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. IPR2020-01711
U.S. Patent No. 9,358,155

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,358,155

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent 9,358,155 ("the '155 patent")
1002	U.S. Patent 9,358,155 File History ('155 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")

Exhibit No.	Description
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")

Exhibit No.	Description
1023	U.S. Patent Application Publication No. 2003/0014042 to Juhasz ("Juhasz")
1024	U.S. Patent 5,876,415 to Pierce ("Pierce")

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 9,358,155 ("the '155 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 9,820,885 ("the '885 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.

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 '155 patent claims nothing more than using known devices to treat glaucoma, an eye disease that can lead to blindness. All limitations of the '155 patent claims are taught in the prior art. For instance, Quintana (Ex.1004) discloses everything claimed from the type of procedure ("ab interno") to the device ("dual blade" cutting device made from a bent needle) to the technique (removing a "strip" of tissue from the eye's trabecular meshwork ("TM") to treat glaucoma). There is nothing in the claims of the '155 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 '155 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 '155 patent to create more permanent openings by removing strips of TM tissue to facilitate fluid outflow and prevent reclosure.

The ‘155 patent attempts to claim these well-known principles but fails to actually set forth anything inventive. The claims relate to devices for removing strips of tissue from the TM 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 surgical procedure performed using the claimed devices (*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 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 cover what was already known in the art, rendering those claims unpatentable.

Accordingly, Petitioner respectfully requests that trial be instituted and claims 1-7 of the ‘155 patent (the “Challenged Claims”) be cancelled.

II. CERTIFICATIONS; GROUNDS

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

NWM certifies that the '155 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 '155 patent. The '155 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 '155 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	4-5	§103	Quintana, Knowledge of a POSITA
Ground 3	1-3, 6-7	§103	Quintana, Lee
Ground 4	4-5	§103	Quintana, Lee, Knowledge of a POSITA
Ground 5	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.

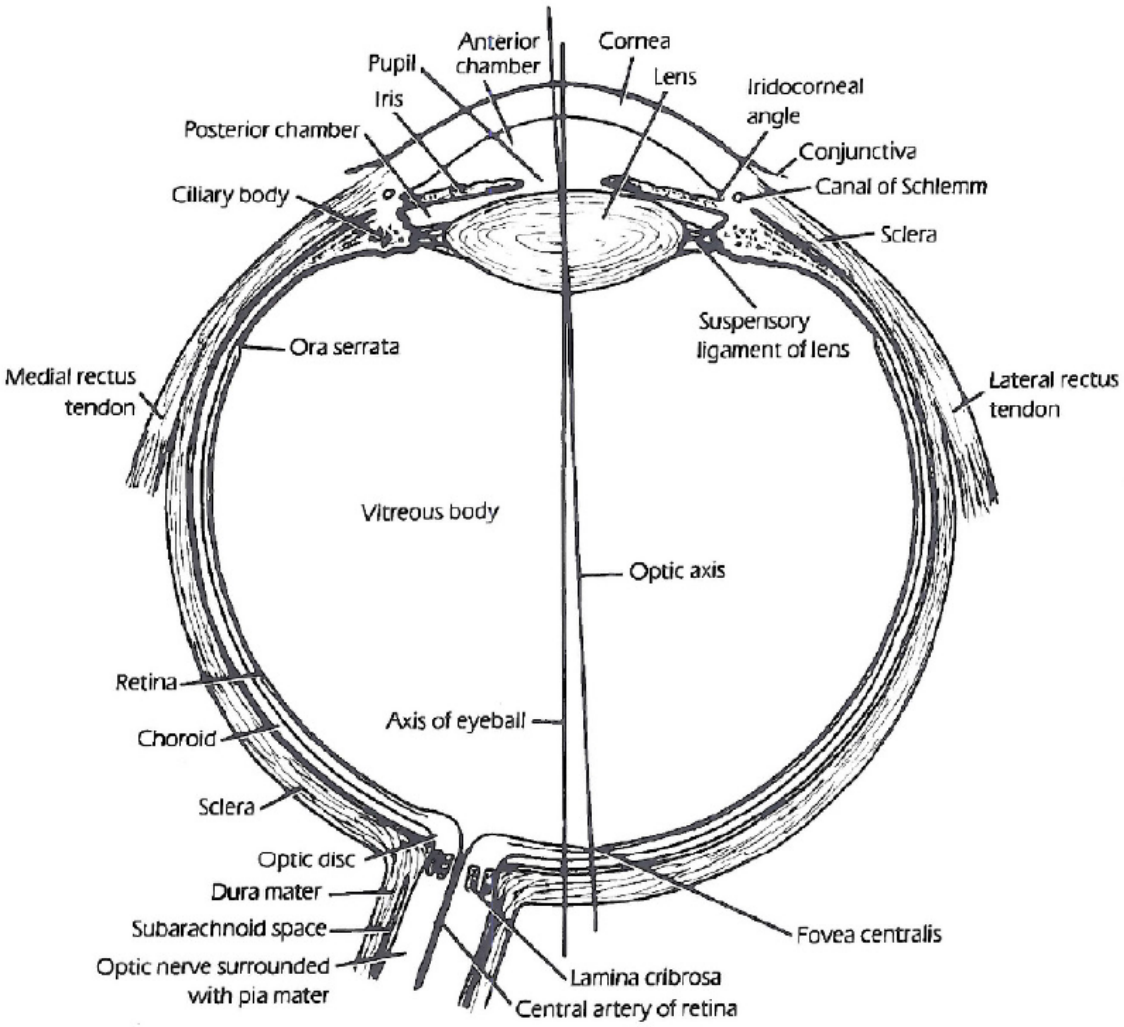
D. Service (§42.105)

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). *Id.*, 11. The cornea is divided into "zones": (1) central; (2) paracentral; (3) peripheral; and (4) limbal. Ex.1009, 4; Ex.1003, ¶34.

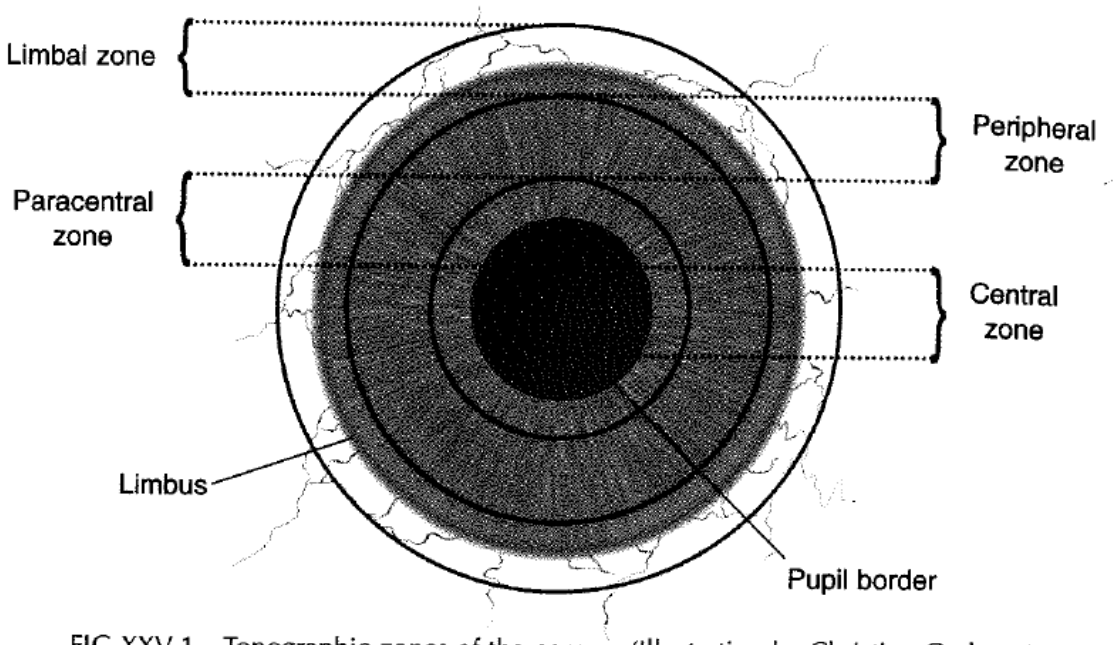


FIG XXV-1—Topographic zones of the cornea. (Illustration by Christine Gralapp.)

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, ¶35.

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, ¶40. The following shows a cutaway of the TM and SC:

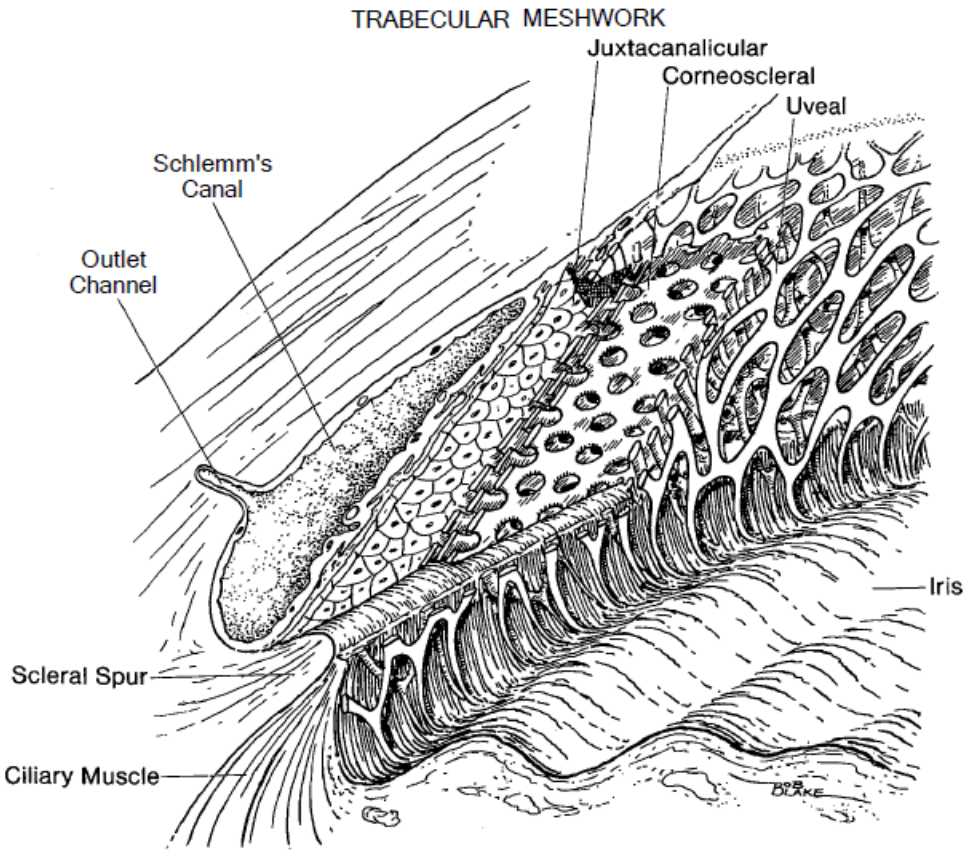


Figure 2.10. Three layers of trabecular meshwork (shown in cutaway views): (1) uveal; (2) corneoscleral; and (3) juxtacanalicular.

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, ¶41.

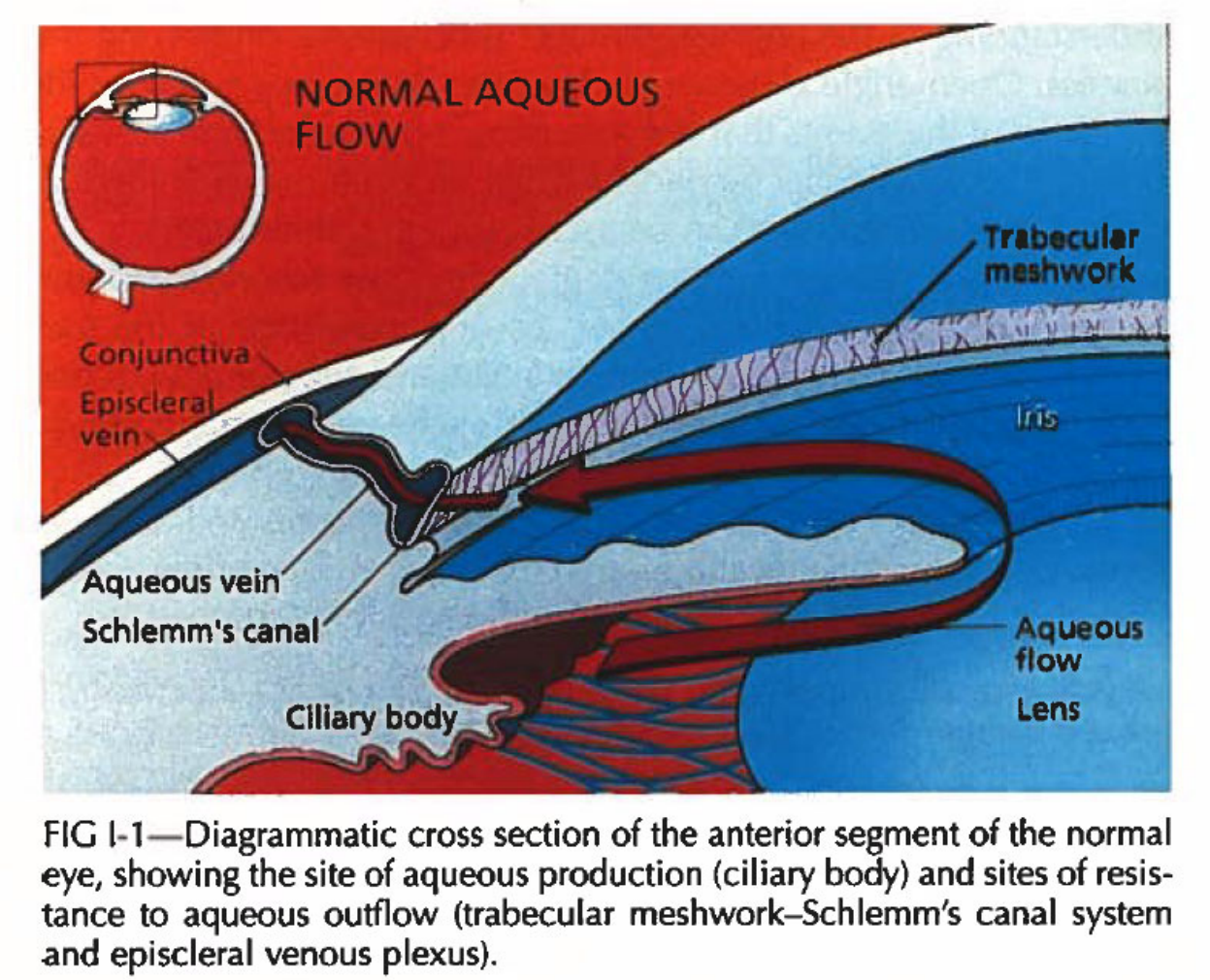


FIG I-1—Diagrammatic cross section of the anterior segment of the normal eye, showing the site of aqueous production (ciliary body) and sites of resistance to aqueous outflow (trabecular meshwork–Schlemm's canal system and episcleral venous plexus).

Ex.1012, 6.

C. Glaucoma

Glaucoma refers to a collection of diseases that can cause irreversible blindness. Ex.1003, ¶42. 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, ¶42.

Two common glaucoma types are open-angle and closed-angle. Ex.1012, 7; Ex.1003, ¶43-44. As shown below, in open-angle glaucoma, the TM restricts aqueous outflow from the AC. Ex.1012, 10.

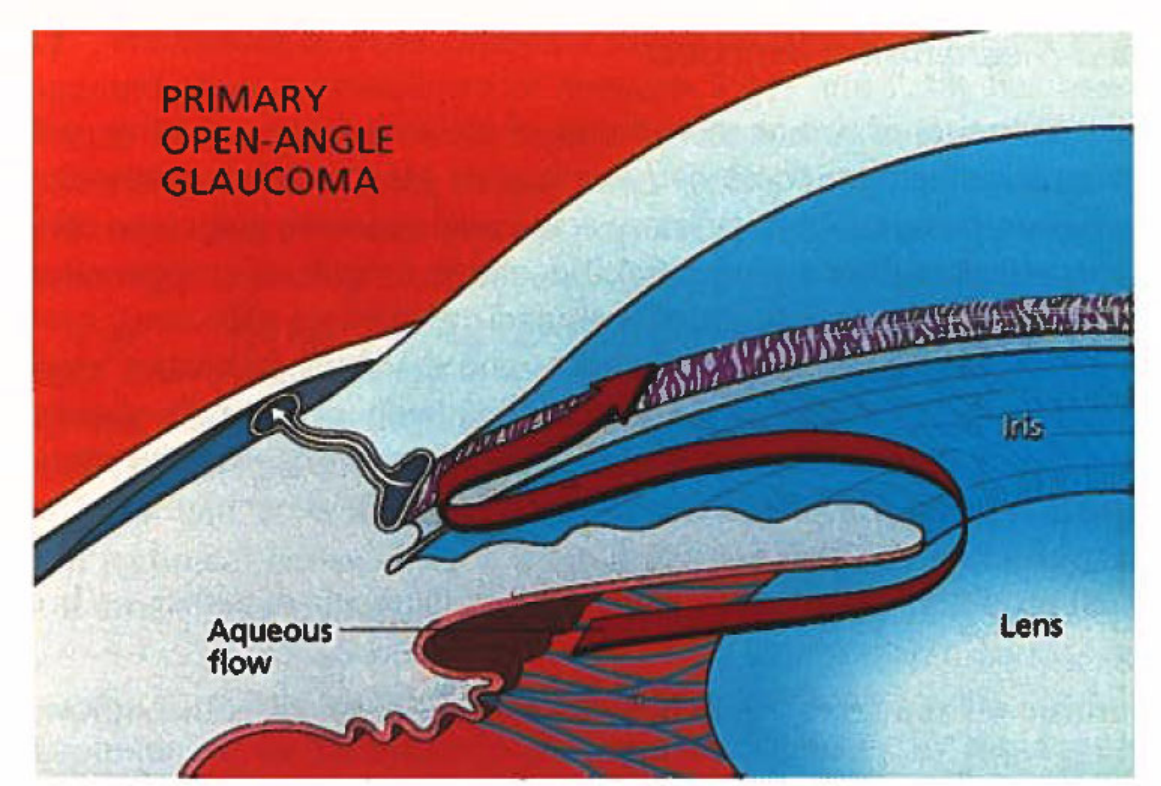


FIG I-2—Schematic of open-angle glaucoma with resistance to aqueous outflow through the trabecular meshwork–Schlemm's canal system in the absence of gross anatomic obstruction. Small white arrow shows normal path of outflow and indicates that resistance in this illustration is relative, not total.

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

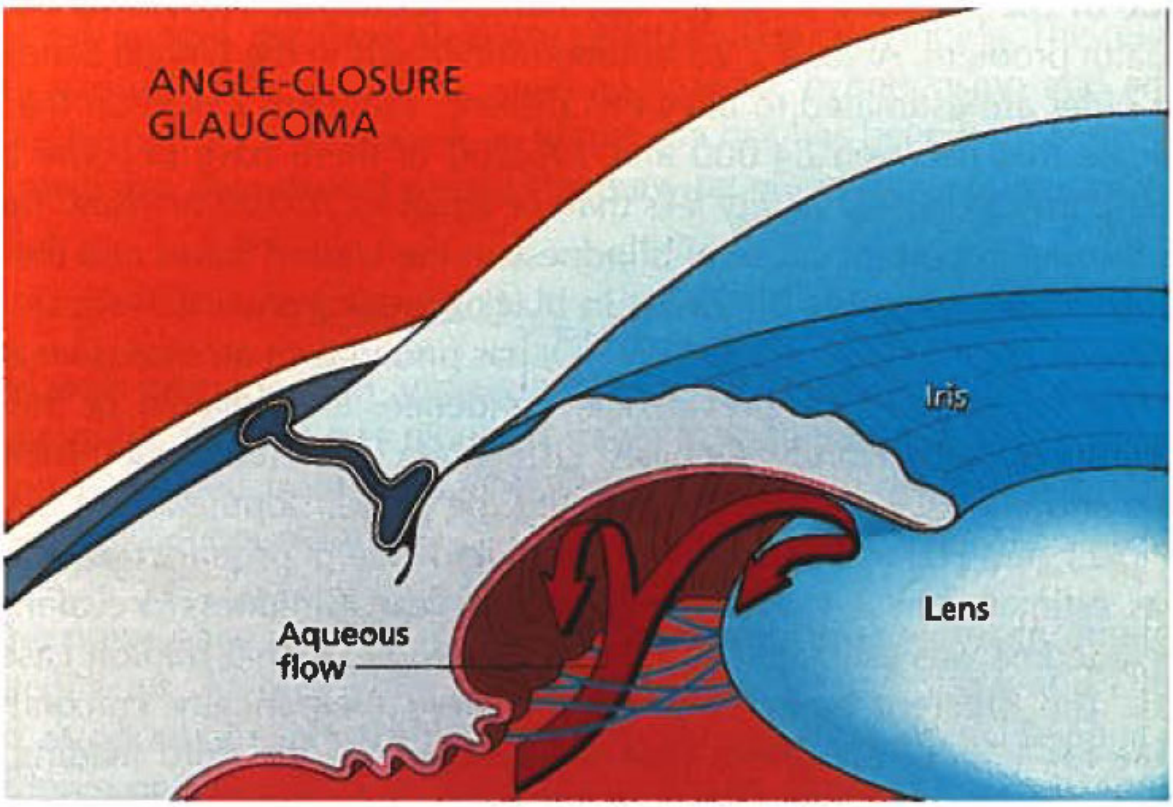


FIG I-3—Schematic of angle-closure glaucoma with pupillary block leading to peripheral iris obstruction of the trabecular meshwork.

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, ¶45.

D. Treatment of Glaucoma

Surgical attempts to treat glaucoma date back centuries and often sought to decrease IOP by improving fluid drainage from the eye. Ex.1012, 4-5; Ex.1003, ¶46.

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, ¶47.

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, ¶49-50.

[2] Procedures for treating glaucoma can be classified as "ab interno" (from inside the eye) or "ab externo" (from outside of eye). *See infra*, §V.A; Ex.1003, ¶48.

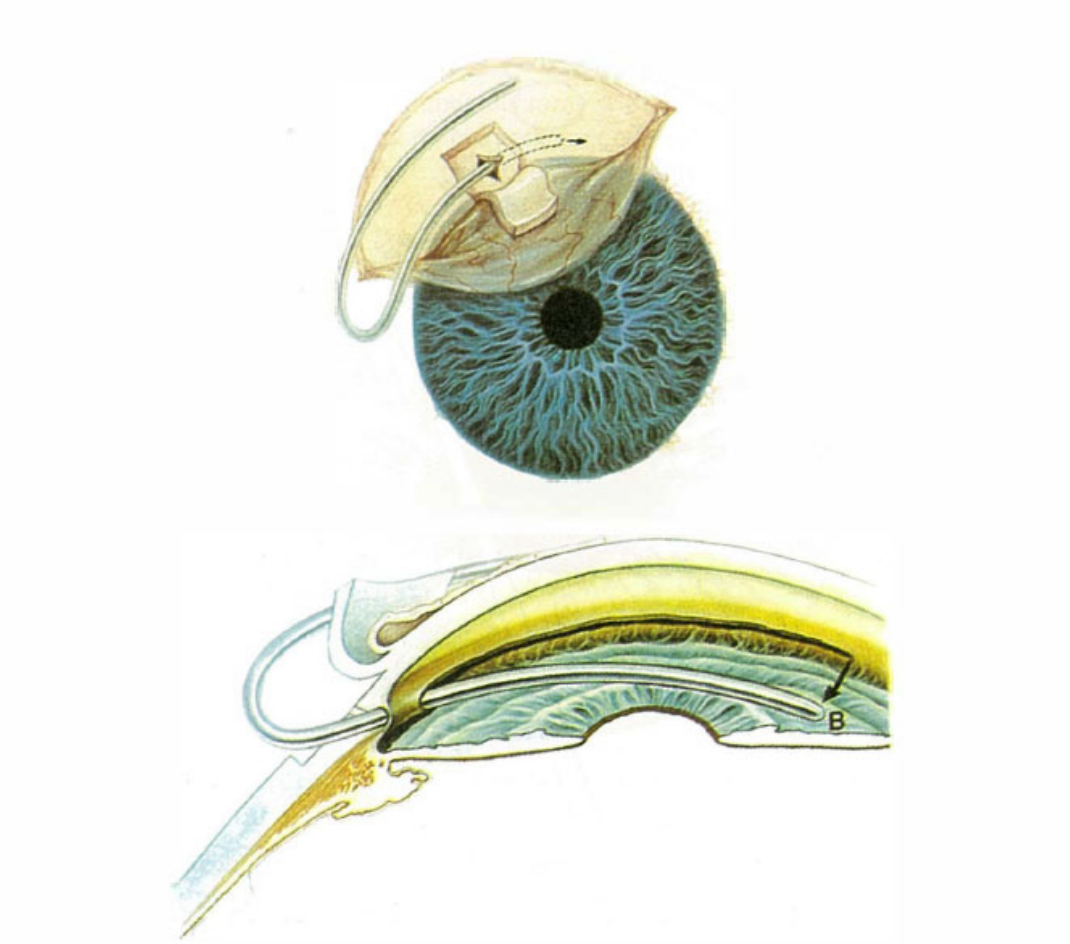


FIG VIII-13-Trabeculotomy. *Top,* Probe is gently passed along Schlemm's canal with little resistance for 6-10 mm. *Bottom,* By rotating the probe internally (8), the surgeon ruptures the trabeculum, and the probe appears in the anterior chamber with minimum bleeding. (Reproduced and modified with permission 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, ¶51.

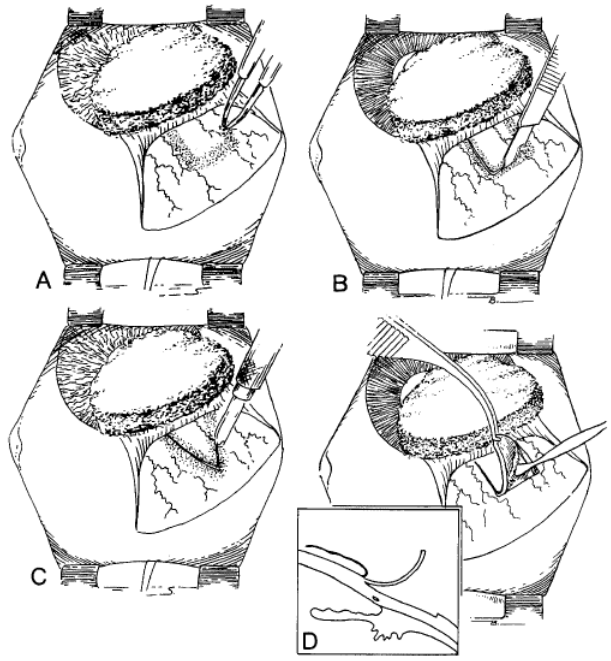


Figure 37.10. Trabeculectomy. A. Cauterization of area intended for margins of scleral flap. B. Margins of scleral flap outlined by partial-thickness incisions. C. Triangular scleral flap as an alternative technique. D. Dissection of scleral flap.

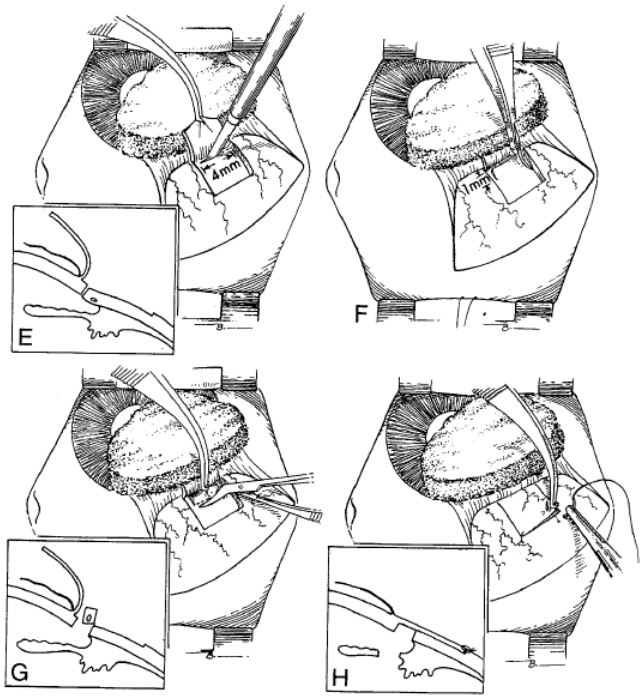


Figure 37.10. (cont'd) E. Anterior chamber entered just behind the hinge of the scleral flap. F. Completion of anterior and lateral margins of deep limbal incision with scissors. G. Flap of deep limbal tissue excised by cutting along scleral spur. H. Approximation of scleral flap. (Portions reprinted 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, ¶¶52-54.

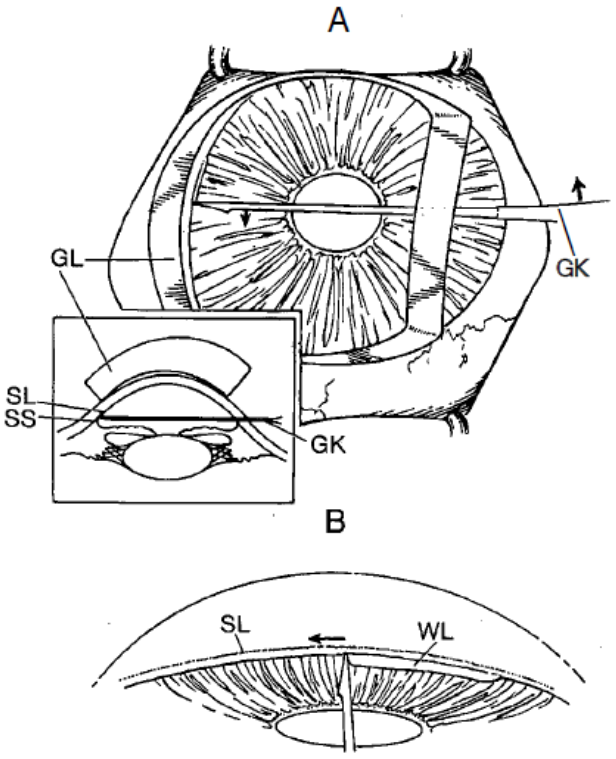


Figure 35.8. Goniotomy. A. With a surgical goniolens *(GL)* positioned on the cornea, a goniotomy knife *(GK)* is inserted through peripheral cornea and passed across the anterior chamber to the angle in the opposite quadrant. B. Under direct gonioscopic visualization, angle tissue is excised between 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, ¶55. Techniques were developed to create larger, more permanent openings by removing strips of tissue to "avoid early reclosure" of the TM. Ex.1007, 4-5; Ex.1003, ¶55. These are referred to as "***excisional goniotomy***" procedures. Ex.1013, 11; Ex.1003, ¶¶55-56.

The '155 patent recognizes goniectomy was a known technique for treating glaucoma. Ex.1001, 1:37-65. 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, ¶57. 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, ¶57.

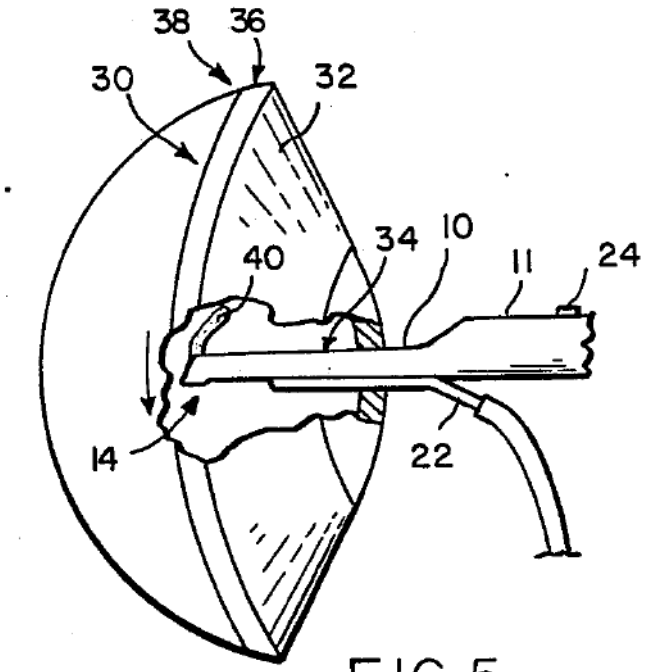


FIG.5

Quintana (Ex.1004) discloses a procedure for "stripping" and "achiev[ing] a section" of TM tissue. Ex.1004, 3, 4. Quintana improved 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, ¶58.

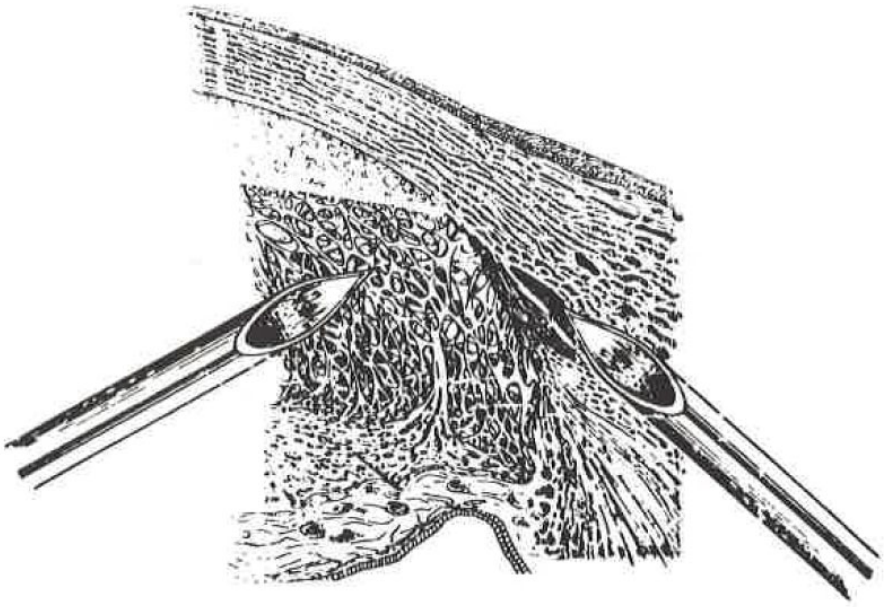


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

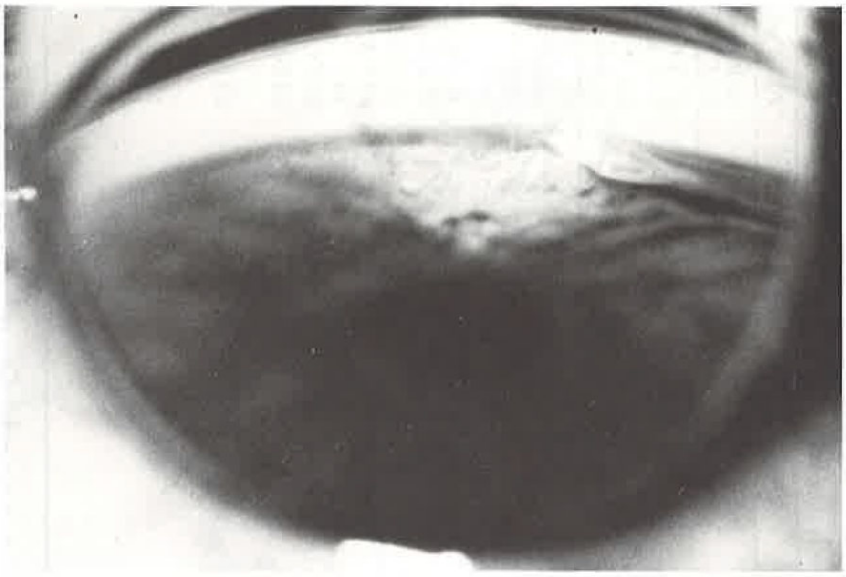


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

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, ¶59.

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, ¶60.

IV. The '155 Patent

A. Overview

The '155 patent discloses devices and methods for performing the well-known goniectomy procedure. Ex.1001, 1:23-2:37. The patent expressly ***admits*** that goniectomy procedures for removing strips of tissue from the eye and instruments for performing these procedures ***were known***. *Id.*, 1:37-65; Ex.1003, ¶61. 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, ¶62. 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, 3:3-43.

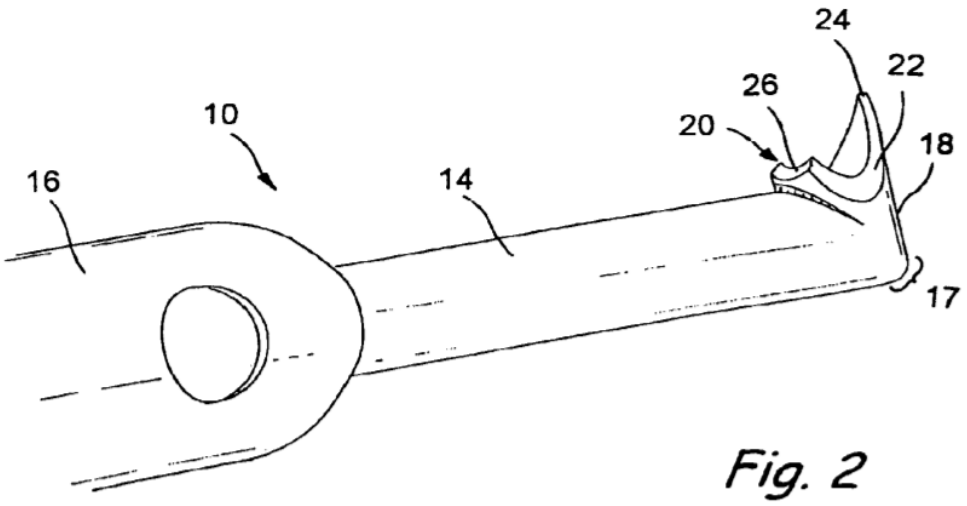


Fig. 2

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.*, 3:25-29. The patent indicates making the device involves nothing more than cutting and bending "standard tubing"—a needle. *Id.*, 4:60-5:12; *see also id.*, Figs.3A-3D (below, showing "standard tubing" cut to form device); Ex.1003, ¶¶63-64.

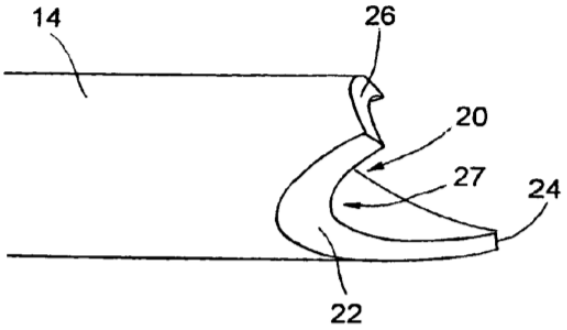


Fig. 3A

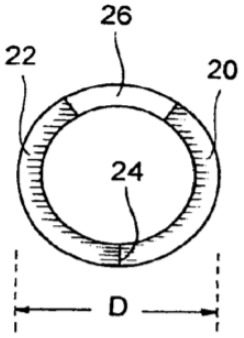


Fig. 3B

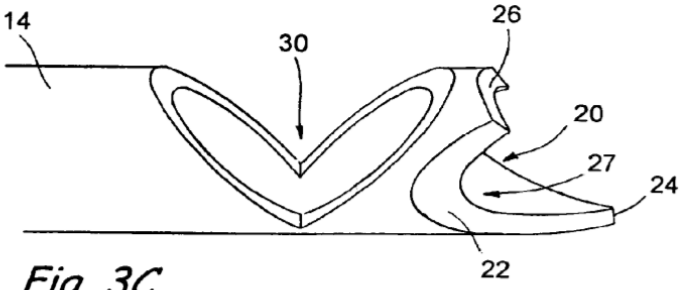


Fig. 3C

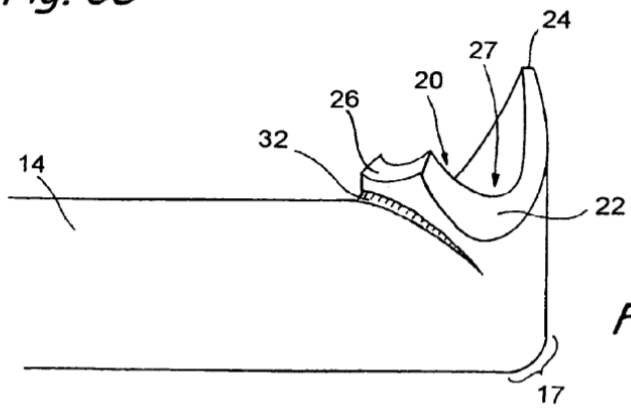


Fig. 3D

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, 5:26-6:24, Fig.4.

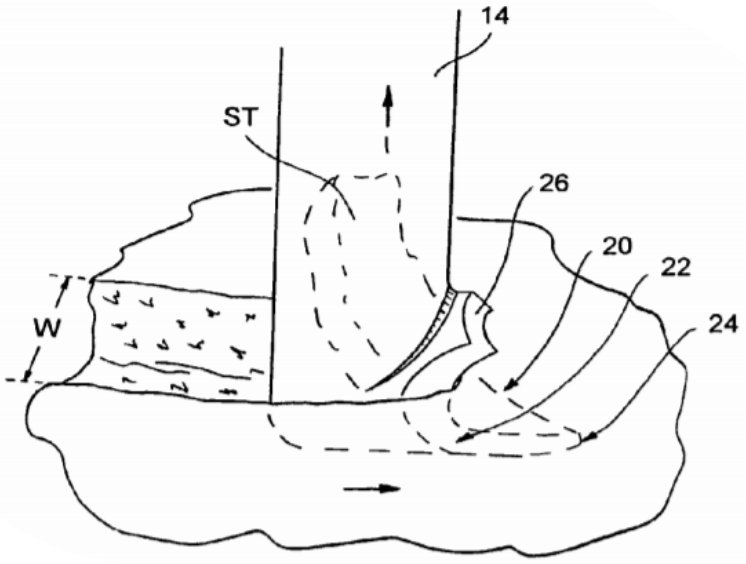


Fig. 4

This procedure had been performed for decades before 2003 to remove strips of TM. Ex.1003, ¶¶65-66.

B. Prosecution History

The '155 patent issued from U.S. Application 14/789,632 ("the '632 application"), filed on July 1, 2015, which 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 '155 patent claims priority to U.S. Provisional Application 60,477,258, filed June 10, 2003. The '155 patent belongs to a large family and thus, only select portions of the prosecution histories are discussed below.

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).

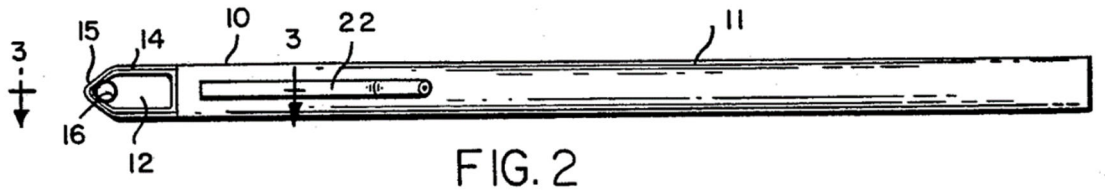


FIG. 2

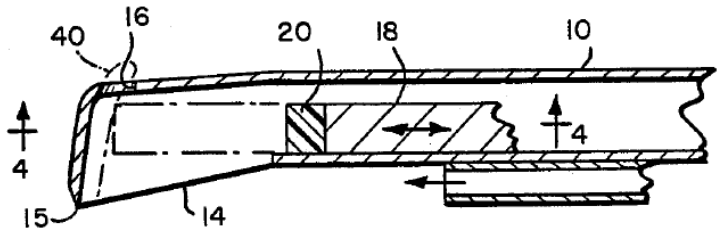
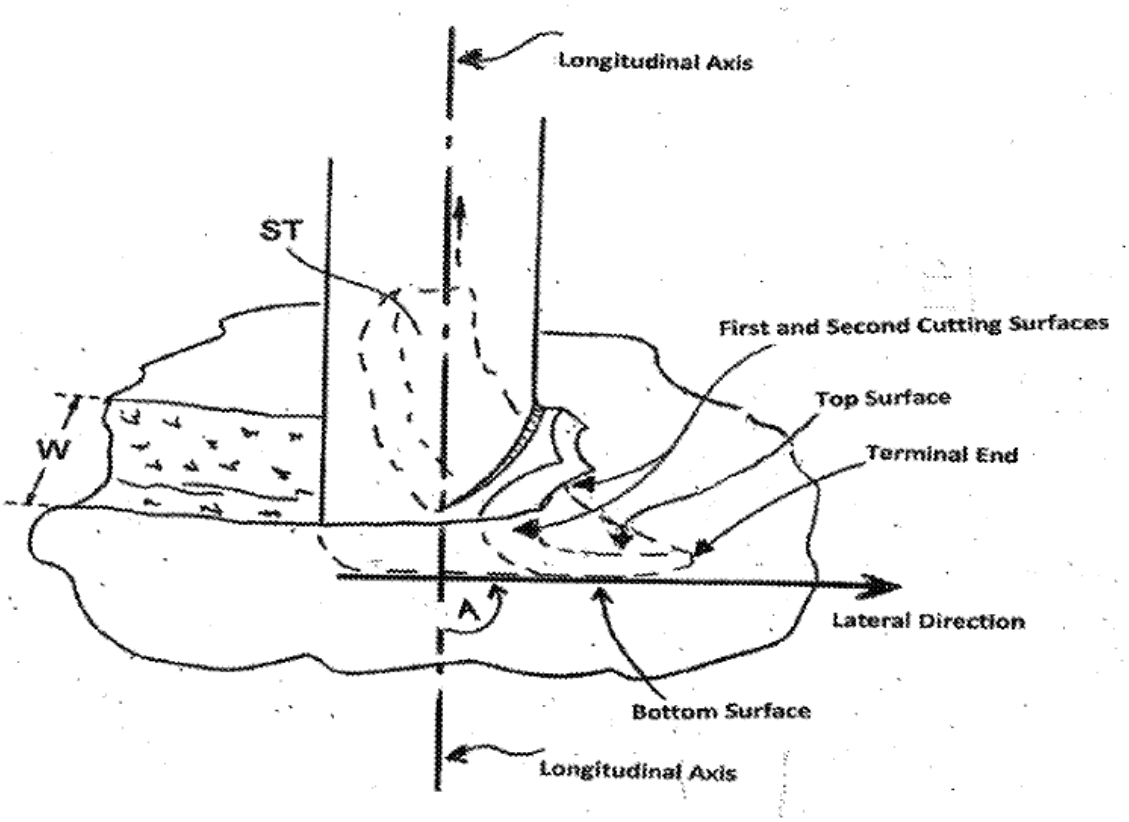


FIG. 3

Given the Examiner's finding that Lee has "dual blades corresponding to the U-shape," a "dual blade device" is simply one with two edges for cutting. Ex.1003, ¶¶70-71.

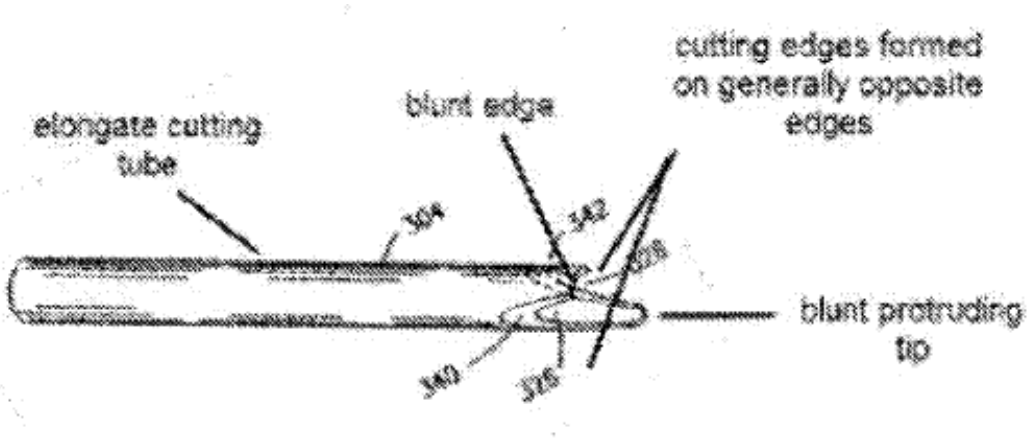
3. '632 Application

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



Ex.1002, 199. A standard needle (such as Quintana's discussed below) would have these same components. Ex.1003,¶73.

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." *Id.*, 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. A needle or needle-like device that includes a bend or curve, such as Quintana's needle described below, would invalidate the '155 patent's claims. Ex.1003, ¶74.

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, ¶26.

D. Effective Filing Date

The '155 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 '155 patent claims.

V. Claim Construction

In IPR proceedings filed after November 12, 2018, claims are construed under the standard used in civil actions according to 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. "ab interno"

In 2003 (and today), a POSITA would understand "ab interno" to mean ***from the inside*** and "ab externo" to mean ***from the outside*** and specify whether target tissue was being approached from inside the eye ("ab interno") or outside of eye ("ab externo"). Ex.1003, ¶76. The patent uses these terms to describe the direction from which the TM is approached. An "ab interno" procedure approaches the TM from ***within*** the AC. Conversely, "ab externo" approaches the TM through an opening on the ***outside*** of the eye. *Id.*, ¶¶77-79.

The intrinsic record supports these definitions. The patent describes "ab interno" as inserting a device "***into the anterior chamber*** of the eye." Ex.1001, 5:19-37 (emphasis added). During prosecution, applicant explained "ab interno" requires approaching the TM from within the AC while "ab externo" involves

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

making an incision on the eye's exterior directly into SC and removing TM through that incision. Ex.1019, 229-30, 264; Ex.1003, ¶¶80-81.

Nothing limits "ab interno" to openings formed in particular parts of the eye. Regardless of the opening's location (whether through the sclera, the scleral side of the limbus, the limbus, the corneal side of the limbus, the cornea), a procedure is "ab interno" if the TM is approached from ***within*** the AC. Ex.1003, ¶¶82-83; Ex.1007, 2.

B. "dual blade device"

According to the intrinsic record, a "dual blade device" has two edges capable of cutting tissue. Ex.1003, ¶84.

The patent discloses a device with first and second cutting edges 20, 22. The patent indicates the edges are "sharp and intended to cut tissue," Ex.1001, 3:16-17, but does not specify how sharp the edges must be. The edges must simply be capable of cutting tissue. *Id.*, 3:16-17, 3:44-53, Fig.4, cls.1-2; Ex.1003, ¶¶85-86.

The "needle cutter device" disclosed is a needle with a bent tip. Nothing in the description provides any indication how the device or the device's cutting edges differ from a standard needle. "Dual blade devices" are not, however, limited to needle-like devices. As explained above, devices with U-shaped cutting edges, like Lee's, are "dual blade" devices. Ex.1022, 320. A "dual blade device"

can thus encompass devices with spaced-apart cutting edges, including needle-like devices and devices such as Lee's. Ex.1003, ¶¶87-90.

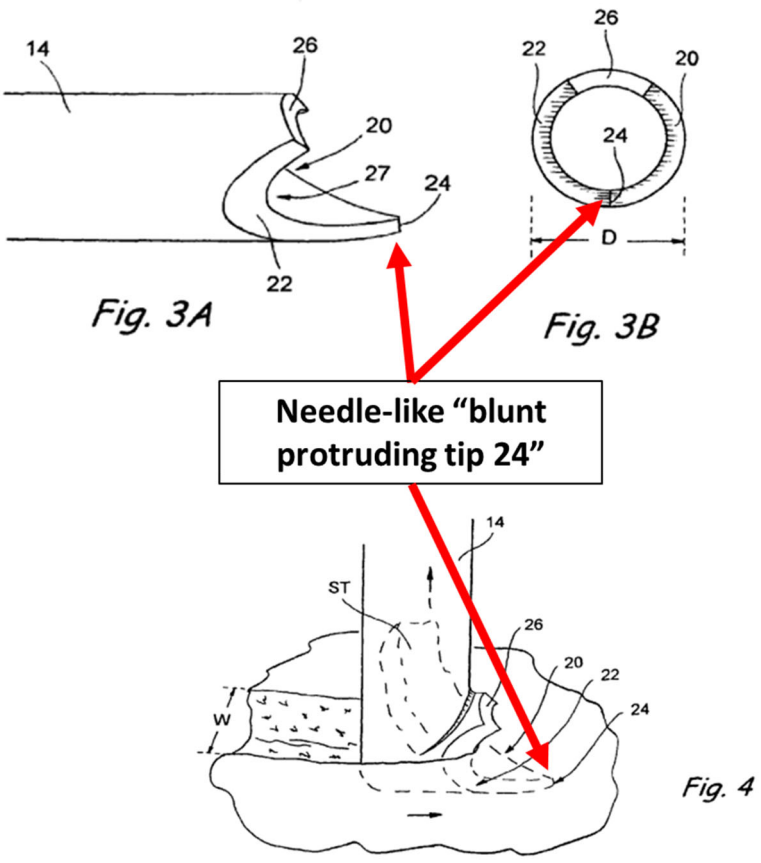
C. "blunt protruding tip"

The scope of the term "blunt protruding tip" must encompass devices with tips that can pierce TM tissue, ***including needles and needle-like devices***. *Id.*, ¶91.

The '155 patent describes a "needle cutter device 10" with a "blunt protruding tip 24" that is "located on the bottom of the distal end of the cutting tube" and is used to "***facilitate insertion***" of the device into its "intended location" in SC. Ex.1001, 3:13-24, 6:9-11. A POSITA would understand insertion of the device into SC necessarily requires the "blunt protruding tip 24" penetrate TM tissue to reach the device's "intended location" in SC. Ex.1003, ¶92. The patent fails to provide any other explanation as to what constitutes a "blunt" tip, like how sharp or dull the tip must be to be "blunt." While the ordinary meaning of "blunt" may be, for example, not sharp,[4] the '155 patent requires that the claimed "blunt protruding tip" has at least some sharpness to allow the tip to pierce the TM to "facilitate insertion" of the device into SC. *Id.*, ¶¶92-93.

[4] *See, e.g.*, *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1368 (Fed. Cir. 2003) ("the specification or the prosecution history of a patent may alter the meaning of a claim term from its conventional usage").

Importantly, the scope of the term "blunt protruding tip" ***cannot exclude needles and needle-like devices***. *Id.* 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) (citations omitted). Here, the ***sole embodiment*** disclosed in the patent is "needle cutter device 10," which has a tip meant for penetrating TM tissue, is made from the same material in the same way as a standard needle, and as shown in the figures has a needle-like tip. Ex.1001, 3:3-24, 4:60-64, 6:9-11; Ex.1003, ¶93.



Ex.1001, Figs.3A, 3B, 4 (annotated). "[B]lunt protruding tip" must encompass the tips of needles, needle-like devices, and other devices with tips that penetrate TM tissue allowing for insertion into SC. Ex.1003, ¶93.

D. "blunt top edge"

Like "blunt protruding tip," the patent provides little explanation for "blunt top edge." Other than stating the "blunt top edge" is located on "needle cutter device" (*i.e.*, "at the top of the distal end of the cutting tube") and how "blunt top edge" is formed (*i.e.*, cutting the end of "standard tubing"), the patent provides no explanation of what constitutes a "blunt" edge, including how sharp or dull the edge must be to be "blunt." *See* Ex.1001, 3:15-16, 4:60-64; Ex.1003, ¶¶94-95. Regardless, for the reasons discussed above, the term "blunt top edge" cannot exclude needles and needle-like devices because that is the ***sole embodiment*** disclosed by the patent. *See supra*, §V.C. The term ***must*** encompass the top edge of the cutting area of devices intended for penetrating TM tissue including needles and needle-like devices. Ex.1003, ¶96.

VI. Detailed Explanation of Unpatentability

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

1. Overview of Quintana

Quintana[5] 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, ¶97.

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

[5] Quintana was not cited during prosecution of the '155 patent.

"stripped" from SC. *Id.* The needle advances 100-120° through SC. *Id.* The technique resulted in an IOP decrease in most cases. *Id.*, 3; Ex.1003, ¶98.

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, ¶99. 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 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, ¶100. 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).

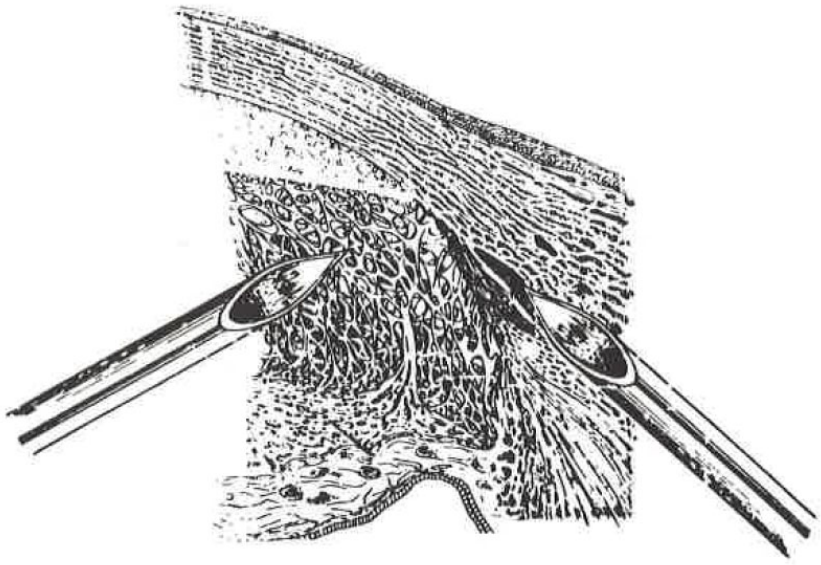
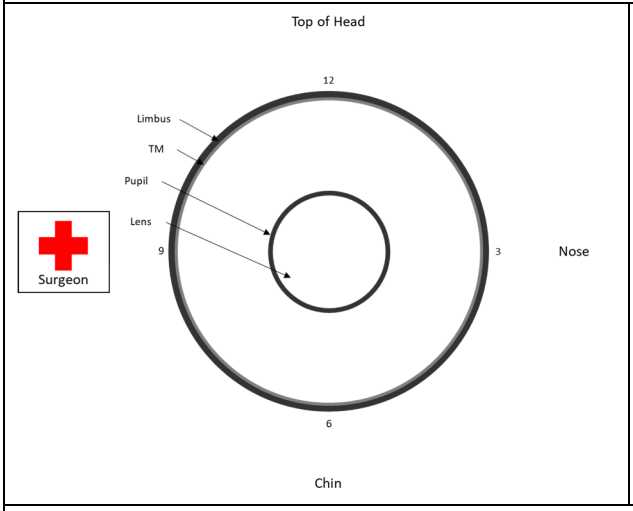
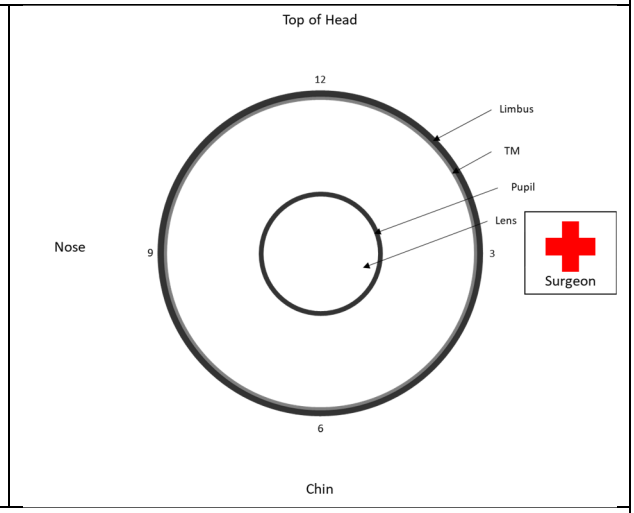
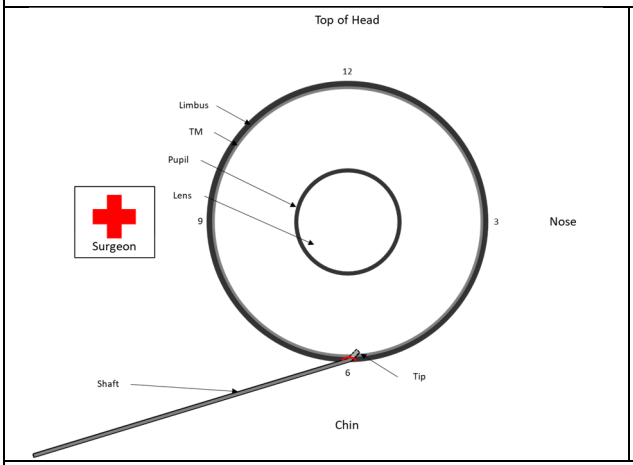
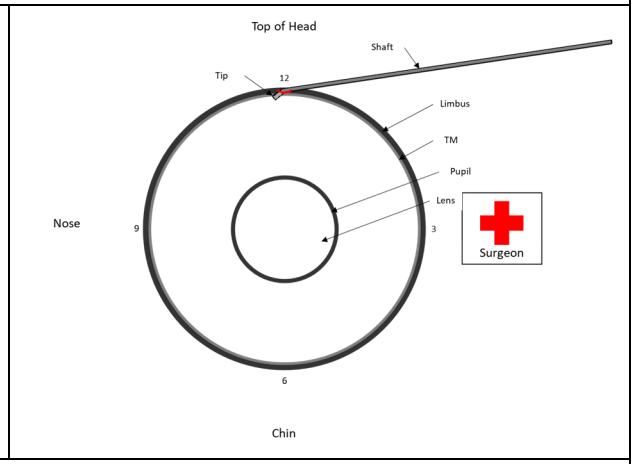
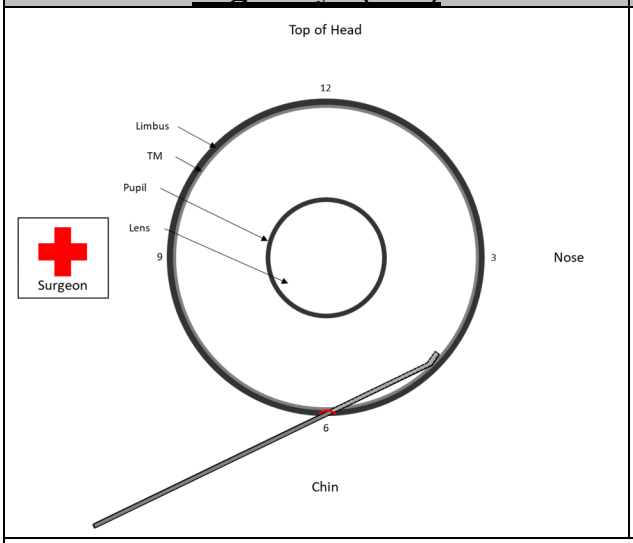
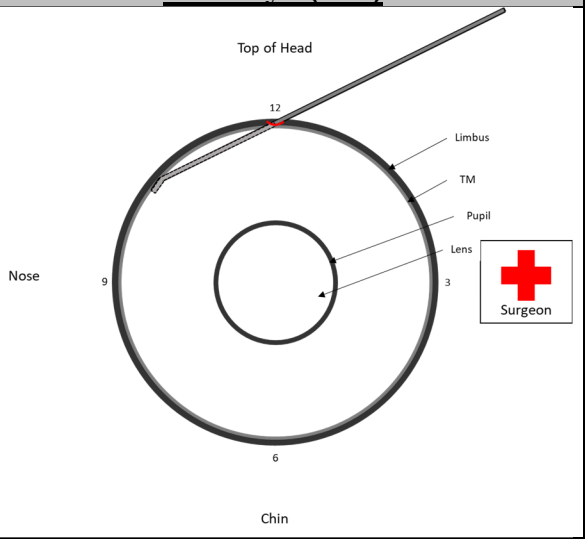


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

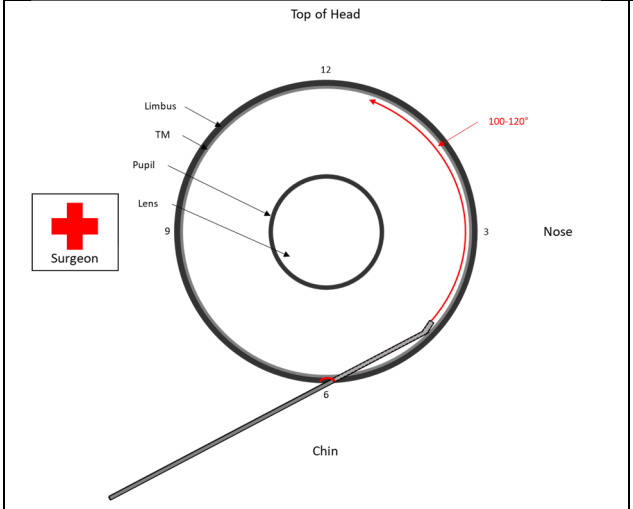
Ex.1004, 4.

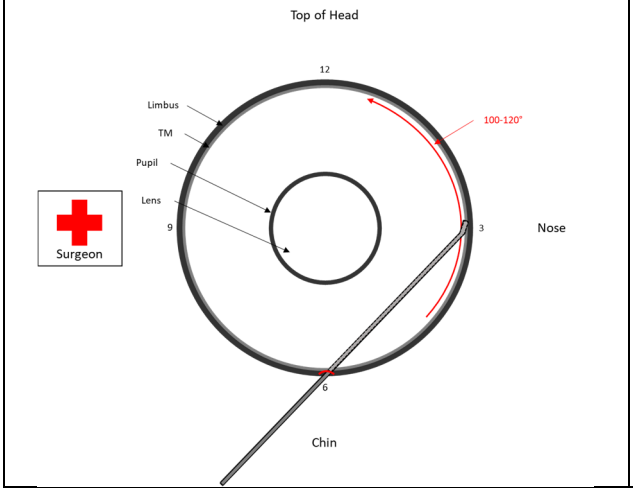
At the direction of NWM's expert, Dr. Peter Netland, illustrations depicting Quintana's procedure were prepared. Ex.1003, ¶101. The illustrations show a patient's right and left eye with the general location and progression of Quintana's needle throughout the procedure. *Id.*

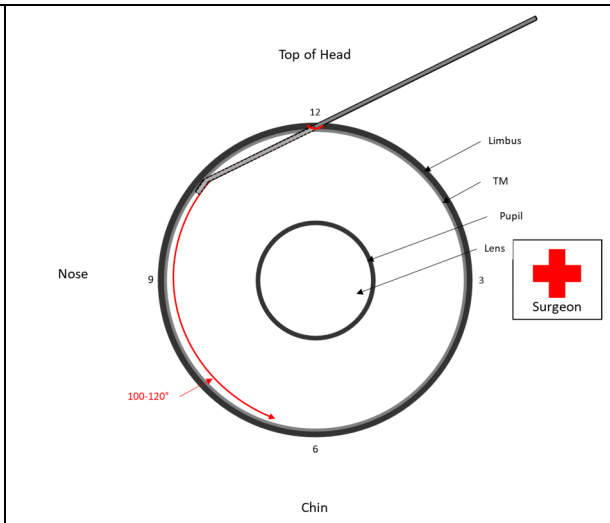
Right Eye (OD)	Left Eye (OS)
Surgeon positioned on temporal side of patient. Ex.1004, 3-4.	
	
"The needle penetrates the anterior chamber at 6 hours (right eye) or 12 hours (left eye) through the scleral side of the limbus." Id., 4.	
	
Needle tip introduced into SC with convexity of tip facing external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

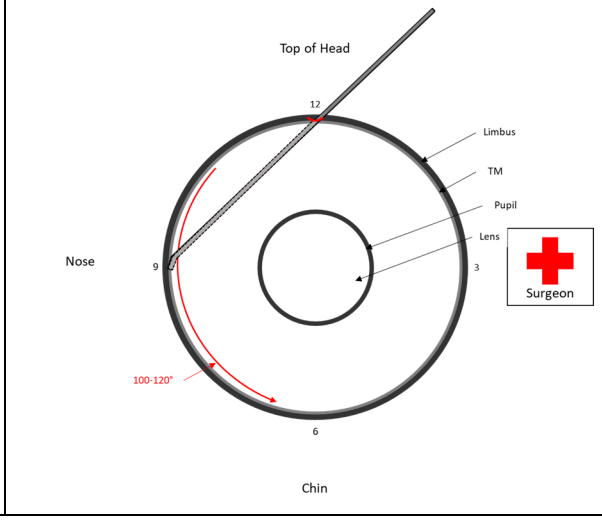
Right Eye (OD)	Left Eye (OS)
	

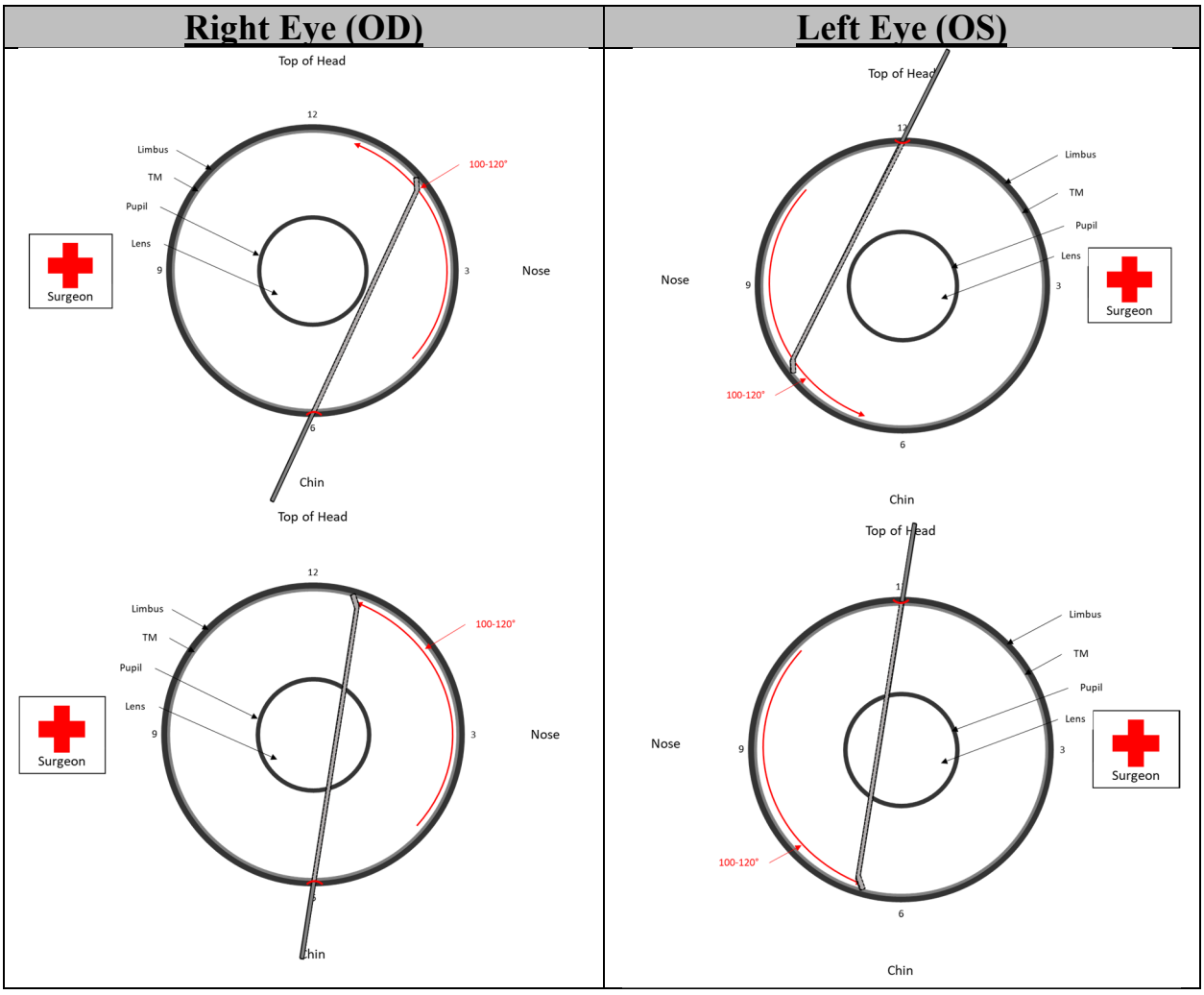
"A 100-120° trabeculotomy can be achieved." Id.











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

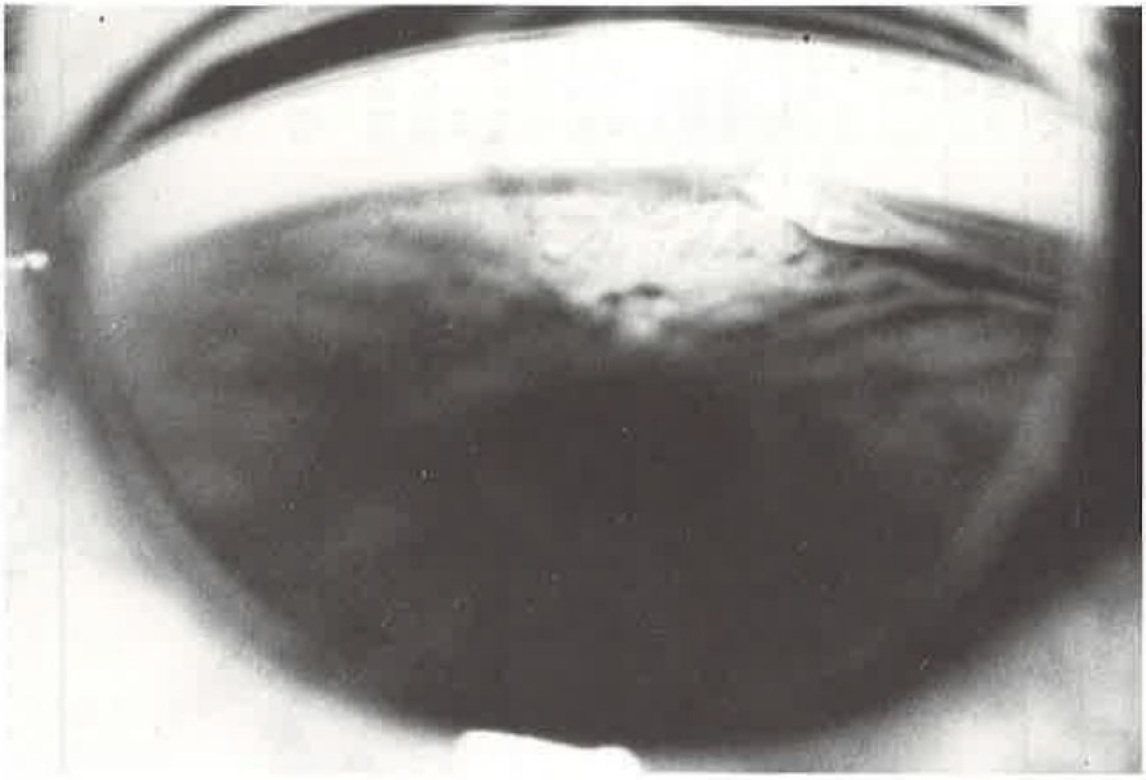
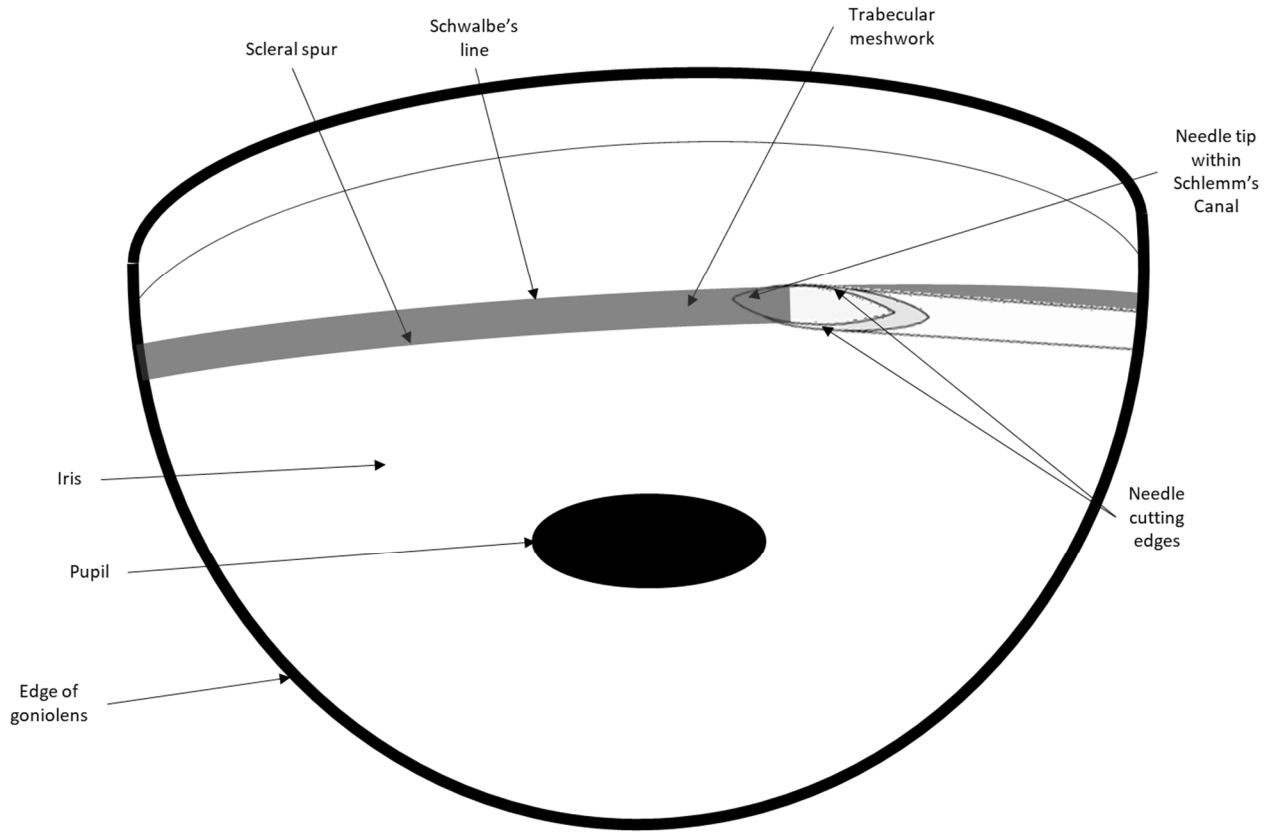


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

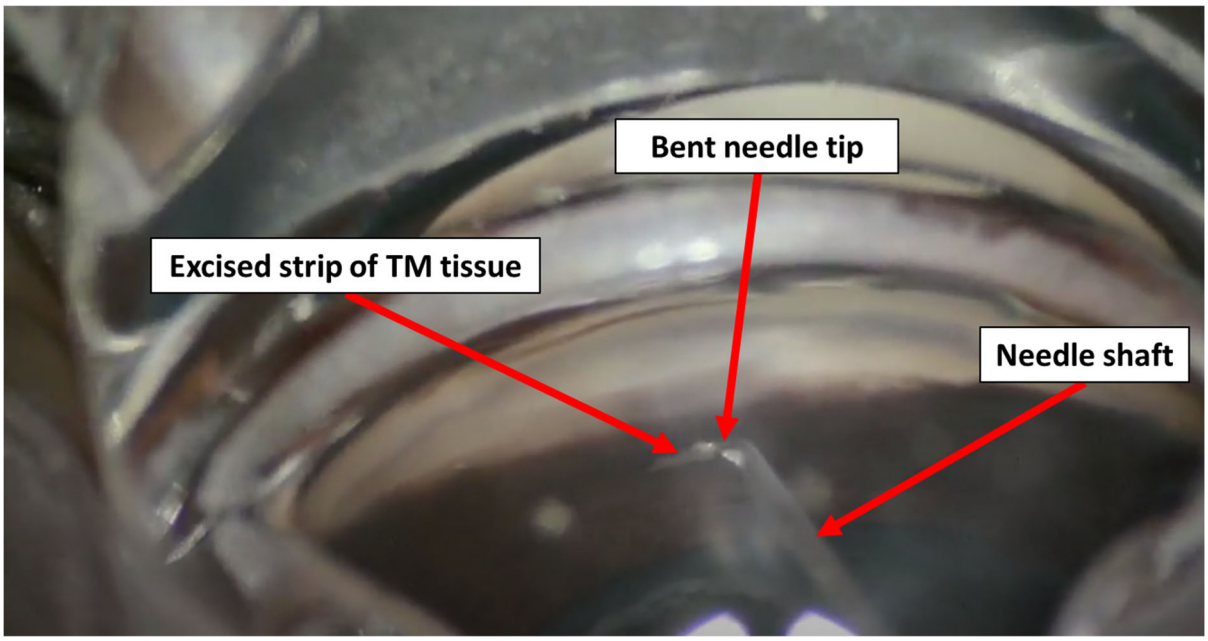
Id., Fig.2. To more clearly visualize Fig.2, the following schematic was prepared at Dr. Netland's direction. Ex.1003, ¶102.



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, ¶¶104-06. Not only is this clear from the reference, Quintana's basic technique has been used in similar procedures to remove strips of TM from SC. *Id.* For example, Shute (Ex.1020) describes a procedure called "bent ab interno needle goniectomy" ("BANG") involving, 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,

¶104. Another surgeon posted a video online showing performance of the BANG procedure, 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, ¶¶105-06. 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, ¶¶105-06.

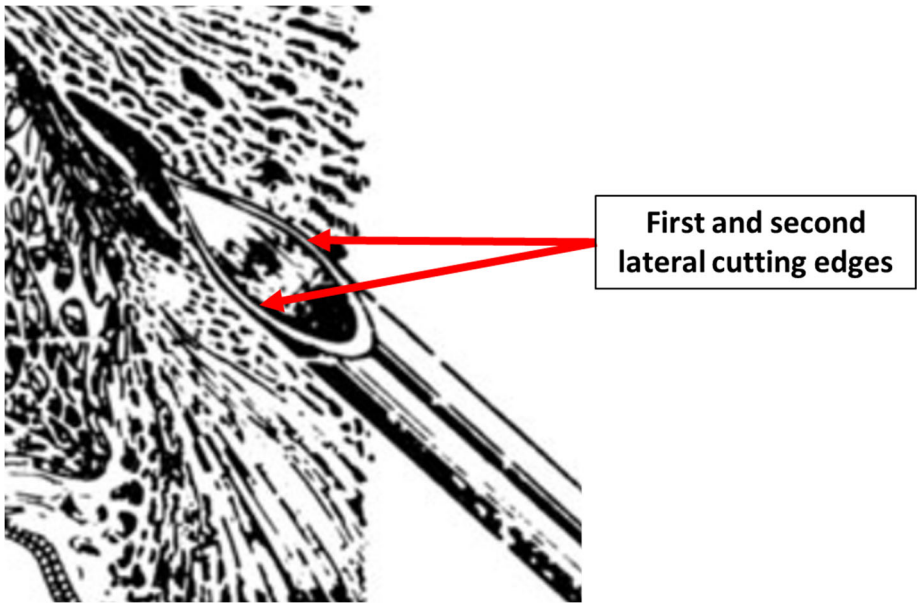


These examples provide further evidence that procedures like Quintana's that use standard needles having bent tips to excise TM tissue from within the AC result in cutting "strips of tissue" from the TM. *Id.*

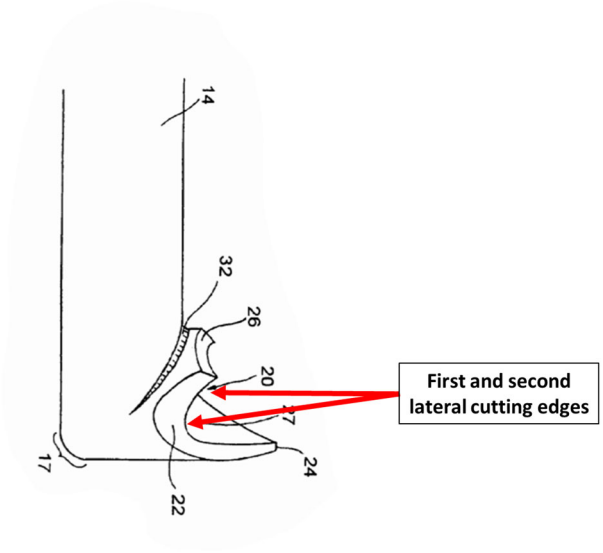
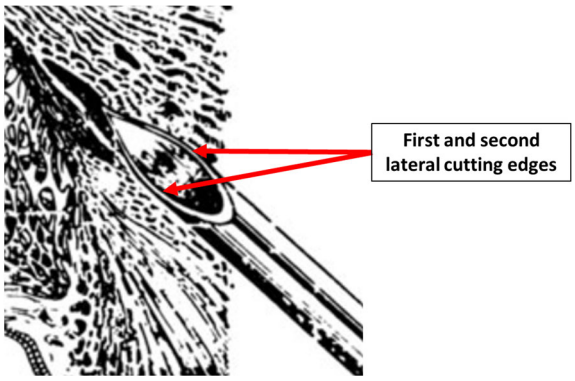
2. Claim 1

a. Element 1.p

Quintana performs a surgical procedure using a "***dual blade device***," *i.e.*, a device with two cutting edges capable of cutting tissue. *See supra*, §V.B; Ex.1003, ¶119. Quintana uses a needle with the tip bent 20-30°. Ex.1004, 3. As shown below, Quintana's needle has two spaced-apart, lateral cutting edges on opposite sides of the needle tube:



Ex.1004, Fig.1 (annotated). Quintana's needle is nearly identical to the "needle cutter device" of the patent—both having lateral cutting edges on opposite sides of a needle tube:

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

Ex.1003, ¶120. The needle tip with lateral cutting edges, *see infra*, §VI.A.2.d, is inserted into SC and “strip[s]” the TM, which “achieves a section of the TM.” Ex.1004, 3-4. Because Quintana’s needle has dual cutting edges that cut tissue, the needle is a “dual blade device.” Ex.1003, ¶121.

Quintana’s needle is used in an “***ab interno***” procedure within a human eye. *Id*., ¶122. An “ab interno” procedure approaches the TM from ***within*** the AC inside the eye. *See supra*, §V.A. Quintana’s procedure is “ab interno” because the needle approaches the TM from ***within*** the AC. Ex.1004, 4. Figure 2 shows Quintana’s needle stripping TM within the AC. *Id.* Moreover, Quintana uses a goniolens to visualize the angle—notable because a goniolens is only necessary in “ab interno” procedures. Ex.1003, ¶¶122-24.

A POSITA ***could not*** interpret Quintana's procedure as "ab externo." *Id.*, ¶¶125-26. Nothing in Quintana indicates that the procedure involves creating an opening on the eye's exterior and approaching the TM through the opening from ***outside*** the patient's eye. *Id.* The fact Quintana describes penetrating "through the scleral side of the limbus" does not indicate the procedure is "ab externo." *Id.* Quintana states "[t]he needle ***penetrates the anterior chamber***" and approaches the TM from ***within*** the AC, indicating the procedure is "ab interno." Ex.1004, 4; Ex.1003, ¶¶125-26.

Quintana's procedure is performed to "***remove a strip of [TM] tissue***." The method "achieves a ***section of the TM***" and Quintana 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.

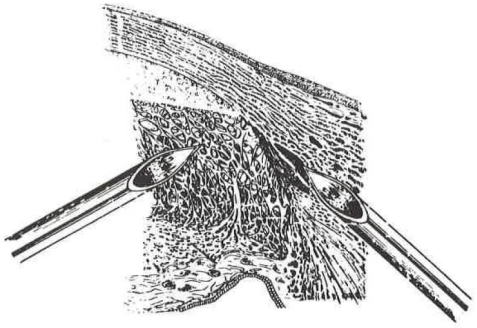


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

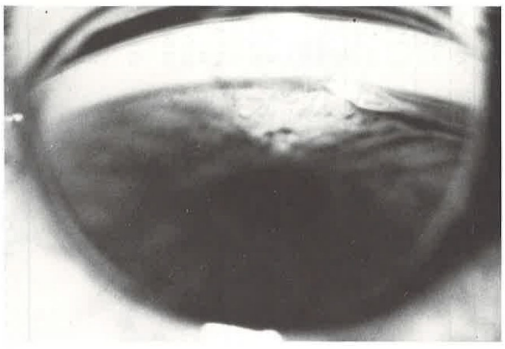


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

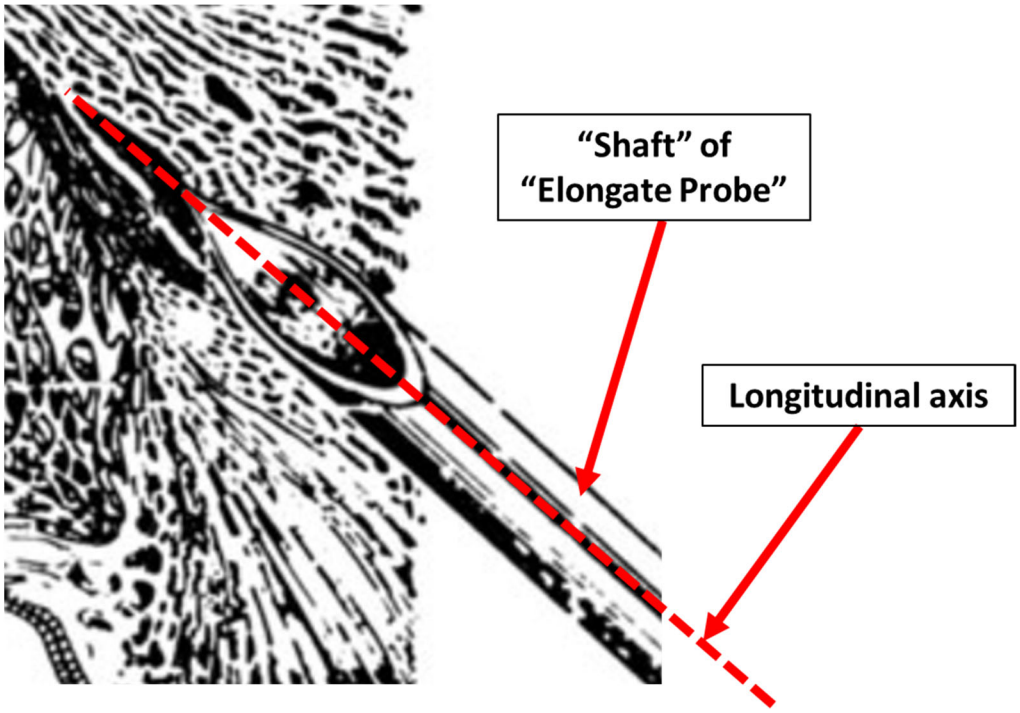
Id., Figs.1-2. These statements demonstrate that a "strip of tissue" is removed from the TM. *Id.*, 4; Ex.1003, ¶¶127-28. As discussed, Quintana's needle has dual, spaced-apart cutting edges. *See also infra,* §VI.A.2.e. Both cutting edges contact the TM and concurrently cut the TM as the tip advances through SC, which necessarily removes a strip of tissue from the TM. Ex.1003, ¶128; *see also id.*, ¶¶104-06.

b. Element 1.a

Quintana states that "[t]he needle is inserted into a syringe." Ex.1004, 3. A POSITA would appreciate that syringes are grasped by a human operator's hand and acts as a "***handle***" for Quintana's device. Ex.1003, ¶129.

c. Element 1.b

Quintana uses a needle inserted into a syringe, and thus the needle is an "***elongate probe***" extending from the syringe or "handle." Ex.1004, 3. 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.

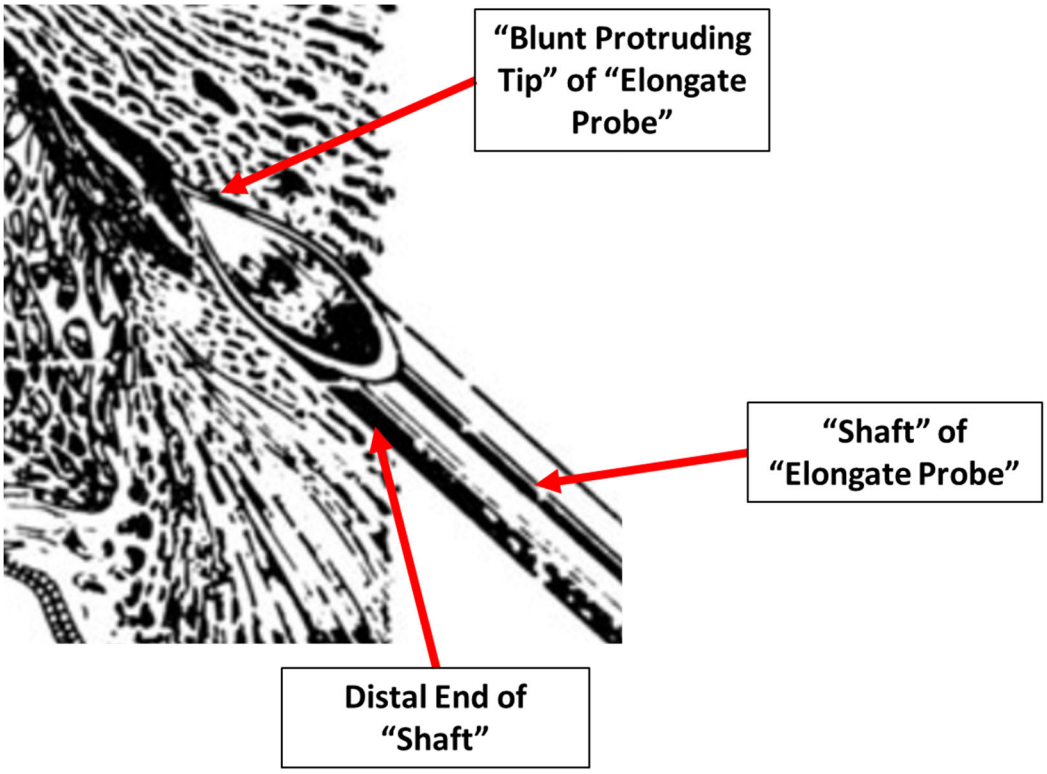


Ex.1004, Fig.1 (annotated); Ex.1003, ¶130.

d. Element 1.c

As explained above, the term "***blunt protruding tip***" must encompass devices with tips that can pierce TM tissue, including needles and needle-like devices, and cannot exclude such devices based on the perceived sharpness of the tip. *See supra*, §V.C; Ex.1003, ¶131.

As shown below, the portion of Quintana's needle extending from the distal end of the shaft is a "blunt protruding tip."



Ex.1004, Fig.1 (annotated). This portion of Quintana's needle is, like the "blunt protruding tip" of the patent's "needle cutter device," located on the bottom of the distal end of the needle tube, is used to facilitate insertion of the tip through the TM into SC, and guides the needle through SC. *Id.*, 4; Ex.1001, 3:10-24; Ex.1003, ¶132.

This portion of Quintana's needle "***extends in a lateral direction from a distal end of the shaft***." The figure above shows the tip of the needle extending laterally from the distal end of the shaft. Ex.1003, ¶133. Quintana also states the tip is bent 20-30° and points toward the AC during the procedure. *Id.*; Ex.1004, 3-4.

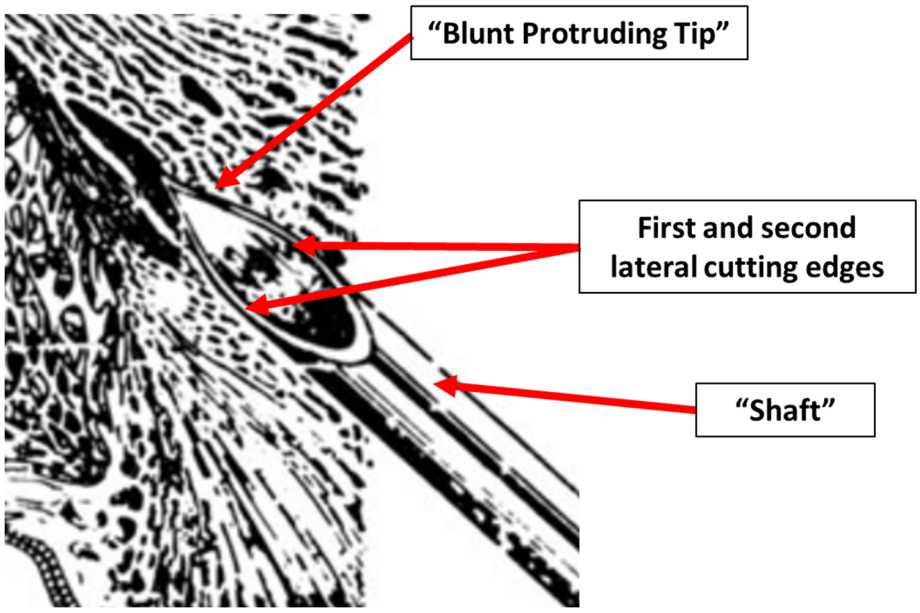
Quintana's needle has the claimed "***bend or curve.***" Quintana's needle "tip" (including the "blunt protruding tip") is bent 20-30° so the convexity of the tip faces the external wall of SC during the procedure to avoid damage to the external wall.[6] Ex.1004, 3 ("we ***bend the tip 20-30°*** with a needle-holder"), 4 ("This is why we ***bend the tip*** and we point it towards the anterior chamber."). A POSITA would appreciate that this angle is relative to the longitudinal axis of the shaft and is within the 30 to 90 degree range in the claim. Ex.1003, ¶134. *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).

e. Element 1.d

Quintana's needle has "***first and second lateral cutting edges formed at stationary side-by-side locations on the shaft***." *See supra,* §VI.A.2.a. Quintana's

[6] Quintana generally refers to the end of the needle, including the bent portion, as the "tip." Ex.1004, 3. As explained above, the blunt protruding tip per the patent is the portion at the end of the needle that is advanced through SC. To avoid confusion, the portion of Quintana's needle that is bent will be referred to as the "bent" or "angled" portion.

needle has cutting edges at fixed locations on opposite sides of the distal end of the needle tube (*i.e.*, shaft).[7]

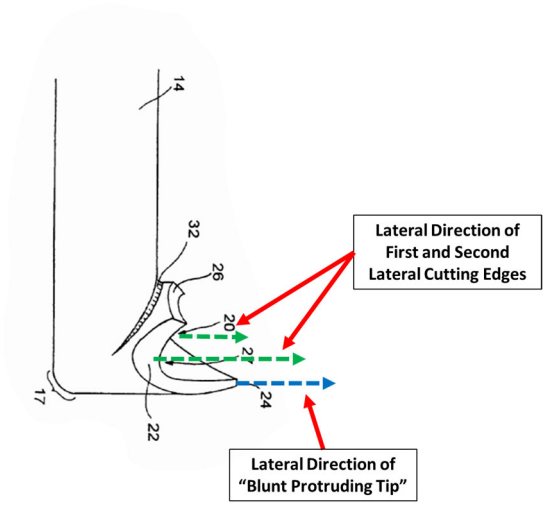
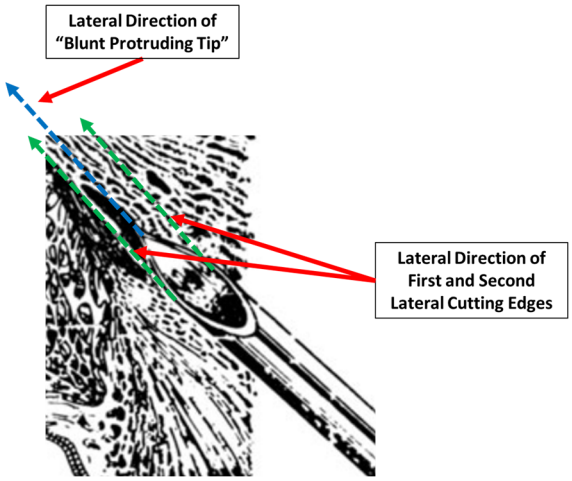


Ex.1004, Fig.1 (annotated); Ex.1003, ¶¶135-36.

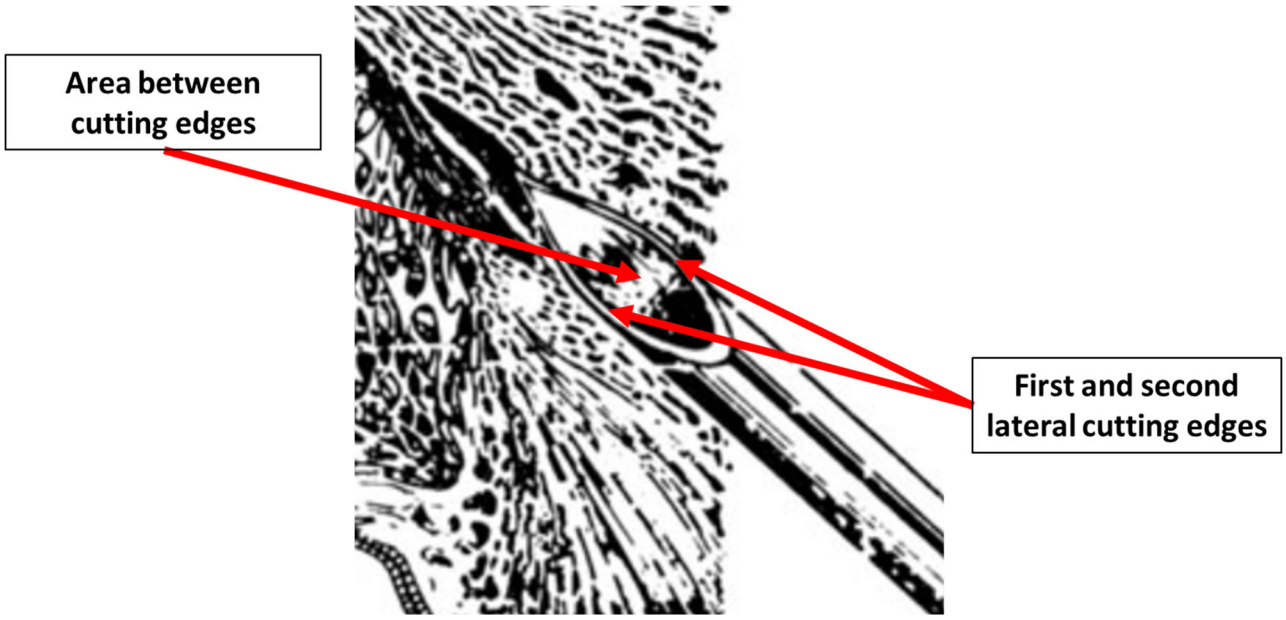
These cutting edges "***fac[e] in the same lateral direction as the blunt protruding tip***." The figure above shows both the cutting edges and blunt protruding tip facing in the direction in which the needle advances through SC. Ex.1003, ¶137. Additionally, the cutting edges and blunt protruding tip of

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

Quintana's needle face in the same direction as do the patent's "needle cutter device." *Id.*

'155 patent, Fig.3D (annotated)	Quintana, Fig.1 (annotated)
	

Finally, the cutting edges are "***spaced apart such that an area exists between the first and second lateral cutting edges***." As shown below, there is an area between the spaced-apart cutting edges of Quintana's needle.

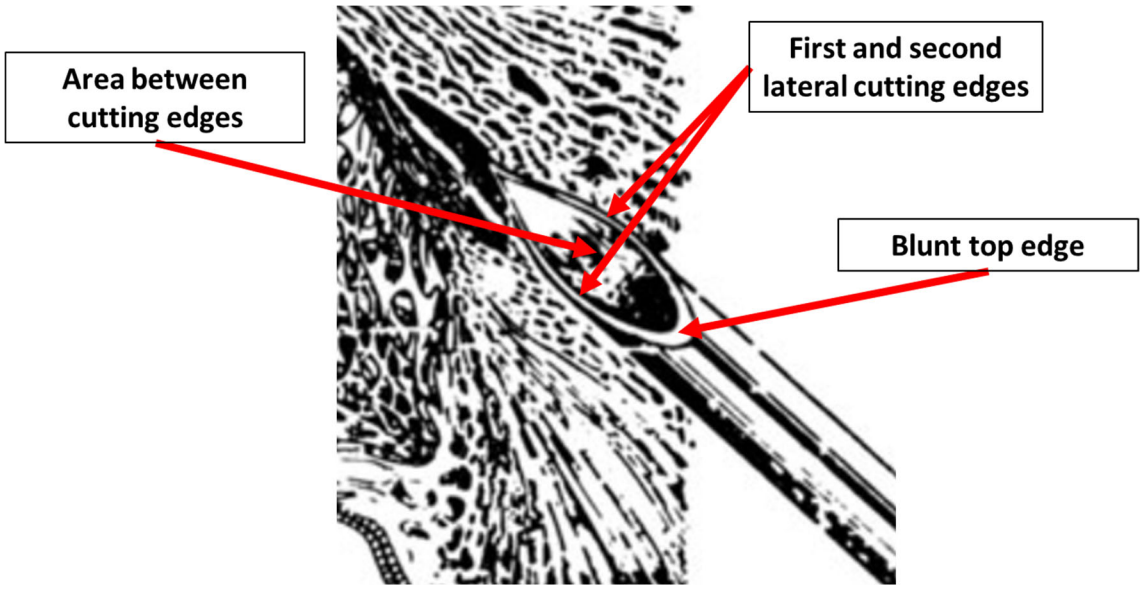


Ex.1004, Fig.1 (annotated); Ex.1003, ¶139.

f. Element 1.e

As explained above, the term "***blunt top edge***" must encompass the top edge of the cutting area of devices intended for penetrating TM tissue, including needles and needle-like devices. *See supra*, §V.D; Ex.1003, ¶140.

As shown below, the portion of Quintana's needle at the distal end of the shaft near where the bevel begins is a "blunt top edge." Ex.1003, ¶140.

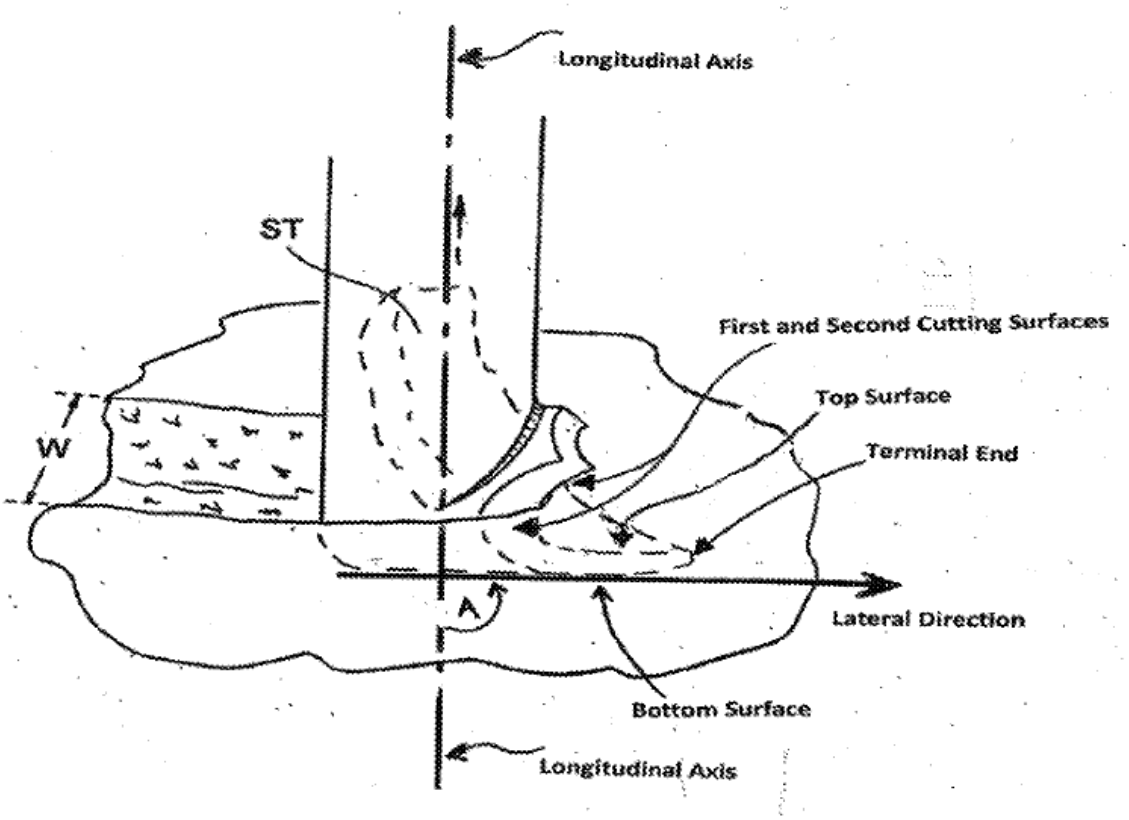


Ex.1004, Fig.1 (annotated). This portion of Quintana's needle is, like the "blunt top edge" of the patent's "needle cutter device," located at the top of the distal end of the needle tube. *Id.*, 4; Ex.1001, 3:10-24; Ex.1003, ¶140.

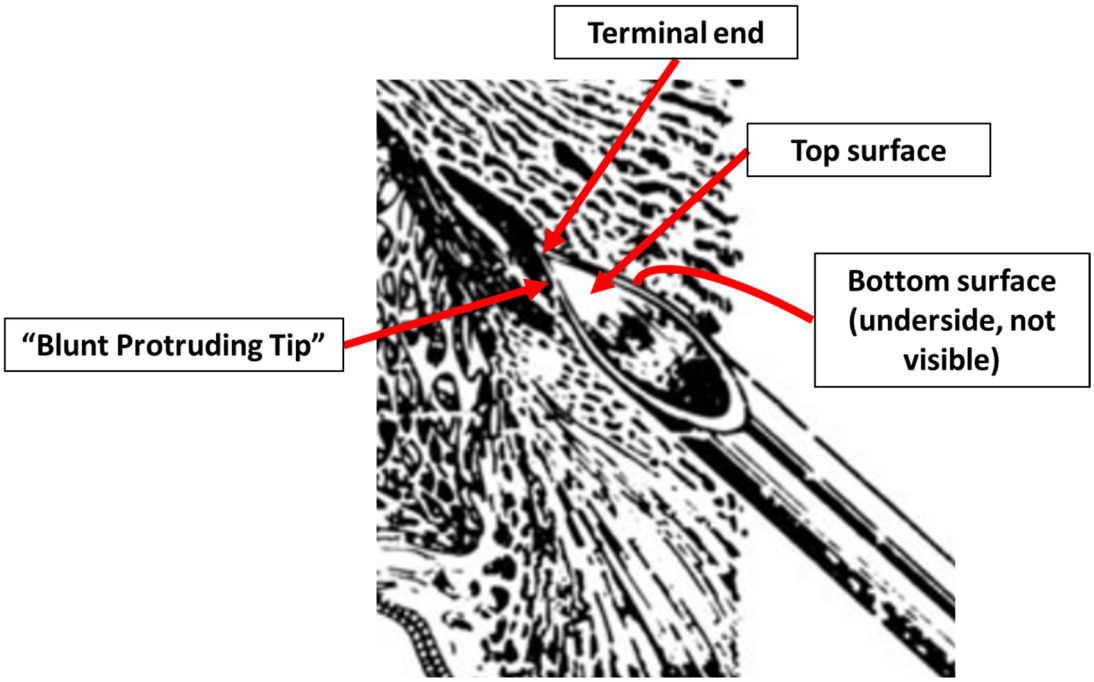
This portion of Quintana's needle "***extends transversely from a top end of the first lateral cutting edge to a top end of the second lateral cutting edge***." The blunt top edge of Quintana's needle extends between the top end of one cutting edge to the other, the same as the blunt top edge of the patent's "needle cutter device." Ex.1003, ¶141. The figure above also shows the "blunt top edge" of Quintana's needle is "***above the area between***" the cutting edges, as it is on the top of the needle tube above the space between the cutting edges when in an operative position. *Id.*

g. Element 1.f

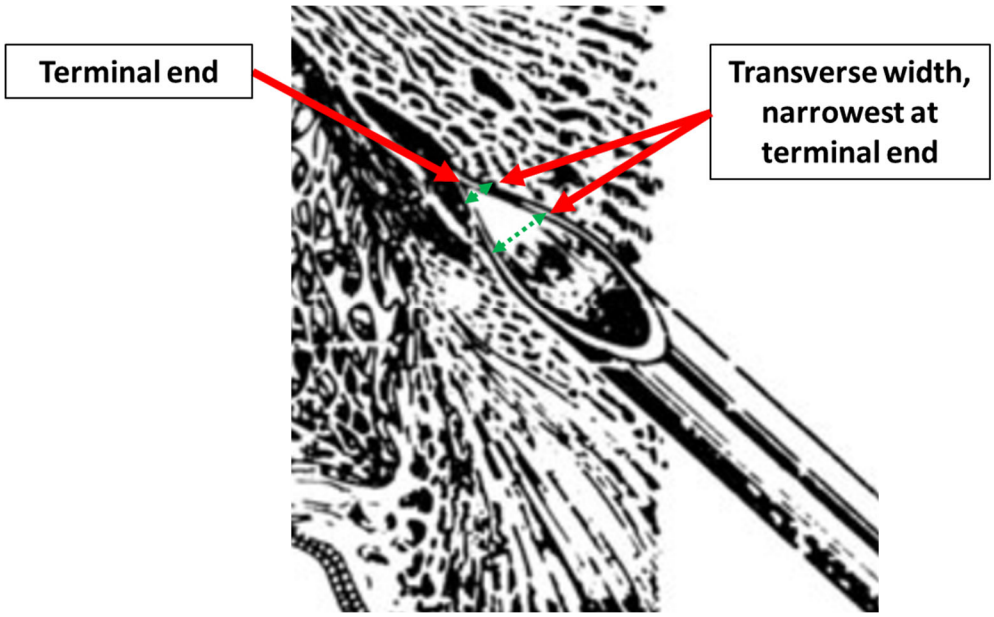
As explained, during prosecution of the '155 patent, applicant provided an annotated version of Fig.4 of the patent labeling various claim elements, including the "***top surface***," "***bottom surface***," and "***terminal end***" of the "blunt protruding tip."



Ex.1002, 199. As shown below, the blunt protruding tip of Quintana's needle has these same features, *i.e.*, a "top surface," a "bottom surface" (which is not visible but a POSITA would understand to be on the underside of the tip opposite the top surface), and a "terminal end."



Ex.1004, Fig.1 (annotated); Ex.1003, ¶142. Further, the "transverse width" of the "blunt protruding tip" is narrowest at the terminal end, as shown below.



Ex.1004, Fig.1 (annotated); Ex.1003, ¶143.

h. Element 1.g

The blunt protruding tip of Quintana's needle is "***below the area between***" the cutting edges, as it is on the bottom of the needle tube below the space between the cutting edges when in an operative position, just as is the "blunt protruding tip" of the patent's "needle cutter device." Ex.1003, ¶144.

Moreover, the blunt protruding tip "***protrud[es] in the lateral direction beyond***" the cutting edges "***such that tissue may pass over the top surface of the blunt protruding tip before coming into contact with the first and second lateral cutting edges.***" The needle's cutting edges are located at fixed locations on the distal end of the shaft and the blunt protruding tip extends farther laterally beyond the cutting edges to penetrate the TM tissue. *Id.*, ¶145. Quintana explains that the tip penetrates the TM, enters SC, and progresses in the angle to "strip[]" TM tissue from SC. Ex.1004, 4. The figure below shows the bent portion of Quintana's needle (including the blunt protruding tip) in SC, with the needle's cutting edges contacting and "stripping" the TM:

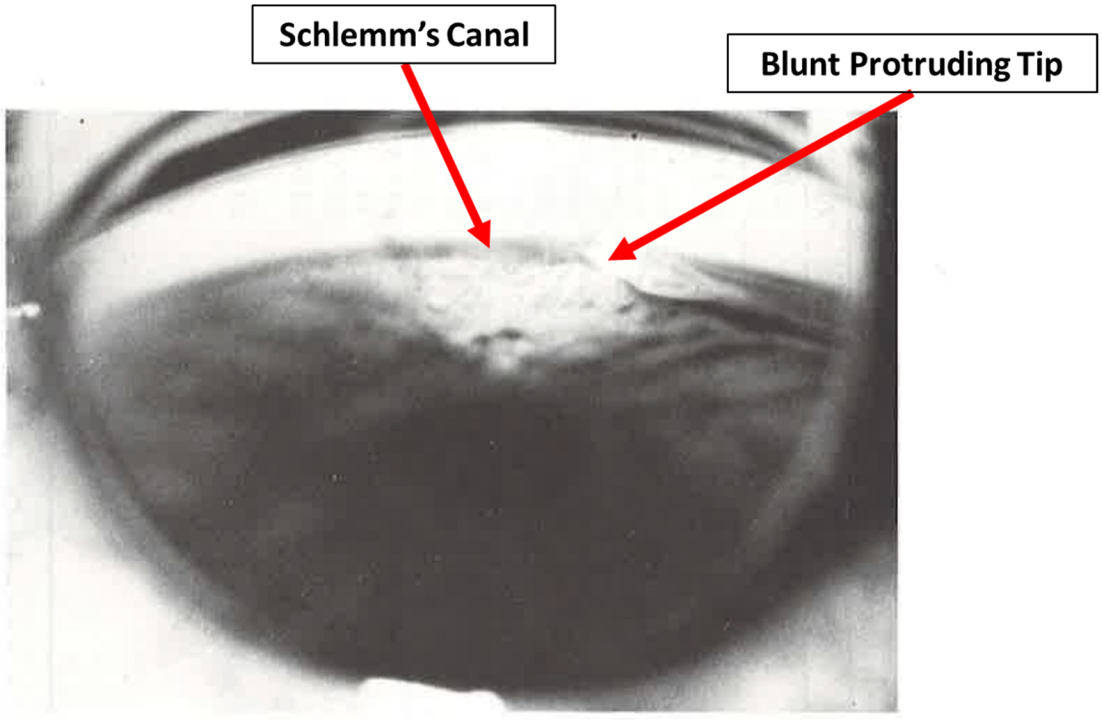


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

Id., Fig.2 (annotated). A POSITA would recognize that as the blunt protruding tip of Quintana's needle advances through SC, TM tissue necessarily passes over the top surface and contacts the needle's cutting edges, resulting in "stripping" of tissue from the TM. Ex.1003, ¶146.

i. Element 1.h

Quintana's needle is "***sized to pass through an incision formed in the eye by a 1.5mm slit knife***." Quintana's needle penetrates the AC, is inserted into the AC, and progresses through the angle. Ex.1004, 4, Figs.1-2. Thus, Quintana's needle, including the distal portion of the shaft and blunt protruding tip, is sized to pass through an incision in the eye. Ex.1003, ¶147.

The claim does not require ***forming*** an incision but instead that the distal portion of the shaft and blunt protruding tip are ***sized*** to pass through an incision formed by a 1.5mm slit knife. A 1.5mm slit knife is a knife with a generally flat blade having a width of 1.5mm, which would form an incision with a width of 1.5mm (or greater). *Id.*, ¶148. The distal portion of the shaft and blunt protruding tip of Quintana's needle are sized to pass through such an incision, as Quintana's needle is a "0.4x15mm needle" with a diameter of 0.4mm and a length of 15mm. Ex.1004, 3. A POSITA would understand a needle with a diameter of 0.4mm would pass through an incision having a width of 1.5mm or greater. Ex.1003, ¶148.

j. Element 1.i

The "blunt protruding tip" is "***sized to fit within***" SC and "***to be advanceable through [SC] with [TM] tissue passing over its top surface and into contact***" with the cutting edges. Quintana's needle 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. As shown below, the bent portion of Quintana's needle (including the blunt protruding tip) is inserted in SC:

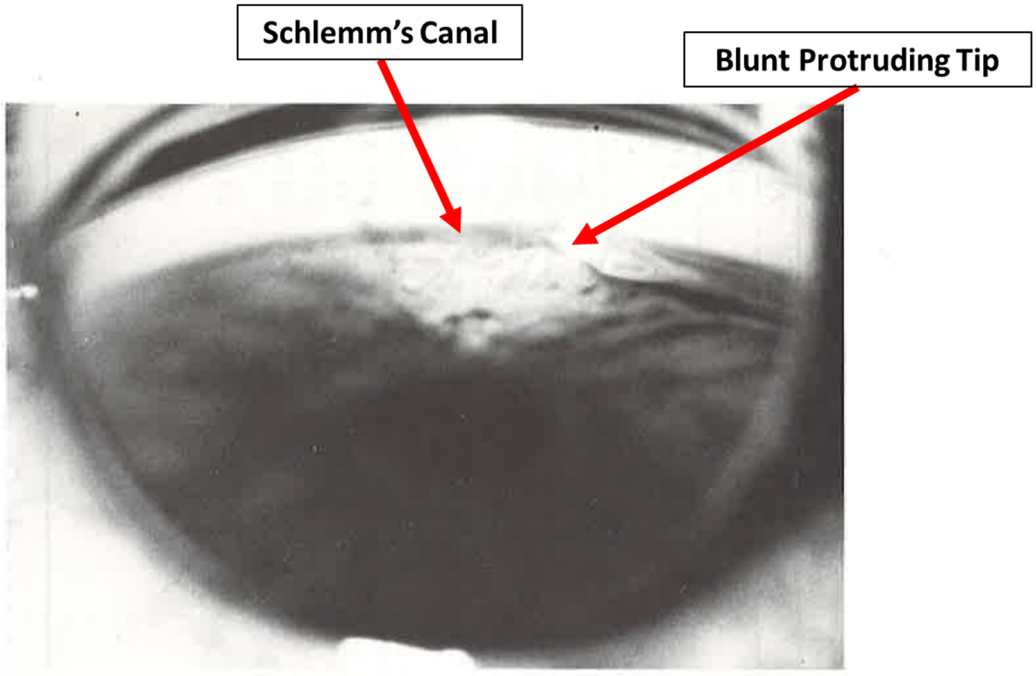
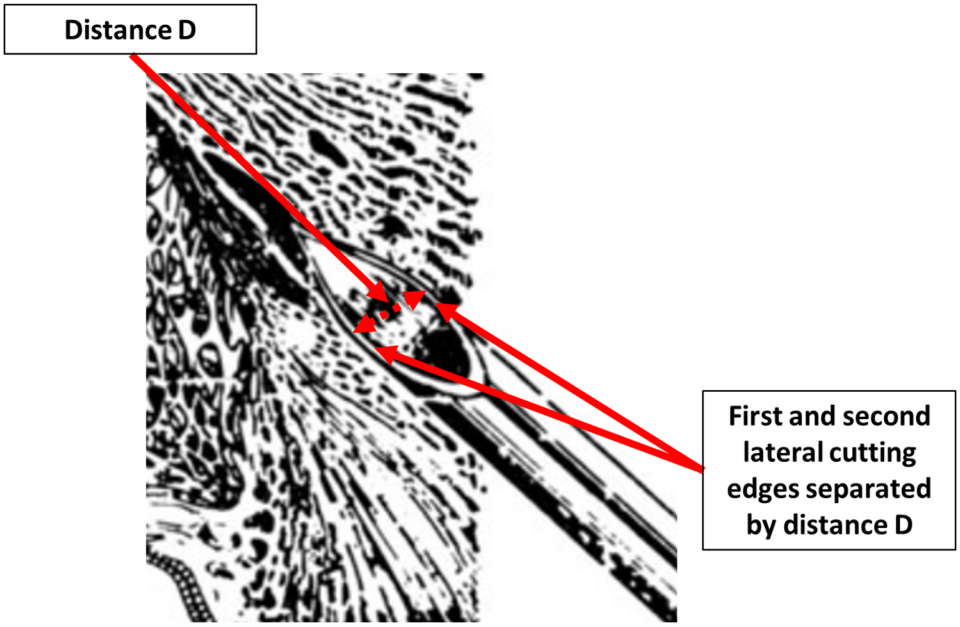


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

Id., Fig.2 (annotated); Ex.1003, ¶149. TM tissue necessarily passes over the top surface of the blunt protruding tip and contacts the needle's cutting edges as the needle advances through SC. *See supra,* §VI.A.2.h; Ex.1003, ¶150. The cutting edges concurrently cut the TM tissue, resulting in removal of a strip of TM tissue. Ex.1003, ¶150.

3. Claim 2

Quintana discloses the limitations of claim 1. *See supra*, §VI.A.2. Further, the needle's cutting edges are spaced apart such that an area exists between the cutting edges, *see supra*, §VI.A.2.e, and as shown below the distance from one cutting edge to the other across this area is "distance D":



Ex.1004, Fig.1 (annotated); Ex.1003, ¶152.

The strip of tissue created when the cutting edges cut TM tissue would necessarily have a width W that is "substantially equal to distance D" because the cutting edges of Quintana's needle concurrently cut the TM tissue, resulting in a strip having a width corresponding to the distance between the cutting edges (*i.e.*, "distance D"). Ex.1003, ¶153.

4. Claim 3

Quintana discloses the limitations 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, 1:41-46. Thus, claim 3 does not cover a novel or nonobvious feature of the alleged invention.

Regardless, Quintana's procedure achieved a strip of tissue with a length of about 2 to 10 mm. Quintana explains that "[a] 100-120° trabeculotomy can be

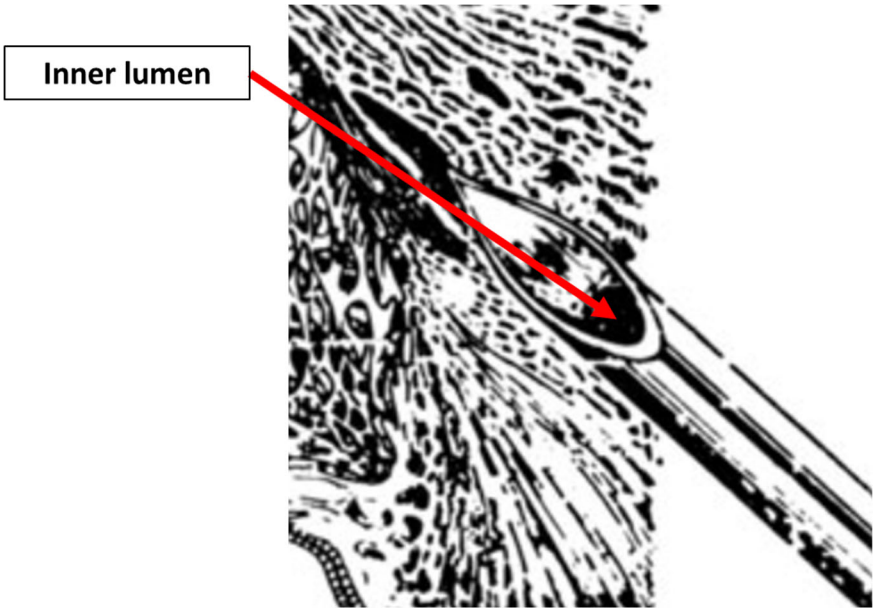
achieved" using its technique. Ex.1004, 4. Given that the circumference of SC (and thus, the TM) is about 36mm, *see* Ex.1010, 5, a "100-120° trabeculotomy" would achieve strips of tissue within the 2 to 10 mm range claimed. Ex.1003, ¶¶156-57. For example, a 100° section of TM would be about 10.08mm 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 can also be achieved. *Id.*

5. Claim 6

Quintana discloses the limitations of claim 1. *See supra*, §VI.A.2. Further, Quintana's needle is inserted into a syringe and held in the surgeon's hand. Ex.1004, 3-4; Ex.1003, ¶159. A POSITA would understand Quintana's needle is "manually operable" because the device is operated by hand to remove strips of TM tissue. Ex.1003, ¶159.

6. Claim 7

Quintana discloses the limitations of claim 1. *See supra*, §VI.A.2. As explained, Quintana's needle is an "elongate probe" having a shaft. *See supra,* §VI.A.2.c. Needle shafts are made of tubing having at least one lumen (*i.e.*, canal or cavity). Ex.1003, ¶161. As shown below, Quintana's needle has an opening to an inner lumen at the end of the shaft.



Ex.1004, Fig.1 (annotated); Ex.1003, ¶161.

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

1. Claim 4

Quintana discloses the limitations of claim 1. *See supra*, §VI.A.2. Further, Quintana's needle has a tip bent 20-30°. Ex.1004, 3. Because the "bottom surface" is part of the blunt protruding tip, bending the needle's tip at an angle as disclosed by Quintana would orient the bottom surface at the same angle as the blunt protruding tip. Ex.1003, ¶164.

It was well-known in the art to use devices having tips, points, or shafts bent at various angles to meet the needs of a given surgery as taught in Quintana itself and various other references. Ex.1003, ¶165. For example, Johnstone discloses a procedure using "a cystotome with the point oriented at right angles to the shaft"

inserted through the TM into SC with the blunt surface facing the external wall of SC so as to cut the inner wall of the canal and the TM "while limiting damage to the external wall of the canal." Ex.1005, 2; *see also* Ex.1006, 4:49-54 (angle of device's cutting edges vary "depending on surgical requirements").

It would have been obvious to modify Quintana's needle by bending the tip at different angles, including the right angle (*i.e.*, 90 degrees) known in the prior art. Ex.1003, ¶¶166-67. First, bending the tip to 90 degrees would have involved combining prior art elements according to known methods or simple substitution to obtain predictable results—for example, combining Quintana's needle with known bends or curves of 90 degrees. *Id.*

Second, it would have been obvious to try simple, straight-forward variations to Quintana's method, such as bending the tip of the needle to different angles. *Id.* Given that there are a finite number of angles to bend the needle tip, a POSITA would have been motivated to try variations, such as an angle of 90 degrees, to expand or improve on Quintana's results. *Id.* A POSITA would have expected success given the successful use of devices bent to different angles in the prior art. *Id.*

Quintana would not have dissuaded a POSITA from modifying the angle of the tip. *Id.*, ¶168. Quintana employs a tangential approach to access the AC angle but acknowledges that other approaches had been used including a perpendicular

approach. Ex.1004, 4. Altering the angle of the bent portion would have allowed for a number of different approaches and vice versa. Ex.1003, ¶168. In other words, the goal of Quintana's procedure was to strip TM tissue from SC and doing so requires orienting the needle's dual cutting edges to contact the TM. A POSITA would appreciate that angling the bent portion of Quintana's needle to approximately 90 degrees would permit a perpendicular approach to orient the tip within the SC. *Id.* Modifying the angle thus does not conflict with Quintana's disclosed method, as various bends and approaches would still achieve Quintana's goal of stripping the TM. *Id.*

2. Claim 5

Quintana discloses the limitations of claim 1. *See supra*, §VI.A.2. It would have been obvious to modify Quintana's procedure to form an incision in the eye using a 1.5mm slit knife. In 2003, it was well-known in the art to form incisions in the eye with different types of knives and blades, including slit knives, the size of which depends on the type of procedure and surgical instrument that would subsequently be inserted through the incision. *See, e.g.*, Ex.1006, 5:61-6:45 (making incision into the AC with a "sharp knife"); Ex.1015, [0076-77], [0121] (using "goniotomy knife" and "20 gauge knife" to create incisions in cornea); Ex.1023, [0004] (using slit knife to create incision into AC); Ex.1024, 4:5-6 (using slit blade to make clear cornea incision). Although Quintana uses a needle to

penetrate the AC, the means for penetrating or incising the AC is not critical to Quintana's procedure. Ex.1003, ¶170. Thus, using a 1.5mm slit knife to create an incision into the AC would simply involve combining prior art elements according to known methods and/or simple substitution of one known way to enter the AC (*e.g.*, penetrating via a needle) for another (*e.g.*, incising the eye using a slit knife). *Id.* Success would have been expected as it was routine to create incisions into a patient's eye using various approaches, including slit knives of different sizes. *Id.*

A POSITA modifying Quintana to form an incision with a 1.5mm slit knife would require both devices (slit knife and needle) to perform the procedure. *Id.*, ¶171. Thus, it would have been obvious to use both devices in combination as part of a system for performing the modified version of the procedure. *Id.*

C. Ground 3: Quintana (Ex.1004) in View of Lee (Ex.1006) Renders Obvious Claims 1-3 and 6-7

As explained above, Quintana discloses all elements of claims 1-3 and 6-7 of the '155 patent (*see supra*, §VI.A). To the extent the Board determines Quintana does not disclose an "ab interno" procedure, a "dual blade device," or a "blunt protruding tip"/"blunt top edge" as required by claim 1, it would have been obvious to modify Quintana based on Lee to render claims 1-3 and 6-7 obvious.

1. Overview of Lee

Lee discloses a device capable of removing tissue from the AC angle and retrieving it for examination. Ex.1006, Abstract. Lee notes "it would be useful to

extract relatively large intact samples of undamaged TM and scar tissue and, perhaps, the surrounding tissue for histopathologic examination." *Id.*, 1:54-2:7. Lee thus designed a device for use in glaucoma surgery "to excise a piece of tissue from the anterior chamber angle . . . and to provide specimens of the abnormal tissues excised for histopathological examination." *Id.*, 3:50-57; Ex.1003, ¶107.

Lee's device includes shaft 10, a bowl-like cavity with a sharpened rim that creates a "more or less U-shaped cutting edge 14 integral with the sides of shaft 10," and protruding distal end 15 for tissue penetration and cutting. Ex.1006, 4:18-48. Lee's device is a "dual blade device" as the U-shaped cutting edge "has ***dual blades corresponding to the U-shape***." *See supra*, §V.B; Ex.1003, ¶108.

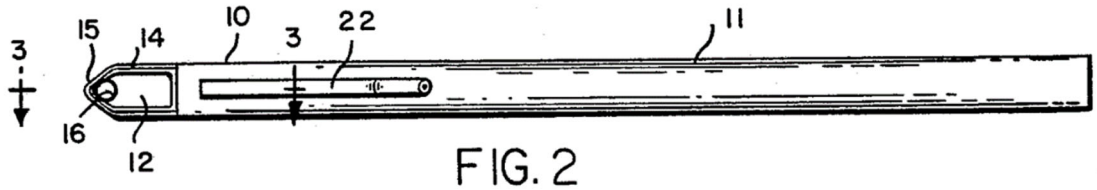


FIG. 2

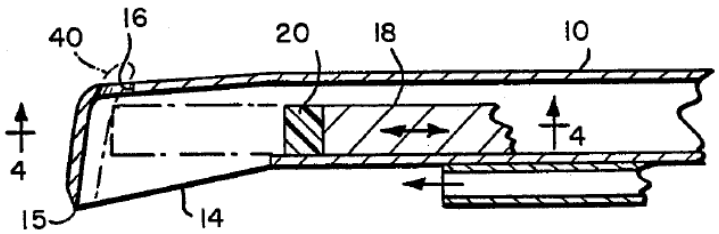


FIG. 3

Ex.1006, Figs.2-3.

Lee teaches using the device in an "ab interno" technique to excise strips of tissue 40, involving introducing the device "into the anterior chamber through the

paracentesis site" in clear cornea. *Id.*, 5:61-65, 6:14-27; Ex.1003, ¶109. Lee was mentioned as the closest prior art during prosecution of the '155 patent's parent application (which issued as the '729 patent), but never formed the basis of any rejections and the grounds herein rely on Lee in a completely different manner than the Examiner did during prosecution. As such, the Lee-based grounds herein should not be rejected under 35 U.S.C. § 325(d).

2. Claim 1

a. Element 1.p

Quintana discloses this limitation. *See supra*, §VI.A.2.a. For example, Quintana's procedure uses a "dual blade device" (*i.e.*, a needle with two spaced-apart cutting edges on opposite sides of the needle tube), is an "ab interno" procedure (as Quintana explicitly states the needle penetrates the eye into the AC and the needle is inserted into and advanced through SC), and "remove[s] a strip" of TM tissue (Quintana explicitly discloses "stripping" TM tissue). *Id.*; Ex.1003, ¶173.

If Quintana somehow does not expressly disclose a "***dual blade device***," a POSITA would have found it obvious to modify Quintana's needle to include dual blades. Quintana indicates the treatment of trabecular glaucomas includes opening of the TM but that the results potentially indicates "some kind of repair in the surgically damaged area." Ex.1004, 3, 8. A POSITA would have been motivated

to refine Quintana's procedure to further open the TM, increase aqueous outflow, and prevent repair of the opened area. Ex.1003, ¶174. A POSITA would have recognized this could be achieved by modifying the cutting edges of Quintana's needle to improve the cutting edges' ability to strip TM tissue from SC, such as by sharpening the edges. *Id.*

By 2003, it had also been known for decades that traditional surgical approaches that incised the TM without tissue removal had limited success and "the failure is usually due to scarring which blocks the incision in the TM." Ex.1006, 1:39-47; Ex.1016, 1:43-48; Ex.1003, ¶¶55, 175. Lee eliminated this issue by using a dual blade device for cutting and extracting large, intact segments of TM tissue. Ex.1006, 1:54-60, 3:39-42; *see supra*, §V.B. Lee's device has dual cutting edges 14 and is used in an "ab interno" procedure to excise tissue, resulting in a "strip of angle tissue 40" that is removed for histopathological examination. Ex.1006, 3:50-57, 6:28-40, Fig.5 (below, cutaway view of eye).

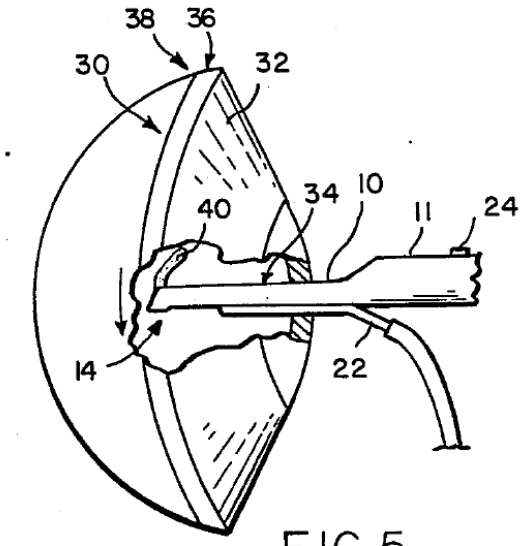


FIG.5

A POSITA would have found it obvious based on Lee to modify Quintana's needle by, for example, sharpening the cutting edges to create a "dual blade device" that could be used to excise strips of TM tissue for Lee's stated reasons. Ex.1003, ¶¶175-76.

To the extent it is determined Quintana does not expressly disclose an "***ab interno***" procedure, it would be obvious to perform Quintana's procedure using an "ab interno" approach. "Ab interno" procedures were well-known by 2003, as admitted by the '155 patent itself. Ex.1001, 1:37-65, 5:19-26; *see also* Ex.1015, [0077-78]; Ex.1003, ¶¶177-78. For example, Lee discloses a procedure involving making an incision "***into the anterior chamber with a sharp knife through clear cornea*** about 1mm. anterior to the limbus." Ex.1006, 5:61-6:45 (emphasis added).

Lee further explains approaching the TM with a device through the AC, *i.e.*, an "ab interno" approach. Ex.1003, ¶178.

Modifying Quintana's method to use an "ab interno" approach "through clear cornea about 1mm. anterior to the limbus" would have been obvious. *Id.*, ¶¶179-82. Quintana penetrated the AC "through the scleral side of the limbus," which is part of the cornea. Ex.1004, 4; Ex.1003, ¶179. A POSITA would understand that the precise entry point into the AC is not crucial to Quintana's method, provided it is somewhere near the limbus so that upon entry the needle is generally parallel to SC. Ex.1003, ¶179. Modifying the entry site in Quintana requires nothing more than simple substitution of one known procedure (*e.g.*, Quintana's approach) for another (*e.g.*, Lee's clear cornea approach) and a POSITA would have expected success. *Id.*

A POSITA would also have been motivated to modify Quintana by penetrating directly through the cornea to make the procedure safer and more convenient. *Id.*, ¶180. By 2003, it had become apparent that corneal incisions heal faster than other incisions and often result in fewer complications. *Id.*; Ex.1007, 5. A POSITA would have been motivated to modify Quintana to penetrate the AC directly through the cornea such as in Lee to improve patient safety and recovery. Ex.1003, ¶180.

b. Element 1.a

Quintana discloses this limitation. *See supra*, §VI.A.2.b. Quintana states the needle is inserted into a syringe, *i.e.*, handle. Ex.1004, 265; Ex.1003, ¶183.

c. Element 1.b

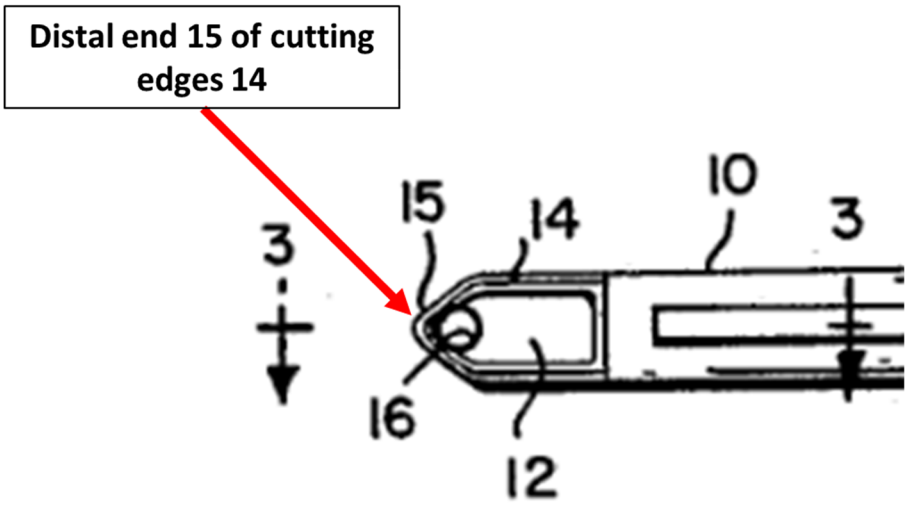
Quintana meets this limitation. *See supra*, §VI.A.2.c. Quintana's needle is inserted into a syringe, Ex.1004, 3, such that the needle is an "elongate probe" extending from the syringe or "handle" and has a shaft, *i.e.*, the tube of the needle. Ex.1003, ¶184.

d. Element 1.c

This limitation is met by Quintana. *See supra*, §VI.A.2.d. Quintana's needle has a "blunt protruding tip" (*i.e.*, the portion of Quintana's needle that extends laterally from the distal end of the shaft) and has a "bend or curve" of approximately 30-90 degrees relative to the longitudinal axis of the shaft (*i.e.*, Quintana explicitly states that the needle tip is bent 20-30°). *Id.*; Ex.1003, ¶185. *E.g.*, *Titanium Metals*, 778 F.2d at 775.

If it is determined Quintana's needle does not have a blunt protruding tip, it would have been obvious to modify Quintana's needle to have such a protruding tip. Quintana takes measures to prevent the tip of the needle from damaging the external wall of SC. Ex.1004, 4. A POSITA would have appreciated the risks and been motivated to modify Quintana's needle improve the safety of the device and procedure, such as by rounding the needle tip or making the tip less sharp/duller.

Ex.1003, ¶186. For example, the distal end 15 of the bowl-like tip of Lee's device protrudes "for ease of tissue penetration and cutting" and is "softly rounded" and "generally parabolic in shape in order to avoid damage to the outer wall of Schlemm's Canal." Ex.1006, 4:38-48.



Id., Fig.2 (annotated). Rounding the terminal end of the tip of Quintana's needle to create a "blunt protruding tip" would have been obvious for the exact reason expressed in the art, *i.e.*, avoiding damage to SC, and a POSITA would have expected success as devices such as Lee's with a rounded tip were still successfully used to penetrate the TM. Ex.1003, ¶186.

e. Element 1.d

Quintana discloses this limitation. *See supra*, §VI.A.2.e. Quintana's needle has spaced-apart, fixed cutting edges on opposite sides of the needle tube, which face in the same direction as the blunt protruding tip and are spaced such that an

area exists between the cutting edges. *Id*.; Ex.1003, ¶187. If these portions of Quintana's needle are not cutting edges, it would have been obvious to modify Quintana's needle to create a "dual blade device" with "first and second lateral cutting edges," as explained above. *See supra*, §VI.C.2.a; Ex.1003, ¶188.

f. Element 1.e

Quintana also discloses this limitation. *See supra*, §VI.A.2.f. The portion of Quintana's needle at the distal end of the shaft near the location where the bevel begins is a blunt top edge that extends between the top ends of the cutting edges. *Id.*; Ex.1003, ¶189.

If it is determined Quintana's needle does not have a blunt top edge, it would have been obvious to modify Quintana's needle to have a blunt top edge for similar reasons to those discussed above regarding blunt protruding tip. *See supra*, §VI.C.2.d. Indeed, a POSITA would have been motivated to modify Quintana's needle for safety reasons and would have known one way of doing so would be to round portions of the needle near the tip such as the top edge. Ex.1003, ¶189. A POSITA would have expected success as devices with rounded portions near the cutting area (*e.g.*, Lee) were used safely and successfully. *Id.*

g. Element 1.f

This limitation is met by Quintana. *See supra*, §VI.A.2.g. Quintana's needle has a blunt protruding tip with a top surface, bottom surface, terminal end, and a transverse width that is narrowest at the terminal end. *Id.*; Ex.1003, ¶190.

h. Element 1.g

Quintana meets this limitation. *See supra*, §VI.A.2.h. Quintana's needle has a blunt protruding tip that is below the area between the cutting edges and protrudes laterally beyond the cutting edges such that tissue passes over the top surface before contacting the cutting edges. *Id.*; Ex.1003, ¶191.

i. Element 1.h

Quintana also meets this limitation. *See supra*, §VI.A.2.i. Quintana's needle is sized to pass through an incision formed by a 1.5mm slit knife because Quintana's 0.4mm diameter needle would pass through a 1.5mm incision. *Id.*; Ex.1003, ¶192.

j. Element 1.i

Quintana discloses this limitation. *See supra*, §VI.A.2.j. The blunt protruding tip of Quintana's needle is inserted into SC and is advanced through it, "stripping" TM tissue. *Id.* TM tissue necessarily passes over the top surface of the blunt protruding tip and into contact with the cutting edges. *Id.*; Ex.1003, ¶193.

3. Claim 2

Quintana and Lee render obvious claim 1. *See supra*, §VI.C.2. Further, as explained above, the cutting edges of Quintana's needle have a space between them that can be termed "distance D," and the strip of tissue cut by these cutting edges would necessarily have a width corresponding to this distance given that the cutting edges concurrently cut the tissue as the needle advances through SC. *See supra*, §VI.A.3; Ex.1003, ¶¶195-96.

4. Claim 3

Quintana and Lee render obvious claim 1. *See supra*, §VI.C.2. Further, not only does the patent admit cutting a strip of TM with a length of about 2 to 10 millimeters was known in the art, Ex.1001, 1:41-46, Quintana discloses the strip of TM tissue achieved has a length of about 2 to 10mm. Quintana explains "[a] 100-120° trabeculotomy can be achieved." Ex.1004, 4. A POSITA would understand based on the circumference of SC (and thus, the TM), which is about 36mm, Ex.1010, 5, a 100° section of TM would equate to a section that is 10.08mm in length. Ex.1003, ¶¶199-200. Given Quintana's statement that a 100-120° "can be achieved," a POSITA would also understand strips of tissue ranging anywhere from 0-10.08mm (or greater) could be achieved. *Id.* *See also supra*, §VI.A.4.

5. Claim 6

Quintana and Lee render obvious claim 1. *See supra*, §VI.C.2. Further, as explained above, Quintana uses a needle inserted into a syringe, which a POSITA

would understand is manually operable, to "strip[]" tissue from the TM. *See supra*, §VI.A.5; Ex.1003, ¶202.

6. Claim 7

Quintana and Lee render obvious claim 1. *See supra*, §VI.C.2. Further, as explained above, Quintana's needle is formed from a tube and a POSITA would recognize that needle tubes have at least one lumen within the tube. *See supra*, §VI.A.6; Ex.1003, ¶204.

D. Ground 4: Quintana (Ex.1004) in View of Lee (Ex.1006) and the Knowledge of a POSITA Renders Obvious Claims 4-5

Quintana in combination with the knowledge of a POSITA renders obvious claims 4-5 (*see supra*, §VI.B). To the extent the Board determines Quintana does not disclose an "ab interno" procedure or a "dual blade device" as required by claim 1 and thus does not render obvious claims 4-5 in combination with the knowledge of a POSITA alone, Quintana in combination with Lee (which renders obvious claims 1-3 and 6-7, *see supra*, §VI.C) further in combination with the knowledge of a POSITA would render obvious claims 4-5.

1. Claim 4

Quintana and Lee render obvious claim 1. *See supra*, §VI.C.2. Further, as explained above, Quintana's needle has a tip bent 20-30°, Ex.1004, 3, and a POSITA would appreciate that by bending the tip of the needle, the bottom surface of the blunt protruding tip of Quintana's needle would necessarily extend at the

same angle as the rest of the blunt protruding tip relative to the longitudinal axis of the shaft. *See supra,* §VI.B.1; Ex.1003, ¶207. Given that it was well-known in the art to use devices having tips, points, or shafts bent at various angles to meet the needs of a given surgery, as evidenced by prior art such as Johnstone (which uses a cystotome with the point "oriented at right angles to the shaft") among others, it would have been obvious to modify Quintana's needle by bending the tip at different angles for various reasons explained above. *See supra,* §VI.B.1; Ex.1003, ¶¶208-11.

2. Claim 5

Quintana and Lee render obvious claim 1. *See supra*, §VI.C.2. Further, as explained above, although Quintana does not disclose forming an incision in the eye with a 1.5 mm slit knife, modifying Quintana's procedure to form an incision in the eye in this manner would have been obvious in view of Lee and the knowledge of a POSITA given that it was well-known in the art to form incisions in the eye with different types of knives and blades, including slit knives of different sizes. *See supra*, §VI.B.2; Ex.1003, ¶213. Moreover, given that the use of a slit knife in Quintana's procedure would have been obvious, it would further have been obvious to create a system including Quintana's device in combination with the 1.5mm slit knife for similar reasons. Ex.1003, ¶214.

E. Ground 5: 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, 1-2. 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, ¶¶110-11. 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, ¶112; *see infra*, §VI.E.2.e.

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, ¶113. 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 gonioscraper is a "***dual blade device***." Ex.1003, ¶¶216-18. The gonioscraper has a tip that is "shaped as a tiny bowl with 300 µm diameter and with its edges sharpened" and is capable of cutting tissue as it was used to "completely remove[] the TM." Ex.1007, 1-2, Fig.1 (below).

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

A "dual blade device" has two spaced-apart edges capable of cutting tissue and can encompass various types of devices, including ones with a U-shaped cutting edge. *See supra*, §V.B. During prosecution, the Examiner found Lee discloses "a device with a U-shaped cutting edge (14) which has ***dual blades corresponding to the U-shape***." Ex.1022, 320 (emphasis added); *see also* Ex.1006, 4:38-41, Figs. 2-3 (below).

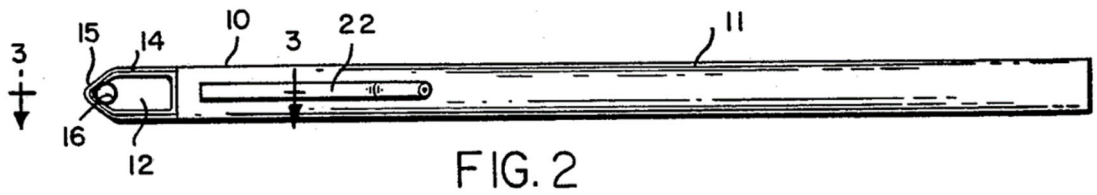


FIG. 2

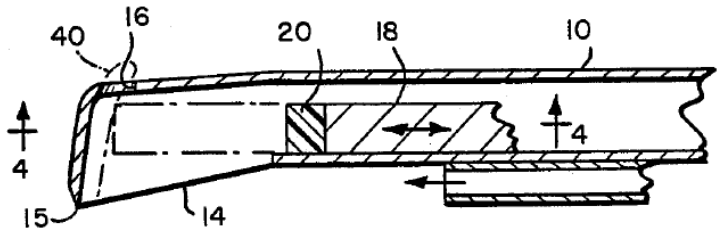


FIG. 3

Jacobi's gonioscraper is, like Lee's device, a "dual blade device," as it has a tip "shaped as a tiny bowl . . . with its edges sharpened," *i.e.*, "dual blades corresponding to the U-shape." Ex.1007, 2; Ex.1022, 320; Ex.1003, ¶¶217-18.

Jacobi's technique is "***ab interno***" because Jacobi's device was "inserted into the anterior chamber through a clear corneal incision at the temporal limbus and directed against the TM at the opposite side." Ex.1007, 2; Ex.1003, ¶219. Figure 2 shows Jacobi's device being directed against the TM from ***within*** the AC.

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; Ex.1003, ¶219.

Jacobi's procedure "***remove[s] a strip of [TM] tissue.***" Jacobi's purpose "was to abrade rather than incise" the TM to "peel" off "***strings*** of trabecular tissue." Ex.1007, 2 (emphasis added). This means Jacobi excises tissue rather than simply cutting a slit in the TM. Ex.1003, ¶220. 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 cutting a "strip of tissue" from the TM as claimed. Ex.1003, ¶220. 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.

b. Element 1.a

Jacobi's gonioscraper "***consists of a small handle*** and a slightly convex-shaped arm." Ex.1007, 2 (emphasis added). The "small handle" portion of Jacobi's gonioscraper is meant for grasping by an operator. Ex.1003, ¶221.

c. Element 1.b

Jacobi's gonioscraper "consists of a small handle and ***a slightly convex-shaped arm for intraocular use***." Ex.1007, 2 (emphasis added). The "convex-shaped arm" is "an elongate probe" that extends from the "handle" portion of the device. Ex.1003, ¶222. As shown below, the "convex-shaped arm" of Jacobi's device includes a shaft, which extends along a longitudinal axis running along the length of the shaft. *Id.*

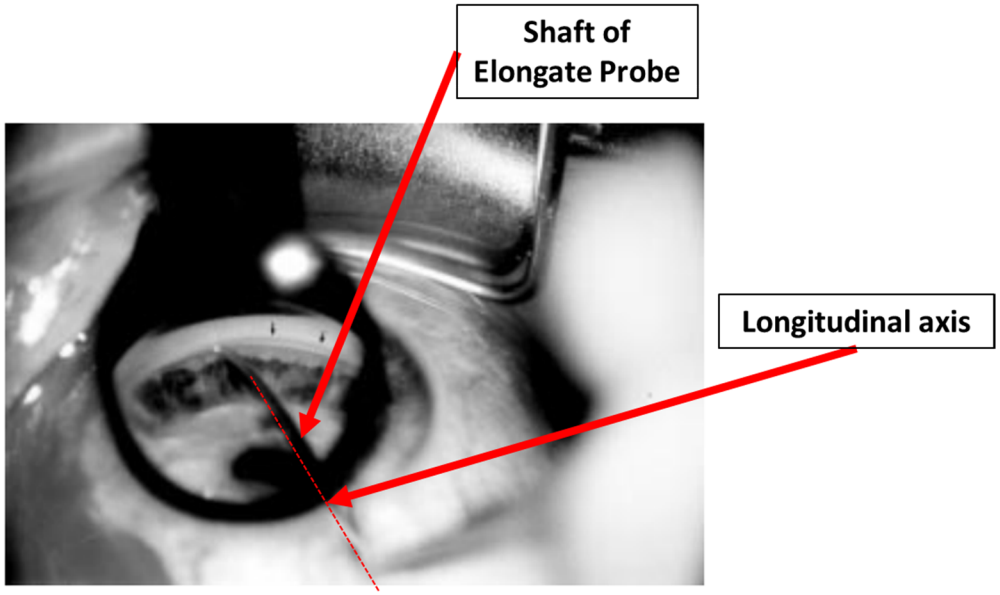


Figure 2 With the aid of an operating microscope and under gonioscopic control ab interno goniocurettage is performed. Following abrasion an irregular pattern of a glistening white band corresponding to the 'denuded' grey-white sulcus scleralis can be seen (black arrows).

Ex.1007, Fig.2 (annotated).

d. Element 1.c

As explained above, the term "***blunt protruding tip***" must encompass devices with tips that can pierce TM tissue and cannot exclude such devices based on the perceived sharpness of the tip. *See supra*, §V.C; Ex.1003, ¶223.

As shown below, the bowl-shaped tip of Jacobi's device is a "blunt protruding tip" that extends from a distal end of the shaft. Ex.1003, ¶224.

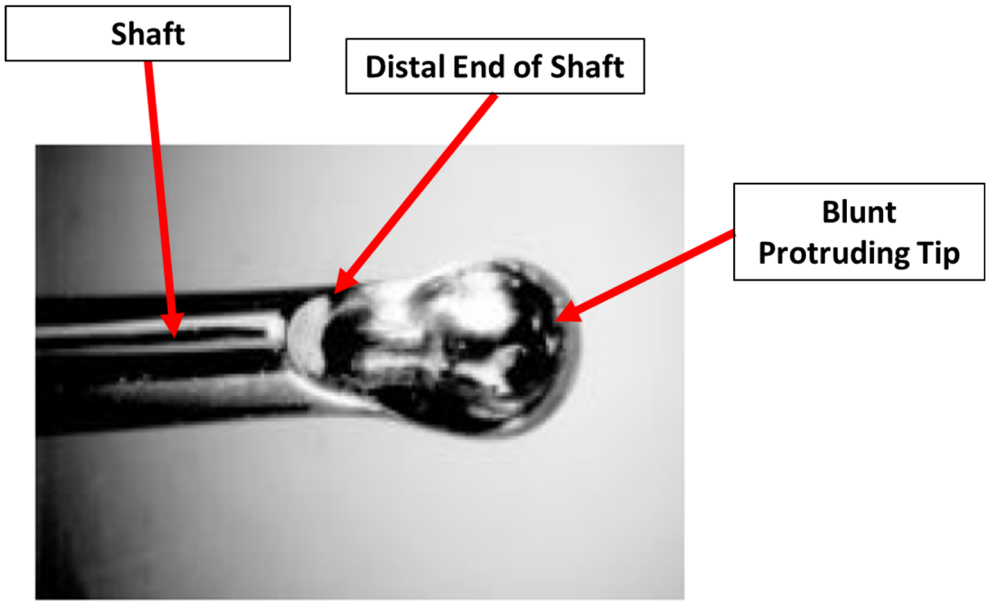


Figure 1 The tip of the 'gonioscraper'. The bowl is 300 µm in diameter with its edges sharpened.

Ex.1007, Fig.1 (annotated). This portion of Jacobi's device is, like the "blunt protruding tip" of the patent's "needle cutter device," located on the bottom of the distal end of the device's shaft, is used to facilitate insertion of the tip through the TM into SC, and guides the needle through SC. *Id.*, 1-2; Ex.1001, 3:10-24; Ex.1003, ¶224.

This portion of Jacobi's gonioscraper "***extends in a lateral direction from a distal end of the shaft***." The figure above from Jacobi shows that the bowl-shaped tip of Jacobi's device extends laterally from the distal end of the shaft. Ex.1003, ¶225.

Jacobi's tip extends from the shaft to form a "***bend or curve***" of approximately 30 to 90 degrees relative to the shaft's longitudinal axis. Ex.1003, ¶226. As shown below, the shaft of Jacobi's device is bent to form an angle. *Id.*

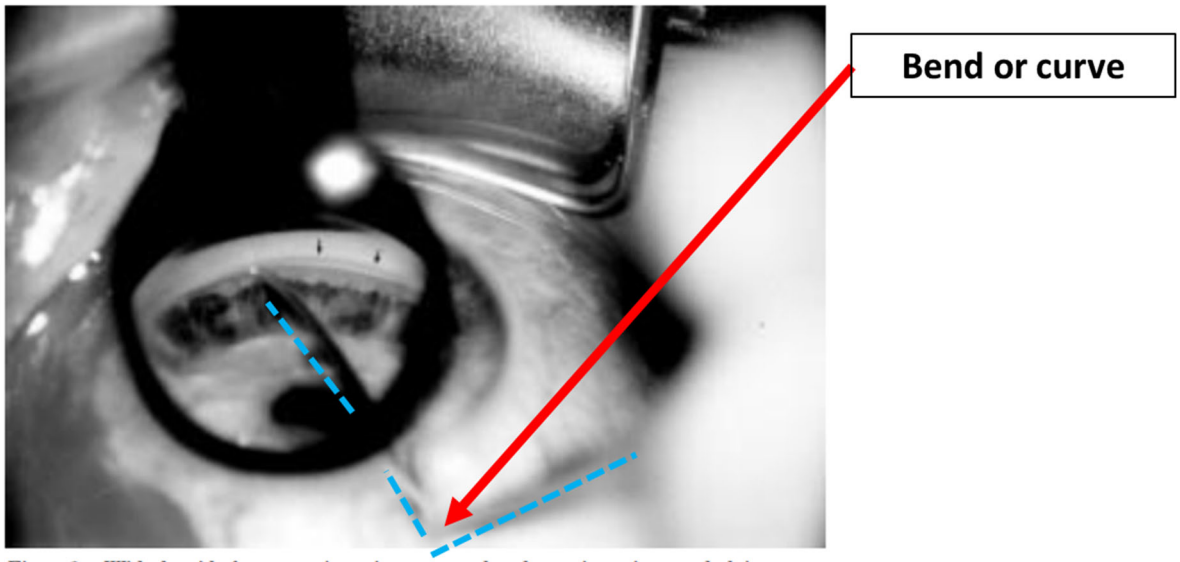
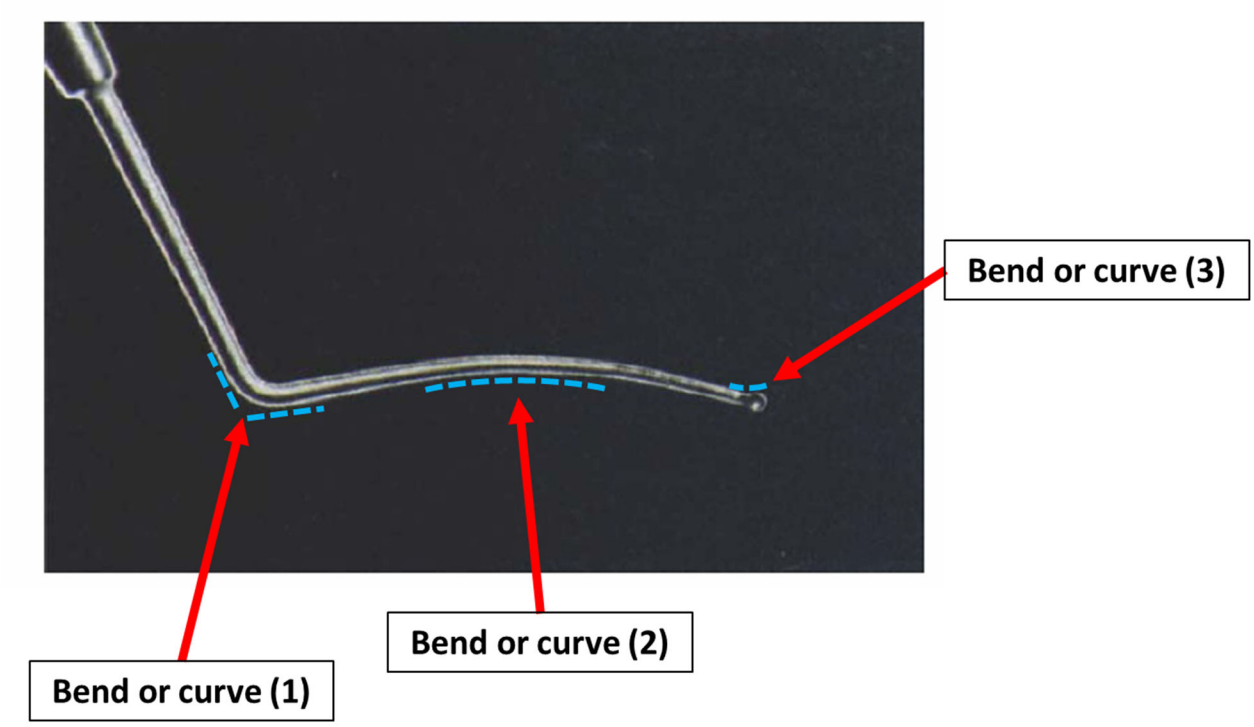


Figure 2 With the aid of an operating microscope and under gonioscopic control ab interno goniocurettage is performed. Following abrasion an irregular pattern of a glistening white band corresponding to the 'denuded' grey-white sulcus scleralis can be seen (black arrows).

Ex.1007, Fig.2 (annotated). Moreover, Jacobi also indicates that "[i]n order to abrade clockwise and anticlockwise the scoop is angulated vertically at 90 degrees to the left and right, respectively." *Id*., 2.

Other images of Jacobi's gonioscraper confirm that the device includes several bends or curves. Jacobi 2000 (Ex.1013) summarizes the procedure disclosed in the earlier paper (Ex.1007) and includes an image showing a side view of the device. Ex.1013, 2. As shown below, the device includes at least: (1) a bend or curve in the shaft (labeled (1)); (2) a bend or curve in the "convex-shaped arm" (labeled (2)); and (3) a bend or curve where the "convex-shaped arm" meets the bowl (labeled (3)). Ex.1003, ¶227.



Ex.1013, Fig.1(b) (annotated). A POSITA would appreciate that the device has "bends or curves," as claimed. Ex.1003, ¶227. Importantly, as shown in the image, the bowl-shaped tip (*i.e.*, blunt protruding tip) extends from a distal end of the shaft of the "convex-shaped arm," forming bend or curve (3). A POSITA would understand that bend or curve (3) is included in the device due to the generally downwardly sloping plane of the portion of the convex-shaped arm near the tip to allow the dual cutting edges to cut the TM. *Id*.

To the extent these "bends or curves" do not have an angle of "***approximately 30 degrees to approximately 90 degrees***," it would have been obvious to modify Jacobi's device to include a "bend or curve" having an angle within the claimed range. It was well-known in the art to use devices having tips,

points, or shafts bent at various angles to meet the needs of a given surgery. Ex.1003, ¶228. For example, Johnstone discloses a procedure using "a cystotome with the point oriented at right angles to the shaft" that is inserted through the TM into SC. Ex.1005, 2. Quintana teaches a procedure using a needle with the tip bent 20-30°. Ex.1004, 3; *see also* Ex.1006, 4:49-54 (angle of device's cutting edges vary "depending on surgical requirements").

Modifying the bends or curves in Jacobi's device to an angle of 30 degrees to approximately 90 degrees would have been obvious to a POSITA. Ex.1003, ¶¶229-30. First, modifying the bends or curves (such as bend or curve (3)) would have involved nothing more than combining prior art elements according to known methods or simple substitution to obtain predictable results—for example, combining Jacobi's device with known bends or curves of 30-90 degrees employed successfully in known devices. *Id.* Second, it would have been obvious to try simple, straight-forward variations to Jacobi's device, such as by bending the tip of Jacobi's device to different angles. *Id.* Given that there are a finite number of angles to bend the tip, a POSITA would have been motivated to try variations, such as an angle of 30-90 degrees, to for example expand on Jacobi's results or suit the needs of a particular procedure, and would have expected success given the successful use of devices bent to different angles in the art. *Id*.

e. Element 1.d

Jacobi's gonioscraper has "***first and second lateral cutting edges formed at stationary side-by-side locations on the shaft***." *See supra,* §VI.E.2.a. As shown below, the device has a cutting edge on each lateral side of the bowl similar to Lee, which begin where the shaft of the arm meets the bowl and extend to the terminal end of the blunt protruding tip:

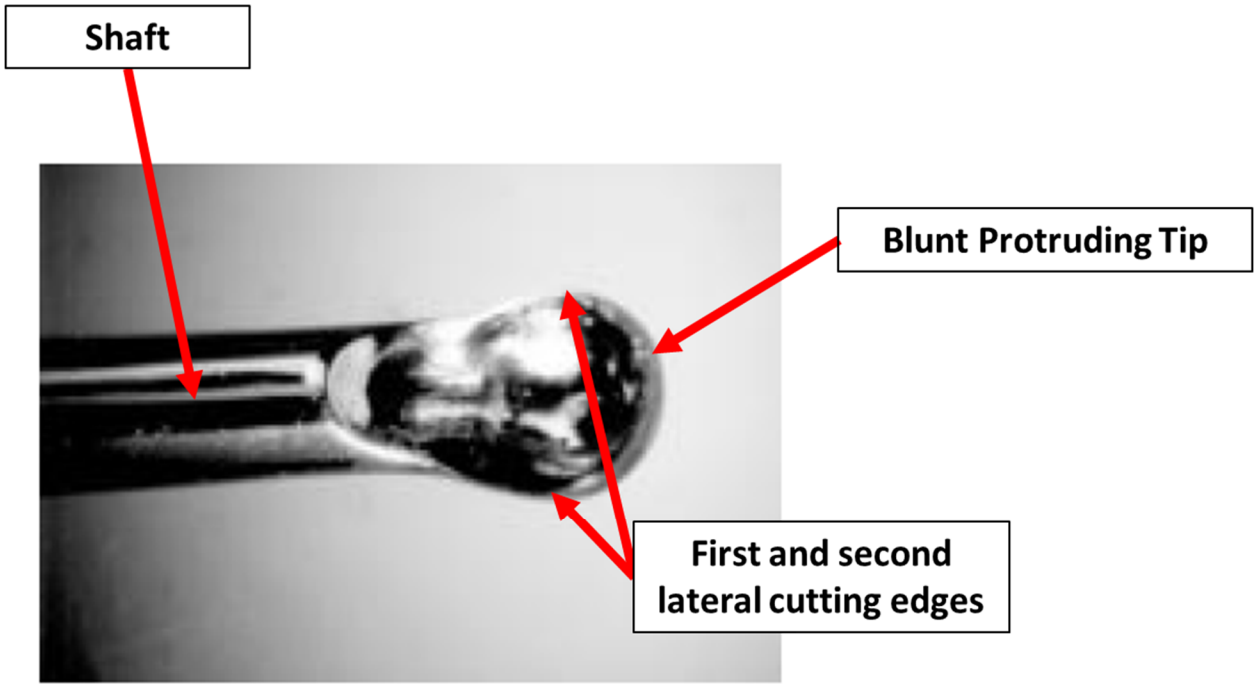


Figure 1 The tip of the 'gonioscraper'. The bowl is 300 μm in diameter with its edges sharpened.

Ex.1007, Fig.1 (annotated); Ex.1003, ¶¶231-32.

Further, as shown below, the cutting edges are "***spaced apart such that an area exists between the first and second lateral cutting edges***" because the cutting edges are separated from one another leaving a space in between.

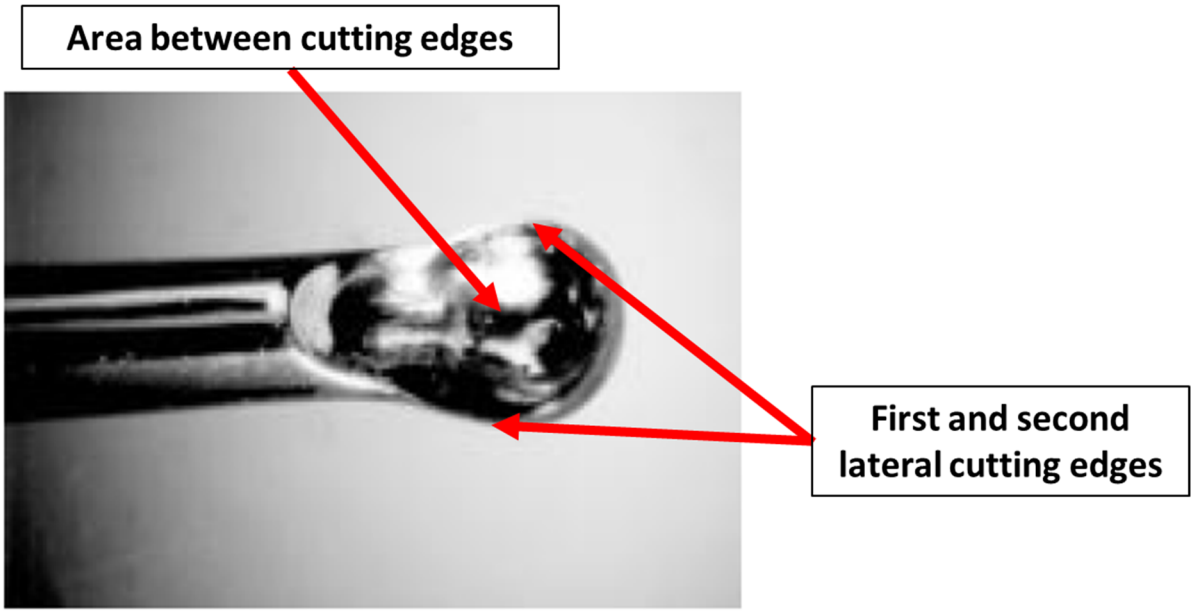


Figure 1 The tip of the 'gonioscraper'. The bowl is 300 μm in diameter with its edges sharpened.

Ex.1007, Fig.1 (annotated); Ex.1003, ¶233.

The claim further requires that the cutting edges "***fac[e] in the same lateral direction as the blunt protruding tip***." Jacobi's bowl-shaped tip is oriented so that the sharpened edges of the bowl face toward the TM tissue within SC during the procedure. Ex.1003, ¶234. If Jacobi's cutting edges do not face in the same direction as the blunt protruding tip, however, modifying Jacobi's device in this manner would have been obvious. *Id.* While the cutting edges of Jacobi's device must face the TM in order to excise TM tissue, a POSITA would understand other aspects of the device (*e.g.*, the angle of the cutting edges or bends or curves in the device) or procedure (*e.g.*, the direction from which the tissue is approached) could be modified. *Id.* For example, Jacobi's procedure involves approaching the TM

from a perpendicular direction in which the device passes across the AC, as shown in Fig.2 below.

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; Ex.1003, ¶234. A POSITA would appreciate that the orientation of Jacobi's bowl-shaped tip could be modified if, for example, a different approach to the TM was desired, such as a tangential approach as used by Quintana. Ex.1003, ¶234 For instance, the bowl of Jacobi's device could be turned so the cutting edges face the TM when using a tangential approach, just as do the cutting edges of Quintana's needle, in which case the cutting edges would face in the same lateral direction as the blunt protruding tip. *Id.*

It would have been obvious to modify Jacobi's device in this manner based on the knowledge of a POSITA for various reasons. Ex.1003, ¶235. In 2003,

surgical devices and procedures were often modified to suit the needs of a particular patient or to meet surgical requirements. *Id.* Moreover, modifying Jacobi's device to change the direction of the cutting edges would have involved simply combining prior art elements according to known methods and/or simple substitution of one known cutting edge orientation (*e.g.*, Jacobi's orientation) for another (*e.g.*, Quintana's orientation). *Id.* A POSITA would have expected success given the successful use of other devices having different orientations in the prior art, including but not limited to Quintana. *Id*.

f. Element 1.e

As explained above, the term "***blunt top edge***" must encompass the top edge of the cutting area of devices intended for penetrating through TM tissue. *See supra*, §V.D; Ex.1003, ¶236. As shown below, the portion of Jacobi's gonioscraper where the shaft's distal end meets the bowl is a blunt top edge. Ex.1003, ¶236.

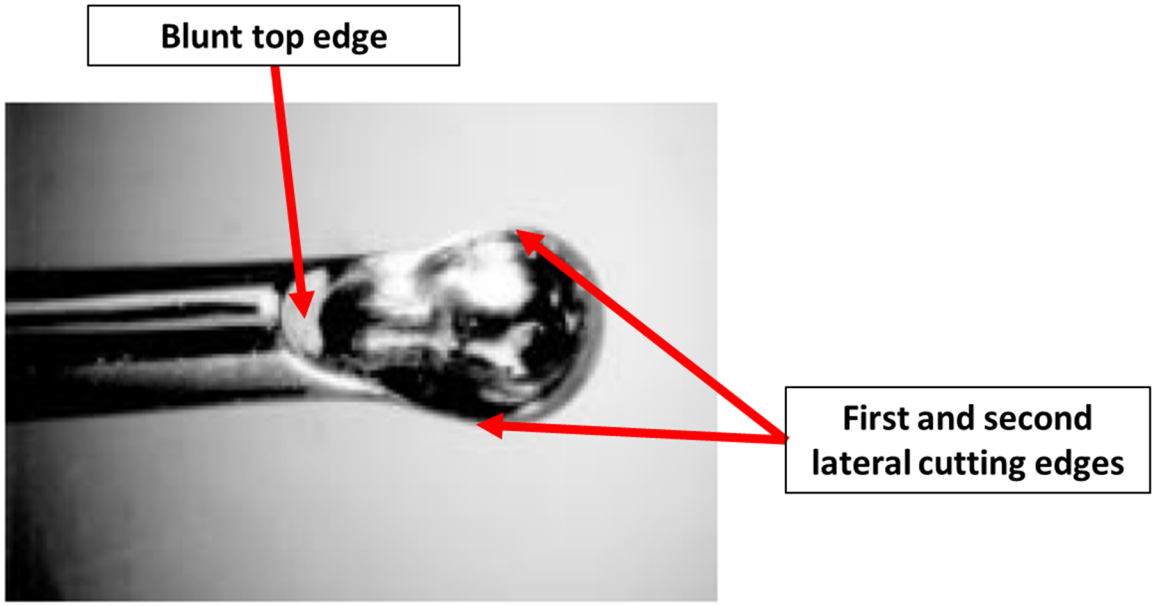


Figure 1 The tip of the 'gonioscraper'. The bowl is 300 µm in diameter with its edges sharpened.

Ex.1007, Fig.1 (annotated). This portion of Jacobi's device is, like the blunt top edge of the patent's "needle cutter device," located at the top of the distal end of the shaft and extends between the dual cutting edges of the device. *Id.*, 2; Ex.1001, 3:10-24; Ex.1003, ¶236.

The blunt top edge "***extends transversely from a top end of the first lateral cutting edge to a top end of the second lateral cutting edge***." The blunt top edge of Jacobi's device extends between the top end of one cutting edge to the other, just as does the blunt top edge of the patent's "needle cutter device." Ex.1003, ¶237. The annotated figure above also shows that the "blunt top edge" of Jacobi's device is "***above the area between***" the cutting edges, as it is located above the space between the cutting edges when the device is in an operative position. *Id.*

g. Element 1.f

Jacobi's blunt protruding tip has a "***top surface***" (the inner surface of the bowl), a "***bottom surface***" (the outer surface of the bowl), and a "***terminal end***" (the "end" of the bowl that penetrates the TM and guides the bowl through SC), as shown below. *Id.*, ¶238.

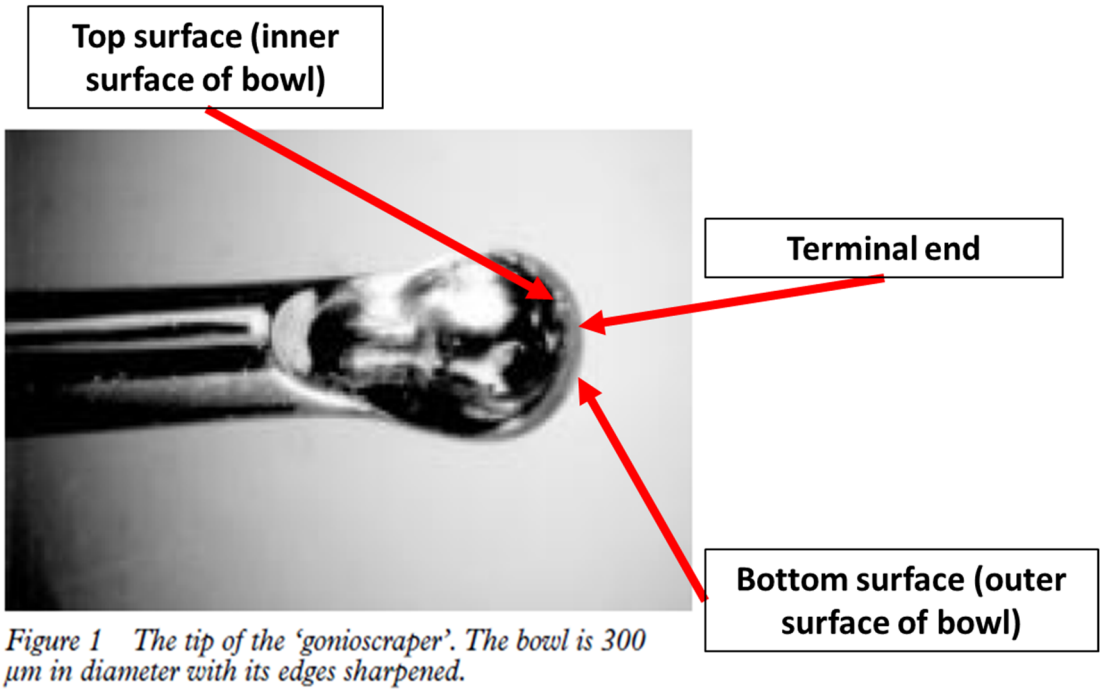


Figure 1 The tip of the 'gonioscraper'. The bowl is 300 μm in diameter with its edges sharpened.

Ex.1007, Fig.1 (annotated). Moreover, the "***transverse width***" of the blunt protruding tip is narrowest at the terminal end, as shown below. Ex.1003, ¶239.

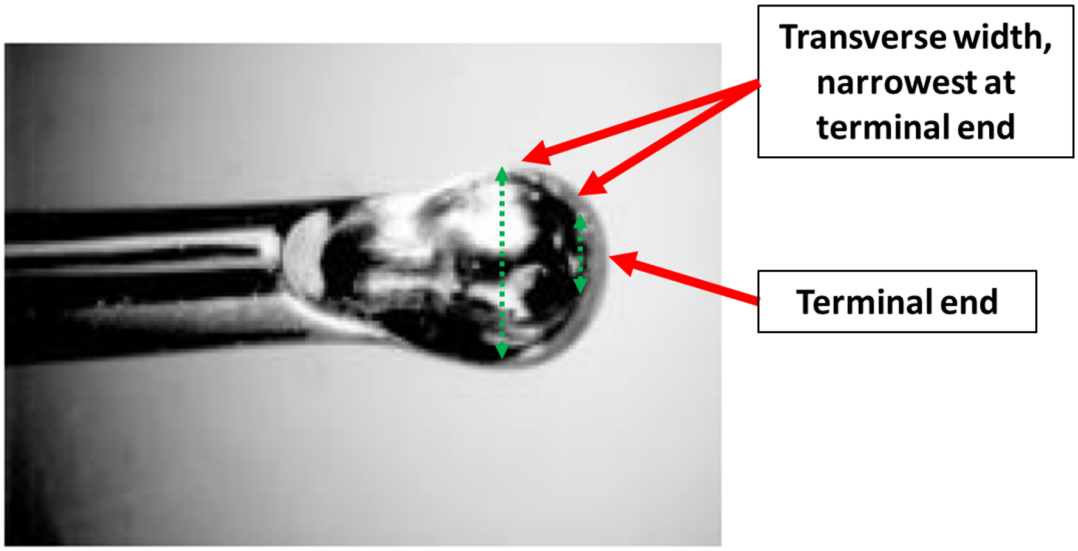


Figure 1 The tip of the 'gonioscraper'. The bowl is 300 µm in diameter with its edges sharpened.

Ex.1001, Fig.1 (annotated).

h. Element 1.g

The blunt protruding tip is "***below the area between***" the cutting edges, as it is below the sharpened edges of the bowl and the area between the cutting edges beginning where the bowl meets the shaft when the device is in an operative position, just as is the blunt protruding tip of the patent's "needle cutter device." Ex.1003, ¶240.

The blunt protruding tip "***protrud[es] in the lateral direction beyond***" the cutting edges "***such that tissue may pass over the top surface of the blunt protruding tip before coming into contact with the first and second lateral cutting edges.***" As explained above, the blunt protruding tip of Jacobi's device extends laterally from the shaft, *see supra*, §VI.E.2.d, and must necessarily

protrude laterally beyond the cutting edges (or at least a portion thereof) because the cutting edges begin where the shaft meets the bowl. Ex.1003, ¶241. As Jacobi's blunt protruding tip advances through SC, TM tissue necessarily contacts the blunt protruding tip, causing the cutting edges of the bowl to concurrently cut the TM tissue. *Id.*, ¶242. A POSITA would understand at least some TM tissue that contacts the blunt protruding tip in this orientation would pass over the top surface of the blunt protruding tip before contacting the cutting edges. *Id.*

If Jacobi's blunt protruding tip is not oriented such that tissue passes over the top surface of the blunt protruding tip before contacting the cutting edges, it would have been obvious to modify Jacobi's device in this manner. *Id.*, ¶¶243-44. 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).

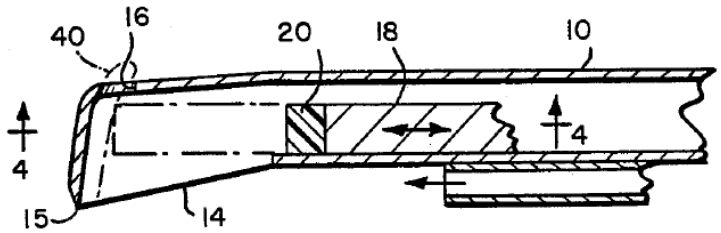


FIG. 3

In this orientation, TM tissue necessarily passes over the top surface of the distal end 15 of Lee's device before contacting the sharpened edges of the bowl. Ex.1003, ¶243.

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 top surface of the bowl-shaped tip before contacting the cutting edges of Jacobi's bowl. *Id.*, ¶244. 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.*

i. Element 1.h

Jacobi's gonioscraper is "***sized to pass through an incision formed in the eye by a 1.5mm slit knife***." Jacobi's procedure involves inserting the gonioscraper "into the [AC] through a clear corneal incision at the temporal limbus," Ex.1007, 2, and therefore Jacobi's device (including at least the distal portion of the shaft and

blunt protruding tip as claimed) is sized to pass through an incision formed in the eye. Ex.1003, ¶245.

As explained above, the claim does not require ***forming*** an incision but instead that the distal portion of the shaft and blunt protruding tip are ***sized*** to pass through an incision formed by a 1.5mm slit knife. A 1.5mm slit knife is a knife with a generally flat blade having a width of 1.5mm, which would form an incision with a width of 1.5mm (or greater). *Id.*, ¶246. The distal portion of the shaft and blunt protruding tip of Jacobi's device are sized to pass through such an incision, as Jacobi's bowl has a diameter of 300μm. *Id*. A POSITA would understand a device having a diameter of 300μm (0.3mm) at its widest point would pass through an incision having a width of at least 1.5mm formed by a 1.5mm slit knife. *Id.*

j. Element 1.i

The blunt protruding tip is "***sized to fit within***" SC and "***to be advanceable through [SC] with [TM] tissue passing over its top surface and into contact***" with the cutting edges. Jacobi states the gonioscraper was inserted into the AC, directed against the TM, and "lightly passed over 2-3 clock hours" to "peel" TM tissue from SC. Ex.1007, 2, Fig.2 (below, depicting device within SC); Ex.1003, ¶247.

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.

As indicated above, TM tissue necessarily passes over the top of the blunt protruding tip and comes into contact with the cutting edges of the bowl as Jacobi's device advances through SC. *See supra,* §VI.E.2.h; Ex.1003, ¶248. The cutting edges concurrently cut the TM tissue, resulting in removal of "strings" of TM tissue. Ex.1007, 2; Ex.1003, ¶248.

3. Claim 2

Jacobi in view of the knowledge of a POSITA render obvious claim 1. *See supra*, §VI.E.2. Further, the cutting edges of Jacobi's gonioscraper are spaced apart such that an area exists between the cutting edges, *see supra*, §VI.E.2.e, and

as shown below the distance from one cutting edge to the other across this area is "distance D."

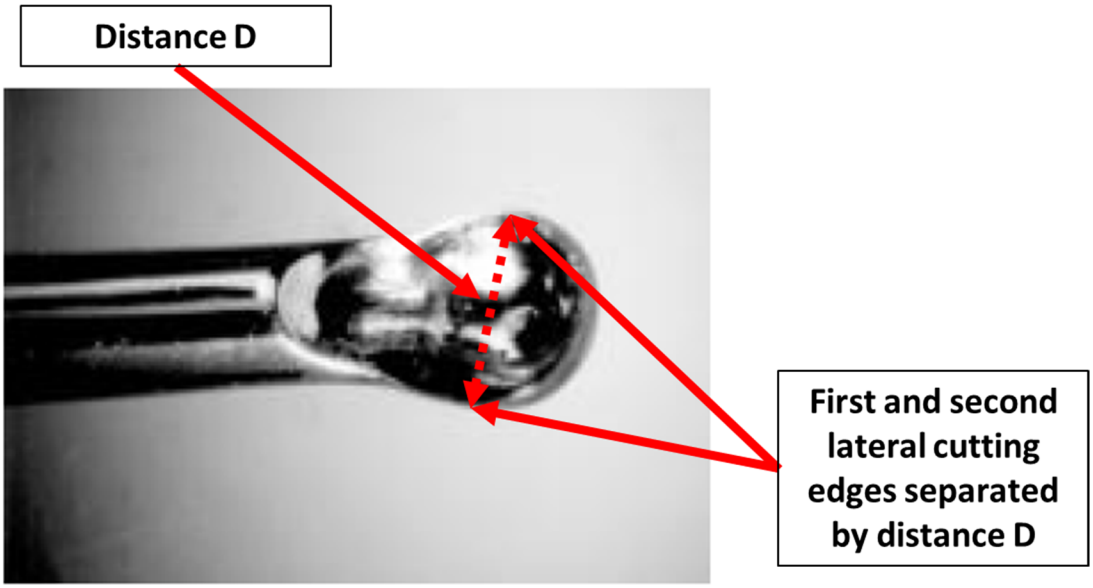


Figure 1 The tip of the 'gonioscraper'. The bowl is 300 µm in diameter with its edges sharpened.

Ex.1007, Fig.1 (annotated); Ex.1003, ¶250. As stated in Jacobi, the bowl has a diameter of 300µm and therefore, "distance D" is 300µm. Ex.1007, 2.

The strip of tissue created when the cutting edges of the bowl cut TM tissue as the device advances through SC would necessarily have a width W that is "substantially equal to distance D." This is because the cutting edges of Jacobi's gonioscraper concurrently cut the TM tissue, which would create a strip having a width corresponding to the distance between the first and second cutting edges (*i.e.*, "distance D"). Ex.1003, ¶251.

4. Claim 3

Jacobi in view of the knowledge of a POSITA render obvious claim 1. *See supra*, §VI.E.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, 1:41-46. Thus, claim 3 does not cover a novel or nonobvious feature of the alleged invention.

Regardless, Jacobi explains that "[g]oniocurettage was performed over 90-120° of the chamber angle circumference in all patients." Ex.1007, 3. 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, ¶¶254-55.

5. Claim 4

Jacobi in view of the knowledge of a POSITA render obvious claim 1. *See supra*, §VI.E.2. Further, as discussed, Jacobi's gonioscraper has several bends or curves. *See supra*, §VI.E.2.d. Because the bottom surface is part of the blunt protruding tip, bending portions of the device would cause the bottom surface to extend at the same angle as the blunt protruding tip. Ex.1003, ¶257.

As explained above for claim 1, it was well-known in the art to use devices having tips, points, or shafts bent at various angles to meet the needs of a given surgery, as shown in various prior art references such as Johnstone, Quintana, and

Lee. *See supra,* §VI.E.2.d; Ex.1003, ¶258. Johnstone, for example, discloses a surgical procedure using "a cystotome with the point oriented at right angles to the shaft" that is inserted through the TM into SC. Ex.1005, 2. For all the reasons discussed above, it would have been obvious to alter the angle of one or more of the bends or curves in Jacobi's device, such as bend or curve (3), to an angle of approximately 90 degrees. *See supra,* §VI.E.2.d; Ex.1003, ¶¶259-60. Doing so would cause the bottom surface of the blunt protruding tip to extend at an angle of approximately 90 degrees, as claimed. Ex.1003, ¶257.

6. Claim 5

Jacobi in view of the knowledge of a POSITA render obvious claim 1. *See supra*, §VI.E.2. Further, although Jacobi does not disclose a 1.5 mm slit knife to form an incision in the eye, modifying Jacobi's procedure to form an incision in this manner would have been obvious to a POSITA for the same reasons discussed above regarding Quintana. *See supra*, §VI.B.2; Ex.1003, ¶260. For example, it was well-known in the art to form incisions in the eye with different types of knives and blades, including slit knives of different sizes, and thus using a 1.5mm slit knife would have involved simple substitution of one known way of entering the AC for another. *See supra*, §VI.B.2; Ex.1003, ¶260. Moreover, given that the use of a 1.5mm slit knife in Jacobi is obvious, it would further have been obvious

to create a system including Jacobi's gonioscraper in combination with the 1.5mm slit knife for similar reasons. Ex.1003, ¶263.

7. Claim 6

Jacobi in view of the knowledge of a POSITA render obvious claim 1. *See supra*, §VI.E.2. Further, Jacobi's procedure involves use of a hand-held device for removing strips of tissue from the TM. Ex.1007, 1-2; Ex.1003, ¶265. A POSITA would appreciate that Jacobi's device is "manually operable," as the surgeon operates the device by hand to remove "strings" of TM tissue. Ex.1003, ¶265.

8. Claim 7

Jacobi in view of the knowledge of a POSITA render obvious claim 1. *See supra*, §VI.E.2. As explained, Jacobi's gonioscraper has a shaft, *see supra*, ¶§VI.E.2.c., but the shaft does not appear to have an inner lumen. It would have been obvious, however, to incorporate a lumen within Jacobi's shaft. Ex.1003, ¶267. Devices with a lumen within the shaft were well-known, such as Lee's device having a "cylindrical hollow shaft" and Quintana's needle. Ex.1006, 4:18-22; Ex.1004, 3; Ex.1003, ¶267. It would have been obvious to modify Jacobi's device to include a lumen within the shaft based on the knowledge of a POSITA as informed by prior art such as Lee and Quintana. For example, a POSITA could have simply substituted one known element (*e.g.*, Jacobi's tubing having no

lumen) for another (*e.g.*, surgical tubing with a lumen), and expected success given the successful use of devices with inner lumens in the art. Ex.1003, ¶267.

VII. Conclusion

For the foregoing reasons, IPR of claims 1-7 of the '155 patent is respectfully requested.

Dated: October 2, 2020

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 dual blade device useable for performing an ab intern [sic] procedure within a human eye to remove a strip of trabecular meshwork tissue, said device comprising:

[1.a] a handle configured to be grasped by an operator's hand;

[1.b] an elongate probe comprising a shaft that extends from the handle along a longitudinal axis;

[1.c] a blunt protruding tip that extends in a lateral direction from a distal end of the shaft to form a bend or curve of approximately 30 degrees to approximately 90 degrees relative to the adjacent longitudinal axis of the shaft;

[1.d] first and second lateral cutting edges formed at stationary side-by-side locations on the shaft, said first and second lateral cutting edges facing in the same lateral direction as the blunt protruding tip and being spaced apart such that an area exists between the first and second lateral cutting edges; and

[1.e] a blunt top edge that extends transversely from a top end of the first lateral cutting edge to a top end of the second lateral cutting edge and traverses above the area between the first and second lateral cutting edges;

[1.f] the blunt protruding tip having a transverse width, a top surface, a bottom surface and a terminal end, the transverse width being narrowest at the terminal end;

[1.g] the blunt protruding tip being below the area between the first and second lateral cutting edges and protruding in the lateral direction beyond the first and second lateral cutting edges such that tissue may pass over the top surface of the blunt protruding tip before coming into contact with the first and second lateral cutting edges;

[1.h] a distal portion of the shaft and the blunt protruding tip being sized to pass through an incision formed in the eye by a 1.5 mm slit knife; and

[1.i] the blunt protruding tip being further sized to fit within Schlemm's Canal of the human eye and, when so positioned, to be advanceable through

Schlemm's Canal with trabecular meshwork tissue passing over its top surface and into contact with the first and second lateral cutting edges.

Claim 2:

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

[2.a] the first and second lateral cutting edges are spaced apart by a distance D and cut a strip of trabecular meshwork tissue having a width W that is substantially equal to distance D.

Claim 3:

[3.p] A device according to claim 1

[3.a] useable for cutting a sector of trabecular meshwork tissue having a length of 2 to 10 millimeters.

Claim 4:

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

[4.a] the bottom surface of the blunt protruding tip extends at an angle of approximately 90 degrees relative to the adjacent longitudinal axis of the shaft.

Claim 5:

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

[5.a] in combination with a 1.5 mm slit knife for forming said incision in the human eye.

Claim 6:

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

[6.a] the device is manually operable to remove a strip of trabecular meshwork tissue.

Claim 7:

[7.p] A device according claim 1 wherein

[7.a] the shaft comprises a tube having at least one lumen.

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 13,943 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

/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. 9,358,155** 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 2, 2020

/s/ *John L. Reulbach III*

John L. Reulbach III

Attorney for Petitioner