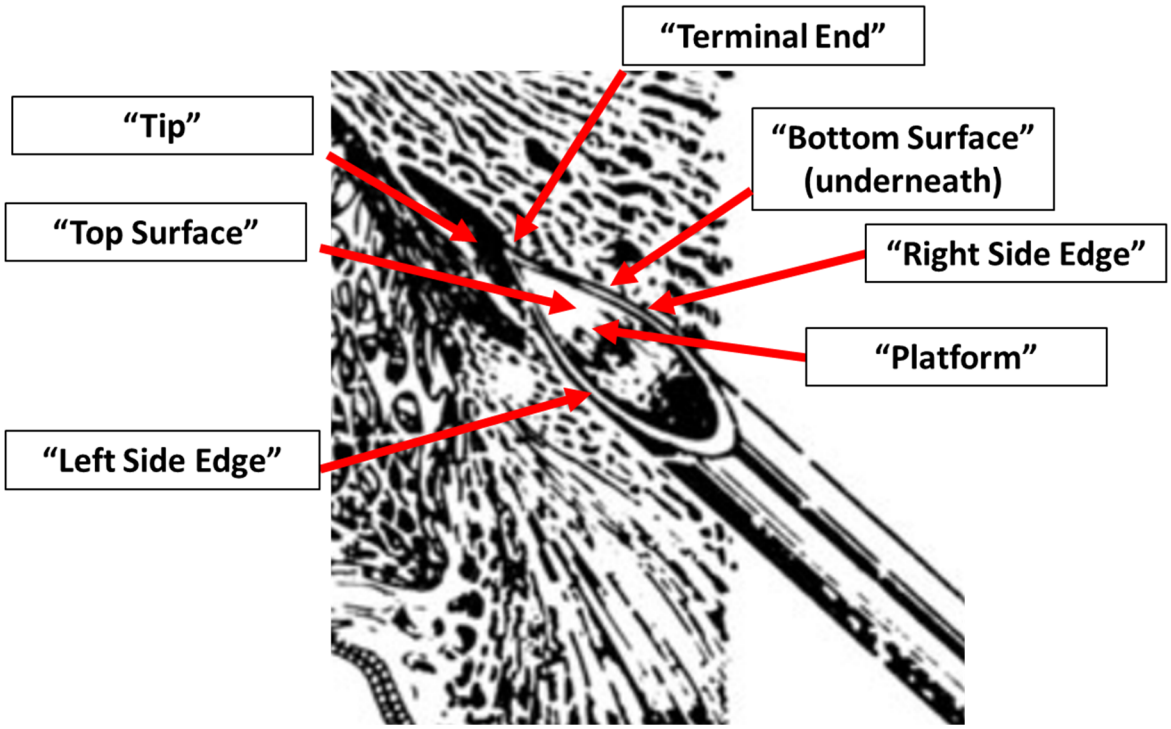
Ex.1004, Fig.1 (annotated); Ex.1003, ¶¶101-02.

d. said tip comprising a platform which has a top surface, a bottom surface, a right side edge, a left side edge and a terminal end, the terminal end being configured to penetrate through trabecular meshwork tissue;

The claimed "platform" is a portion of the tip of a device having a top surface, a bottom surface, a right side edge, a left side edge, and a terminal end. Ex.1003, ¶103. Indeed, although the claim requires the tip to include a "platform," the patent does not specifically identify the platform portion of the tip or even use the term in the specification or drawings. The claim requires the platform to have certain features and thus, to the extent a portion of the tip of a device has these features, it is a platform as claimed. *Id.*

Notably, although the platform portion of the tip is not specifically identified in the patent, the term cannot exclude needles and needle-like devices because the ***sole embodiment*** disclosed by the patent is a needle having a bent tip. *Id.*, ¶104. It is axiomatic that "[a] claim construction that 'excludes the preferred embodiment is rarely, if ever, correct.'" *SynQor, Inc. v. Artesyn Techs., Inc.*, 709 F.3d 1365, 1378–79 (Fed. Cir. 2013) (quoting *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1290 (Fed.Cir.2010)). As explained above, the ***sole embodiment*** described by the patent is "needle cutter device 10," which has a needle-like tip 24 that pierces TM tissue to "facilitate insertion" of the device into SC. Ex.1001, 3:3-24, 6:9-11. The claimed "needle cutter device 10" is made from the same material and in the same way a standard needle is made and is shown in the figures as having a needle-like tip. *Id.*, 4:60-64, Figs.3A, 3B, 4; Ex.1003, ¶104. Thus, the term "platform" ***cannot*** exclude needles and needle-like devices and such devices must have the claimed "platform" given that the sole embodiment in the patent is a needle-like device. *Id.*

As shown below, Quintana's tip includes a "platform" with a top surface, bottom surface, right and left side edges, and a terminal end.

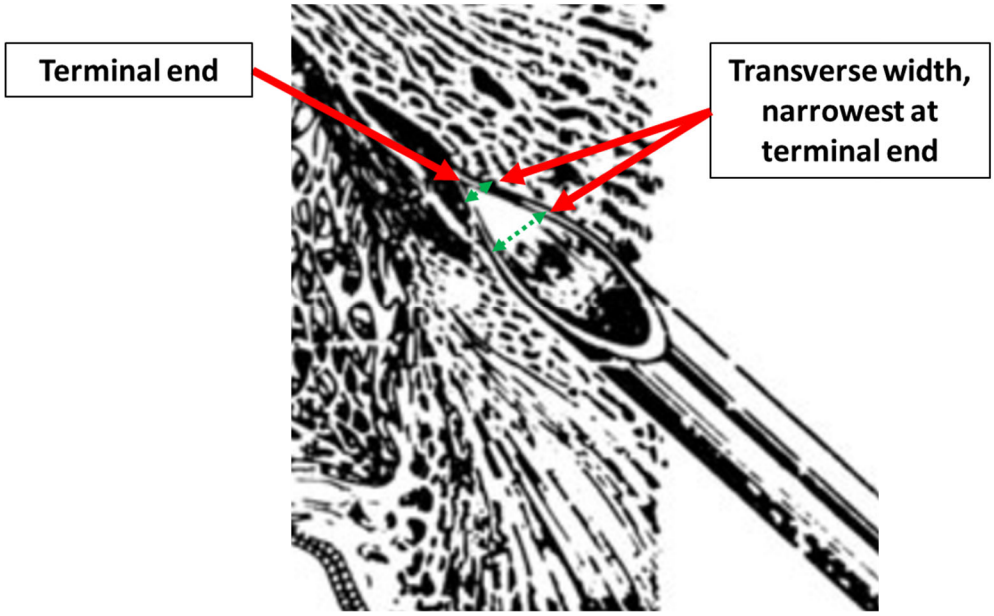


Ex.1004, Fig.1 (annotated); Ex.1003, ¶105. Quintana's needle, like the patent's "needle cutter device," has a tip with a portion that has a top surface, a bottom surface, a right side edge, a left side edge, and a terminal end, *i.e.*, a "platform" as claimed. *Id.* The figure shows the terminal end of the platform penetrating the TM tissue to enter SC. Ex.1003, ¶105; Ex.1004, 4, Fig.2 (showing tip of Quintana's needle, including terminal end of platform, in SC).

e. the tip having a transverse width from the right side edge to the left side edge, said transverse width being narrowest at the terminal end; and

The tip of Quintana's needle has a "transverse width" as claimed. Like the patent's "needle cutter device," the tip of Quintana's needle has a width from the right side edge to the left side edge. The tip of Quintana's needle becomes

narrower toward the terminal end to facilitate penetrating the TM. Ex.1004, 4, Figs.1-2. As shown below, the tip is narrowest at the terminal end.

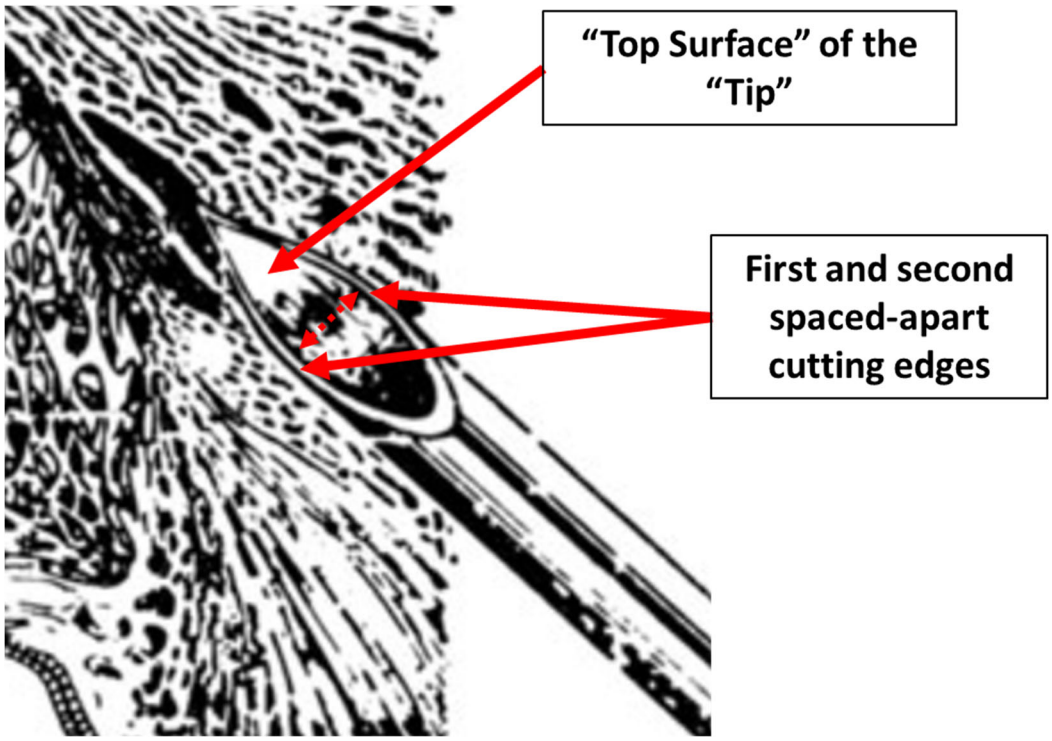


Id, Fig.1 (annotated); Ex.1003, ¶106.

f. first and second spaced-apart cutting edges positioned on the device so as to cut tissue that passes along the top surface of the tip and into contact with the cutting edges;

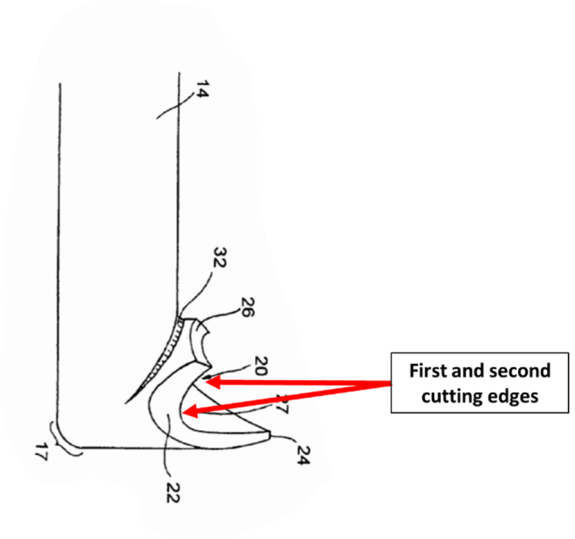
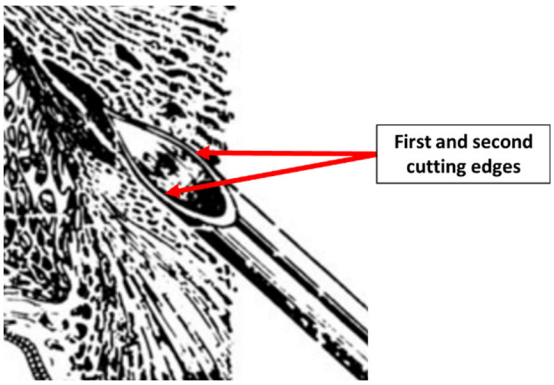
Quintana's needle has "first and second spaced-apart cutting edges." As shown below, Quintana's needle has two cutting edges spaced apart on opposite sides of the distal end of the needle tube.[5]

[5] Even if Quintana does not refer to these edges as "cutting edges," a prior art reference need not use the exact words used in the claim to anticipate. *In re*



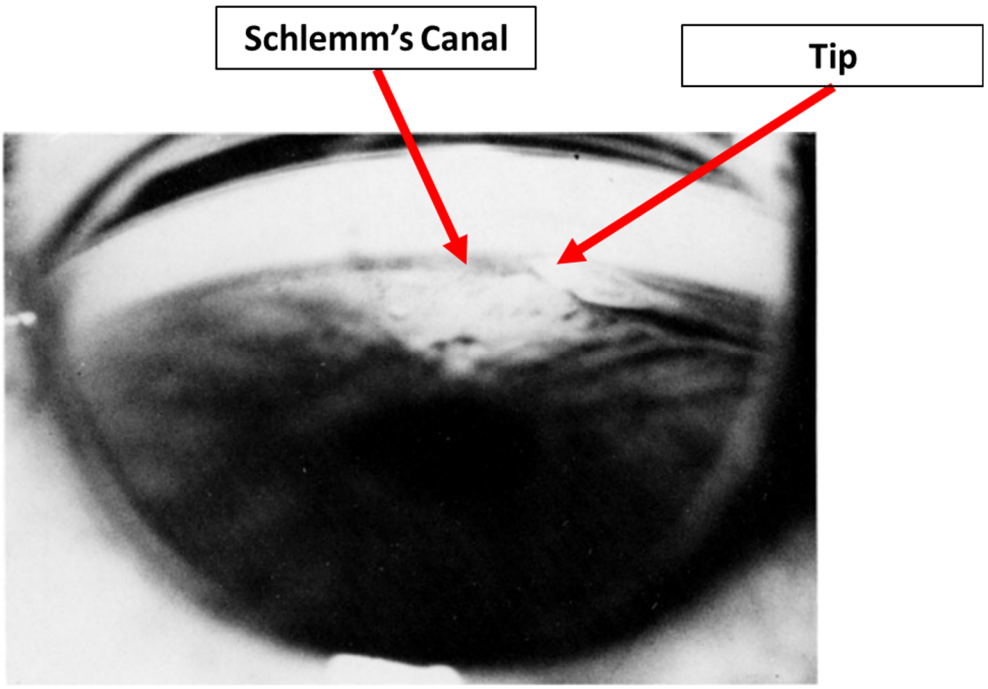
Ex.1004, Fig.1 (annotated); Ex.1003, ¶107. Both the "needle cutter device" of the '885 patent and Quintana's needle have first and second cutting edges spaced apart on opposite sides of the tube:

Gleave, 560 F.3d 1331, 1334 (Fed. Cir. 2009) ("reference need not satisfy an *ipsissimis verbis* test").

‘885 patent, Fig.3D (annotated)	Quintana, Fig.1 (annotated)
	

Ex.1003, ¶108.

The cutting edges of Quintana’s needle cut TM tissue that passes over the top surface of the tip. *Id.*, ¶¶108-10. As explained above, the tip of Quintana’s needle is inserted into SC and used to “strip[]” the TM, which “achieves a section of the TM.” Ex.1004, 3-4. A POSITA would appreciate that the portion of Quintana’s needle that cuts the TM tissue are the cutting edges. Ex.1003, ¶108. Moreover, the TM tissue must move along the top surface of Quintana’s tip before being cut by the cutting edges. *Id.*, ¶¶109-10. As shown in Fig.2 below, as the tip of Quintana’s needle advances through SC, TM tissue necessarily passes over the top surface of the tip and comes into contact with the cutting edges, as claimed. *Id.*



Ex.1004, Fig.2 (annotated).

g. b) inserting the probe into the anterior chamber of the eye;

Quintana discloses "inserting the probe into the anterior chamber of the eye" because Quintana explicitly states "[t]he needle ***penetrates the anterior chamber*** at 6 hours (right eye) or 12 hours (left eye) through the *scleral* side of the limbus." Ex.1004, 4 (italics in original; bold emphasis added); Ex.1003, ¶111. Quintana further explains that after penetrating the AC, the needle (*i.e.*, the probe) "is progressively introduced in the angle," which is within the AC. Ex.1004, 4; Ex.1003, ¶111.

h. c) advancing the tip through trabecular meshwork tissue and into the Schlemm's Canal of the eye such

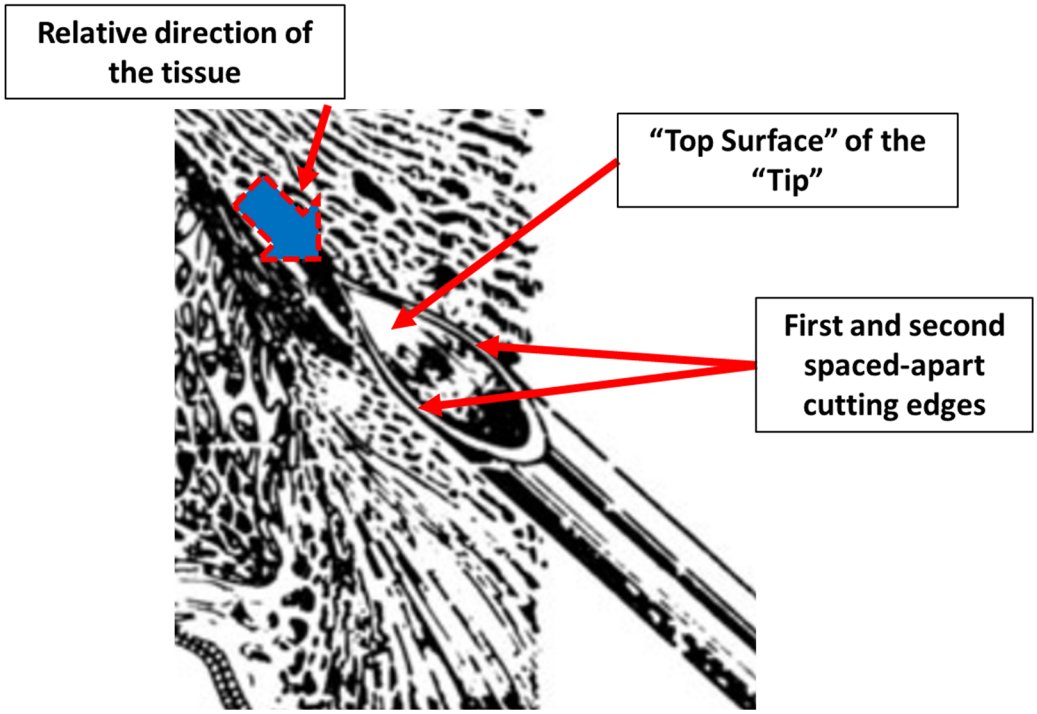
that trabecular meshwork tissue is in contact with the top surface

Quintana indicates that the tip of the needle penetrates the TM and the needle is "progressively introduced in the angle" such that "the tip of the instrument is introduced into Schlemm's canal," indicating that the needle tip is advanced through the AC, pierces through the TM, and is positioned within SC. Ex.1004, 4; Ex.1003, ¶112. Quintana further states that the "TM is stripped" from SC "as the needle progresses in the angle." Ex.1004, 4. Figure 2 shows the needle tip, including the top surface of the tip, and cutting edges contacting the TM and the caption explicitly indicates "[t]he tip of the needle strip[s]" the TM. *Id.*, Fig.2 (caption). By penetrating through the TM with the needle's bent portion and then positioning it within SC, the top surface would necessarily contact the TM. Ex.1003, ¶112.

i. d) moving the probe to cause the tip to advance through the Schlemm's Canal such that trabecular meshwork tissue moves along the top surface of the tip and into contact with the first and second spaced-apart cutting edges, thereby cutting a strip of the trabecular meshwork tissue.

Quintana explains that the needle tip is "progressively introduced" in the AC angle, that the "tip of the instrument is introduced into SC," and that the "TM is stripped . . . from the canal's lumen" as the needle "progresses in the angle." Ex.1004, 4. The tip of the needle thus advances through SC. Ex.1003, ¶113.

As explained above, the TM tissue passes over the top surface of the tip of Quintana's needle and contacts the cutting edges, which cuts a strip of tissue from the TM as claimed. *See supra*, §VI.A.2.f. As indicated by Quintana, the tip of the needle, including the top surface of the tip, penetrates the TM, is introduced into SC, and progresses in the angle. Ex.1004, 4. As shown below, the TM tissue must necessarily pass over the top surface of the tip to contact and be cut by the cutting edges. Ex.1003, ¶114.



Ex.1004, Fig.1 (annotated). Moreover, Quintana's statements that the "TM is stripped" and that the method "achieves a section of the TM" demonstrate that a "strip of tissue" is cut from the TM, as claimed. Ex.1004, 4; Ex.1003, ¶115. A

POSITA would appreciate that the cutting edges concurrently cut the TM to create the strip of tissue. *Id.*; *see also id.*, ¶¶84-86.

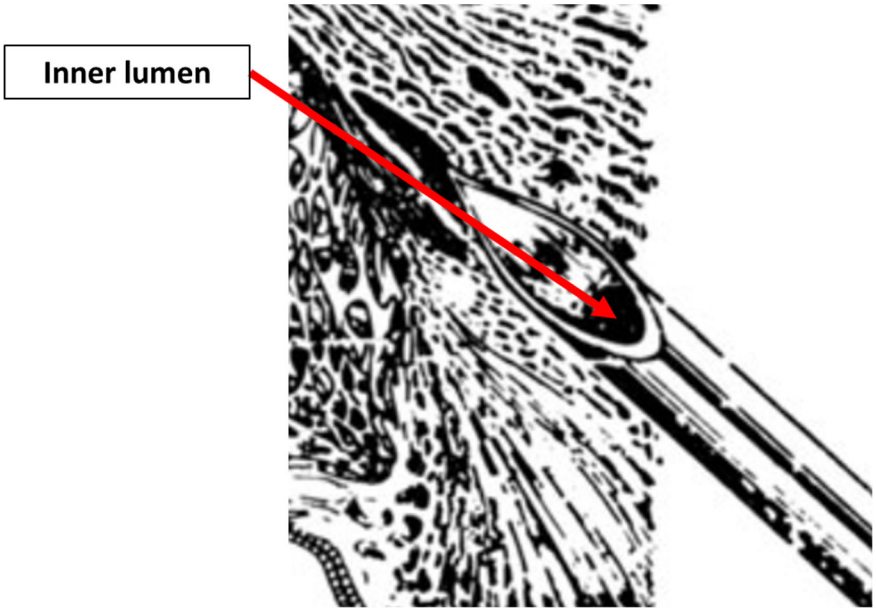
3. Claim 2 - *A method according to claim 1 further comprising the step of keeping the anterior chamber filled.*

Quintana discloses the limitations of claim 1. *See supra*, §VI.A.2. According to Quintana, "***[h]ealon can be injected at will at any time*** if the surgeon wants to deepen the angle. There is usually no chamber loss, but if this is the case, ***healon is injected***." Ex.1004, 4 (emphasis added). "Healon" is a viscoelastic fluid commonly used for ophthalmic procedures. *See, e.g.*, Ex.1011, 34-35, 51-52. Injecting a viscoelastic fluid within the AC would keep the AC filled by filling the AC with fluid. Ex.1003, ¶117. Quintana's statement that there is "no chamber loss" would also indicate to a POSITA that the AC remains filled with fluid (aqueous and/or viscoelastic fluid), further indicating the AC is kept filled as claimed. *Id*., ¶118.

4. Claim 3 - *A method according to claim 2 wherein the device further comprises an infusion lumen and wherein fluid is infused through the infusion lumen to keep the anterior chamber filled.*

Quintana discloses the limitations of claim 2. *See supra*, §VI.A.3. Further, Quintana performs the procedure with a needle inserted into a syringe. Ex.1004, 3. A POSITA would appreciate that needles are made of tubing having at least one

lumen. Ex.1003, ¶120. Fig. 1 below shows Quintana's needle, which has an opening at the end of the needle shaft into an inner lumen.



Ex.1004, Fig.1 (annotated); Ex.1003, ¶120.

Quintana also explicitly indicates that the needle is "inserted into a syringe filled with 'healon'" and as discussed above, describes injecting healon at any time during the procedure to deepen the angle and to prevent chamber loss, which would keep the AC filled as claimed. Ex.1004, 3, 4; Ex.1003, ¶120. Thus, the inner lumen of the needle acts as an infusion lumen through which fluid is injected, as claimed.

5. Claim 6 - *A method according to claim 1 wherein the strip of trabecular meshwork tissue cut in step d has a length of about 2 to 10 millimeters*.

Quintana discloses the limitation of claim 1. *See supra*, §VI.A.2. Further, the patent admits that cutting a strip of TM with a length of about 2 to 10

millimeters was known in the art. *See* Ex.1001, 1:39-45. Thus, claim 6 does not cover a novel or nonobvious feature of the alleged invention.

Moreover, Quintana's procedure achieved a strip of tissue with a length of about 2 to 10 mm. Quintana states "[a] 100-120° trabeculotomy can be achieved" using the technique. Ex.1004, 4. Given that the circumference of SC (and thus, the TM) is about 36mm, *see* Ex.1010, 5, a "100-120° trabeculotomy" would achieve strips of tissue within the 2 to 10 mm range claimed. Ex.1003, ¶124. For example, a 100° section of TM would be about 10.08mm in length, which is "about" 10mm as claimed (100°/360°=0.28; 28% of 36mm=10.08mm). *Id.* Quintana's explanation that a "100-120° trabeculotomy ***can be achieved***" would also indicate to a POSITA that shorter segments ranging from 0-10.08mm (or more) of TM are achieved. *Id.*

6. Claim 9 - *A method according to claim 1 wherein the method is performed under direct visualization through a lens device positioned on an anterior aspect of the eye*.

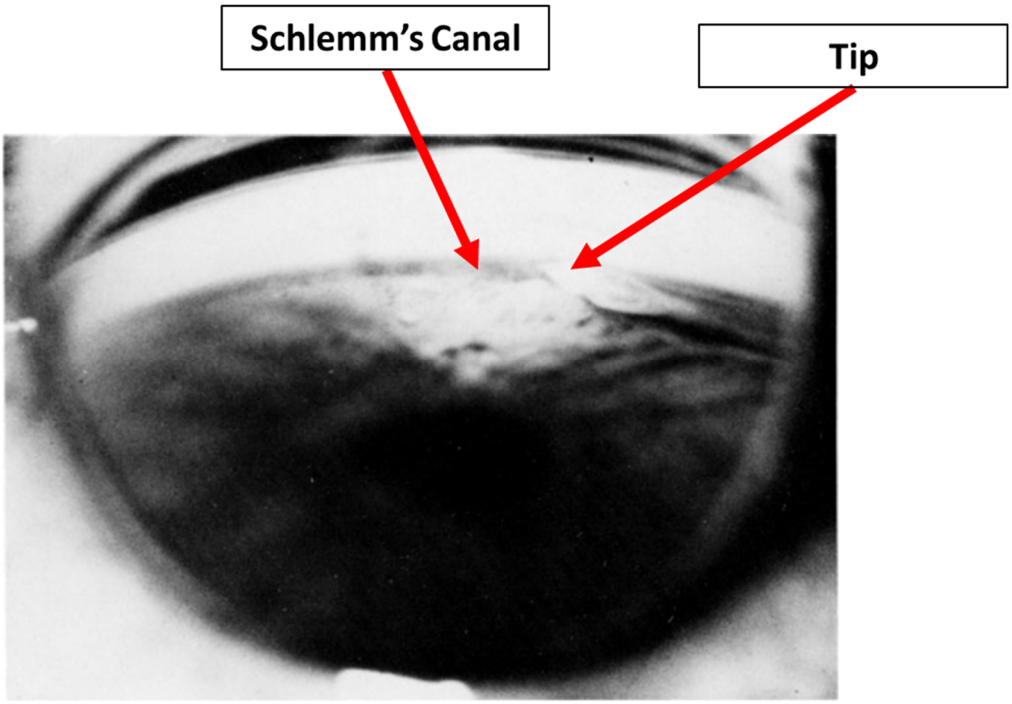
Quintana discloses the limitations of claim 1. *See supra*, §VI.A.2. Further, Quintana uses a "Swann lens" for "angle visualization," which is inserted on the eye during the procedure. Ex.1004, 3-4. A POSITA would understand Quintana's statement that the Swann lens (*i.e.*, a lens device) is "inserted" to involve positioning the device "on an anterior aspect of the eye" and performance of the

procedure after insertion of the device to disclose performing the procedure under direct visualization. Ex.1003, ¶126.

7. Claim 10 - *A method according to claim 1 wherein the tip extends laterally from said end of the probe at an angle of between approximately 30 and approximately 90 degrees relative to the longitudinal axis of the probe and wherein step d comprises moving the distal end of the probe laterally such that the tip advances through Schlemm's Canal.*

Quintana discloses the limitations of claim 1. *See supra*, §VI.A.2. Quintana's needle tip is bent 20-30°, which Quintana explains is done so the convexity of the tip faces the external wall of SC such that the structure is not damaged. Ex.1004, 3-4. The angle formed by the bent portion is "between approximately 30 and approximately 90 degrees relative to the longitudinal axis of the probe," as Quintana's range overlaps with the claimed range. Ex.1003, ¶128. *E.g.*, *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985) (claim anticipated if prior art discloses example within claimed range).

Moreover, as explained above, the distal end of Quintana's needle (*i.e.*, probe) moves laterally causing the tip to advance through SC. *See supra*, §VI.A.2.i. Indeed, Quintana explicitly states that the tip is introduced into SC and "progresses in the angle." Ex.1004, 4, Fig.2 (below).



Id., Fig.2 (annotated); Ex.1003, ¶129. A POSITA would understand that to "progress[] in the angle," the needle must move laterally to cause the tip to advance through SC. Ex.1003, ¶129.

B. Ground 2: Quintana (Ex.1004) in View of the Knowledge of a POSITA Renders Obvious Claims 4-5, 7-8, and 11

1. Claim 4 - *A method according to claim 3 wherein step a comprises: forming an incision in the eye; causing fluid to flow out of the infusion lumen and into the incision, thereby spreading or opening the incision; and thereafter inserting the probe through the incision and into the anterior chamber of the eye.*

Quintana discloses the limitations of claim 3. *See supra*, §VI.A.4. Further, Quintana discloses "forming an incision in the eye" because Quintana explicitly states "[t]he needle ***penetrates the anterior chamber*** at 6 hours (right eye) or 12

hours (left eye) through the *scleral* side of the limbus." Ex.1004, 4 (italics in original; bold emphasis added); Ex.1003, ¶133.

Quintana further "causing fluid to flow out of the infusion lumen and into the incision." Indeed, as explained above, Quintana expressly discloses a needle inserted into a syringe filled with "healon" and that after insertion of the device within the AC (*i.e.*, through the incision) healon can be injected to deepen the angle or prevent chamber loss. Ex.1004, 3-4. A POSITA would appreciate that by injecting fluid into the eye, the volume of fluid within the AC would increase, causing the outer surface of the eye to expand. Ex.1003, ¶134. This would necessarily cause openings (such as an incision) on the outer surface of the eye to spread further open. *Id.*

Finally, Quintana discloses "inserting the probe through the incision and into the anterior chamber of the eye," as Quintana expressly states that the needle penetrates the AC, advances toward the TM, pierces the TM, and is advanced through the angle. Ex.1004, 4; Ex.1003, ¶135.

Even if Quintana does not explicitly disclose causing a fluid to flow into the incision thereby spreading or opening the incision, however, a POSITA would have found it obvious to do so. Ex.1003, ¶136. Infusing fluid into the eye to spread or otherwise open an incision was well known in the art in 2003. *Id.* For example, it was well known that injecting fluid into the AC could be used as a

means for holding open a "cleft" in the eye during or after a surgical procedure. Ex.1011, 53-54. It was also known to inject fluid into the eye during surgical procedures to deepen the angle and prevent collapse of the AC. Ex.1007, 2; Ex. 1004, 4. A POSITA would understand that injecting fluid into an incision to hold the incision open, to deepen the angle, and/or prevent AC collapse would increase the volume of fluid in the eye, causing the outer surfaces of the eye to stretch and spread or widen openings in the eye. Ex.1003, ¶136. Based on this knowledge, a POSITA would have found it obvious to inject fluid into Quintana's incision, resulting in spreading or widening of the opening, and would have expected success due to successful procedures disclosed in the art, including for the explicit purpose of holding incisions open. *Id.*

2. Claim 5 - *A method according to claim 3 wherein the device further comprises an aspiration lumen and the method further comprises aspirating fluid through the aspiration lumen*.

Quintana discloses the limitations of claim 3. *See supra*, §VI.A.4. Quintana discloses a needle inserted into a syringe filled with healon and thus discloses a device with a lumen used for infusion. *Id.* It further would have been obvious to incorporate an aspiration lumen in Quintana's needle. Indeed, devices for aspirating fluid and debris were well-known in the art in 2003, including as disclosed in Jacobi. *See* Ex.1007, 2 ("the viscoelastic along with abraded trabecular debris were removed by means of an irrigation-aspiration probe"). It

would have been obvious to a POSITA to improve upon Quintana's needle by incorporating an aspiration lumen for aspirating fluid and debris. Ex.1003, ¶138. It was known that leaving strips of tissue and debris within the eye could have negative implications such as the formation of scar tissue and blocking the aqueous outflow system, and thus incorporating an aspiration lumen for aspirating fluid and debris from the eye would have been obvious to a POSITA to prevent these known issues. *Id.* Additionally, such a modification would have involved nothing more than combining prior art elements according to known methods with a reasonable expectation of success based on the use of similar devices and techniques in the prior art. *Id.*

3. Claim 7 - *A method according to claim 1 wherein, after cutting of the strip of trabecular meshwork tissue in step d, the strip of trabecular meshwork tissue remains connected to the eye and wherein the method further comprises the step of disconnecting the strip of strip of trabecular meshwork tissue from the eye.*

Quintana discloses the limitations of claim 1. *See supra* §VI.A.2. Further, by 2003, it was well-known that portions of tissue left within the eye, including portions of tissue remaining connected to the TM, could return to their predissection positions or cause scar tissue to form, blocking outflow. Ex.1003, ¶140. Johnstone performed several procedures and found in one instance a "flap" of TM tissue was left "that appeared to be capable of returning to its predissection position" following the procedure. Ex.1005, 8. Johnstone thus removed the "flap"

to increase outflow. *Id.* Similarly, Jacobi's "ab interno" procedure peeled TM tissue from the chamber angle, resulting in "strings" of TM tissue that Jacobi removed with an irrigation-aspiration probe. Ex.1007, 2. Johnstone and Jacobi both recognized that their respective flaps or strings needed to be removed or risk blockage. Ex.1007, 2; Ex.1005, 8. Knowing portions of tissue remaining connected to the TM could block outflow, a POSITA performing Quintana's method would have been motivated to disconnect tissue remaining connected to the TM and remove the tissue from the eye, and would have expected success given the successful results of doing so in the prior art. Ex.1003, ¶¶140-41. As explained further below with respect to claim 8, a POSITA would have known the tissue could be removed from the eye in a number of ways, including by Quintana's needle itself, an irrigation-aspiration probe such as disclosed in Jacobi, or other devices for removing tissue from the eye such as forceps. *See infra,* §VI.B.4.

4. Claim 8 - *A method according to claim 7 wherein the step of disconnecting the strip of trabecular meshwork tissue from the eye comprises using a tissue disconnecting apparatus to disconnect the strip of trabecular meshwork tissue from the eye.*

Quintana discloses the limitations of claim 7. *See supra* §VI.B.3. As explained for claim 7, a POSITA would have been motivated to disconnect and remove strips of tissue remaining connected to the TM to prevent blockages of

aqueous outflow. *Id.* A POSITA would have known that this could be accomplished using a variety of known "tissue disconnecting apparatuses," which would be understood to be any instrument capable of disconnecting a strip of tissue from the TM. Ex.1003, ¶143. This could include for example: (a) Quintana's needle that strips TM tissue (Ex.1004, 3-4); (b) Jacobi's gonioscraper that peels TM tissue by passing the device "in sweeping movements" to disconnect tissue (Ex.1007, 2); (c) Jacobi's irrigation-aspiration probe, which could be used by suctioning tissue connected to the TM and pulling the tissue to tear it (sever it) from the TM (*id.*); or (d) Ferrari's forceps, which were used to remove TM tissue in strings of varying length (Ex.1018, 1). Ex.1003, ¶143. Given that each well-known instrument is capable of disconnecting tissue from the TM, a POSITA would appreciate that each could be used as the claimed "tissue disconnecting apparatus." *Id.*, ¶¶143-44.

5. Claim 11 - *A method according to claim 1 wherein a curve is formed in the elongate probe proximal to the end of the probe from which the tip laterally extends.*

Quintana discloses the limitations of claim 1. *See supra*, §VI.A.2. Quintana teaches that the needle tip is bent 20-30°, which Quintana explains is done so the convexity of the tip faces the external wall of SC such that the structure is not damaged. Ex.1004, 3-4. Further, by 2003, devices having a curve in the elongate probe proximal to the end from which the tip laterally extends were well-known.

Ex.1003, ¶¶146-47. For example, Anctil and Jacobi both teach devices having curves proximal to the end of the probe and recognized that forming curves in the probe proximal to the tip allowed the device to meet the particular needs of a given surgery. Ex.1025, 8:66-9:15; Ex.1007, Fig.2; Ex.1013, Fig.2; Ex.1003, ¶¶146-47. With the knowledge that bending or forming curves in a probe can allow a surgeon to access anatomical locations based on the needs of a given procedure, surgery, or patient, a POSITA performing Quintana's method would have been motivated to form a curve in the probe proximal to the end from which the tip extends to meet the needs of a given surgery. Ex.1003, ¶148. Moreover, modifying Quintana's needle to have a curve in the needle shaft would have involved nothing more than simple substitution of one prior art element (*i.e.*, Quintana's needle) for another (*e.g.*, a device having a bend in the shaft such as Anctil) and therefore would have been obvious to a POSITA. *Id.*

C. Ground 3: Jacobi (Ex.1007) in View of the Knowledge of a POSITA Render Obvious Claims 1-11

1. Overview of Jacobi

Jacobi discloses an ab interno technique called "goniocurettage," which employs a "gonioscraper" device. Ex.1007, 1. According to Jacobi, in most cases of open-angle glaucoma, outflow resistance lies in the cribriform layer of the TM, and "simple disruption of the TM . . . removes little tissue and allows filling in and scarring to occur with subsequent closure of the trabecular opening." *Id.*, 1-2.

Accordingly, Jacobi describes a new approach "to abrade rather than incise" the TM in order to "peel" off "strings of trabecular tissue." *Id.*, 2; Ex.1003, ¶¶90-91. In other words, ***Jacobi touts tissue removal over a single incision***.

Jacobi's gonioscraper has a handle, a convex-shaped arm, and a bowl-like tip with sharpened edges. Ex.1007, 2. The tip is shown in Fig.1 below.

Figure 1 The tip of the 'gonioscraper'. The bowl is 300 μm in diameter with its edges sharpened.

Id., 2. Figure 2 below also shows the gonioscraper device has a bend or curve. Ex.1003, ¶92.

Jacobi performed goniocurettage both ex vivo and in vivo. Ex.1007, 2. In both the ex vivo procedure and in vivo surgery, Jacobi inserted the device into the AC through a clear corneal incision at the limbus, directed the device against the

TM on the opposite side, and used the device to "peel" tissue from the TM. *Id.*; Ex.1003, ¶93. Fig.2 below shows the procedure.

Figure 2 With the aid of an operating microscope and under gonioscopic control ab interno goniocurettage is performed. Following abrasion an irregular pattern of a glistening white band corresponding to the 'denuded' grey-white sulcus scleralis can be seen (black arrows).

Ex.1007, Fig.2.

Jacobi's procedure resulted in "strings of trabecular tissue." *Id.*, 2. Jacobi states at the end of surgery the viscoelastic along with trabecular debris were removed by means of an irrigation-aspiration probe. *Id.* Preliminary reports showed "[a]ll six patients experienced an absolute decrease in IOP." *Id.*, 5.

2. Claim 1

a. A method for cutting a strip of trabecular meshwork tissue within an eye of a subject, said eye having an

anterior chamber, trabecular meshwork tissue and a Schlemm's canal, said method comprising:

Jacobi's procedure "abrade[s] rather than incise[s]" the TM to "peel" off "strings of trabecular tissue." Ex. 1007, 2. This means Jacobi excises tissue rather than simply cutting a slit in the TM. Ex.1003, ¶150. Jacobi reports that "gonioscopically, ***strings of trabecular tissue could be observed intraoperatively to be removed by goniocurettage***." Ex.1007, 303. Peeling "strings of TM" tissue is "cutting a strip" of TM tissue as claimed. Ex.1003, ¶151.

A POSITA would understand that the patients' eyes in Jacobi would include "an anterior chamber, trabecular meshwork tissue and a Schlemm's canal," as claimed. *Id.*, ¶152. Human eyes contain an AC, TM, and SC, *see supra*, §III, and Jacobi explicitly states that the procedure involves creating an incision through the cornea of the eye into the AC, directing the gonioscraper device against the TM, and advancing the device through SC to "peel" TM tissue from SC. Ex. 1007, 2.

b. a) providing or obtaining a device which comprises; an elongate probe that extends along a longitudinal axis;

Jacobi's gonioscraper "consists of a small ***handle*** and ***a slightly convex-shaped arm for intraocular use***." *Id.* (emphasis added). As shown below, the convex-shaped arm of the device is "an elongate probe" that extends along a longitudinal axis. Ex.1003, ¶153.

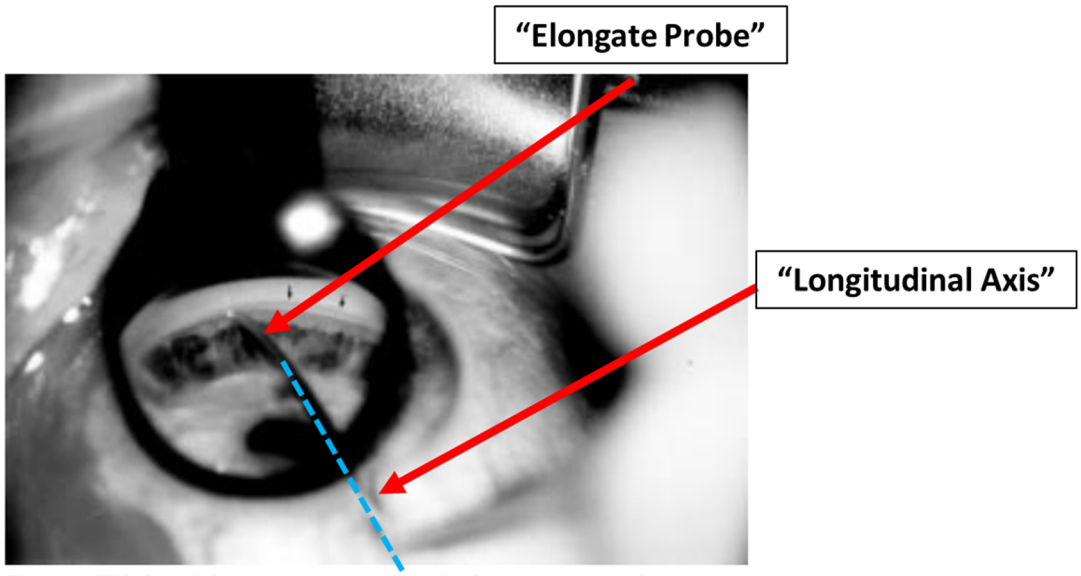


Figure 2 With the aid of an operating microscope and under gonioscopic control ab interno goniocurettage is performed. Following abrasion an irregular pattern of a glistening white band corresponding to the 'denuded' grey-white sulcus scleralis can be seen (black arrows).

Ex.1007, Fig.2 (annotated).

c. a tip which extends laterally from an end of the probe,

Jacobi's gonioscraper includes a tip that is "shaped as a tiny bowl with 300 µm diameter and with its edges sharpened." Ex.1007, 2. Jacobi's figures shown that the bowl-shaped tip extends laterally from the convex-shaped arm of Jacobi's device. Ex.1003, ¶154.

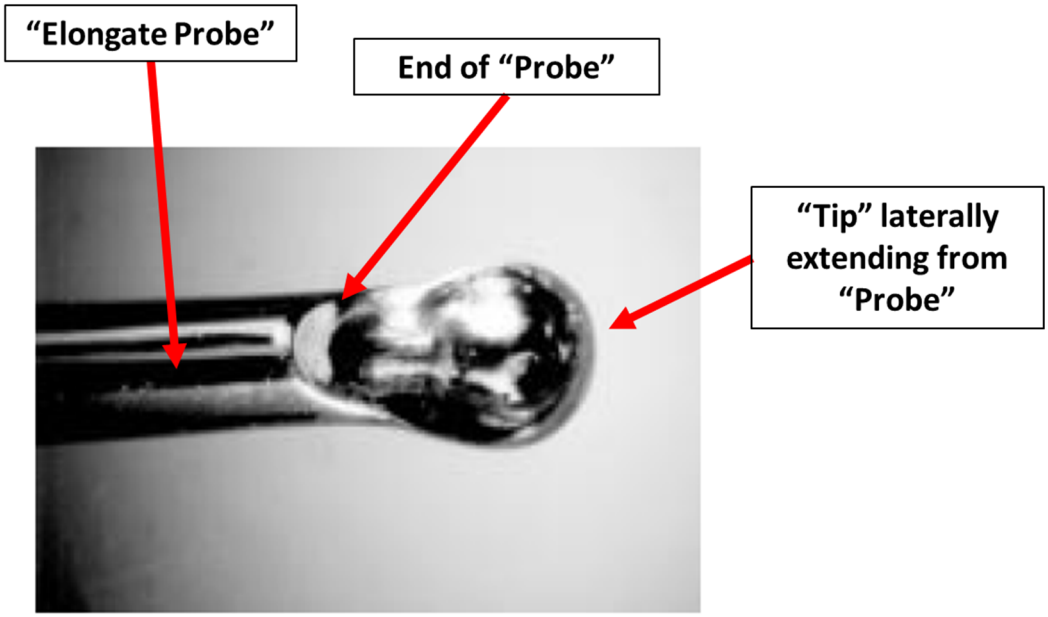


Figure 1 The tip of the 'gonioscraper'. The bowl is 300 μm in diameter with its edges sharpened.

Ex.1007, Fig.2 (annotated).

d. said tip comprising a platform which has a top surface, a bottom surface, a right side edge, a left side edge and a terminal end, the terminal end being configured to penetrate through trabecular meshwork tissue;

As discussed above, *see supra,* §VI.A.2.d, the claimed "platform" is a portion of the tip of a device having a top surface, a bottom surface, a right side edge, a left side edge, and a terminal end. Ex.1003, ¶155. Indeed, although the claim requires the tip to include a "platform," the patent does not specifically identify the platform portion of the tip or even use the term in the specification or drawings. The claim requires the platform to have certain features and thus, to the extent a portion of the tip of a device has these features, it is a platform as claimed.

The bowl-shaped tip of Jacobi's gonioscraper includes a "platform." Ex.1003, ¶156. Jacobi's platform is a portion of the bowl-shaped tip with a top surface (inner surface of the bowl), bottom surface (underside of the bowl), right and left side edges (edges of the bowl), and a terminal end (portion of the bowl directly opposite the location where the shaft meets the bowl-shaped tip and that is inserted into the TM).

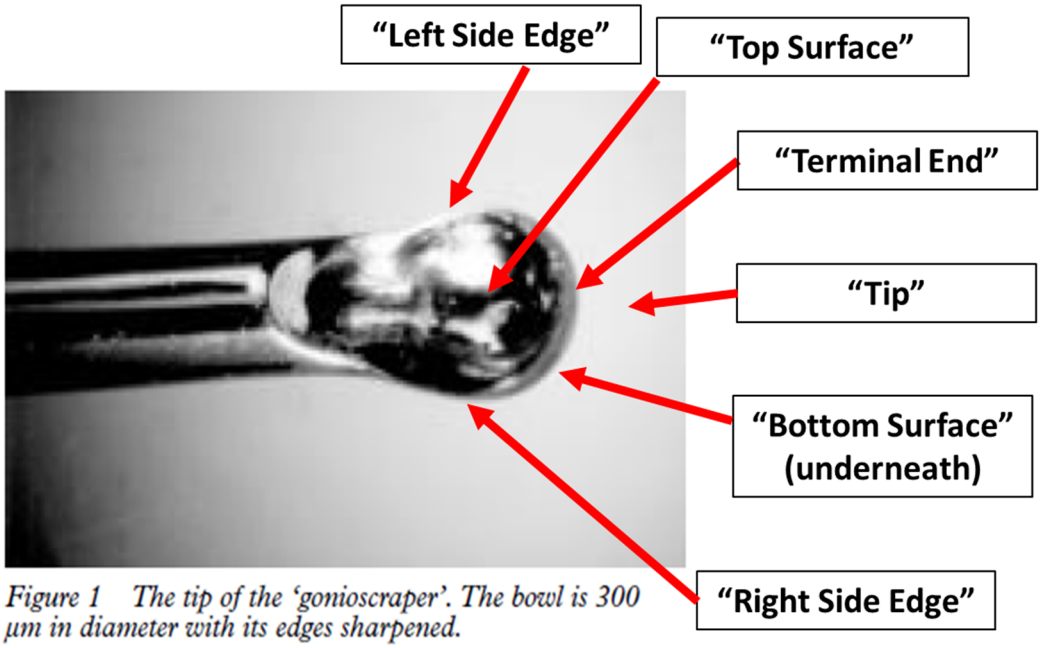


Figure 1 The tip of the 'gonioscraper'. The bowl is 300 μm in diameter with its edges sharpened.

Ex.1007, Fig.1 (annotated); Ex.1003, ¶156.

Additionally, a POSITA would understand that the terminal end of the device pierces through the TM tissue to enter SC. Ex.1003, ¶157. Indeed, Jacobi indicates that the tip is directed against the TM and is advanced through SC. Ex.1007, 2. In order for the tip to peel "strings" of TM tissue from SC, the

terminal end of the tip must first penetrate the TM to position the tip within SC. Ex.1003, ¶157.

e. the tip having a transverse width from the right side edge to the left side edge, said transverse width being narrowest at the terminal end; and

As shown below, the bowl-shaped tip of Jacobi's gonioscraper is widest in the center from one edge of the bowl to the other. Ex.1007, Fig.1. Moreover, the bowl-shaped tip becomes narrower toward the terminal end. Ex.1003, ¶158.

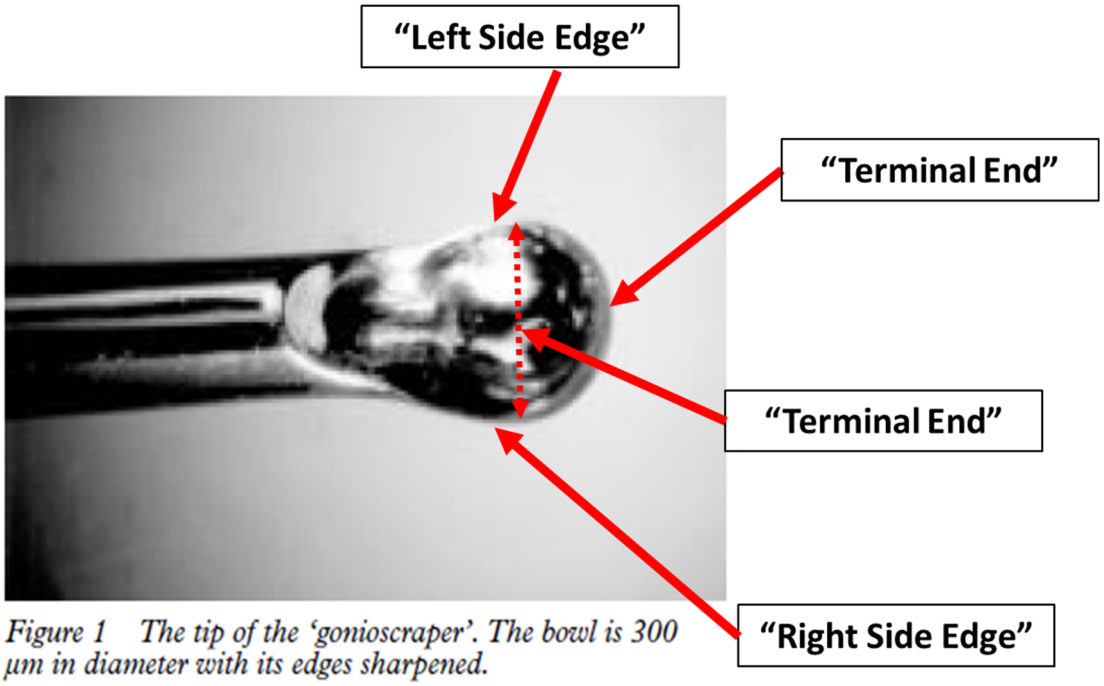


Figure 1 The tip of the 'gonioscraper'. The bowl is 300 μm in diameter with its edges sharpened.

Ex.1007, Fig.1 (annotated).

f. first and second spaced-apart cutting edges positioned on the device so as to cut tissue that passes along the

top surface of the tip and into contact with the cutting edges;

Jacobi's gonioscraper has "first and second spaced-apart cutting edges." Ex.1003, ¶159. Indeed, the bowl-shaped tip of Jacobi's device has sharpened edges. Ex.1007, 1-2, Fig.1 (below). The sharpened edges of Jacobi's bowl-shaped tip are first and second cutting edges. Ex.1003, ¶¶159-60. As explained above, during prosecution of the '729 patent, the Examiner determined that Lee's U-shaped cutting edge (14) has "***dual blades corresponding to the U-shape***." Ex.1022, 320 (emphasis added); *see also* Ex.1006, 4:38-41, Figs. 2-3 (below).

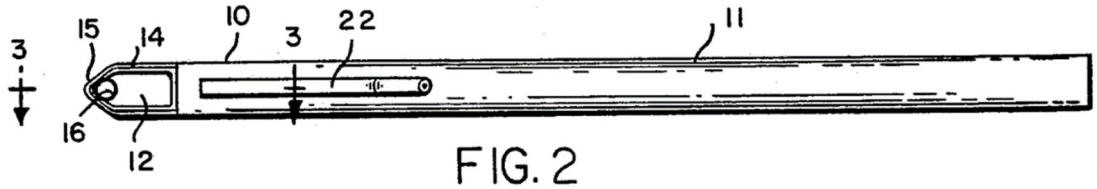


FIG. 2

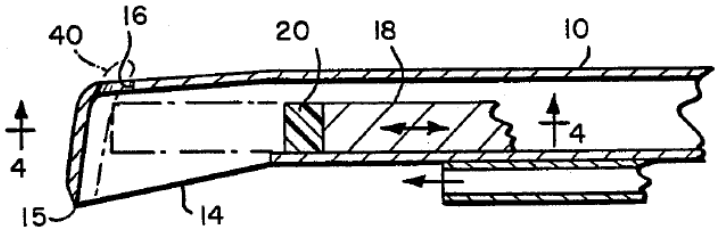
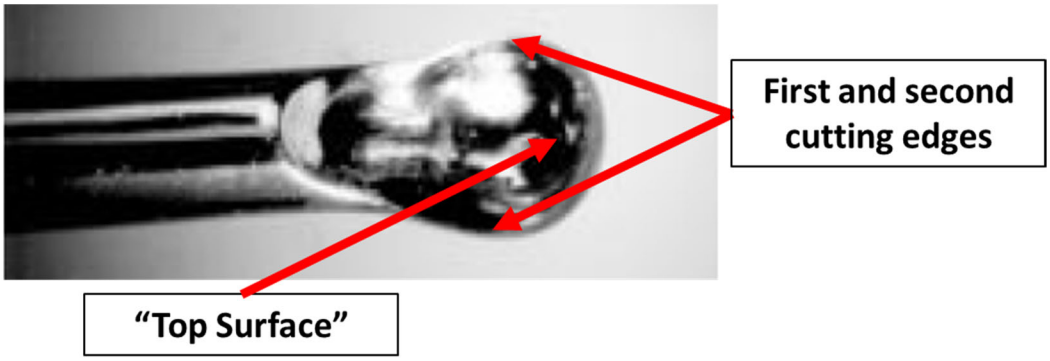


FIG. 3

Like Lee's device, Jacobi's gonioscraper is a "dual blade device," as it has a similar U-shaped cutting edge with dual blades corresponding to the U-shape. Ex.1007, 2; Ex.1022, 320; Ex.1003, ¶160. As shown below, these dual blades are

first and second cutting edges that are spaced-apart on opposite sides of the bowl-shaped tip.



Ex.1007, Fig.1 (annotated).

Jacobi's sharpened cutting edges cut TM tissue. Ex.1007, ¶161. To "peel" the TM and create "strings" of TM tissue, a POSITA would understand that both cutting edges of the gonioscraper must concurrently cut the TM. *Id.* Further, a POSITA would appreciate that when Jacobi's device is oriented within and advanced through SC, at least a portion of TM tissue that contacts the bowl-shaped tip would pass over the top surface of the tip (*i.e.*, the inner surface of the bowl) and then contact the cutting edges, as specified by the claim. *Id.*

If it is determined TM tissue would not pass over the top surface of Jacobi's tip and contact the cutting edges, a POSITA would have found it obvious to modify Jacobi's device such that the TM tissue would pass over the top surface of the tip. *Id.*, ¶¶162-63. For example, a POSITA would have known that extending the terminal end of Jacobi's bowl would cause TM tissue to pass over the top surface of the tip before contacting the cutting edges. *Id.* Devices having a

slightly protruding terminal end were well-known in the art. *Id.* For example, Lee's bowl-like cavity has a sharpened rim with a distal end 15 that "protrudes a distance of about 0.5 to 1.0mm ***for ease of tissue penetration and cutting.***" Ex.1006, 4:38-48, Fig.3 (below).

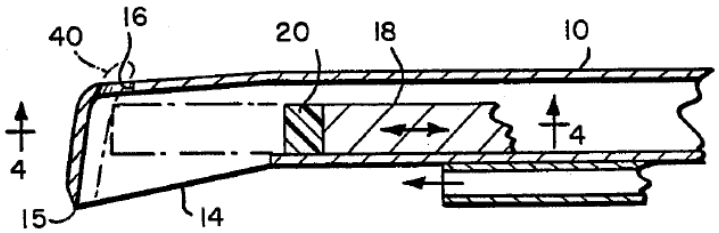


FIG. 3

In this orientation, TM tissue necessarily passes over the top surface of the distal end 15 of Lee's device and then contacts the sharpened edges 14. Ex.1003, ¶162.

Based on the knowledge of a POSITA as informed by the prior art such as Lee, it would have been obvious to modify Jacobi's bowl-shaped tip to have a protruding terminal end in order to, for example, make it easier to penetrate the TM with the device's tip. *Id.*, ¶163. Incorporating a protruding terminal end into Jacobi's device would also have involved nothing more than the substitution of one prior art element for another, such as substituting the terminal end of Jacobi's device with the protruding terminal end of Lee's device. *Id.* A POSITA would have expected success given the known prior art devices having such elements and the successful use of such devices to remove strips of tissue from the TM. *Id.* A POSITA would appreciate that, as a result of modifying Jacobi's tip to have a

protruding terminal end, TM tissue would pass over the top surface of Jacobi's bowl-shaped tip (including the top surface of the protruding terminal end) before contacting Jacobi's cutting edges, as specified by the claim.

g. b) inserting the probe into the anterior chamber of the eye;

Jacobi states that the device is "***inserted into the anterior chamber*** through a clear corneal incision at the temporal limbus and directed against the trabecular meshwork at the opposite side" following injection of viscoelastic. Ex.1007, 1. Fig.2 below shows the device within the AC and directed against the TM. Ex.1003, ¶164.

Figure 2 With the aid of an operating microscope and under gonioscopic control ab interno goniocurettage is performed. Following abrasion an irregular pattern of a glistening white band corresponding to the 'denuded' grey-white sulcus scleralis can be seen (black arrows).

Ex.1007, Fig.2.

h. c) advancing the tip through trabecular meshwork tissue and into the Schlemm's Canal of the eye such that trabecular meshwork tissue is in contact with the top surface;

As discussed, Jacobi's gonioscraper is "inserted into the anterior chamber through a clear corneal incision at the temporal limbus and ***directed against the trabecular meshwork*** at the opposite side." Ex.1007, 1. From here, Jacobi's tip penetrates through the TM and into SC. *Id.*, 2; Fig. 2 (below); Ex.1003, ¶165.

Figure 2 With the aid of an operating microscope and under gonioscopic control ab interno goniocurettage is performed. Following abrasion an irregular pattern of a glistening white band corresponding to the 'denuded' grey-white sulcus scleralis can be seen (black arrows).

Id., Fig.2. As described above, in this orientation, the TM tissue must be in contact with the top surface of Jacobi's bowl-shaped tip before it is removed by the cutting edges. *See supra*, §VI.C.2.f.; Ex.1003, ¶166.

i. d) moving the probe to cause the tip to advance through the Schlemm's Canal such that trabecular meshwork

tissue moves along the top surface of the tip and into contact with the first and second spaced-apart cutting edges, thereby cutting a strip of the trabecular meshwork tissue.

Jacobi states that once the device has been directed against the TM, it is "lightly passed over 2-3 clock hours to either side at the nasal circumference of the anterior chamber angle in sweeping movements." Ex.1007, 2. A POSITA would appreciate that causing the tip of the gonioscraper to advance through the TM in this manner would require moving the handle and convex-shaped arm of the device. Ex.1003, ¶167. As described above, in this orientation, the TM tissue must be in contact with and pass over the top surface of Jacobi's bowl-shaped tip before it comes into contact with the cutting edges. *See supra*, §VI.C.2.f.; Ex.1003, ¶168.

Jacobi indicates that strips of TM tissue are cut from the TM. Indeed, Jacobi's purpose "was to abrade rather than incise" the TM and that the procedure resulted in "strings of trabecular tissue" within the AC. Ex.1007, 2. A POSITA would appreciate that, based on Jacobi's express disclosures, Jacobi excises tissue in strips rather than simply cutting a slit in the TM. Ex.1003, ¶169. In order to create a strip, a POSITA would understand that both cutting edges of the gonioscraper must concurrently cut the TM. *Id.* If the cutting edges did not concurrently cut the TM, Jacobi would not have obtained strings of tissue but

would rather have created a slit-like opening as in traditional approaches—what Jacobi expressly sought to avoid. *Id.*; Ex.1007, 2.

3. Claim 2 - *A method according to claim 1 further comprising the step of keeping the anterior chamber filled.*

Jacobi in view of the knowledge of a POSITA renders obvious claim 1. *See supra*, §VI.C.2. Further, Jacobi performs the procedure "following injection of viscoelastic" and thus discloses keeping the AC filled with viscoelastic (*i.e.*, a fluid commonly used for ophthalmic procedures) while performing goniocurettage. Ex.1007, 2; Ex.1003, ¶171. Jacobi also indicates goniocurettage requires "a deep and stable anterior chamber," which would further indicate to a POSITA that the chamber is kept filled with fluid (viscoelastic or aqueous) so that it does not collapse. Ex.1007, 5; Ex.1003, ¶172.

4. Claim 3 - *A method according to claim 2 wherein the device further comprises an infusion lumen and wherein fluid is infused through the infusion lumen to keep the anterior chamber filled.*

Jacobi in view of the knowledge of a POSITA renders obvious claim 2. *See supra*, §VI.C.3. Further, Jacobi indicates that the procedure is performed following injection of viscoelastic. Ex.1007, 2. It would have been obvious to incorporate an infusion lumen into Jacobi's device to allow for injection of viscoelastic. Ex.1003, ¶¶174-76. By 2003, devices including infusion lumen for infusing fluid were well-known. *Id.*, ¶175. For example, Lee's device has an

"irrigation port" (*i.e.*, an infusion lumen) that is used to "maintain fluid levels in the anterior chamber of the eye during a surgical procedure and to help protect the cornea and the lens from injury." Ex.1006, 5:6-15. A POSITA would have been motivated to incorporate such an infusion lumen into Jacobi's device for various reasons, including Lee's explicit teachings that an irrigation port can be used to maintain fluid levels in the AC and protect the cornea and lens. Ex.1003, ¶¶175-76. Moreover, modifying Jacobi's device to include an infusion lumen would also have involved simply combining prior art elements according to known methods, such as incorporating a known infusion lumen into Jacobi's device with known infusion lumen to achieve a deep and stable AC. *Id.* Finally, a POSITA would have been motivated to reduce the number of devices required for performance of the procedure and would have found it obvious to add an infusion lumen to the device to avoid the necessity of a separate infusion device. *Id.*

5. Claim 4 - *A method according to claim 3 wherein step a comprises: forming an incision in the eye, causing fluid to flow out of the infusion lumen and into the incision, thereby spreading or opening the eye, and thereafter inserting the probe through the incision and into the anterior chamber of the eye.*

Jacobi in view of the knowledge of a POSITA renders obvious claim 3. *See supra*, §VI.C.4. Further, Jacobi discloses "forming an incision in the eye" and "inserting the probe through the incision and into the anterior chamber of the eye," as claimed, because Jacobi states that "[f]ollowing injection of viscoelastic, the

'gonioscraper' was ***inserted into the anterior chamber through a clear corneal incision*** at the temporal limbus and directed against the trabecular meshwork at the opposite side." Ex.1007, 2; Ex.1003, ¶178.

Jacobi also discloses "causing fluid to flow…into the incision." According to Jacobi, fluid (*i.e.*, viscoelastic) is injected into the AC prior to inserting the device through the incision, the purpose of which is to provide a deep and stable AC. Ex.1007, 2, 7. A POSITA would appreciate that by injecting fluid into the eye (through an infusion lumen or otherwise), the volume of fluid within the AC would increase, causing the outer surface of the eye to expand. Ex.1003, ¶179. This would necessarily cause openings (such as an incision) in the eye to spread further open. *Id.* Although Jacobi does not explicitly indicate that the fluid flows into the incision through an infusion lumen, modifying Jacobi's device to incorporate an infusion lumen would have been obvious, as discussed above. *See supra*, §VI.C.4.

Even if Jacobi does not explicitly disclose causing a fluid to flow into the incision thereby spreading or opening the incision a POSITA would have found it obvious to do so. Ex.1003, ¶180. Infusing fluid into the eye to spread or otherwise open an incision was well known in the art in 2003. *Id.* For example, it was well known that injecting fluid into the AC could be used as a means for holding open a "cleft" in the eye during or after a surgical procedure. Ex.1011, 53-54. It was also

known to inject fluid into the eye during surgical procedures to deepen the angle and prevent collapse of the AC, as indicated in Jacobi itself. Ex.1007, 2; Ex. 1004, 4. A POSITA would understand that injecting fluid into an incision to hold the incision open, to deepen the angle, and/or prevent AC collapse would increase the volume of fluid in the eye, causing the outer surfaces of the eye to stretch and spread or widen openings in the eye. Ex.1003, ¶180. Based on this knowledge, a POSITA would have found it obvious to inject fluid into Jacobi's incision, resulting in spreading or widening of the opening, and would have expected success due to successful procedures disclosed in the art, including for the explicit purpose of holding incisions open. *Id*.

6. Claim 5 - *A method according to claim 3 wherein the device further comprises an aspiration lumen and the method further comprises aspirating fluid through the aspiration lumen.*

Jacobi in view of the knowledge of a POSITA renders obvious claim 3. *See supra*, §VI.C.4. Jacobi discloses inserting the device into the AC of an eye following injection of viscoelastic, *see id.*, but does not teach the device further includes an aspiration lumen through which fluid is aspirated. Devices for aspirating fluid and debris were well-known in the art in 2003, however, including as disclosed in Jacobi itself. *See* Ex.1007, 2 ("the viscoelastic along with abraded trabecular debris were removed by means of an irrigation-aspiration probe"). It would have been obvious to a POSITA to improve upon Jacobi's device by

incorporating an aspiration lumen for aspirating fluid and debris. Ex.1003, ¶182. It was known that leaving strips of tissue and debris within the eye could have negative implications such as the formation of scar tissue and blocking the aqueous outflow system, and thus incorporating an aspiration lumen for aspirating fluid and debris from the eye would have been obvious to a POSITA to prevent these known issues. *Id.* Such a modification to Jacobi's device also would also have involved nothing more than combining prior art elements according to known methods with a reasonable expectation of success based on the use of similar devices and techniques in the prior art. *Id*.

7. Claim 6 - *A method according to claim 1 wherein the strip of trabecular meshwork tissue cut in step d has a length of about 2 to 10 millimeters*.

Jacobi in view of the knowledge of a POSITA renders obvious claim 1. *See supra,* §VI.C.2. Further, the patent admits that cutting a strip of TM with a length of about 2 to 10 millimeters was known in the art. *See* Ex.1001, 1:39-45. Thus, claim 6 does not cover a novel or nonobvious feature of the alleged invention.

In any event, Jacobi explains that "[g]oniocurettage was performed over 90-120° of the chamber angle circumference in all patients." Ex.1007, 4. A POSITA would understand based on the circumference of SC (and thus, the TM), which is about 36mm, Ex.1010, 5, a 90° section of TM would equate to a section that is

9mm in length, which is within the claimed range (90°/360°=0.25; 25% of 36mm=9mm). Ex.1003, ¶¶185-86.

8. Claim 7 - ***A method according to claim 1 wherein, after cutting of the strip of trabecular meshwork tissue in step d, the strip of trabecular meshwork tissue remains connected to the eye and wherein the method further comprises the step of disconnecting the strip of strip of trabecular meshwork tissue from the eye.***

Jacobi in view of the knowledge of a POSITA renders obvious claim 1. *See supra*, §VI.C.2. Jacobi teaches a procedure where the TM tissue is "abraded" to "peel" it from the TM, resulting in "strings of trabecular tissue" that were "removed by means of an irrigation-aspiration probe." Ex.1007, 2. Jacobi recognized that prior procedures often "allow[ed] filling in and scarring to occur with subsequent closure of the trabecular opening," *id.*, and thus a POSITA would have known that if any strings of tissue remained connected to the TM following the procedure, those strings of tissue should be disconnected and removed. Ex.1003, ¶188.

Moreover, by 2003, it was well-known that portions of tissue remaining connected to the TM could return to their predissection positions or cause scar tissue to form. Ex.1003, ¶189. For example, Johnstone describes a "flap" of TM tissue was left "that appeared to be capable of returning to its predissection position," which could block aqueous outflow. *Id.*; Ex.1005, 8. Johnstone removed the "flap," causing an increase in outflow in the majority of eyes.

Ex.1005, 8. Given this knowledge that tissue remaining could block outflow, a POSITA would have been motivated to disconnect any strips of tissue that remained connected to the TM following Jacobi's procedure and to remove the disconnected strips of tissue from the patient's eye. Ex.1003, ¶189.

9. Claim 8 - *A method according to claim 7 wherein the step of disconnecting the strip of trabecular meshwork tissue from the eye comprises using a tissue disconnecting apparatus to disconnect the strip of trabecular meshwork tissue from the eye.*

Jacobi in view of the knowledge of a POSITA renders obvious claim 7. *See supra* §VI.C.8. As explained for claim 7, a POSITA would have been motivated to disconnect and remove strips of tissue remaining connected to the TM to prevent blockages of aqueous outflow. *Id.* A POSITA would have known that this could be accomplished using a variety of known "tissue disconnecting apparatuses," which would be understood to be any instrument capable of disconnecting a strip of tissue from the TM. Ex.1003, ¶191. This could include for example: (a) Quintana's needle that strips TM tissue (Ex.1004, 3-4); (b) Jacobi's gonioscraper that peels TM tissue by passing the device "in sweeping movements" to disconnect tissue (Ex.1007, 2); (c) Jacobi's irrigation-aspiration probe, which could be used by suctioning tissue connected to the TM and pulling the tissue to tear it (sever it) from the TM (*id.*); or (d) Ferrari's forceps, which were used to remove TM tissue in strings of varying length (Ex.1018, 1). Ex.1003, ¶191. Given that each well-

known instrument is capable of disconnecting tissue from the TM, a POSITA would appreciate that each could be used as the claimed "tissue disconnecting apparatus." *Id.*, ¶191.

10. Claim 9 - *A method according to claim 1 wherein the method is performed under direct visualization through a lens device positioned on an anterior aspect of the eye.*

Jacobi in view of the knowledge of a POSITA renders obvious claim 1. *See supra*, §VI.C.2. Jacobi additionally indicates that the procedure "was performed under direct visualisation of the anterior chamber angle with an operating microscope and a surgical gonioscopy lens" and that successful treatment requires "[c]lear visualisation of the chamber angle structures by gonioscopy." Ex.1007, 2, 5. Visualization of the AC angle using a gonioscopy lens involves positioning the lens on an anterior aspect of the eye. Ex.1003, ¶193.

11. Claim 10 - *A method according to claim 1 wherein the tip extends laterally from said end of the probe at an angle of between approximately 30 and approximately 90 degrees relative to the longitudinal axis of the probe and wherein step d comprises moving the distal end of the probe laterally such that the tip advances through Schlemm's Canal.*

Jacobi in view of the knowledge of a POSITA renders obvious claim 1. *See supra*, §VI.C.2. Further, Jacobi's gonioscraper has several bends or curves. Ex.1003, ¶¶195-96. As shown below, the shaft of Jacobi's device is bent to form an angle.

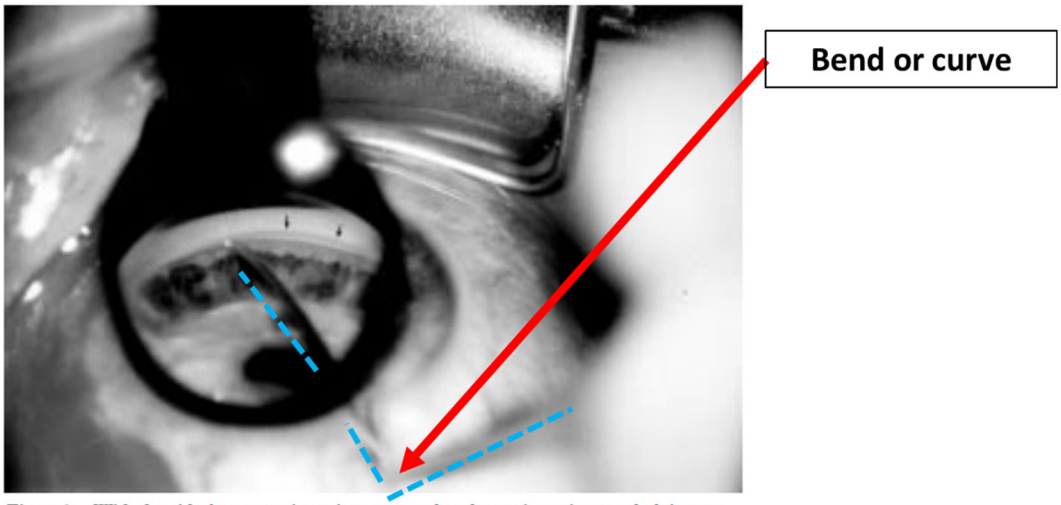
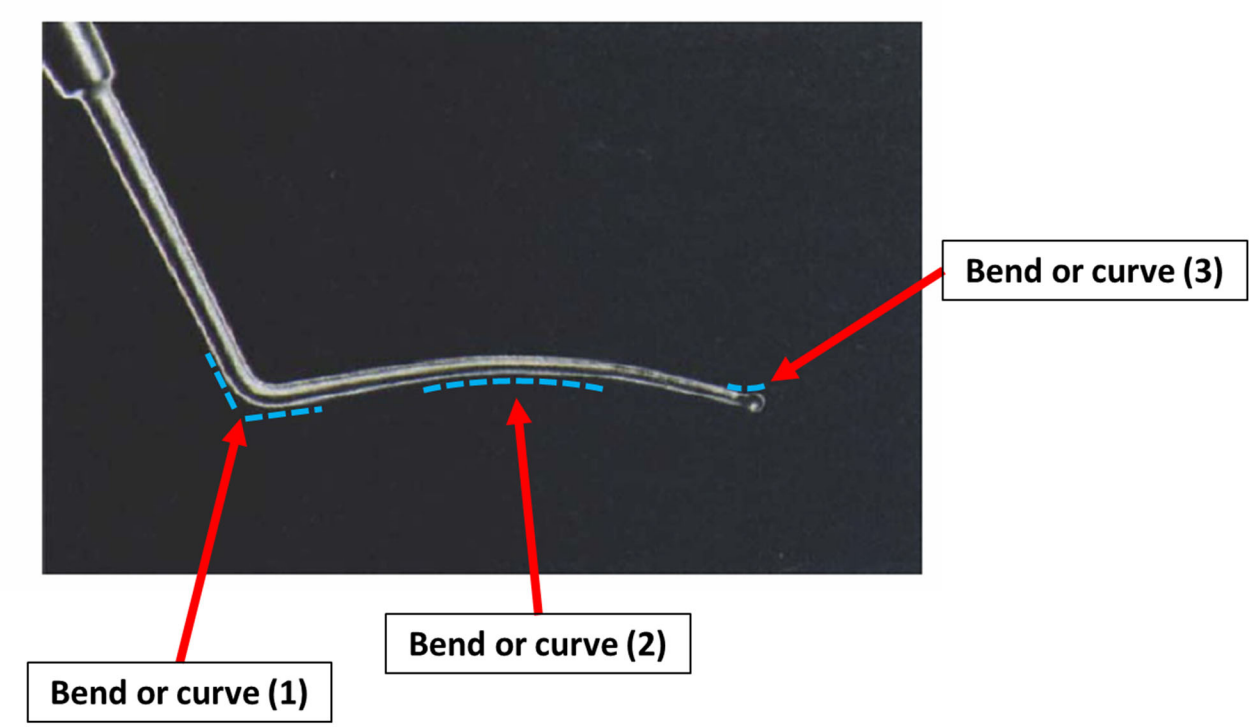


Figure 2 With the aid of an operating microscope and under gonioscopic control ab interno goniocurettage is performed. Following abrasion an irregular pattern of a glistening white band corresponding to the 'denuded' grey-white sulcus scleralis can be seen (black arrows).

Ex.1007, Fig.2 (annotated).

Other images of Jacobi's device further confirm that the device includes several bends or curves. As shown below, Jacobi 2000 (Ex.1013) includes an image of Jacobi's device that includes a number of bends or curves (labeled in the annotated image below). Ex.1013, 2; Ex.1003, ¶196.



Ex.1013, Fig.1(b) (annotated).

It was also well-known in the art to use devices with portions bent at various angles to meet the needs of a given surgery. Ex.1003, ¶197. For example, Johnstone discloses an "ab interno" procedure using "a cystotome with the point oriented at right angles to the shaft" inserted through the TM into SC." Ex.1005, 2; *see also* Ex.1006, 4:49-54 (angle of device's cutting edges vary "depending on surgical requirements"). Quintana also discloses a needle device with the tip bent 20-30°. Ex.1004, 3. Based on the knowledge of a POSITA as informed by prior art references such as Quintana and Johnstone, it would have been obvious to alter the angle of one or more of the bends or curves in Jacobi's device. For example, it would have been a simple matter of combining prior art elements according to

known methods or simple substitution of one known element for another to modify bend or curve (3) of Jacobi's device to an angle of between approximately 30 to 90 degrees, as specified in the claim. Ex.1003, ¶198. Indeed, a POSITA would recognize the angle of the gonioscraper's bend or curve could be substituted with another angle (such as an angle of between approximately 30 to 90 degrees) with an expectation of success given Johnstone's and Quintana's results using devices with different angled portions. *Id.* For similar reasons, a POSITA would have found it obvious to try variations to the angle of the bends or curves in Jacobi's device, given there are a finite number of "bend or curve" angles that could be employed. *Id.*, ¶199.

Moreover, as explained above, the bowl-shaped tip of Jacobi's device advances through SC, as claimed. *See supra*, §VI.C.i; *e.g.*, Ex.1007, 2 (device was "lightly passed over 2-3 clock hours to either side at the nasal circumference of the anterior chamber angle in sweeping movements"), Fig.2 (below); Ex.1003, ¶200.

Figure 2 With the aid of an operating microscope and under gonioscopic control ab interno goniocurettage is performed. Following abrasion an irregular pattern of a glistening white band corresponding to the 'denuded' grey-white sulcus scleralis can be seen (black arrows).

Id., Fig.2. A POSITA would understand that passing the tip of the device to either side of the chamber angle such that the tip advances through SC, as specified in Jacobi, requires moving the handle and convex-shaped arm of the device laterally. Ex.1003, ¶200.

12. Claim 11 - *A method according to claim 1 wherein a curve is formed in the elongate probe proximal to the end of the probe from which the tip laterally extends.*

Jacobi in view of the knowledge of a POSITA renders obvious claim 1. *See supra*, §VI.C.2. Further, as discussed, Jacobi's gonioscraper has several bends or curves. Ex.1003, ¶¶202-03; Ex.1007, Fig.2 (below); Ex.1013, 2 (below); *see also supra*, §VI.C.11.

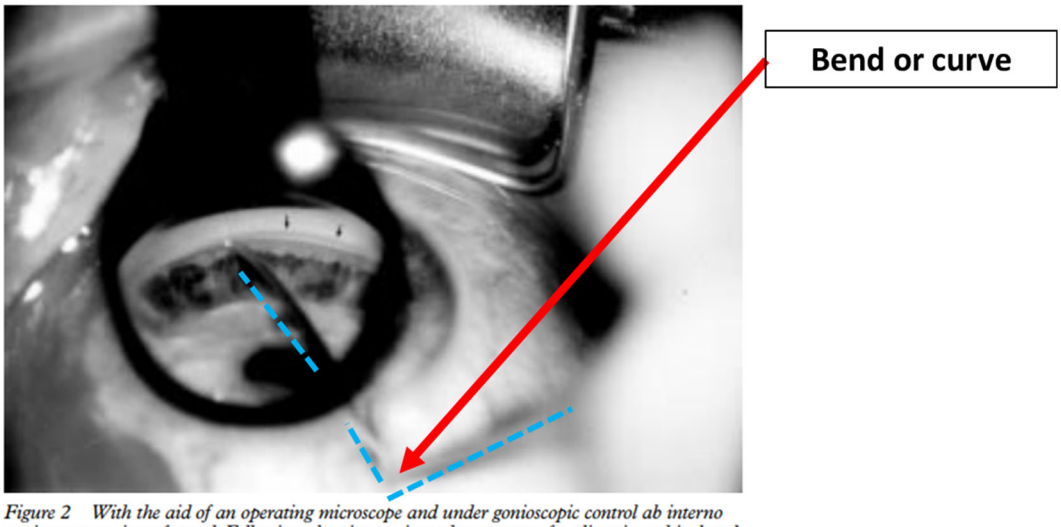
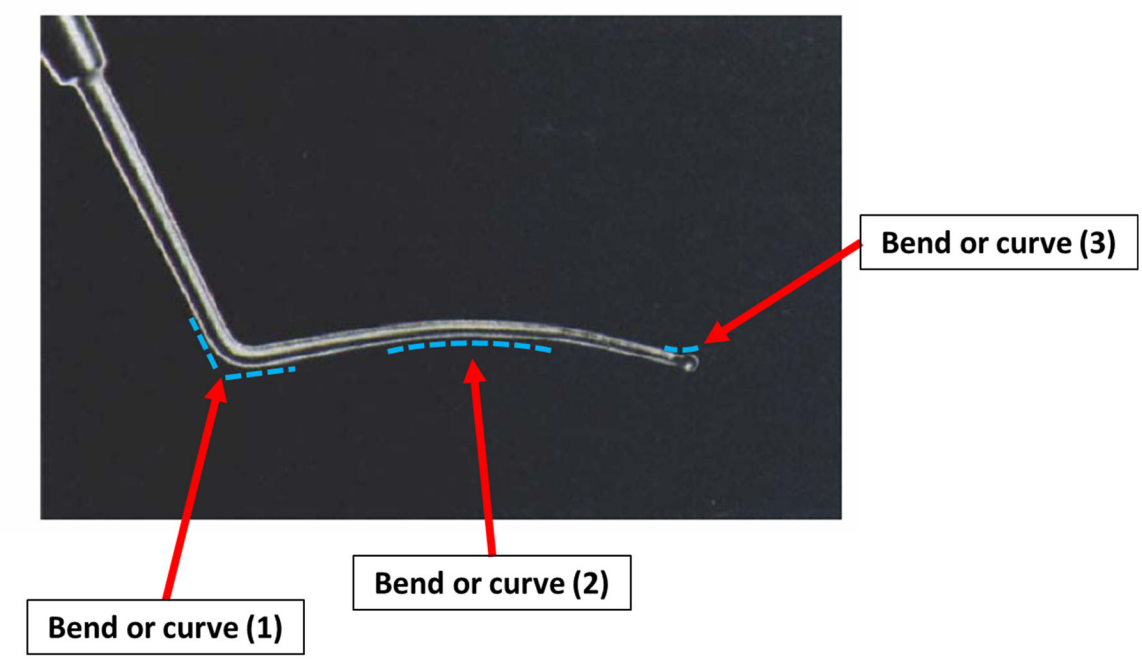


Figure 2 With the aid of an operating microscope and under gonioscopic control ab interno goniocurettage is performed. Following abrasion an irregular pattern of a glistening white band corresponding to the 'denuded' grey-white sulcus scleralis can be seen (black arrows).

Ex.1007, Fig.2 (annotated).



Ex.1013, Fig.1(b) (annotated). A POSITA would appreciate that at least bends or curves (1) and (2) are proximal to the end of the probe from which the tip extends, as required by claim 11. Ex.1003, ¶203.

VII. Conclusion

For the foregoing reasons, IPR of claims 1-11 of the '885 patent is respectfully requested.

Dated: October 2, 2020

Respectfully submitted,

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Claim Appendix

Claim 1:

[1.p] A method for cutting a strip of trabecular meshwork tissue within an eye of a subject, said eye having an anterior chamber, trabecular meshwork tissue and a Schlemm's canal, said method comprising:

[1.a] a) providing or obtaining a device which comprises;

[1.a.1] an elongate probe that extends along a longitudinal axis;

[1.a.2] a tip which extends laterally from an end of the probe, said tip comprising a platform which has a top surface, a bottom surface, a right side edge, a left side edge and a terminal end, the terminal end being configured to penetrate through trabecular meshwork tissue;

[1.a.3] the tip having a transverse width from the right side edge to the left side edge, said transverse width being narrowest at the terminal end; and

[1.a.4] first and second spaced-apart cutting edges positioned on the device so as to cut tissue that passes along the top surface of the tip and into contact with the cutting edges;

[1.b] b) inserting the probe into the anterior chamber of the eye;

[1.c] c) advancing the tip through trabecular meshwork tissue and into the Schlemm's Canal of the eye such that trabecular meshwork tissue is in contact with the top surface;

[1.d] d) moving the probe to cause the tip to advance through the Schlemm's Canal such that trabecular meshwork tissue moves along the top surface of the tip and into contact with the first and second spaced-apart cutting edges, thereby cutting a strip of the trabecular meshwork tissue.

Claim 2:

[2.p] A method according to claim 1 further comprising the step of

[2.a] keeping the anterior chamber filled.

Claim 3:

[3.p] A method according to claim 2 wherein

[3.a] the device further comprises an infusion lumen and wherein fluid is infused through the infusion lumen to keep the anterior chamber filled.

Claim 4:

[4.p] A method according to claim 3 wherein step a comprises:

[4.a] forming an incision in the eye;

[4.b] causing fluid to flow out of the infusion lumen and into the incision, thereby spreading or opening the incision; and

[4.c] thereafter inserting the probe through the incision and into the anterior chamber of the eye.

Claim 5:

[5.p] A method according to claim 3 wherein

[5.a] the device further comprises an aspiration lumen and the method further comprises aspirating fluid through the aspiration lumen.

Claim 6:

[6.p] A method according to claim 1 wherein

[6.a] the strip of trabecular meshwork tissue cut in step d has a length of about 2 to 10 millimeters.

Claim 7:

[7.p] A method according to claim 1 wherein,

[7.a] after cutting of the strip of trabecular meshwork tissue in step d, the strip of trabecular meshwork tissue remains connected to the eye and wherein the method further comprises the step of disconnecting the strip of strip of trabecular meshwork tissue from the eye.

Claim 8:

[8.p] A method according to claim 7 wherein

[8.a] the step of disconnecting the strip of trabecular meshwork tissue from the eye comprises using a tissue disconnecting apparatus to disconnect the strip of trabecular meshwork tissue from the eye.

Claim 9:

[9.p] A method according to claim 1 wherein

[9.a] the method is performed under direct visualization through a lens device positioned on an anterior aspect of the eye.

Claim 10:

[10.p] A method according to claim 1 wherein

[10.a] the tip extends laterally from said end of the probe at an angle of between approximately 30 and approximately 90 degrees relative to the longitudinal axis of the probe and wherein step d comprises moving the distal end of the probe laterally such that the tip advances through Schlemm's Canal.

Claim 11:

[11.p] A method according to claim 1 wherein

[11.a] a curve is formed in the elongate probe proximal to the end of the probe from which the tip laterally extends.

CERTIFICATE OF COMPLIANCE

The undersigned certifies that this Petition complies with the type-volume limitations of 37 C.F.R. §42.24 because it contains 12,434 words (as determined by the Microsoft Word word-processing system used to prepare the Petition), excluding the parts of the brief exempted by 37 C.F.R. §42.24.

Dated: October 2, 2020

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing **PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 9,820,885** was served as of the below date via Federal Express on the following individuals:

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