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. IPR2021-00065
U.S. Patent No. 10,123,905

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 10,123,905

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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")
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1021	Arsham Sheybani, *Bent Ab-interno Needle Goniectomy (BANG)*, YouTube (Aug. 24, 2017), https://youtu.be/b5QxWts-Pxs ("BANG Video")
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1023	U.S. Patent 9,107,729 File History ("'729 patent file history")

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 10,123,905 ("the '905 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 9,820,885 ("the '885 patent"), and U.S. Patent 9,999,544 ("the '544 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 filed a petition for IPR regarding the '155 patent on October 2, 2020. *See* IPR No. 2020-01711. NWM also filed a petition for IPR regarding the '885 patent on October 2, 2020. *See* IPR No. 2021-00017.

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 ‘905 patent claims nothing more than using known devices to treat glaucoma, an eye disease that can lead to blindness. All limitations of the ‘905 patent claims are taught in the prior art. For instance, Quintana (Ex.1004) discloses everything claimed from the device (tissue cutting device with two “knife blades” made from a bent needle) to the type of procedure (inserting the device into the anterior chamber (“AC”)) to the technique (cutting a “strip” of tissue from the eye’s trabecular meshwork (“TM”) to treat glaucoma). There is nothing in the claims of the ‘905 patent that was not known and/or obvious.

For decades, a common method of treating glaucoma 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 used devices to create a single, slit-like incision to allow fluid to drain from the eye. Decades before the ‘950 patent’s 2003 filing date, 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 ‘905 patent to create more

permanent openings by removing strips of TM tissue to facilitate fluid outflow and prevent reclosure.

The ‘905 patent attempts to claim these well-known principles but fails to actually set forth anything inventive. The claims relate to devices for forming an opening in the TM of the eye to perform a surgical procedure that the patent admits was known for decades. The devices include 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 generic, broadly-claimed, known devices—nothing inventive or novel.

As demonstrated below, the claimed devices are not patentably distinct from the prior art. Even setting aside that the patent admits the very surgical procedure performed using the claimed device (*i.e.*, goniectomy) was known, the claimed 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/edges 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 1-7 of the '905 patent (the "Challenged Claims") be cancelled.

II. CERTIFICATIONS; GROUNDS

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

NWM certifies that the '905 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 '905 patent. The '905 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 '905 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, 6-7	§102	Quintana
Ground 2	2, 4-5	§103	Quintana, Knowledge of a POSITA
Ground 3	1-7	§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.

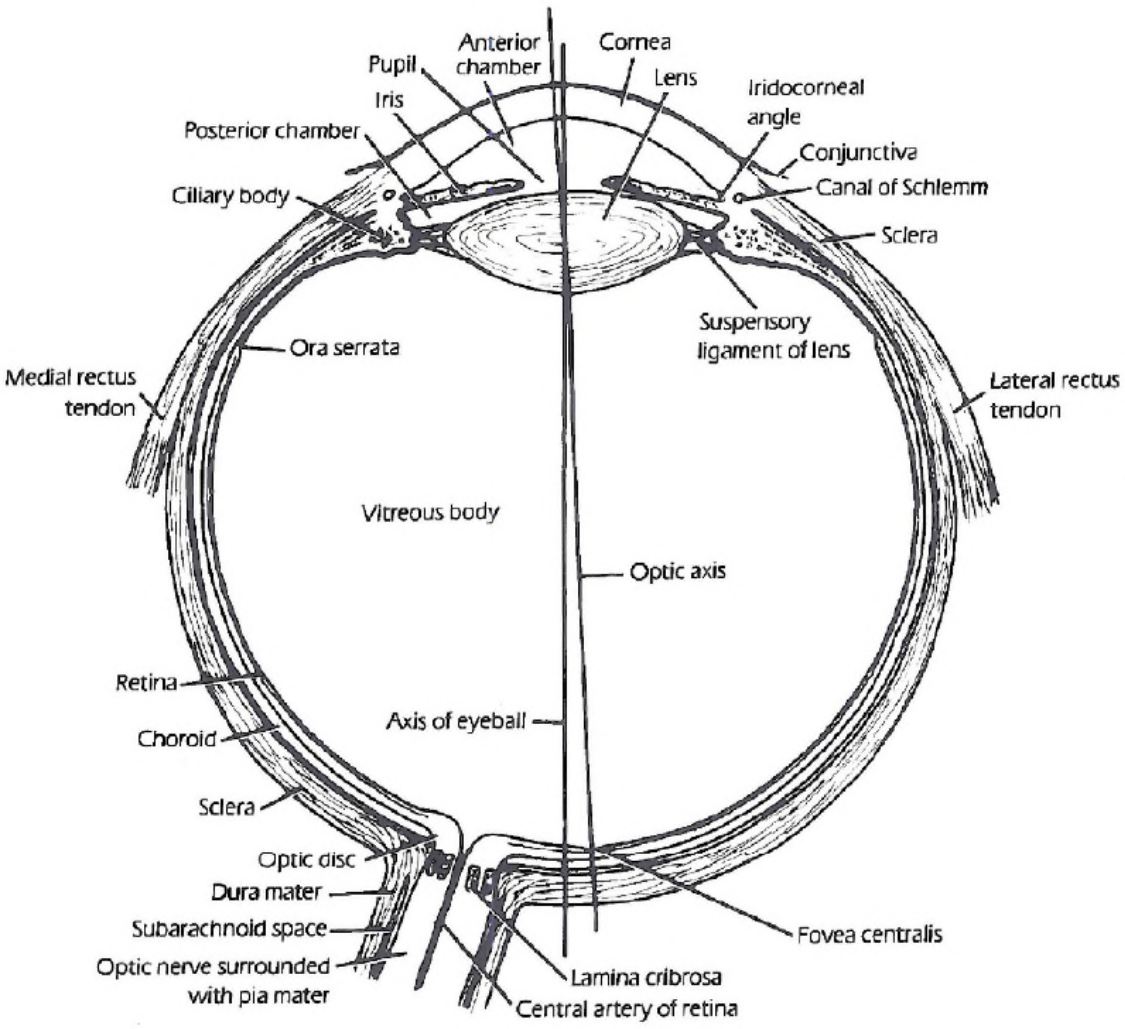
D. Service (§42.105)

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.

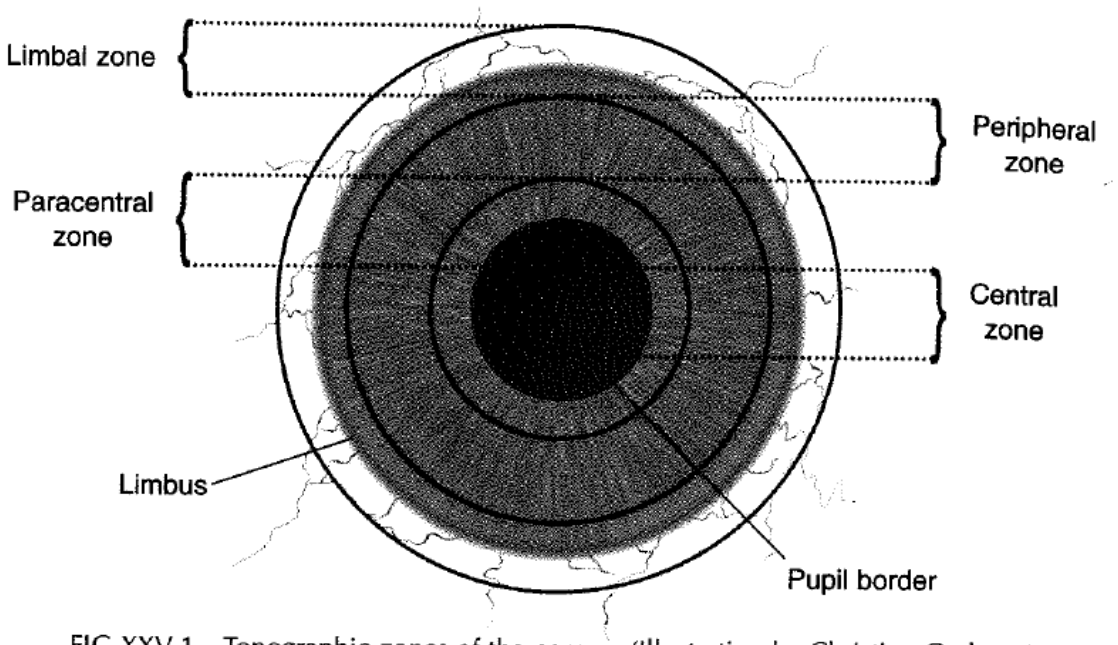


FIG XXV-1—Topographic zones of the cornea. (Illustration by Christine Gralapp.)

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** (or "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:

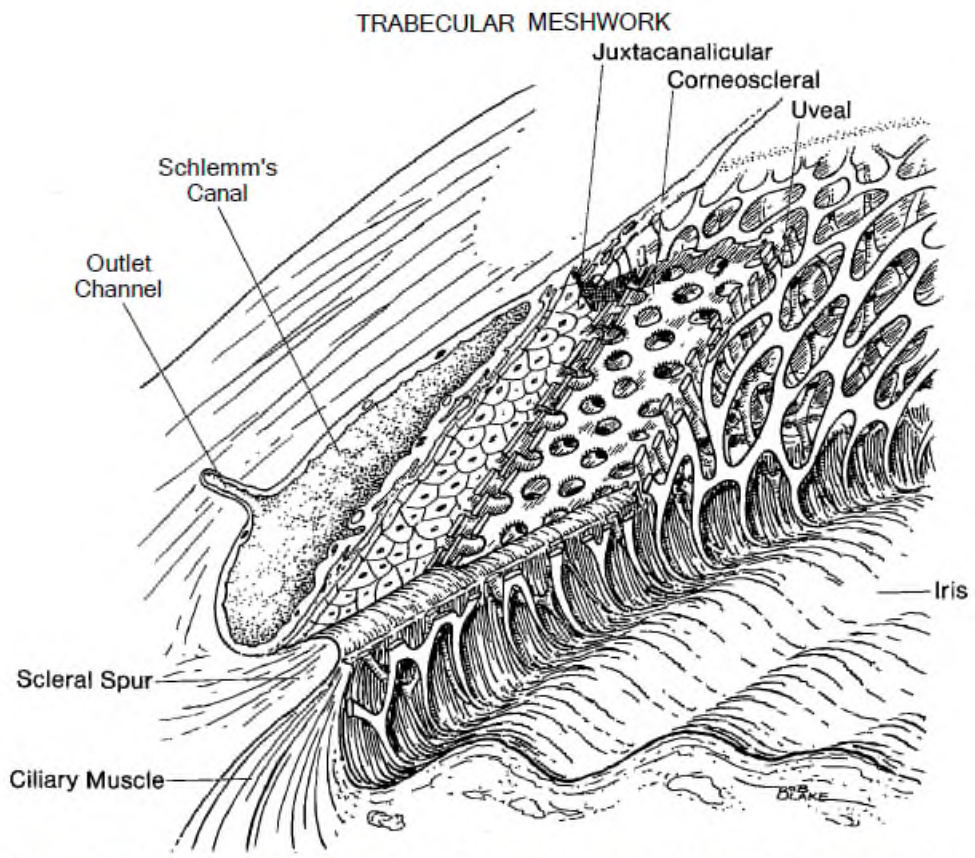


Figure 2.10. Three layers of trabecular meshwork (shown in cutaway views): (1) uveal; (2) corneoscleral; and (3) juxtacanalicular.

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.

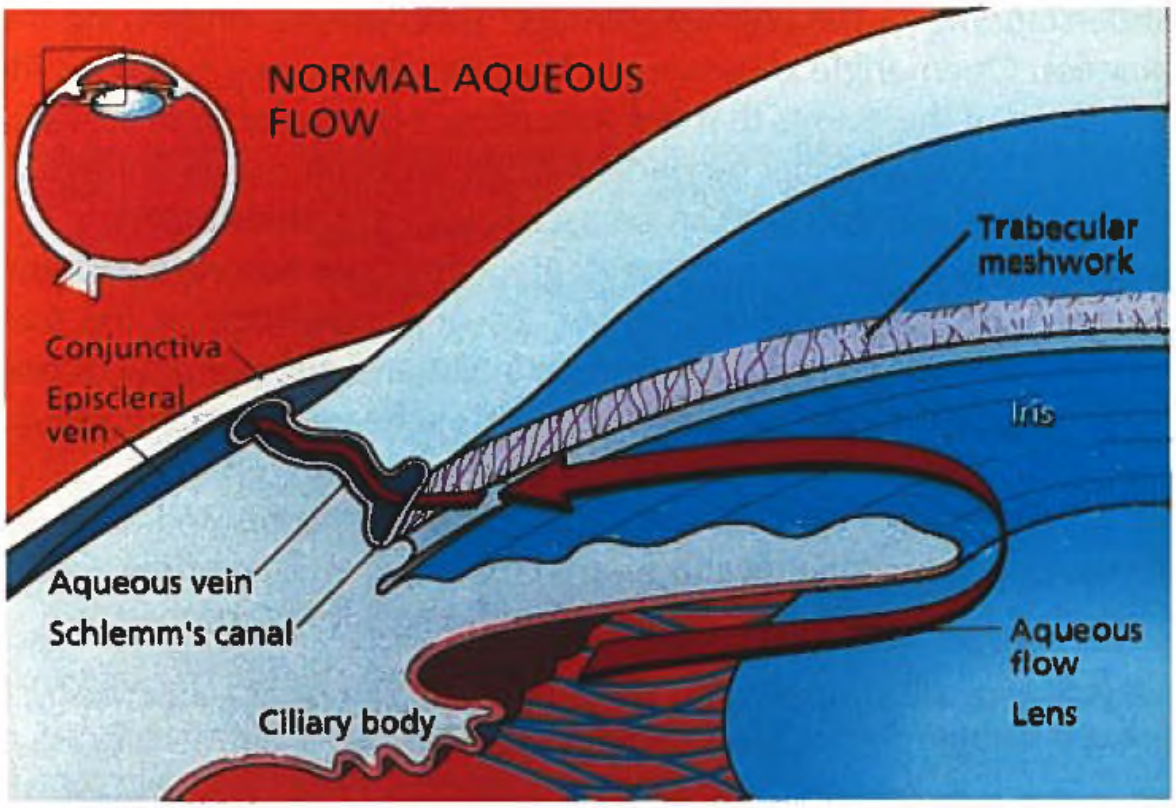


FIG I-1—Diagrammatic cross section of the anterior segment of the normal eye, showing the site of aqueous production (ciliary body) and sites of resistance to aqueous outflow (trabecular meshwork–Schlemm's canal system and episcleral venous plexus).

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, ¶42-43. As shown below, in open-angle glaucoma, the TM restricts aqueous outflow from the AC. Ex.1012, 10.

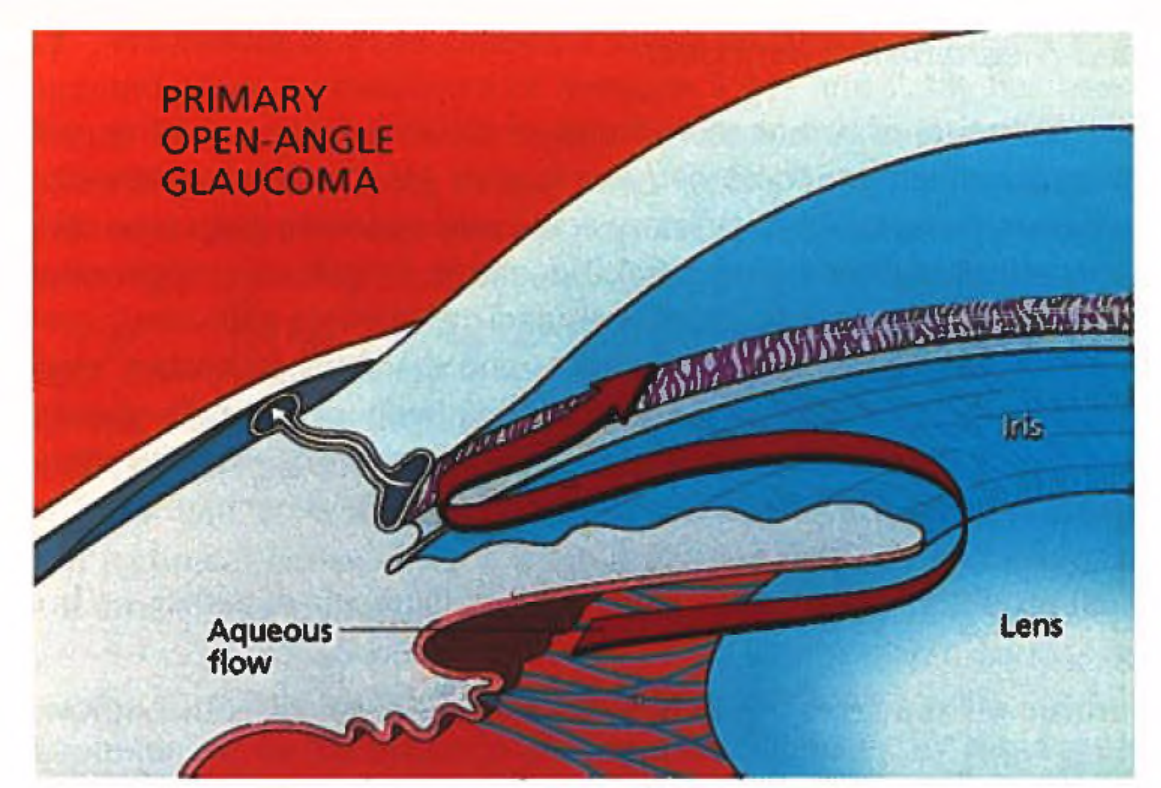


FIG I-2—Schematic of open-angle glaucoma with resistance to aqueous outflow through the trabecular meshwork–Schlemm's canal system in the absence of gross anatomic obstruction. Small white arrow shows normal path of outflow and indicates that resistance in this illustration is relative, not total.

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

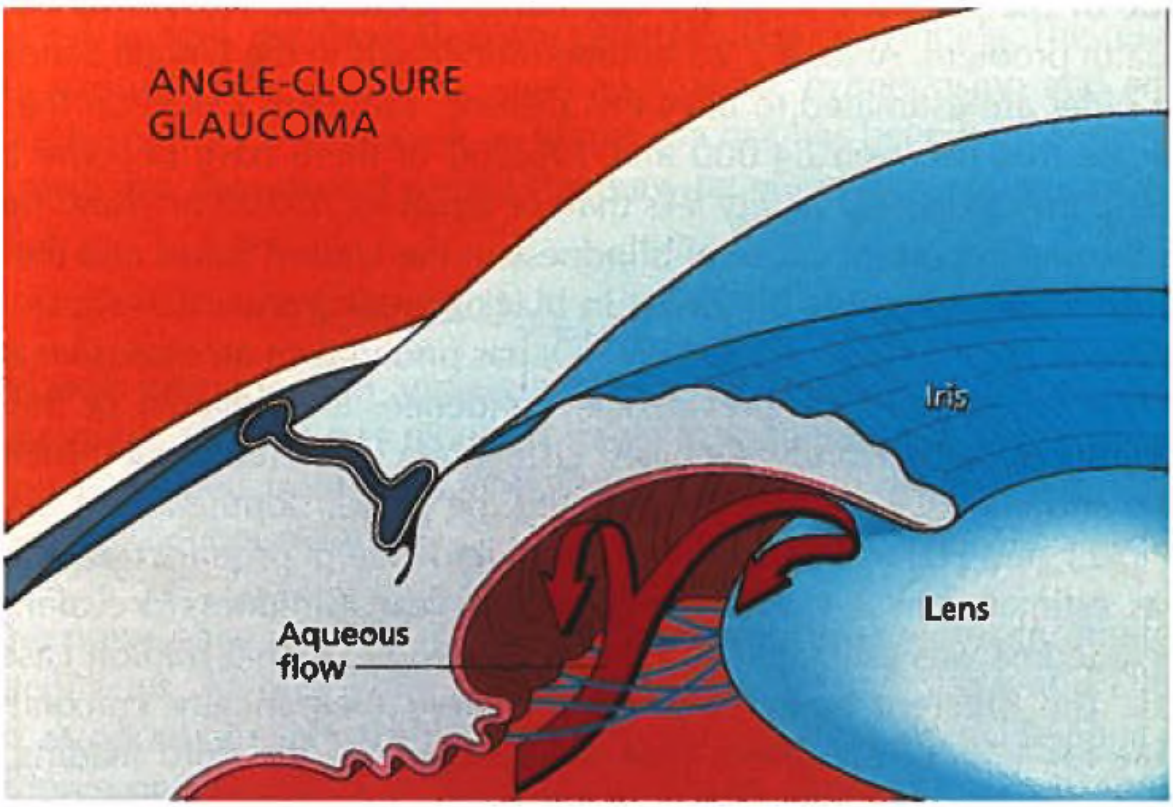


FIG I-3—Schematic of angle-closure glaucoma with pupillary block leading to peripheral iris obstruction of the trabecular meshwork.

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 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 the eye ("ab externo"). *Id.*

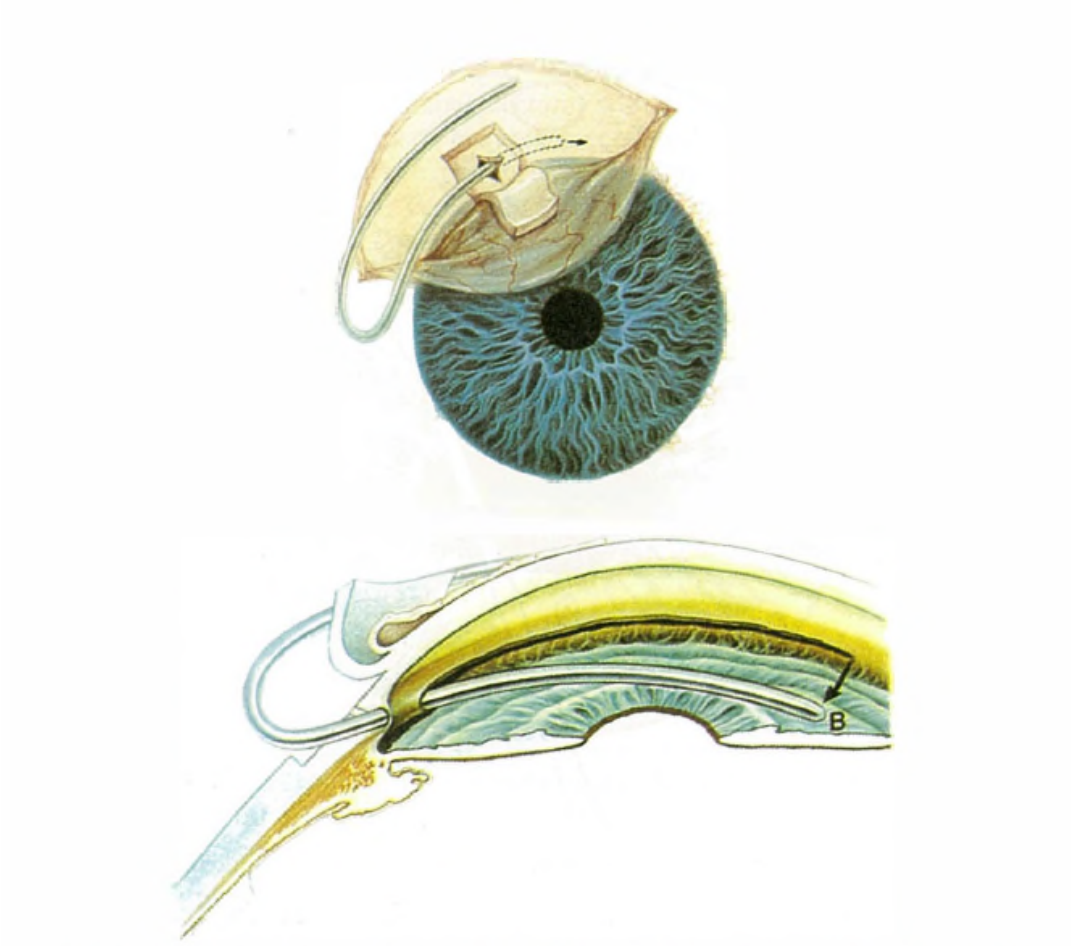


FIG VIII-13-Trabeculotomy. *Top,* Probe is gently passed along Schlemm's canal with little resistance for 6-10 mm. *Bottom,* By rotating the probe internally (8), the surgeon ruptures the trabeculum, and the probe appears in the anterior chamber with minimum bleeding. (Reproduced and modified with permission 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, ¶52.

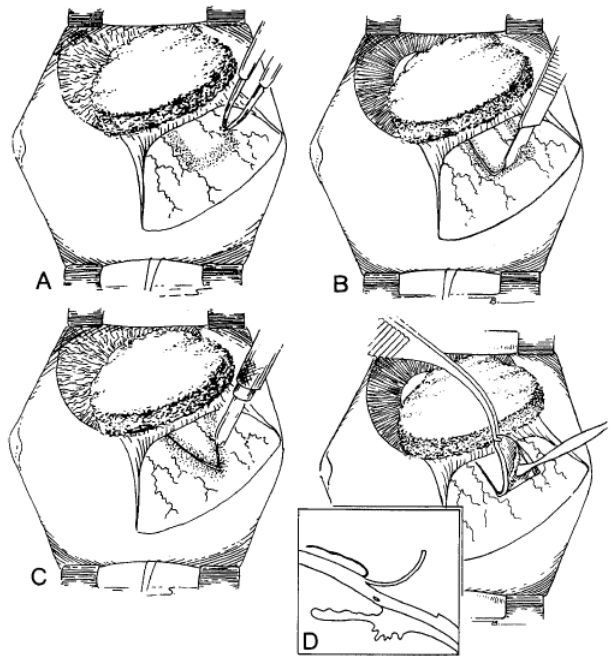


Figure 37.10. Trabeculectomy. A. Cauterization of area intended for margins of scleral flap. B. Margins of scleral flap outlined by partial-thickness incisions. C. Triangular scleral flap as an alternative technique. D. Dissection of scleral flap.

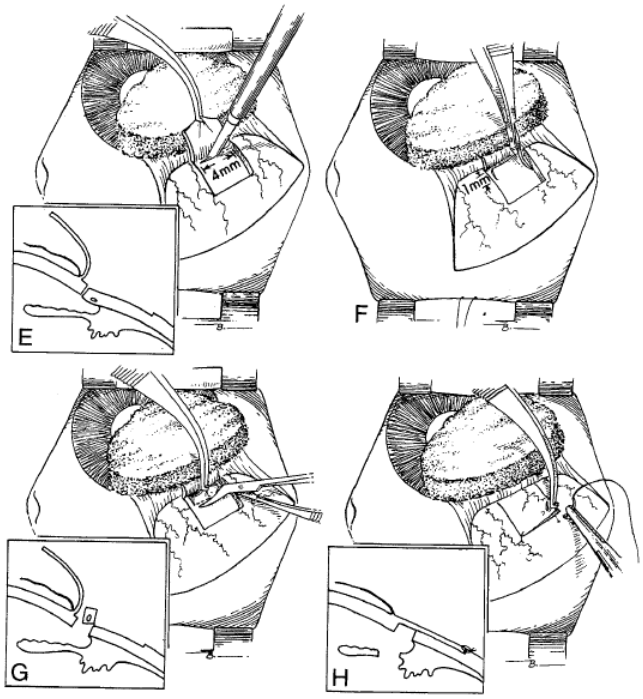


Figure 37.10. (cont'd) E. Anterior chamber entered just behind the hinge of the scleral flap. F. Completion of anterior and lateral margins of deep limbal incision with scissors. G. Flap of deep limbal tissue excised by cutting along scleral spur. H. Approximation of scleral flap. (Portions reprinted 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.

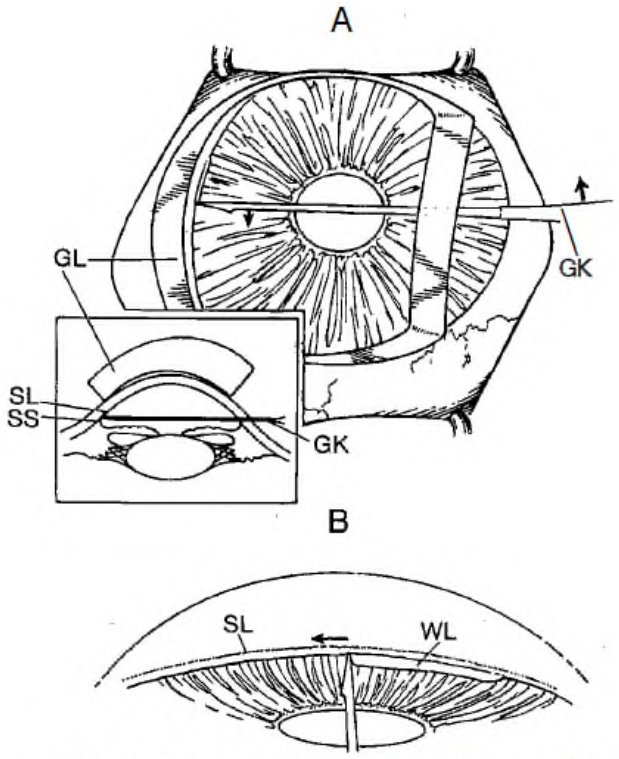


Figure 35.8. Goniotomy. A. With a surgical goniolens *(GL)* positioned on the cornea, a goniotomy knife *(GK)* is inserted through peripheral cornea and passed across the anterior chamber to the angle in the opposite quadrant. B. Under direct gonioscopic visualization, angle tissue is excised between 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 success with these approaches, 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 herein. Ex.1013, 11; Ex.1003, ¶¶54-55.

The '905 patent recognizes goniectomy was a known technique for treating glaucoma. Ex.1001, 2:25-37. 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.

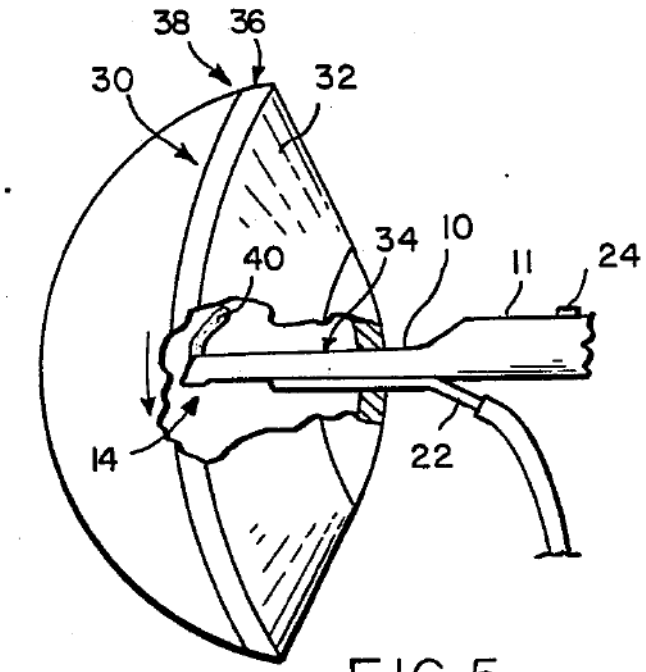


FIG.5

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.

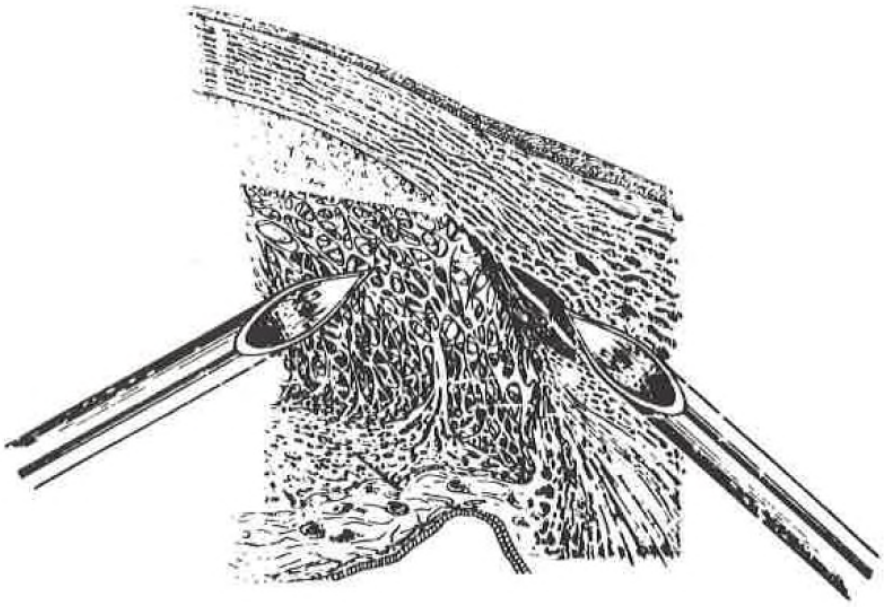


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

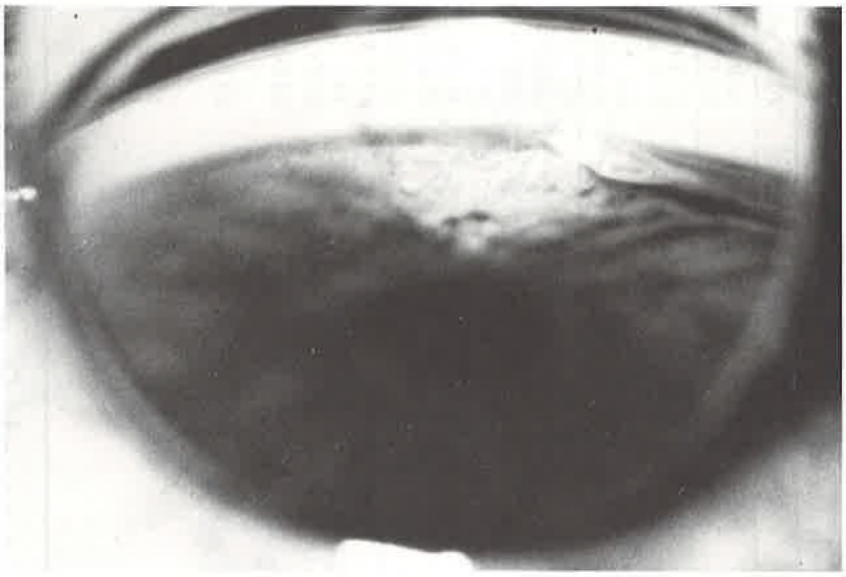


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

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 '905 Patent

A. Overview

The '905 patent discloses devices and methods for performing the well-known goniectomy procedure. *E.g.*, Ex.1001, Abstract, 5:11-28, 9:58-11:16. The patent expressly ***admits*** that goniectomy procedures and devices for ***removing strips of tissue from the eye were known***. *Id.*, 2:25-37; Ex.1003, ¶60. Neither its devices nor methods are valid over the prior art.

The patent claims a device that is effectively a needle with a bent tip. Ex.1003, ¶61. The patent discloses a device that includes a probe-like shaft with a distal end. Ex.1001, 6:63-7:6. The device also includes a "tissue cutting or

ablating apparatus" used to remove tissue from a surgical site. *Id.* According to the patent, the cutting or ablating apparatus may comprise "an electrosurgical tissue cutting/ablating apparatus," such as "a bipolar electrode." *Id.*, 8:41-48. While the majority of the patent focuses electrosurgical tissue cutting/ablating apparatuses, the patent indicates generally that alternate mechanisms or apparatuses operative to cut or ablate tissue may also be used, including among others "mechanical tissue cutting or ablation apparatus (e.g., knife blade(s), scissor(s), rotating cutter(s), etc.)." *Id.*, 8:60-9:8.

The device disclosed and claimed in the patent may include "a protector 24 having a first side located adjacent to the cutting or ablating apparatus, and a second side located on a distal-most portion of the device 10," which is "structured and designed to preventing [*sic*] damage to surfaces of Schlemm's canal" while the device is in use. *Id.*, 9:9-17. The protector "is structured to isolate or protect adjacent tissue located adjacent to the second side of the protector 24." *Id.*, 9:18-28. In one embodiment, the patent discloses a device with a "protector member" with a first side, a second side, a tip and an incline, as shown in FIGS. 5A and 5B. *Id.*, 13:26-34. The cutting or ablating apparatus in this device is an electrically conductive member 45. *Id.*, 13:35-46.

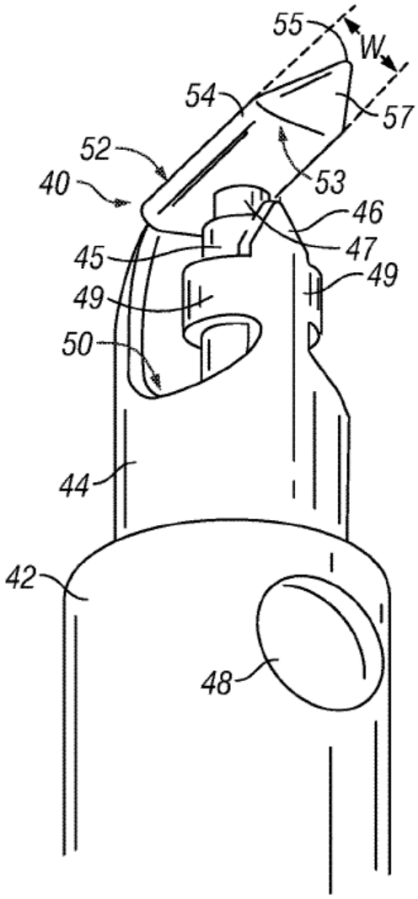


FIG. 5A

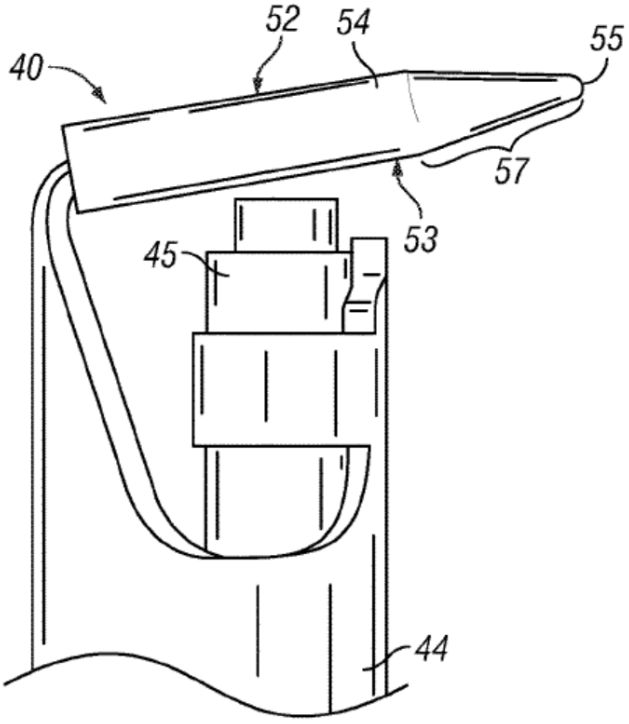


FIG. 5B

Id., Figs.5A-5B.

The patent indicates making the device involves nothing more than cutting and bending standard hypodermic tubing (*i.e.*, hypotubing), in the exact same fashion that a standard needle is created. *Id.*, 11:20-13:19; *see also id.*, Figs.3A-3G (below, showing "hypotubing" cut and bent to form device); Ex.1003, ¶¶65-66.

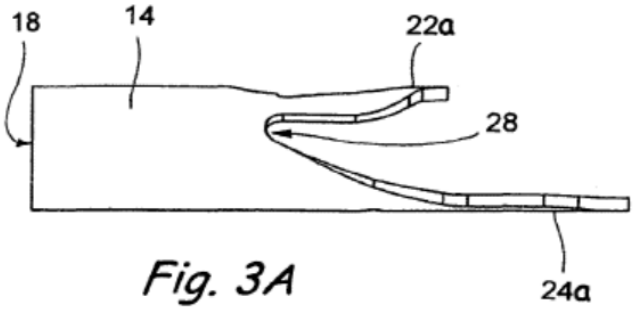


Fig. 3A

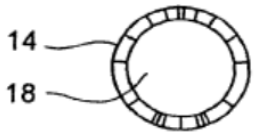


Fig. 3A'

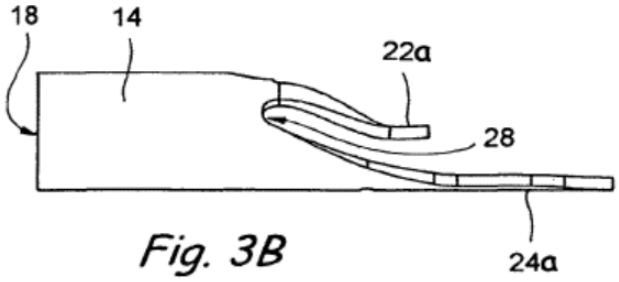


Fig. 3B

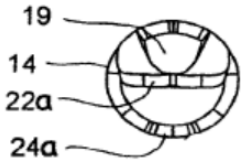


Fig. 3B'

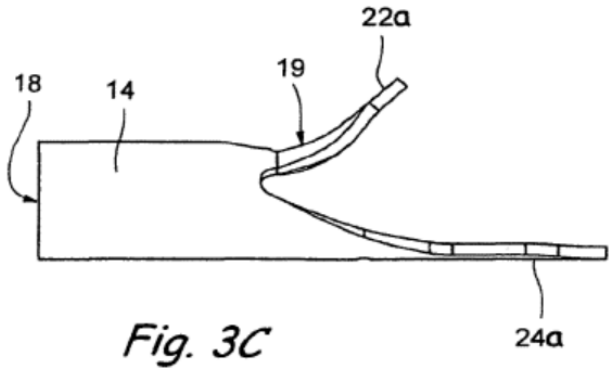


Fig. 3C

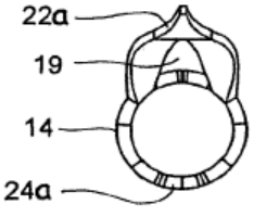


Fig. 3C'

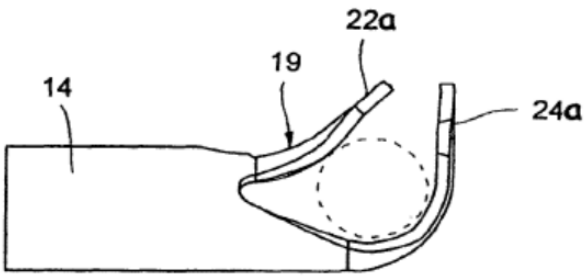


Fig. 3D

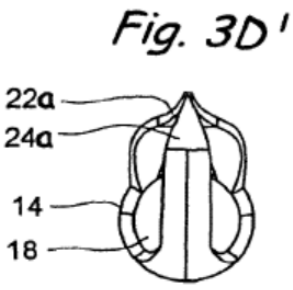


Fig. 3D'

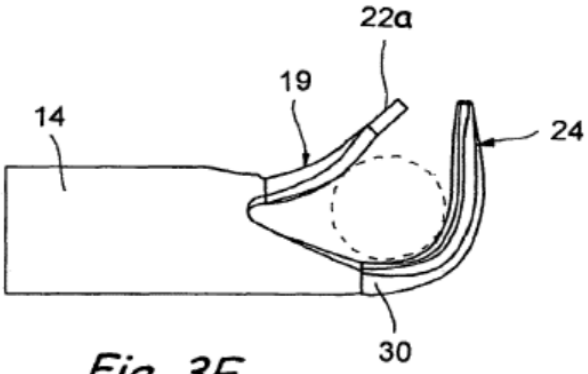


Fig. 3E

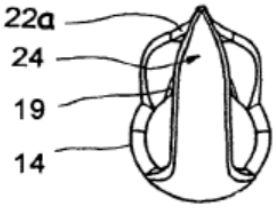


Fig. 3E'

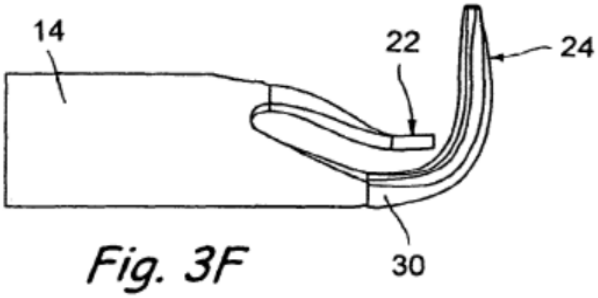


Fig. 3F

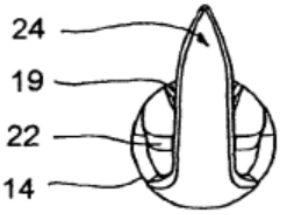
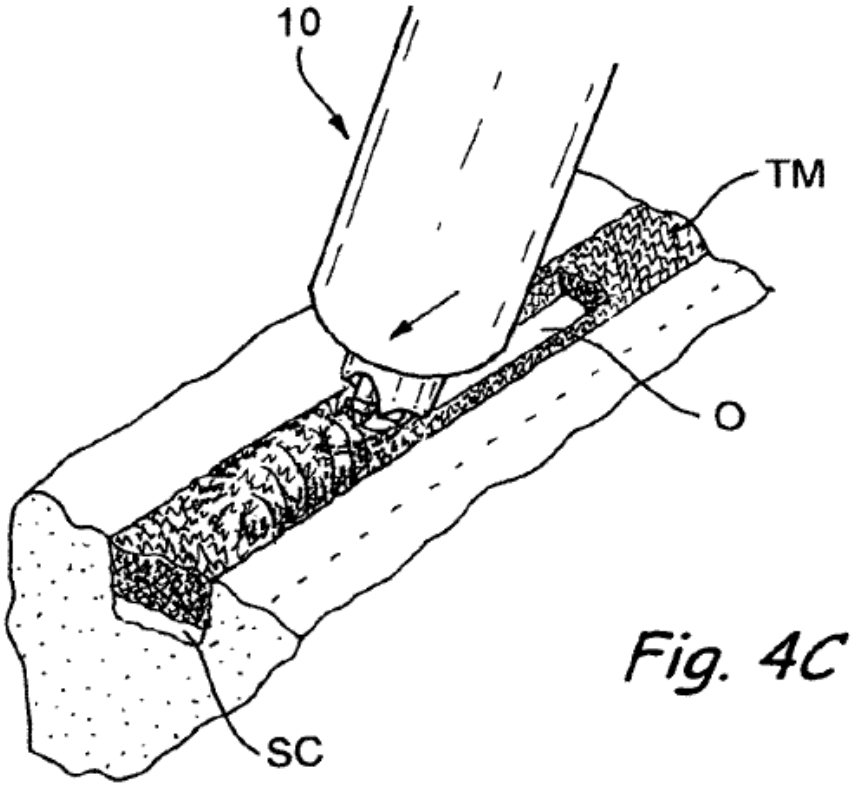


Fig. 3F'

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 and advancing the tip of the device through SC such that the tissue cutting or ablating

apparatus of the device cuts a strip of tissue from the TM. Ex.1001, 9:62-11:16, Fig.4C.



This procedure had been performed for decades before 2003 to remove strips of TM. Ex.1003, ¶¶67-68.

B. Prosecution History

The '905 patent issued from U.S. Application 14/923,302 ("the '302 application"), filed on October 26, 2015. The '302 application is a divisional of U.S. Application 10/560,266 ("the '266 application"), filed as PCT/US2004/018483 on June 10, 2004. The '905 patent also claims priority to U.S. Provisional Application 60/477,258 ("the '258 provisional"), filed June 10,

2003. Select portions of the prosecution history of the '905 patent and family members are discussed below.

1. '266 Application

The '266 application was filed with claims directed a device for cutting or ablating tissue that could include, among others, at least one knife blade. Ex.1022, 71-78, 138-41. The Examiner rejected the claims as anticipated and/or obvious by Baerveldt (Ex.1015) because "[i]t would have been obvious to the artisan [of] ordinary skill to use polyimide for the insulator, to configure the cutter as two knife blades or two scissors, since these are recognized as equivalents in the [area] of eye surgery, thus producing a device as claimed." *Id.*, 138-39. Below is a figure of a device disclosed in Baerveldt referred to as a "goniectomy cutting probe."

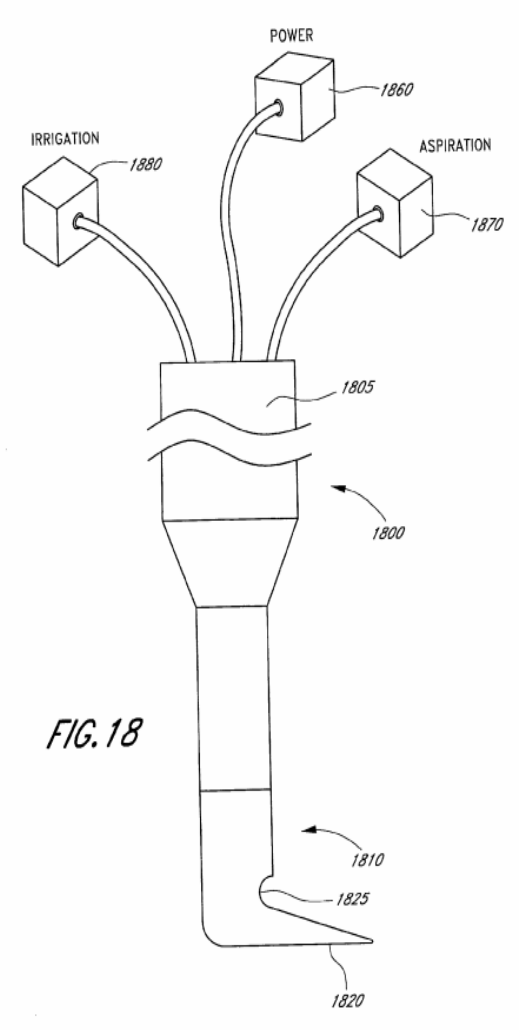


FIG. 18

Ex.1015, Fig.18.

Based on this rejection, the applicant cancelled claims relating to mechanical tissue cutting apparatuses (including claims requiring knife blades), and amended the remaining claims to require "an energy emitting member . . . operative to emit tissue or ablating energy" and a "protector being at least partially formed of an insulating material to deter thermal damage . . . when the energy emitting member is emitting tissue cutting or ablation energy." Ex.1002, 147-57. The '266 application subsequently went abandoned.

2. ‘302 Application

During prosecution of the ‘302 application (which issued as the ‘905 patent), claims directed to a device that is insertable into the anterior chamber of the eye and useable to form an opening in the trabecular meshwork were filed by the applicant. Ex.1002, 88-90. The Examiner rejected the claims as obvious over Baerveldt. *Id.*, 423. According to the Examiner, Baerveldt teaches a “device for cutting trabecular meshwork with cutter than can be optical fiber conducting ultraviolet laser energy [0135]; mechanical [0127]; bipolar or monopolar electrode [0100], [0101], or ultrasound [0096] . . . [and] has a protector member with an inclined face which is insertable into and advancable [*sic*] through Schlemm’s canal (see e.g., Fig. 18 and [0125].” *Id.* The Examiner stated, “***it would have been obvious to one having ordinary skill in the art to employ a knife blade*** or scissor in place of the rotary cutter of Baerveldt et al. since these are equivalents in the art . . . and to employ at least a first and second scissor or knife blade, since this is ***merely a duplication of parts for multiplied effect***.” *Id.* (emphasis added). Further, the Examiner found “it would have been ***obvious*** to one having ordinary skill in the art to ***configure the tip with a width which tapers to its narrowest point at the tip*** - this would facilitate insertion and promote the guiding function, and to form a device to ***excise a strip of tissue between 50 and 200 microns wide***, since

this is ***well within the scope of one having ordinary skill in the art***, [and] merely provides a ***predictable result***." *Id*. (emphasis added).

The applicant subsequently amended the claims to, among other things, specify "a plurality of knife blades positioned to cut tissue" in place of the "tissue cutting or ablating apparatus." *Id.*, 437-39. The applicant argued that none of the references, including Baerveldt:

> describe or suggest any device having a plurality of knife blades, much less one wherein the knife blades are positioned on a device having the claimed protector member. ***The term 'knife blades' is to be interpreted as meaning blades in fixed positions on a device used for manual cutting of tissue.*** This is in accordance with the well understood and typical usage of that term in the field of ophthalmic surgery instruments.

Id., 440 (emphasis added).

An interview was conducted and the summary indicates that the Examiner and applicant discussed the scope of the Baerveldt reference. *Id*., 459. According to the summary, "[t]he examiner and applicant reviewed the portions of the Bearveldt [*sic*] reference that pertained to only using mechanical cutting devices (the embodiments of Figures 18-23) both of which required the use of moving devices (i.e. rotating cutters or guillotine-type cutters). Then applicant noted that the devices using energy to (e.g. RF. laser) to destroy the tissue. and those using rotating or otherwise moving mechanical elements would produce turbulence and bubbles in the aqueous which would obscure the view of the surgeon which would

not occur with stationary knife blades." *Id.* The application was then allowed. *Id.*, 457-58.

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 '905 patent claims priority to the '258 provisional filed June 10, 2003. Because the prior art relied upon in this Petition published well before 2003, for this Petition alone NWM will assume a June 10, 2003 effective filing date for the '905 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). Except as noted below, Petitioner submits no terms require construction.[3]

A. "knife blades"

The claims require a device with, among other things, "a plurality of knife blades positioned to cut tissue that passes over the first side of the protector member." Ex.1001, cl.1. The term "knife blades" according to the '905 patent means blades in fixed positions on a device used for manual cutting of tissue. Ex.1003, ¶76.

As discussed above, the patent discloses a device with a tissue cutting/ablating apparatus, which can be, among other things, a "mechanical tissue cutting or ablation apparatus (e.g., knife blade(s), scissor(s), rotating cutter(s), etc.)" among many other alternatives. Ex.1001, 8:60-9:8; *see supra*, §IV.A. The patent does not provide additional detail regarding a device that uses mechanical tissue cutting or ablation apparatuses, such as knife blades. Ex.1003, ¶¶77-78. None of the embodiments in the patent have "knife blades." *Id.*

During prosecution, however, the applicant explicitly defined the term "knife blades." Ex.1002, 437-41. The applicant stated, "the term 'knife blades' is

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

to be interpreted as meaning blades in fixed positions on a device used for manual cutting of tissue." *Id.*, 440. Notably, the applicant also pointed to known examples of "knife blades" in the art, admitting the claimed "knife blades" were known. *Id.*, 440-41; Ex.1003, ¶79.

Accordingly, based on the intrinsic record, "knife blades" are blades in fixed positions on a device used for manual cutting of tissue. Ex.1003, ¶80.

VI. Detailed Explanation of Unpatentability

A. Ground 1: Quintana (Ex.1004) Anticipates Claims 1, 3, and 6-7

1. Overview of Quintana

Quintana[4] describes an "ab interno" method for treating glaucoma. 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.* Quintana's technique "***achieves a section*** of the TM without damage to the external wall of SC." *Id.* (emphasis added); Ex.1003, ¶81.

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

[4] Quintana was not cited during prosecution of the '905 patent.

needle to penetrate the AC. *Id*., 4. 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*. 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. *Id.* 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, ¶82.

Quintana specifically indicates that the needle penetrates the AC "through the scleral side of the limbus . . . in order to run parallel to SC." Ex.1004, 4. Quintana did this to cause 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, ¶83. Penetrating the AC at or near the limbus would still have allowed the needle to run parallel to SC upon entry for the same reason. *Id.*

Quintana states the 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, ¶84. 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).

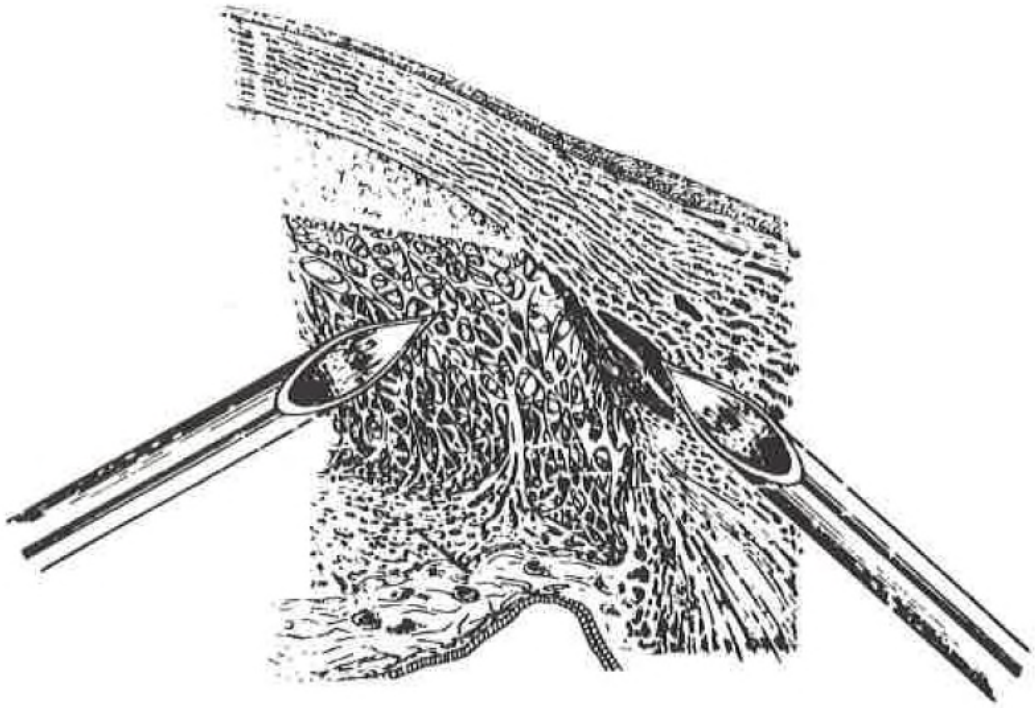
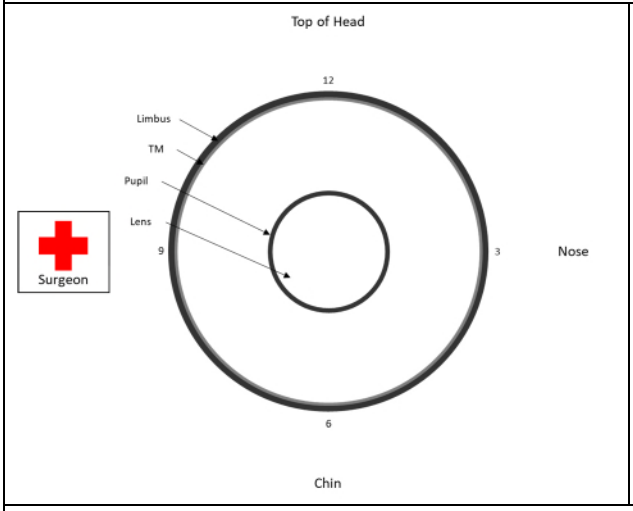
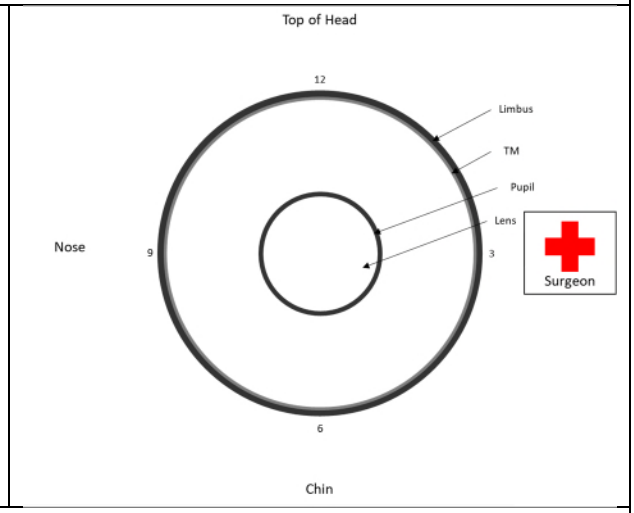
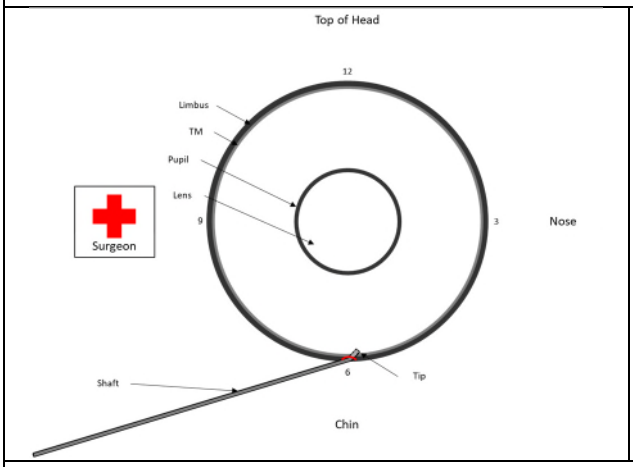
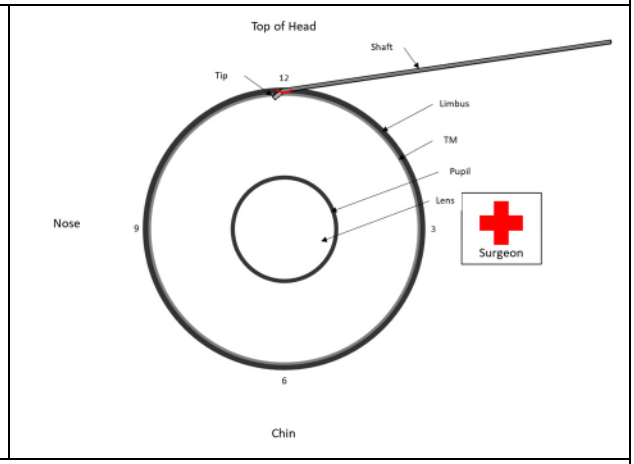
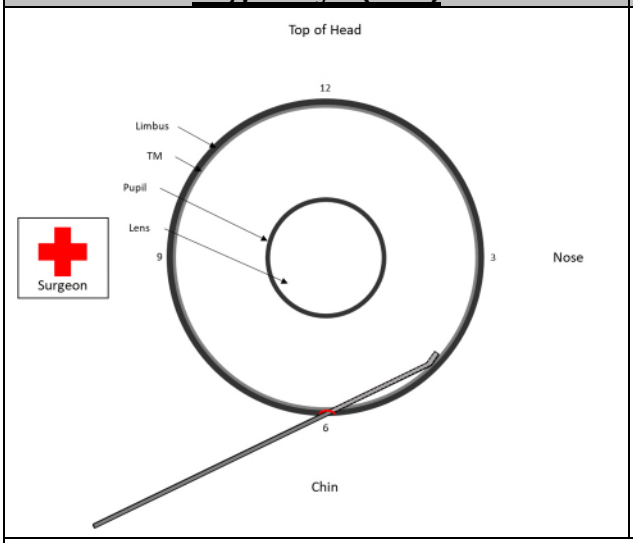
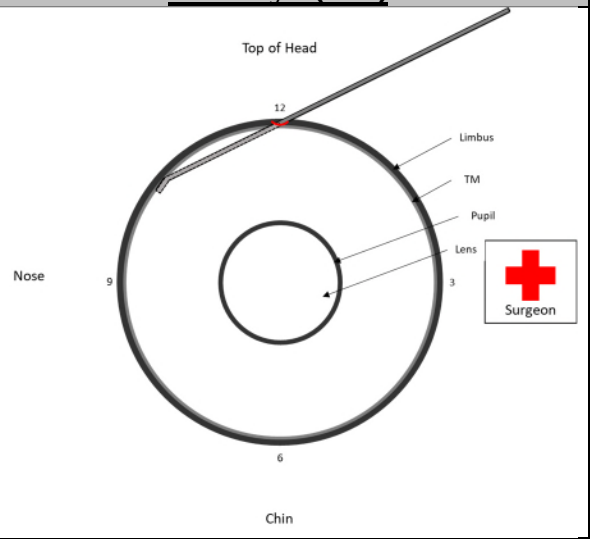


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

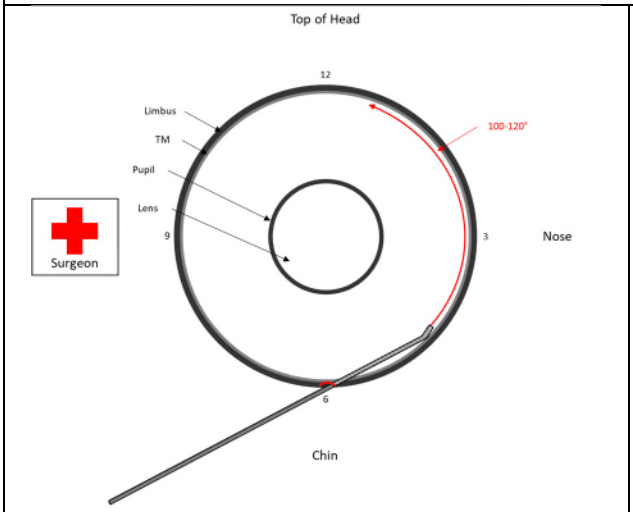
Ex.1004, 4.

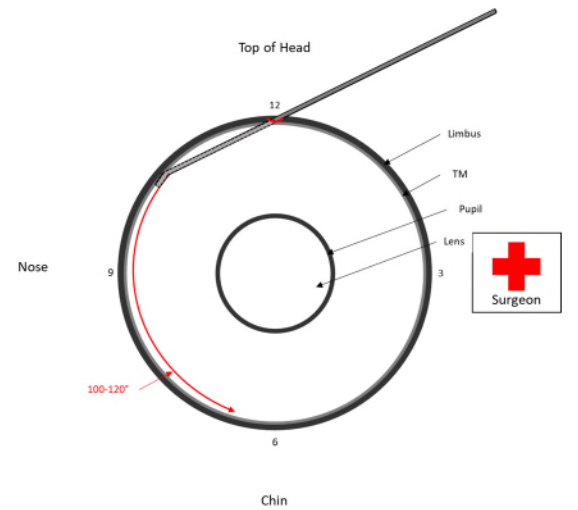
At the direction of NWM's expert, Dr. Peter Netland, illustrations depicting Quintana's procedure were prepared. Ex.1003, ¶85. The illustrations show a patient's right and left eye with the general location and progression of Quintana's needle throughout the procedure. *Id.*

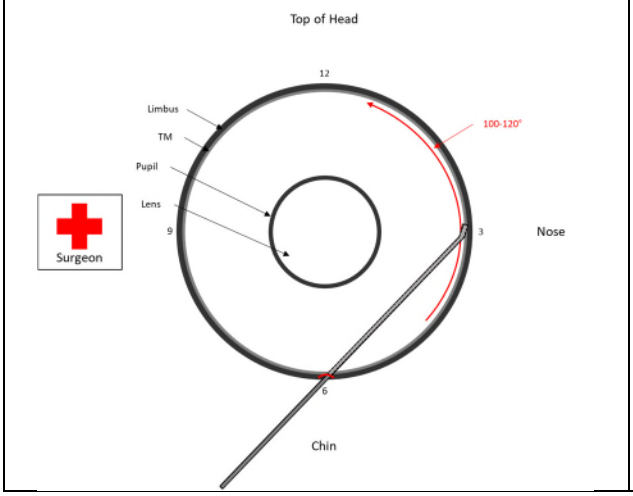
Right Eye (OD)	Left Eye (OS)
Surgeon positioned on temporal side of patient. Ex.1004, 3-4.	
	
"The needle penetrates the anterior chamber at 6 hours (right eye) or 12 hours (left eye) through the scleral side of the limbus." Id., 4.	
	
Needle tip introduced into SC with convexity of tip facing external 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.	

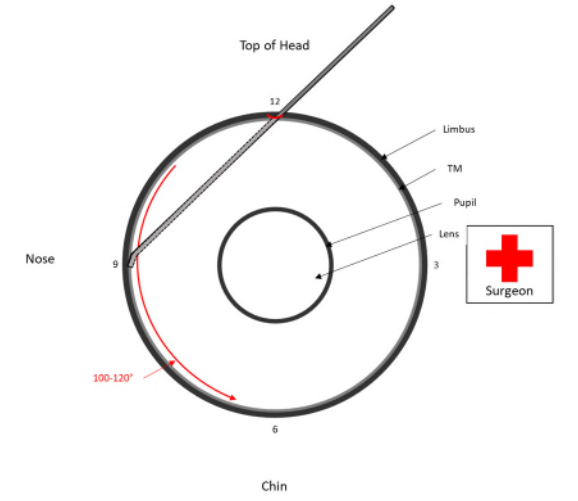
Right Eye (OD)	Left Eye (OS)
	

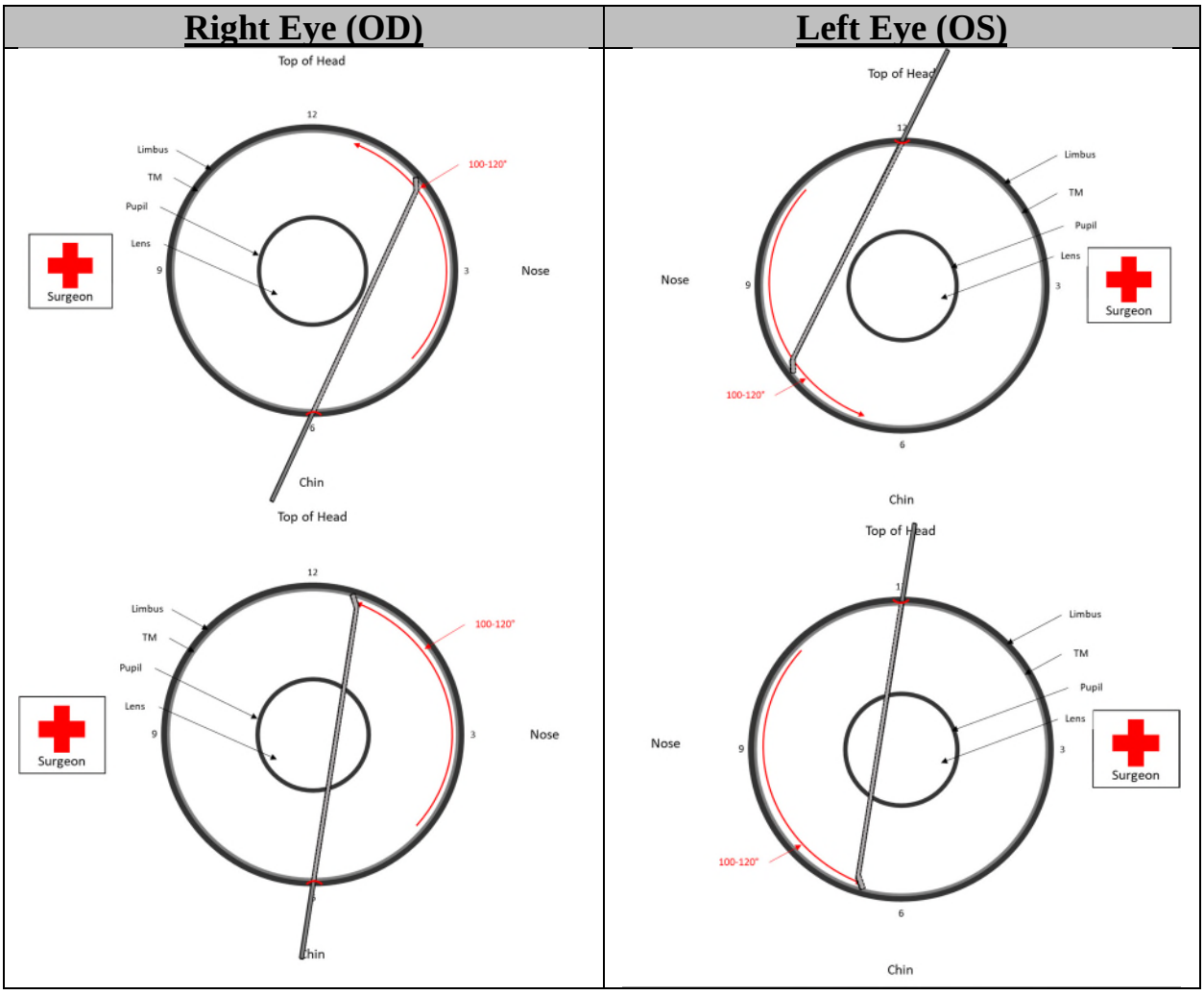
"A 100-120° trabeculotomy can be achieved." Id.











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

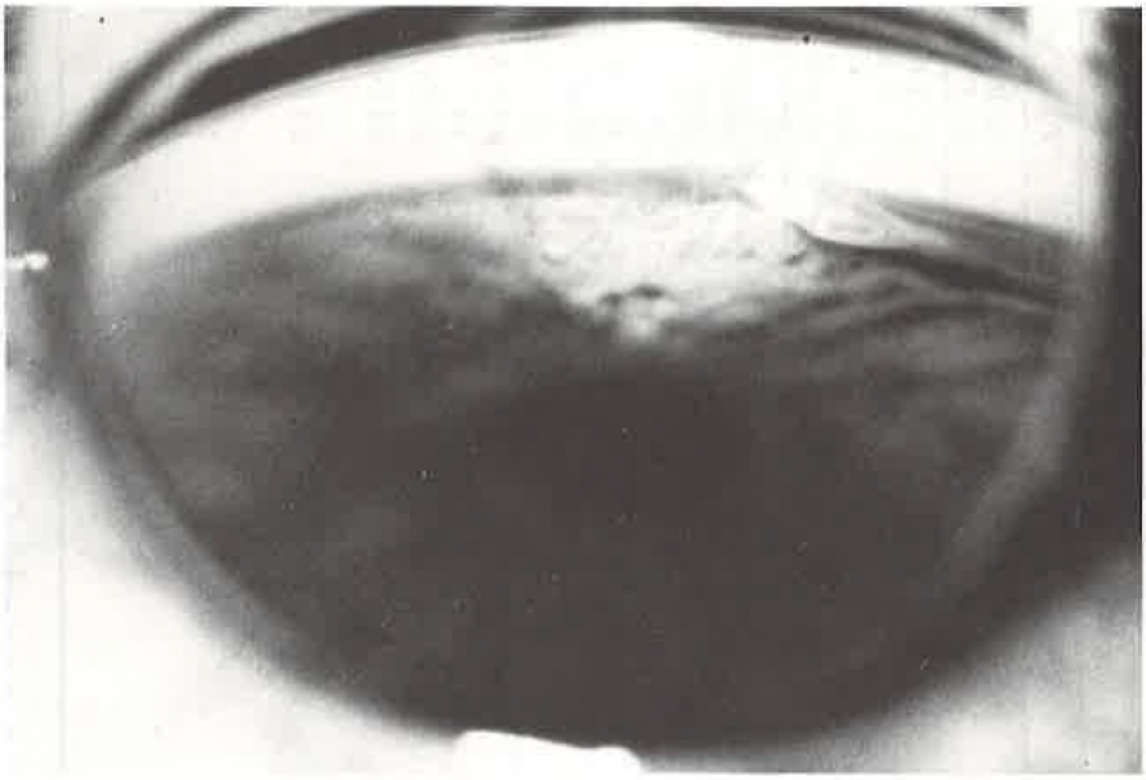
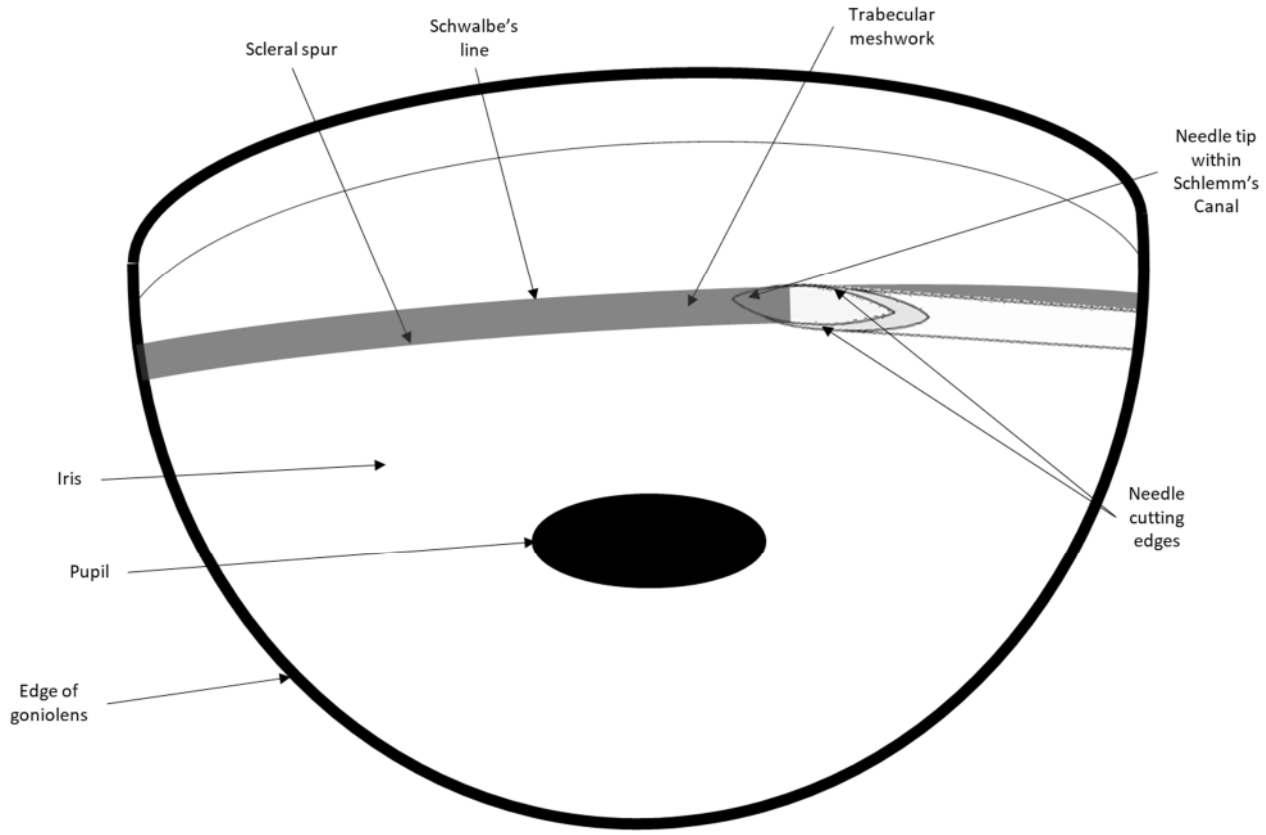


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

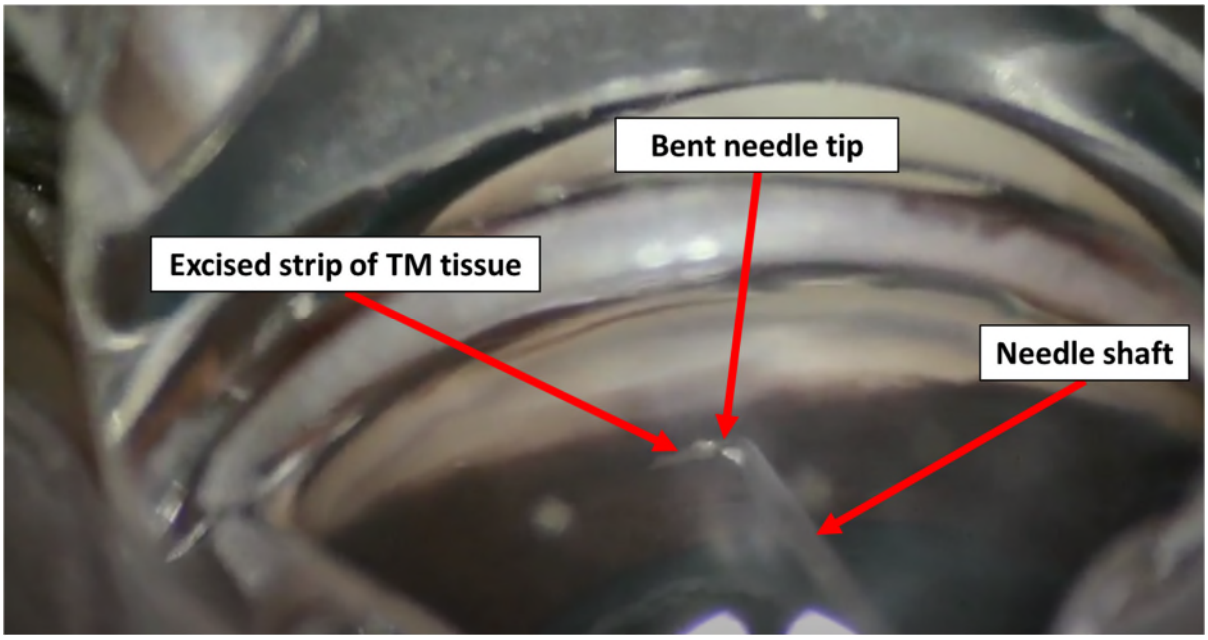
Id., Fig.2. To more clearly visualize Fig.2, the following schematic was prepared at Dr. Netland's direction. Ex.1003, ¶86.



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, ¶¶88-90. Not only is this demonstrated explicitly in Quintana, but 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, ¶88. 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, ¶¶89-90. 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, ¶¶89-90.



Id. 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. Element 1.p

Quintana's procedure uses a needle inserted into the AC within the eye and "***achieves a section of the trabecular meshwork***." Ex.1004, 3-4 (emphasis added). As Quintana explicitly indicates, the "needle ***penetrates the anterior chamber***," "is progressively introduced in the angle," "the tip of the instrument is introduced into ***Schlemm's canal***," and "the ***TM*** is stripped slowly, gently and easily from the canal's lumen towards the anterior chamber as the needle progresses in the angle." *Id.* (emphasis added). Figs. 1 and 2 depict cutting a strip of TM tissue from within the AC of a patient's eye and Fig. 2's caption indicates the figure shows the "tip of the needle stripping the [TM]." *Id.*, 4-5; Ex.1003, ¶100.

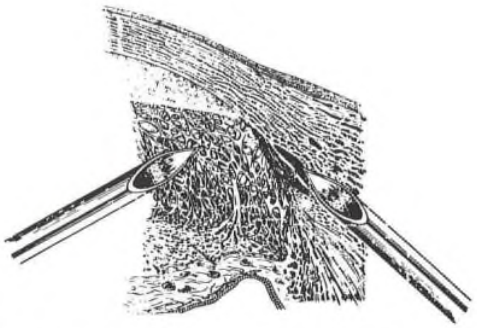


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

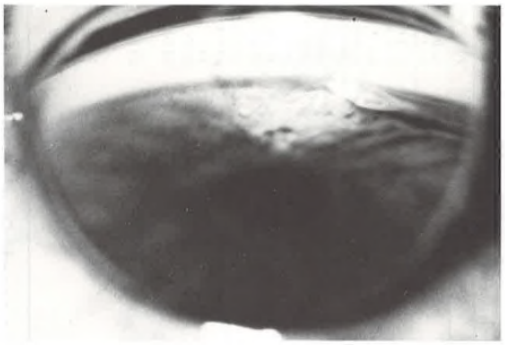
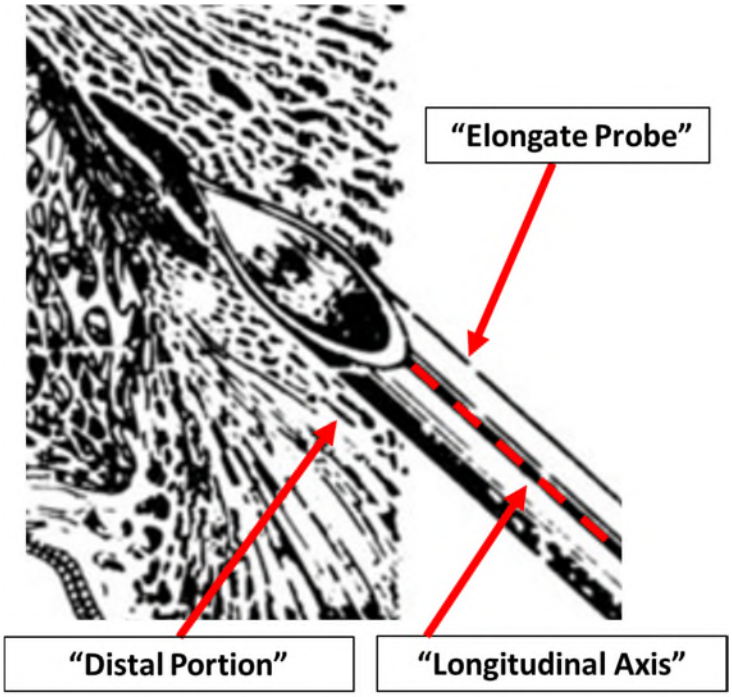


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

Ex.1004, Figs. 1-2. A POSITA would understand that "stripping" the trabecular meshwork to "achieve[] a section of the trabecular meshwork" removes a strip from the TM and forms an "opening" in the TM of the eye. Ex.1003, ¶101.

b. Element 1.a

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, ¶102. As shown below, the needle includes a shaft, *i.e.*, the needle tubing, which extends along a longitudinal axis and has a distal portion.



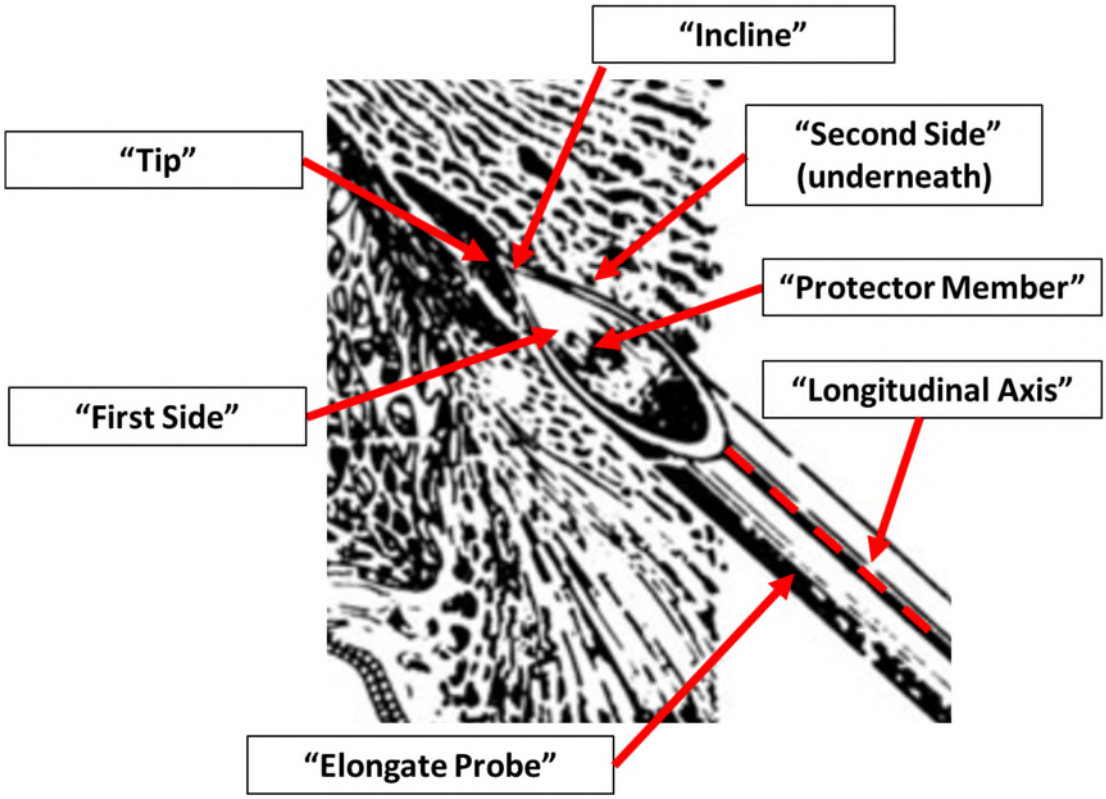
Ex.1004, Fig.1 (annotated); Ex.1003, ¶102. Quintana indicates that the needle penetrates the AC and the needle tip is introduced into SC. Ex.1004, 4. Thus, a POSITA would appreciate that the distal portion of the needle is insertable into the AC of the eye. Ex.1003, ¶103.

c. Element 1.b

The patent discloses devices with "protector 24," which the patent indicates is "structured to isolate or protect adjacent tissue located adjacent the second side of the protector 24." Ex.1001, 9:18-23; *see also id.*, 2:66-3:8. In another embodiment, the patent discloses "protector member 24," which "may operate in substantially the same fashion." *Id.*, 13:21-35. Figs.5A-5B depict a device with "protector member 24" at the end of the device's shaft, which has a first side 53, second side 52, tip 55, and incline 57. *Id.* The claims also require that the "protector member" have these components (*i.e.*, a first side, a second side, and a tip). The "protector member" is thus a portion at the distal end of the device having a first side, a second side, a tip, and an incline that protects tissue located near the second side of the protector member. Ex.1003, ¶104.

As discussed, the tip of Quintana's needle is bent 20-30°. Ex.1004, 3. Moreover, Quintana explicitly states that the tip of the needle penetrates the TM and strips TM tissue from SC. *Id.*, 4. Importantly, Quintana also explains that the needle is oriented such that the convexity of the tip faces the external wall of SC during the procedure to avoid damaging the external wall of SC. *Id.* A POSITA would appreciate that by bending the needle tip and orienting it such that the convex, outer portion of the tip faces the wall of SC, tissue near the convex side of the tip is protected. Ex.1003, ¶105. Accordingly, Quintana's needle has a

"protector member," *i.e.*, the portion at the bottom of the end of the needle that extends laterally from the probe, and the protector member has a first side, a second side, and a tip as shown below.



Ex.1004, Fig.1 (annotated); Ex.1003, ¶105. Moreover, given Quintana's disclosure that the tip of the needle is bent 20-30°, the protector member is necessarily oriented in a lateral direction relative to the longitudinal axis of the probe. Ex.1003, ¶106.

In addition, a POSITA would understand that Quintana's needle has a beveled distal end that slopes upwardly from the very tip to the portion where the bevel meets the needle shaft. Ex.1003, ¶¶107-08. Fig.1 below shows the beveled

portion of the needle, *i.e.*, an incline that slopes upwardly from the tip. *Id.*; Ex.1004, Fig.1.

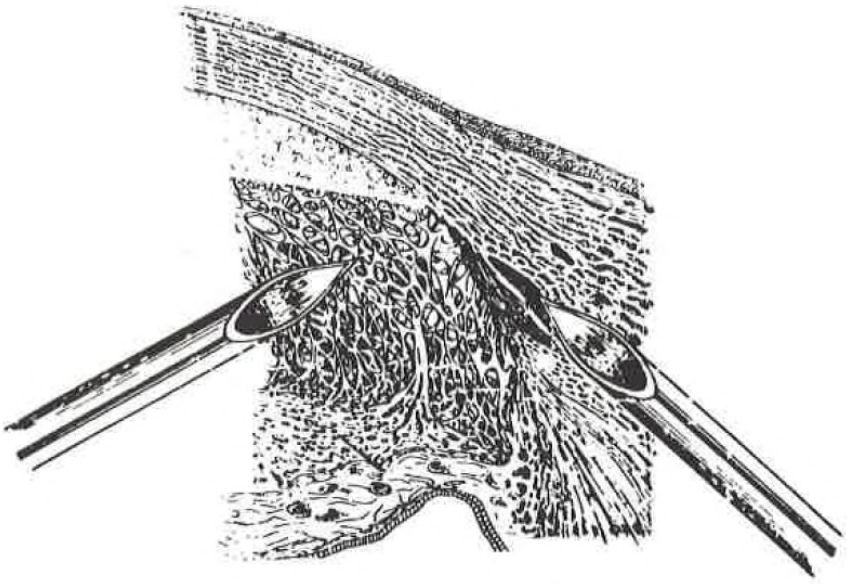
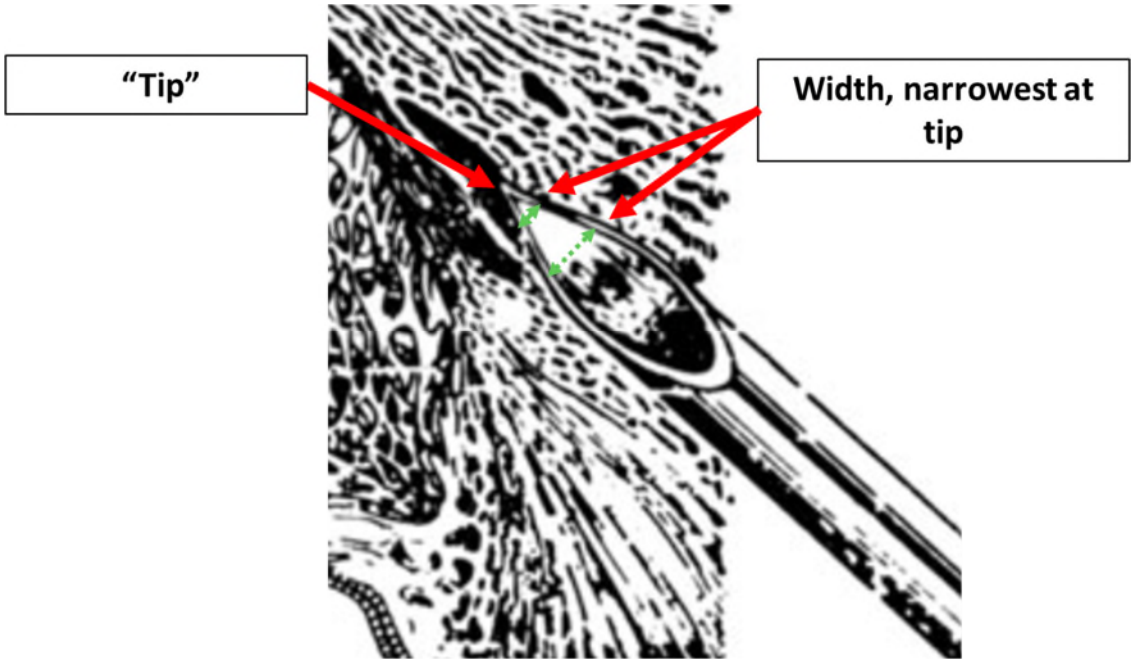


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

Id., Fig.1.

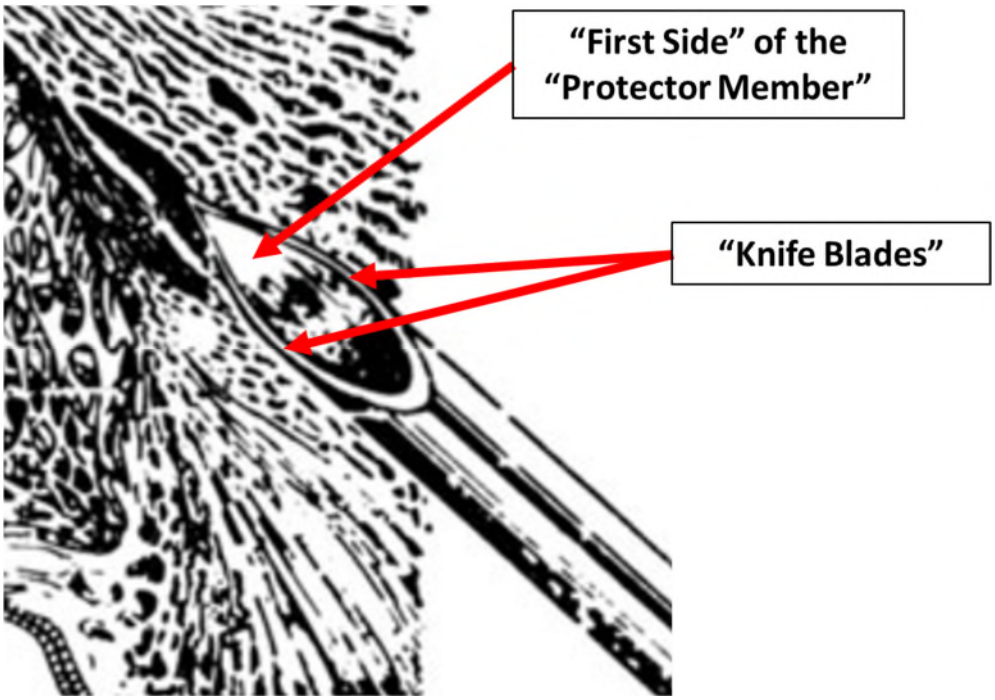
Finally, the distal end of Quintana's needle has a width which tapers to its narrowest point at the tip, as claimed. As shown in Fig.1 below, the distal end of Quintana's needle has a width that narrows to its narrowest point at the tip (*e.g.*, to facilitate penetration of the needle into tissue). Ex.1004, Fig.1; *see also id.*, 4 (describing needle penetrating into AC and piercing TM); Ex.1003, ¶109.



Id., Fig.1 (annotated).

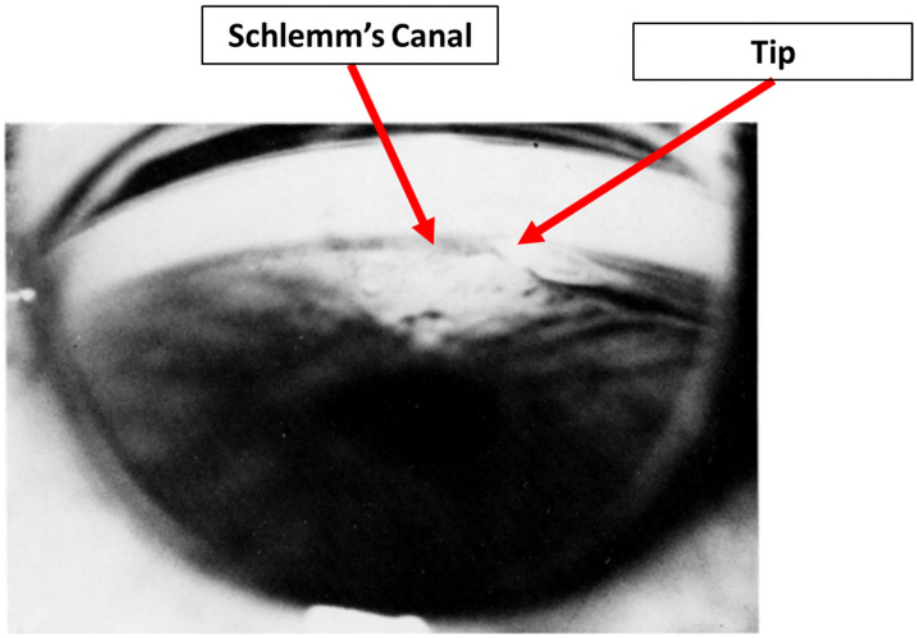
d. Element 1.c

As explained above, "knife blades" according to the '905 patent are blades in fixed positions on a device used for manual cutting of tissue. *See supra*, §V.A. Quintana's needle has "knife blades," *i.e.*, cutting edges at fixed locations on opposite sides of the distal end of the needle tube. Ex.1004, 3, Figs.1-2. As Quintana's needle is advanced through the TM (which is performed manually by the surgeon), the cutting edges of the needle concurrently cut the TM, resulting in strips of TM tissue excised from the TM. Ex.1004, 4; Ex.1003, ¶¶111-12. As shown below, Quintana has two "knife blades" positioned on opposite sides of the needle tube:



Ex.1004, Fig.1 (annotated).

The knife blades cut tissue which passes over the first side of the "protector member." According to Quintana, "the tip of the instrument" "is introduced into Schlemm's canal, and the TM is stripped slowly, gently and easily from the canal's lumen towards the anterior chamber as the needle progresses in the angle." *Id.*, 4. As shown below, the cutting edges of the needle contact and strip TM tissue from the TM and SC:



Id., Fig.2 (annotated). A POSITA would recognize that as the tip of Quintana's needle (including the protector member) advances through SC, TM tissue necessarily passes over the top surface of the needle tip (the first side of the protector member) in order to contact the needle's cutting edges and achieve strips of TM tissue. Ex.1003, ¶113.

e. Elements 1.d

After penetrating the eye into the AC, the tip of Quintana's needle (including the protector member) is "progressively introduced" in the AC angle, the "tip of the instrument is introduced into SC," and the "TM is stripped . . . from the canal's lumen" as the needle "progresses in the angle." Ex.1004, 4; Ex.1003, ¶114. As

shown below, the bent portion of Quintana's needle (including the protector member) pierces the TM and is inserted into SC.

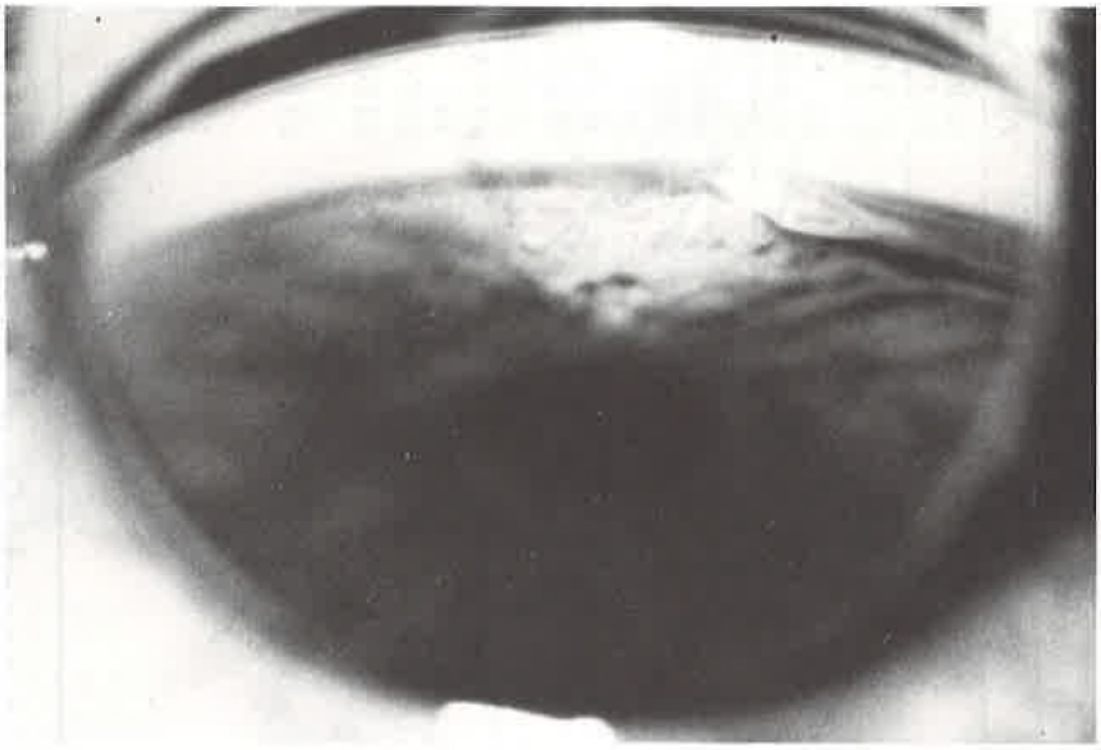


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

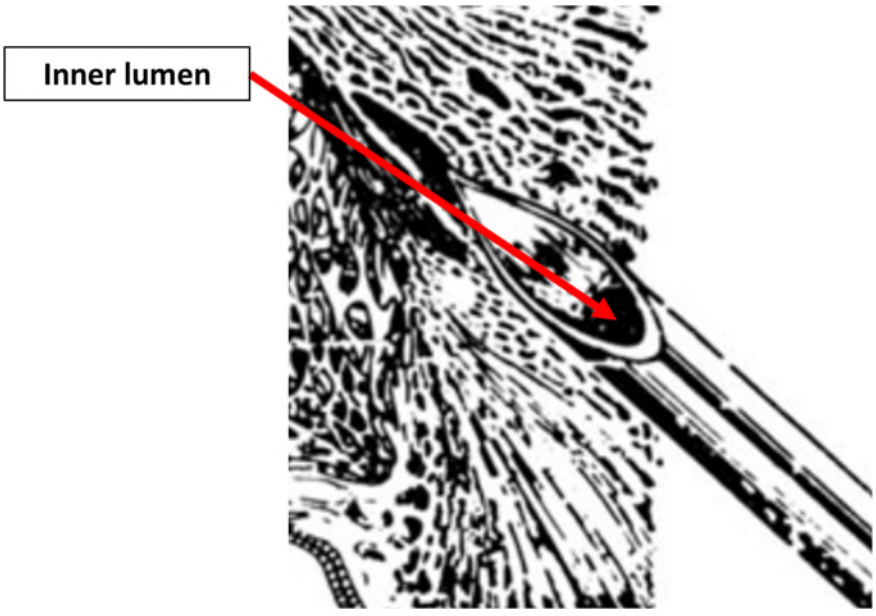
Id., Fig.2. Clearly, lateral advancement of the needle tip (including the protector member) through SC occurs through movement of the needle device by the surgeon. *Id.*, 3-4.

As shown above, the "protector member" (including the incline and the first side of the protector member) contacts the TM. *Id.*; Ex.1003, ¶116. As explained above, the TM tissue must necessarily pass over the top of the needle tip (which includes the incline and first side of the protector member) before coming into

contact with and being cut by the cutting edges (*i.e.*, knife blades) of Quintana's needle. *See supra*, §VI.A.d. Quintana explicitly states that this procedure results in a strip of TM tissue being excised from the TM. Ex.1004, 3 ("achieves a section of the [TM]"), 4 ("the TM is stripped slowly, gently and easily from the canal's lumen"), Fig.2 caption ("tip of the needle stripping the [TM]"); Ex.1003, ¶¶115-16; *see also id.*, ¶¶88-90. .

3. Claim 3

Quintana discloses the limitations of claim 1. *See supra*, §VI.A.2. 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, ¶118. 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, ¶118.

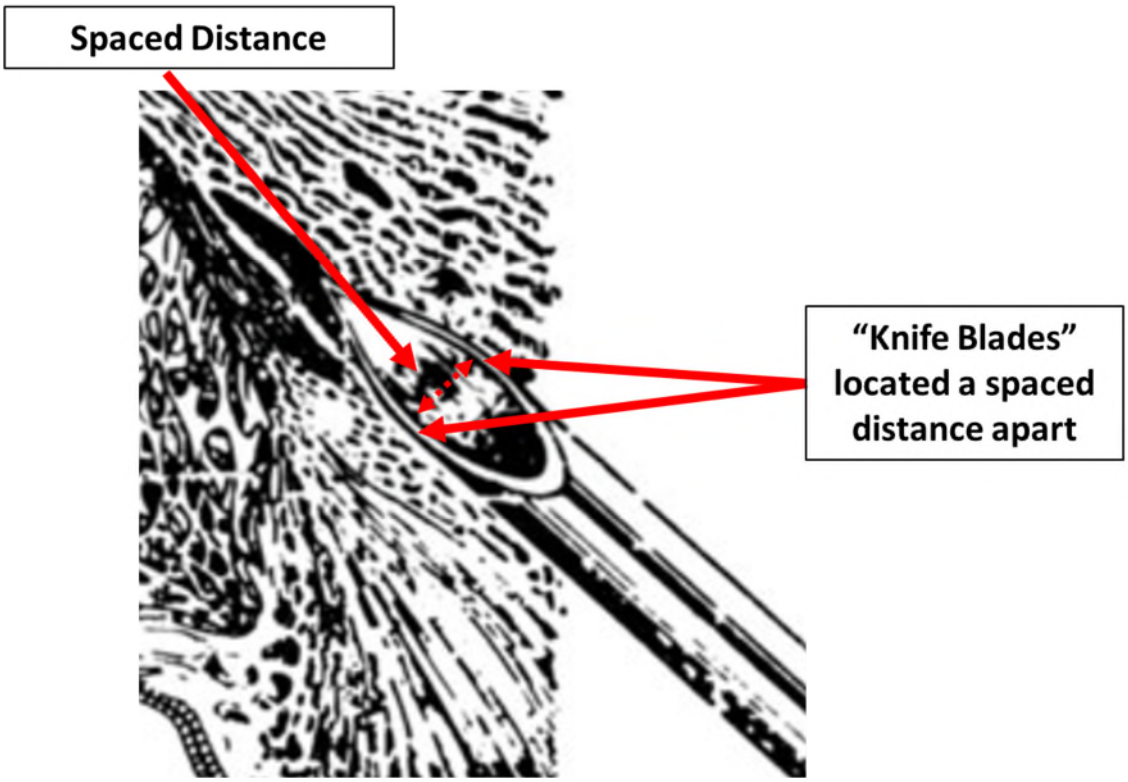
Quintana also explicitly indicates that the needle is "inserted into a syringe filled with 'healon'" and describes injecting healon during the procedure. Ex.1004, 3-4; Ex.1003, ¶118. Thus, the inner lumen of the needle acts as an irrigation lumen through which fluid is injected, as claimed. Ex.1003, ¶118.

4. Claim 6

Quintana discloses the limitations of claim 1. *See supra*, §VI.A.2. Quintana's "trabecultome is a 0.4 x 15 mm needle" which is bent 20-30° to form an angled portion. Ex.1004, 3. To strip the TM, the tip of the trabecultome is inserted into SC oriented such that "the ***convexity of the tip is facing the external wall of the canal***" so that "***this structure is not damaged***." *Id.*, 4. As explained above, the convex, outer portion of the needle tip includes the second side of the protector member. *See supra*, §VI.A.2.c. This portion is therefore configured to prevent damage to adjacent tissue, *i.e.*, the external wall of SC. Ex.1003, ¶120.

5. Claim 7

Quintana discloses the limitations of claim 1. *See supra*, §VI.A.2. Further, Quintana's trabecultome has "knife blades" on opposite sides of the needle which concurrently cut TM to produce strips. *See supra*, §VI.A.2.d. As shown below, the cutting edges are spaced apart such that an area exists between the cutting edges (labeled "spaced distance" below):



Ex.1004, Fig.1 (annotated); Ex.1003, ¶122. The strip of tissue created when the cutting edges cut TM tissue would necessarily have a width that is "substantially equal" to the distance between the cutting edges, as these cutting edges concurrently cut the TM tissue to achieve a strip of tissue that would have a width corresponding to the distance between the cutting edges. Ex.1003, ¶123.

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

1. Claim 2

Quintana discloses the limitations of claim 1. *See* §VI.A.2. Further, the '905 patent admits that cutting a strip of TM with a width from 50 to 200μm was known in the art. Ex.1001, 2:25-30. During prosecution of the '905 patent, the

Examiner also found this was "well within the scope of one having ordinary skill in the art." *See supra*, §IV.B.2; Ex.1002, 423. Thus, claim 2 does not cover a novel or nonobvious feature of the alleged invention.

Further, Quintana's "trabeculotome is a 0.4 x 15 mm needle, or an insulin type needle" having a diameter of 0.4mm and a length of 15mm. Ex.1004, 3; Ex.1003, ¶126. As the "knife blades" concurrently cut the TM such that the "TM is stripped," the resulting strip of tissue would have a width substantially equal to the distance between the "knife blades," *i.e.*, approximately the diameter of the needle (0.4mm or 400μm). *See supra*, §VI.A.5; Ex.1003, ¶126. While the width of this strip is slightly larger than the claimed range, a POSITA would have found it obvious to modify Quintana's needle to produce strips between 50 and 200μm. Ex.1003, ¶¶127-29. A POSITA would have appreciated that smaller surgical devices could be used to perform Quintana's procedure based on the particular procedure or specific patient. *Id*., ¶127. Moreover, use of a needle with a smaller diameter would involve simple substitution of one known element for another to obtain predictable results. *Id.* Accordingly, a POSITA would have found it obvious to modify Quintana's procedure to produce a strip of TM having a width from 50 to 200μm. *Id*., ¶¶127-29. Moreover, an invention is obvious when, as here, the only difference between the prior art and the claimed invention are changes in size or shape, where the changes to the size or shape do not result in

patentable significance or a different product. *Gardner v. TEC, Syst., Inc.*, 725 F.2d 1338, 1349 (Fed. Cir. 1984); *In re Dillon*, 919 F.2d 688, 697-98 (Fed. Cir. 1990).

2. Claim 4

Quintana discloses the limitations of claim 1. *See supra*, §VI.A.2. As discussed, Quintana discloses a device with a lumen used for infusion. *See supra*, §VI.A.3. 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 Quintana's needle by incorporating an aspiration lumen for aspirating fluid and debris. Ex.1003, ¶131. 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.* Modifying Quintana's needle in this way 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.*

3. Claim 5

Quintana discloses the limitations of claim 1. *See supra*, §VI.A.2. Quintana's needle has an irrigation lumen. *See supra*, §VI.A.3. As explained for claim 4, a POSITA would have been motivated to include an aspiration lumen in Quintana's needle as well. *See supra*, §VI.B.2. Incorporating an aspiration lumen in a device with an irrigation lumen 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. Ex.1003, ¶¶133-34.

C. Ground 3: Jacobi (Ex.1007) in View of the Knowledge of a POSITA Renders Obvious Claims 1-7

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, ¶¶94-95. 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, ¶96.

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, ¶97. 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. Element 1.p

Jacobi's procedure involves inserting the gonioscraper into the AC to "***scrape pathologically altered trabecular meshwork***" and "***abrade rather than incise***" the TM, in order to "peel" off "strings of trabecular tissue." Ex.1007, 2. This means Jacobi excises tissue to create an opening in the TM, rather than simply

cutting a slit in the TM. Ex.1003, ¶136. Jacobi reports that "gonioscopically, ***strings of trabecular tissue could be observed intraoperatively to be removed by goniocurettage***." Ex.1007, 2. Peeling "strings of TM" tissue is forming an opening in the TM tissue as claimed. Ex.1003, ¶136. Jacobi explains that to perform the procedure, 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, ¶¶136-37.

b. Element 1.a

Jacobi's gonioscraper "consists of a small ***handle*** and ***a slightly convex-shaped arm for intraocular use***." Ex.1007, 2 (emphasis added). As shown below, the convex-shaped arm of the device is "an elongate probe" that extends along a longitudinal axis and has a distal portion. Ex.1003, ¶138.

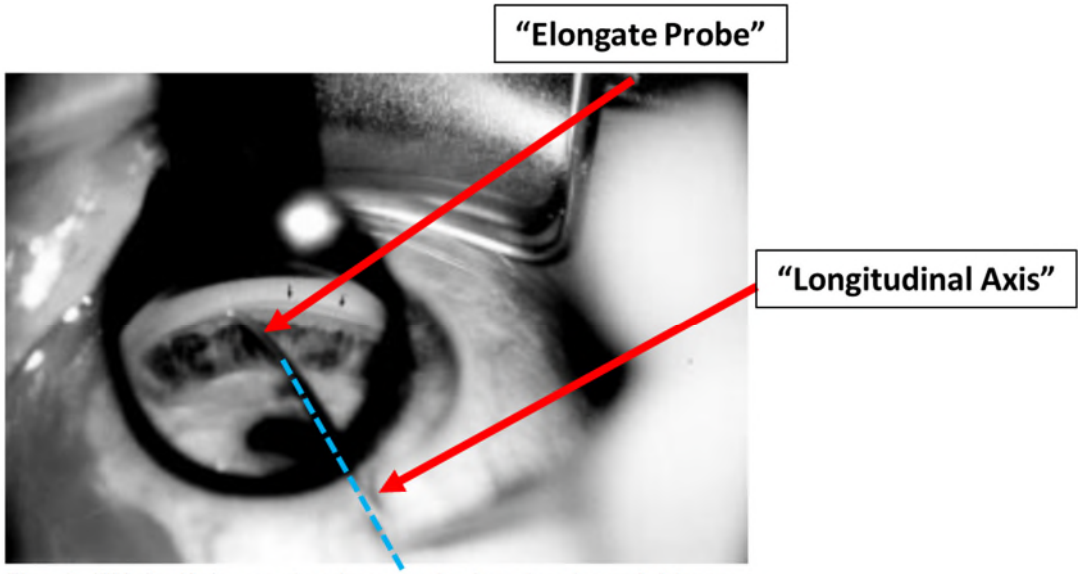


Figure 2 With the aid of an operating microscope and under gonioscopic control ab interno goniocurettage is performed. Following abrasion an irregular pattern of a glistening white band corresponding to the 'denuded' grey-white sulcus scleralis can be seen (black arrows).

Ex.1007, Fig.2 (annotated).

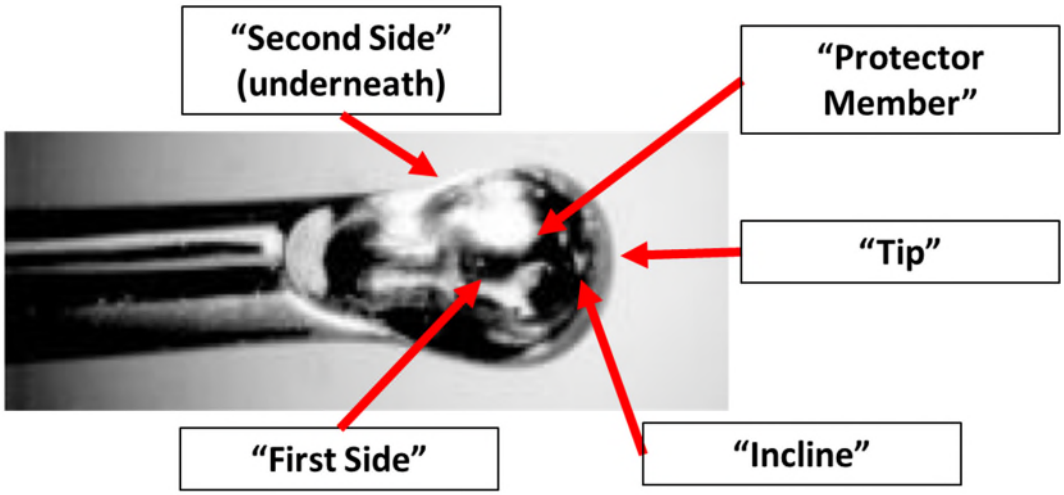
The distal end of Jacobi's gonioscraper is "shaped as a tiny bowl with 300 µm diameter and with its edges sharpened." *Id.*, 2. Jacobi states that the device was "***inserted into the anterior chamber*** through a clear corneal incision" "[i]n order to ***peel off trabecular meshwork***." *Id.* A POSITA would understand that the end of the device inserted into the AC would be the end with the bowl-shaped tip. Ex.1003, ¶139.

c. Element 1.b

As discussed above, the claimed "protector member" is a portion at the distal end of the device having a first side, a second side, a tip, and an incline that protects tissue located near the second side of the protector member. *See supra,* §VI.A.2.c; Ex.1003, ¶140.

Jacobi's describes that "the tip of the [gonioscraper] has a tiny bowl with a 300 µm diameter and with its edges sharpened." Ex.1007, 2. Additionally, "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***." *Id.* Further, "***to peel off trabecular meshwork*** the [gonioscraper] was lightly passed over 2-3 clock hours on either side at the nasal circumference of the anterior chamber angle in sweeping movements "so as "***not to traumatise adjacent intraocular structures***." *Id.* A POSITA would appreciate

that the bowl-shaped tip is oriented such that the outer, convex surface of the bowl faces the wall of SC, which protects tissue near the convex side of the tip. Ex.1003, ¶¶141-42. Accordingly, Jacobi's device has a "protector member," *i.e.*, the bowl-shaped portion that, as shown below, extends laterally (*i.e.*, to the side) from the probe and has a first side, a second side, an incline, and a tip.



Ex.1007, Fig.1 (annotated); Ex.1003, ¶¶141-43. Additionally, a POSITA would appreciate that the "tip" portion of the bowl would facilitate insertion of the device into tissue. Ex.1003, ¶143. Given the bowl shape, the tip and inner surface of the bowl slopes upwardly from the tip, as claimed. *Id.*

The bowl-shaped tip of Jacobi's gonioscraper also has a width which tapers to its narrowest point at the tip. The bowl of Jacobi's gonioscraper has a width between the edges of the bowl that is widest at the center and becomes narrower toward the tip to facilitate penetrating the TM. Ex.1003, ¶144. As shown below, the bowl-shaped tip (*i.e.*, the protector member) is narrowest at the tip.

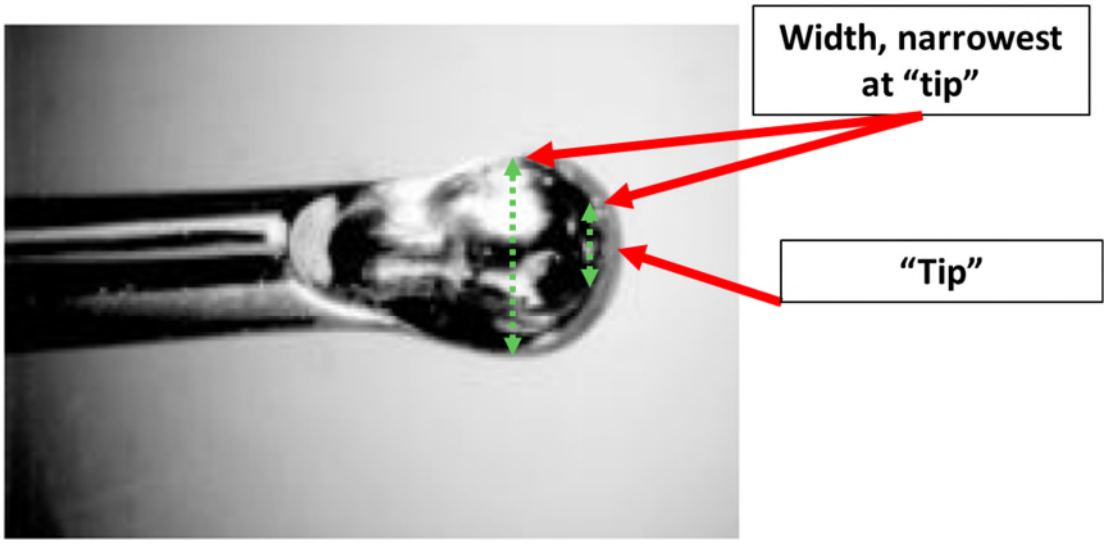


Figure 1 The tip of the 'gonioscraper'. The bowl is 300 µm in diameter with its edges sharpened.

Ex.1007, Fig.1 (annotated); Ex.1003, ¶144.

d. Element 1.c

As explained above, "knife blades" according to the '905 patent are blades in fixed positions on a device used for manual cutting of tissue. *See supra*, §V.A. Jacobi's device has a distal end "shaped as a tiny bowl with 300 µm diameter and with its ***edges sharpened***" which cut tissue. Ex.1007, 1-2. During prosecution of another application in the '905 patent's family, the Examiner found that Lee (Ex.1006) disclosed "a device with a U-shaped cutting edge (14) which has dual blades corresponding to the U-shape." Ex.1023, 320; *see also* Ex.1006 (Lee), 4:38-41, Figs. 2-3 (below).

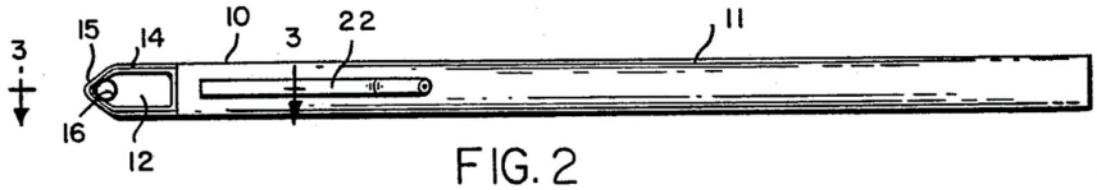


FIG. 2

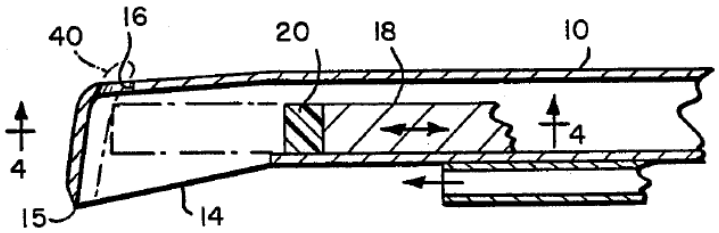
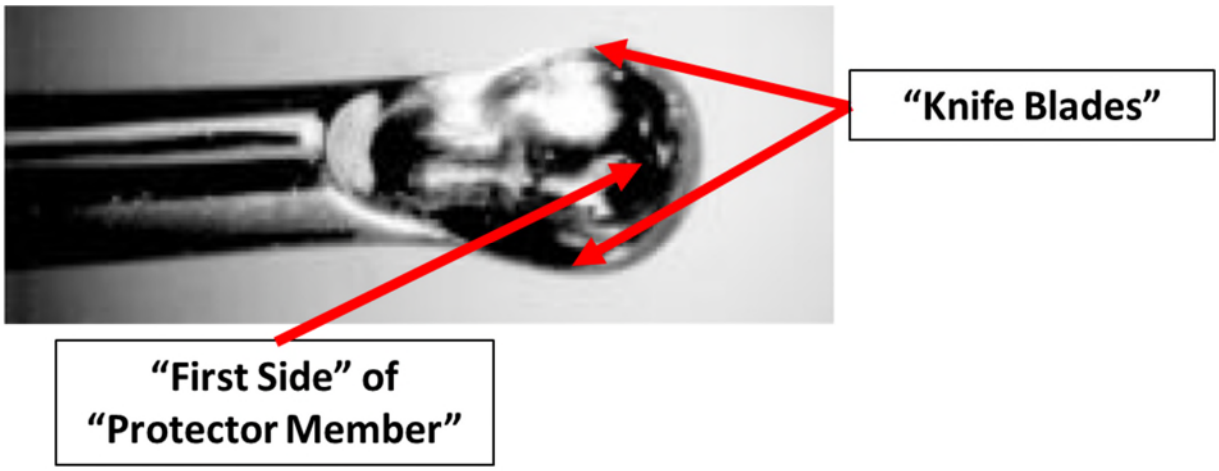


FIG. 3

Thus, Jacobi's device, like Lee's device, has dual blades corresponding to the U-shape. Ex.1003, ¶¶146-47. As shown below, Jacobi's gonioscraper has two sharpened "knife blades" that are spaced-apart on opposite sides of the bowl-shaped tip. *Id.*



Ex.1007 (Jacobi), Fig.1 (annotated). Further, according to Jacobi, the procedure resulted in "***strings of trabecular tissue.***" Ex. 1007, 2. A POSITA would understand that for strings to be produced, as opposed to an incision, both "knife

blades" would need to concurrently cut TM which passes over the first side of the "protector member" before being cut by the "knife blades." *Id.*; Ex.1003, ¶148. As Jacobi's bowl-shaped tip advances through SC, TM tissue necessarily contacts the tip (*i.e.*, protector member), causing the cutting edges of the bowl to cut the TM tissue. *Id.* A POSITA would understand at least some TM tissue that contacts the tip in this orientation would pass over the inner surface of the bowl (*i.e.*, the first side of the protector member) before contacting the cutting edges. *Id.*

If Jacobi's blunt protruding tip is not oriented such that tissue passes over the inner surface of the bowl (*i.e.*, the first side of the protector member) before contacting the cutting edges, it would have been obvious to modify Jacobi's device in this manner. *Id.*, ¶¶149-50. For example, a POSITA would have known that extending the terminal end of Jacobi's bowl would cause TM tissue to pass over the inner surface of the bowl (*i.e.*, the first side of the protector member) 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).

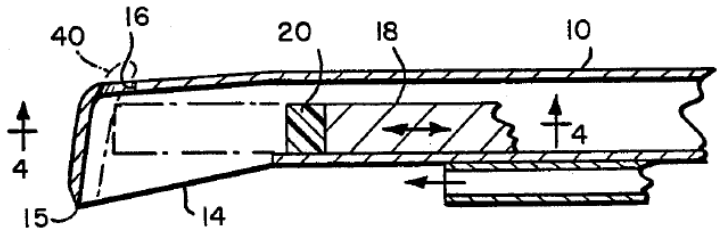


FIG. 3

In this orientation, TM tissue necessarily passes over the top surface of the distal end 15 of Lee's device before contacting the sharpened edges of the bowl. Ex.1003, ¶¶149-50.

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 which case TM tissue would necessarily pass over the inner surface of the bowl-shaped tip (*i.e.*, the first side of the protector member) before contacting the cutting edges of Jacobi's bowl. *Id.* A POSITA would have known that a protruding terminal end could make it easier to penetrate the TM with the tip of the device. *Id.* Moreover, modifying Jacobi's device in this manner would involve nothing more than substituting one prior art element (*i.e.*, Jacobi's terminal end) for another (*i.e.*, a protruding terminal end), and a POSITA would have expected success given the successful employment of devices with a protruding terminal end in the prior art, such as Lee. *Id.*

e. Elements 1.d

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. As shown in Fig.2 below, Jacobi's bowl-shaped tip (the protector member) penetrates "tip" first through the TM and into SC, where it is passes over the angle in "sweeping movements." *Id.*, 2; Fig. 2 (below); Ex.1003, ¶151. Clearly, lateral advancement of the gonioscraper (including the protector member) through SC occurs through movement of the device by the surgeon. *Id.*, 2.

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. According to Jacobi, the procedure results in "strings of trabecular tissue [that] could be observed intraoperatively to be removed by goniocurettage." *Id.*, 1-2; Ex.1003, ¶153.

As described above, in this orientation, the TM tissue must be in contact with protector member and at least a portion of the TM tissue in contact with the protector member would pass over the incline and the first side of the protector member (*i.e.*, the inner surface of the bowl) before it is removed by the cutting edges. *See supra*, §VI.C.2.d.; Ex.1003, ¶¶151-53. To the extent TM tissue would not move along the incline of the protector member of Jacobi's device before contacting the knife blades, it would have been obvious to modify Jacobi's device such that TM tissue would pass over the incline before contacting the knife blades for the reasons discussed above. *See supra*, §VI.C.1.d; Ex.1003, ¶¶148-50, 152.

3. Claim 2

Jacobi in view of the knowledge of a POSITA renders obvious claim 1. *See supra*, §VI.C.2. Further, the '905 patent admits that cutting a strip of TM with a width from 50 to 200μm was known in the art. Ex.1001, 2:25-30. During prosecution of the '905 patent, the Examiner also found this was "well within the scope of one having ordinary skill in the art." *See supra*, §IV.B.2; Ex.1002, 423. Thus, claim 2 does not cover a novel or nonobvious feature of the alleged invention.

Further, the distal end of Jacobi's gonioscraper "is shaped as a tiny bowl with 300 μm diameter and with its edges sharpened." Ex.1007, 2. As the "knife blades" concurrently cut the TM to produce "strings of trabecular tissue," the resulting strip of tissue would have a width substantially equal to the distance between the "knife blades," *i.e.*, approximately the diameter of the bowl (300μm). Ex.1003, ¶155. While the width of this strip is slightly larger than the claimed range, a POSITA would have found it obvious to modify Jacobi's device to produce strips between 50 and 200μm. Ex.1003, ¶¶156-58. A POSITA would have appreciated that smaller surgical devices could be used to perform Jacobi's procedure based on the particular procedure or specific patient. *Id.* Moreover, use of a device having a bowl-shaped tip with a smaller diameter would involve simple substitution of one known element for another to obtain predictable results. *Id.* Accordingly, a POSITA would have found it obvious to modify Jacobi's procedure to produce a strip of TM having a width from 50 to 200μm. *Id.* Moreover, an invention is obvious when, as here, the only difference between the prior art and the claimed invention are changes in size or shape, where the changes to the size or shape do not result in patentable significance or a different product. *Gardner*, 725 F.2d at 1349; *Dillon*, 919 F.2d at 697-98.

4. Claim 3

Jacobi in view of the knowledge of a POSITA renders obvious claim 1. *See supra*, §VI.C.2. Further, Jacobi indicates that the procedure is performed following injection of viscoelastic. Ex.1007, 2. It would have been obvious to incorporate an irrigation lumen into Jacobi's device to allow for injection of viscoelastic. Ex.1003, ¶¶160-62. By 2003, devices including irrigation lumen for infusing fluid were well-known. *Id.*, ¶161. For example, Lee's device has an "irrigation port" (*i.e.*, an irrigation 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 irrigation 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, ¶¶161-62. Moreover, modifying Jacobi's device to include an irrigation lumen would also have involved simply combining prior art elements according to known methods, such as incorporating a known irrigation lumen into Jacobi's device with known irrigation 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 irrigation lumen to the device to avoid the necessity of a separate irrigation device. *Id.*

5. Claim 4

Jacobi in view of the knowledge of a POSITA renders obvious claim 1. *See supra*, §VI.C.2. 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. 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, ¶164. 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*.

6. Claim 5

Jacobi in view of the knowledge of a POSITA renders obvious claim 1. *See supra*, §VI.C.2. As explained above for claim 3, it would have been obvious to include an irrigation lumen in Jacobi's gonioscraper. *See supra*, §VI.C.3. Also, as explained above for claim 4, it would have been obvious to include an aspiration lumen in the device. *See supra*, §VI.C.4. Including both an irrigation lumen and aspiration lumen would have been obvious for the same reasons discussed above for claims 3 and 4. *See supra*, §§VI.C.3, VI.C.4; Ex.1003, ¶166.

7. Claim 6

Jacobi in view of the knowledge of a POSITA renders obvious claim 1. *See supra*, §VI.C.2. Further, as explained above, Jacobi's device has a bowl-shaped tip (protector member). Ex.1007, 2. To peel strings of TM tissue from the TM, Jacobi passes the device over the AC angle in "sweeping movements." *Id.* As shown in Fig.2, the device is oriented such that the convex, outer surface of the bowl is adjacent to the external wall of SC. *Id.*, Fig.2. Thus, as the tip advances through SC, the convex, outer surface of the bowl (protector member) protects SC from damage, as claimed. Ex.1003, ¶168; *see also supra*, §VI.C.2.c.

8. Claim 7

Jacobi in view of the knowledge of a POSITA renders obvious claim 1. *See supra*, §VI.C.2. Further, Jacobi's device has "knife blades" on opposite sides of the bowl which concurrently cut TM to produce strings of TM tissue. *See supra*,

§VI.C.2.d. As shown below, the cutting edges (*i.e.*, knife blades) are spaced apart such that an area exists between the cutting edges (labeled "spaced distance" below):

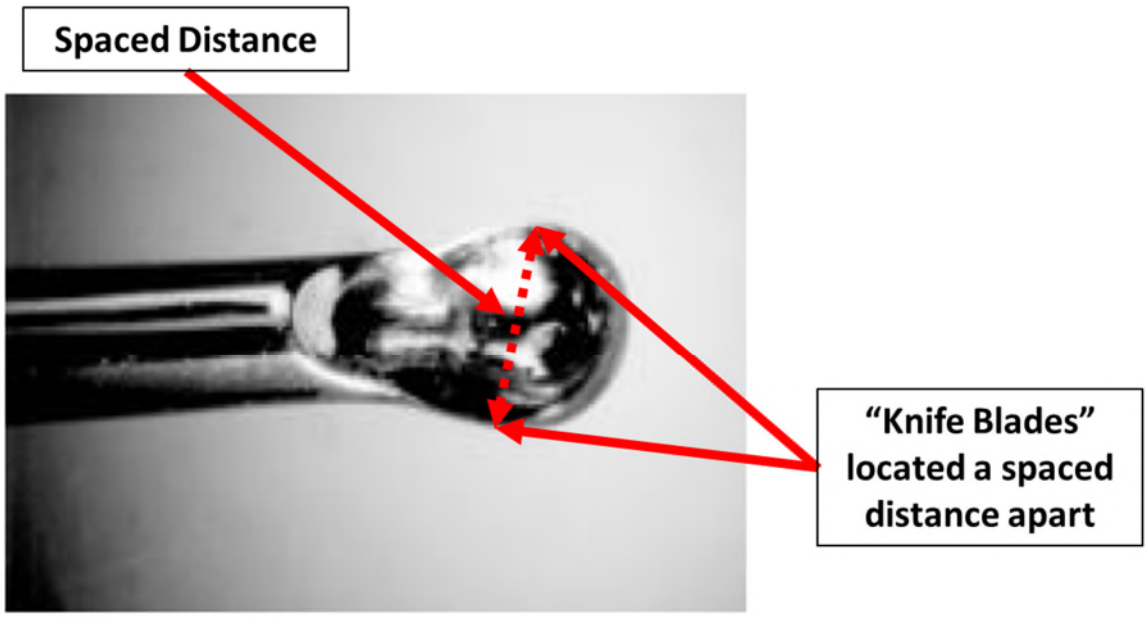


Figure 1 The tip of the 'gonioscraper'. The bowl is 300 µm in diameter with its edges sharpened.

Ex.1007, Fig.1 (annotated); Ex.1003, ¶170. The strip of tissue created when the cutting edges cut TM tissue would necessarily have a width that is "substantially equal" to the distance between the cutting edges, as these cutting edges concurrently cut the TM tissue to achieve a strip of tissue that would have a width corresponding to the distance between the cutting edges. Ex.1003, ¶171.

VII. Conclusion

For the foregoing reasons, IPR of claims 1-7 of the '905 patent is respectfully requested.

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Respectfully submitted,

/s/ *Todd R. Tucker*

Todd R. Tucker (Reg. No. 40,850)
ttucker@calfee.com
Kyle Deighan (Reg. No. 75,525)
kdeighan@calfee.com
John Reulbach (to be admitted *pro hac vice*)
jreulbach@calfee.com
CALFEE, HALTER & GRISWOLD LLP
The Calfee Building
1405 East Sixth Street
Cleveland, Ohio 44114
P: 216-622-8200
F: 216-241-0816

Attorneys for Petitioner

Claim Appendix

Claim 1:

[1.p] A device that is insertable into the anterior chamber of an eye and useable to form an opening in the trabecular meshwork of that eye, said device comprising:

[1.a] an elongate probe having a longitudinal axis and a distal portion that is insertable into the anterior chamber of the eye;

[1.b] a protector member on a distal end of the distal portion of the probe, said protector member being oriented in a lateral direction relative to said longitudinal axis and having a first side, a second side and a tip, wherein the first side of the protector member comprises an incline which slopes upwardly from the tip and wherein the protector member has a width which tapers to its narrowest point at the tip; and

[1.c] a plurality of knife blades positioned to cut tissue that passes over the first side of the protector member;

[1.d] wherein the protector member is configured such that, after an insertion of the distal portion of the elongate probe into an anterior chamber of an eye, the protector member is insertable, tip first, through the trabecular meshwork and into Schlemm's Canal, the distal end of the probe being thereafter moveable in the lateral direction thereby causing the protector member to advance through Schlemm's Canal such that trabecular meshwork tissue passes over the incline and a strip of trabecular meshwork tissue becomes cut by said knife blades.

Claim 2:

[2.p] A device according to claim 1 wherein

[2.a] the knife blades are operative to cut a strip of tissue having a width from 50 μm to 200 μm, from the trabecular meshwork.

Claim 3:

[3.p] A device according to claim 1 further comprising

[3.a] an irrigation lumen.

Claim 4:

[4.p] A device according to claim 1 further comprising

[4.a] an aspiration lumen.

Claim 5:

[5.p] A device according to claim 1 further comprising

[5.a] an irrigation lumen and an aspiration lumen.

Claim 6:

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

[6.a] the second side of the protector member is configured so as not to damage tissues adjacent thereto as the protector member is advanced through Schlernm's Canal.

Claim 7:

[7.p] A device according to claim 1 wherein

[7.a] said knife blades are located a spaced distance apart to cut a strip of tissue the width of which is substantially equal to the distance between the first and second knife blades.

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 9,315 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 16, 2020

/s/ *Todd. R. Tucker*

Todd R. Tucker (Reg. No. 40,850)
ttucker@calfee.com
Kyle Deighan (Reg. No. 75,525)
kdeighan@calfee.com
John Reulbach (to be admitted *pro hac vice*)
jreulbach@calfee.com
CALFEE, HALTER & GRISWOLD LLP
The Calfee Building
1405 East Sixth Street
Cleveland, Ohio 44114
P: 216-622-8200
F: 216-241-0816

Attorneys for Petitioner

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing **PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 10,123,905** was served as of the below date via Federal Express on the following individuals:

Wiley Rein LLP
Attn: Lawrence M. Sung and Xiaomin Su
1776 K Street N.W.
Washington DC 20006

Dated: October 16, 2020

/s/ *John L. Reulbach III*

John L. Reulbach III

Attorney for Petitioner