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. IPR2020-01573
U.S. Patent No. 9,107,729

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,107,729

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EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent 9,107,729 ("the '729 patent")
1002	U.S. Patent 9,107,729 File History ('729 patent file history")
1003	Declaration of Dr. Peter Netland ("Decl.")
1004	Manuel Quintana, *Gonioscopic Trabeculotomy. First Results*, in 43 SECOND EUROPEAN GLAUCOMA SYMPOSIUM, DOCUMENTA OPHTHALMOLOGICA PROCEEDINGS SERIES 265 (E.L. Greve, W. Leydhecker, & C. Raitta ed., 1985) ("Quintana")
1005	M. Johnstone *et al.*, "Microsurgery of SC and the Human Aqueous Outflow System," *Am. J. Ophthalmology* 76(6):906-917 (1973) ("Johnstone")
1006	U.S. Patent 4,900,300 to Lee ("Lee")
1007	Philipp C. Jacobi *et al.*, "Technique of goniocurettage: a potential treatment for advance chronic open angle glaucoma," 81 BRITISH J. OPHTHALMOLOGY 302-307 (1997) ("Jacobi")
1008	Richard S. Snell *et al.*, *Clinical Anatomy of the Eye*, Malden, Massachusetts: Blackwell Science, Inc. (2nd ed., 1998) ("Snell")
1009	Am. Acad. Of Ophthalmology, *Section 8 External Disease and Cornea*, in BASIC AND CLINICAL SCIENCE COURSE 2001-2002 (2001) ("AAO Cornea")
1010	Michael John Hogan, *History of the Human Eye: An Atlas and Textbook.* Philadelphia, Pennsylvania: W. B. Saunders Company (1971) ("Hogan")
1011	M. Bruce Shields, *Textbook of Glaucoma, Fourth Edition*. Baltimore, Maryland: Williams & Wilkins (1998) ("Shields")

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

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 9,107,729 ("the '729 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 9,358,155 ("the '155 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.

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 ‘729 patent claims nothing more than using known techniques and devices to treat glaucoma, an eye disease that can lead to blindness. All limitations of the ‘729 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 (cutting a “strip of tissue” from the eye’s trabecular meshwork (“TM”) to treat glaucoma). Simply put, there is nothing in the claims of the ‘729 patent that was not known and/or obvious.

For decades, a common method of treating glaucoma has centered on creating openings in the TM, a tissue that regulates fluid outflow from the eye. Fluid build-up in the eye causes elevated intraocular pressure (“IOP”), which is the only modifiable risk factor for glaucoma, and removing sections of TM has long been known to lower IOP. Older surgical approaches to opening the TM created a single, slit-like incision to allow fluid to drain from the eye, but decades before the ‘729 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 ‘729 patent to create more permanent openings by removing strips of TM tissue to facilitate fluid outflow and prevent reclosure.

The ‘729 patent attempts to claim these well-known principles but fails to actually set forth anything inventive. The claims relate to methods for forming an opening in the TM but list steps that the patent itself admits were known and used in surgical procedures decades prior to the patent. The claims merely define a device for performing these well-known methods that includes nothing more than known components commonly used in surgical instruments for treating glaucoma. Tellingly, the patent ***describes the claimed device as effectively nothing more than a needle with a bent tip***. The claims attempt to cover a known technique for removing TM tissue using generic, broadly-claimed, known devices—nothing inventive or novel.

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

simply cover what was already well-known in the art, rendering those claims unpatentable.

Accordingly, Petitioner respectfully requests that trial be instituted and claims 1-10 of the '729 patent (the "Challenged Claims") be cancelled.

II. CERTIFICATIONS; GROUNDS

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

NWM certifies that the '729 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 '729 patent. The '729 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 '729 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

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

Jacobi	Published 1997	§§102(a) and (b)	1007

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

C. IPR Fee (§42.15(a))

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

D. Service (§42.105)

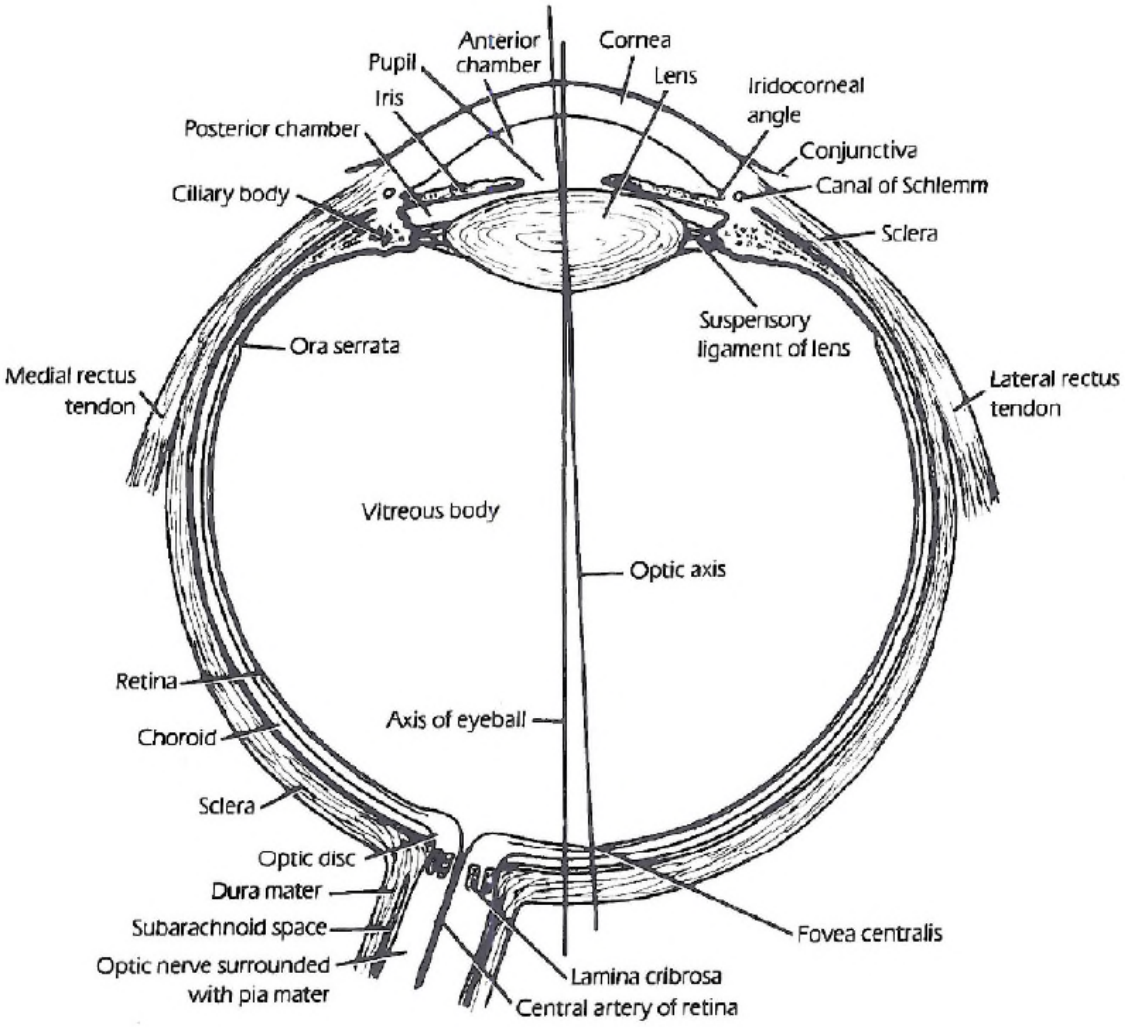
Proof of service of this petition is provided below.

III. Background Technology

A. Eye Anatomy

Human eyes take in light and convert it to a neural signal to provide vision. Ex.1008, 8-9, 47. Eyes have three layers: (1) an outer **fibrous layer**; (2) a middle

vascular layer; and (3) an inner **neural layer**. *Id.*, 11. The schematic diagram below depicts the layers and other structures of the eye.



Ex.1008, 9.

The outer fibrous layer includes the **cornea** (transparent part allowing light to enter) and **sclera** (opaque white part). Ex.1008, 1. The cornea is divided into "zones": (1) central; (2) paracentral; (3) peripheral; and (4) limbal. Ex.1009, 4; Ex.1003, ¶35.

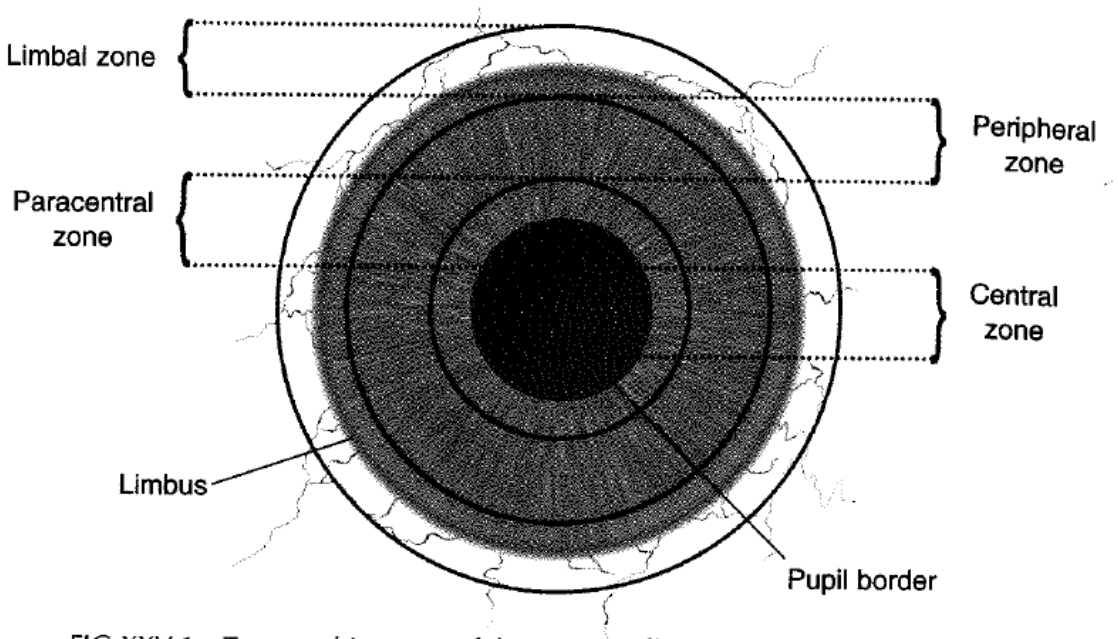


FIG XXV-1—Topographic zones of the cornea. (Illustration by Christine Gralapp.)

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, ¶36.

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

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

B. Aqueous Humor Outflow

Aqueous humor, a clear fluid that protects and nourishes the eye, flows from the posterior chamber into the AC via the pupil. Ex.1011, 27. Normally, aqueous drains through the **TM**, a filterlike tissue between the iris and cornea, and into **Schlemm's Canal ("SC")**, a canal running circularly about the eye. *Id.*, 16-17; Ex.1006, 1:9-27; Ex.1003, ¶41. The following shows a cutaway of the TM and SC:

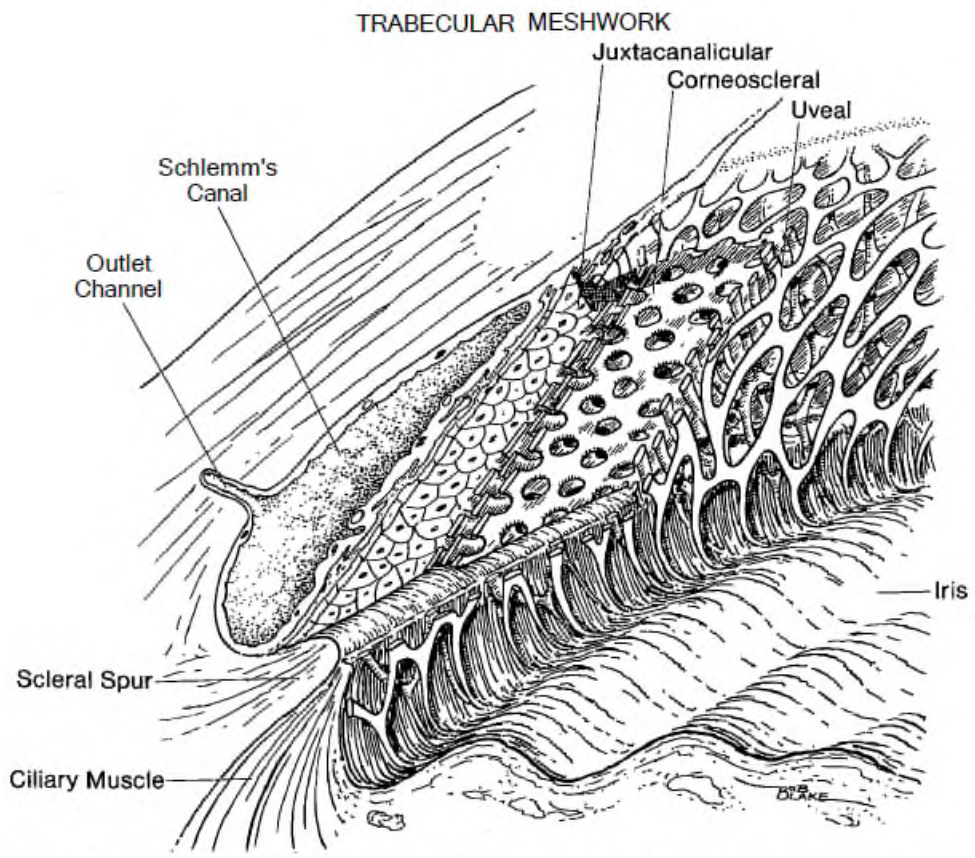


Figure 2.10. Three layers of trabecular meshwork (shown in cutaway views): (1) uveal; (2) corneoscleral; and (3) juxtacanalicular.

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, ¶42.

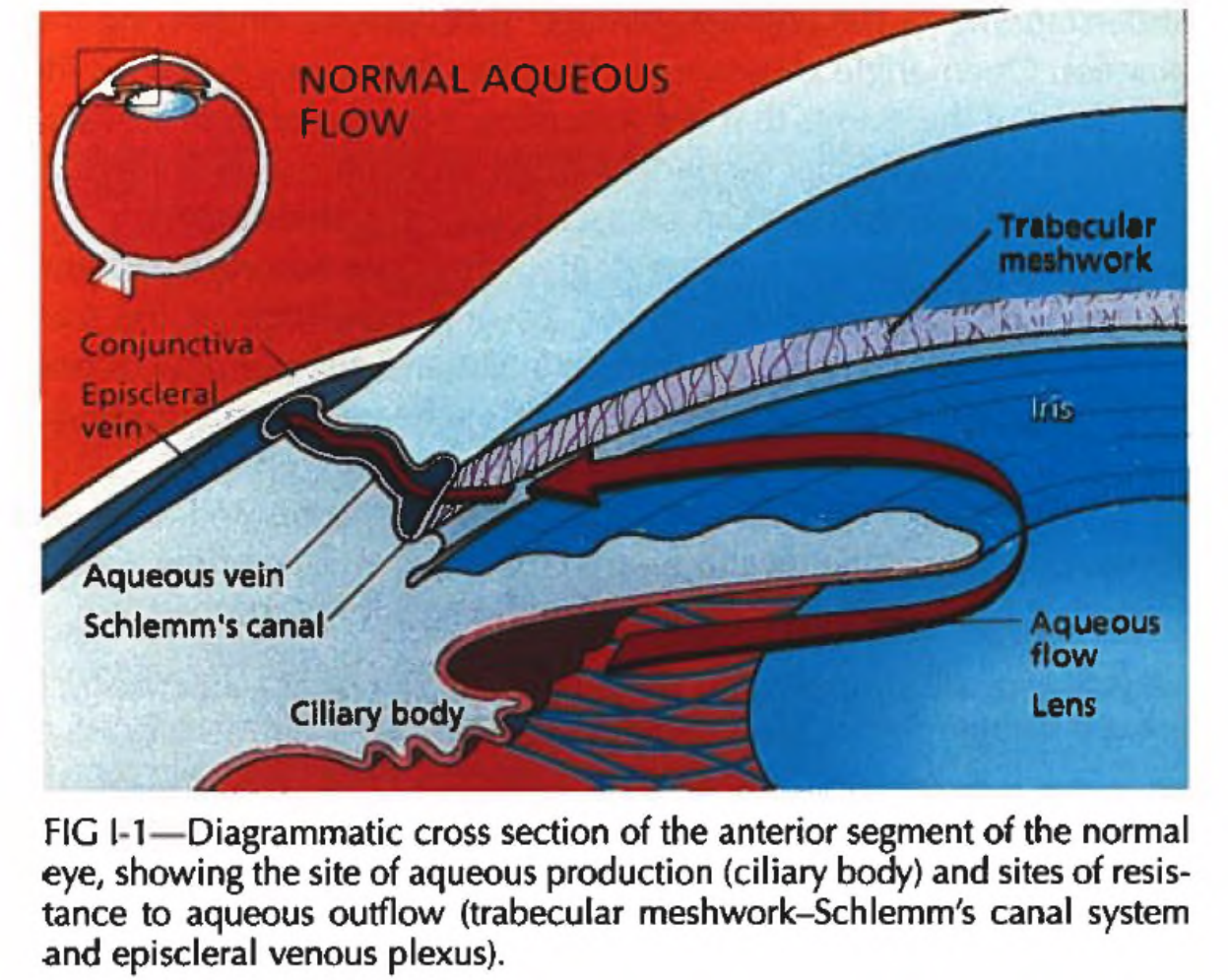


FIG I-1—Diagrammatic cross section of the anterior segment of the normal eye, showing the site of aqueous production (ciliary body) and sites of resistance to aqueous outflow (trabecular meshwork–Schlemm's canal system and episcleral venous plexus).

Ex.1012, 6.

C. Glaucoma

Glaucoma refers to a collection of diseases that can cause irreversible blindness. Ex.1003, ¶43. 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, ¶43.

Two common glaucoma types are open-angle and closed-angle. Ex.1012, 7; Ex.1003, ¶44-45. As shown below, in open-angle glaucoma, the TM restricts aqueous outflow from the AC. Ex.1012, 10.

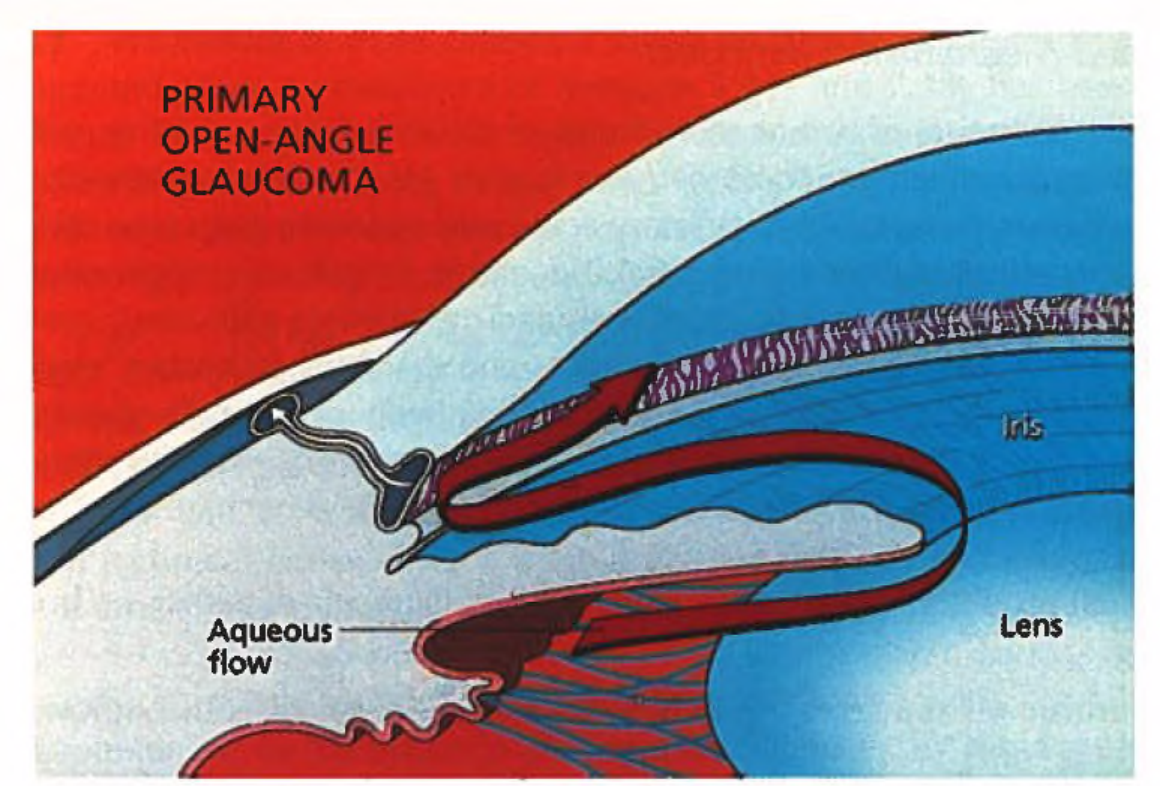


FIG I-2—Schematic of open-angle glaucoma with resistance to aqueous outflow through the trabecular meshwork–Schlemm's canal system in the absence of gross anatomic obstruction. Small white arrow shows normal path of outflow and indicates that resistance in this illustration is relative, not total.

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

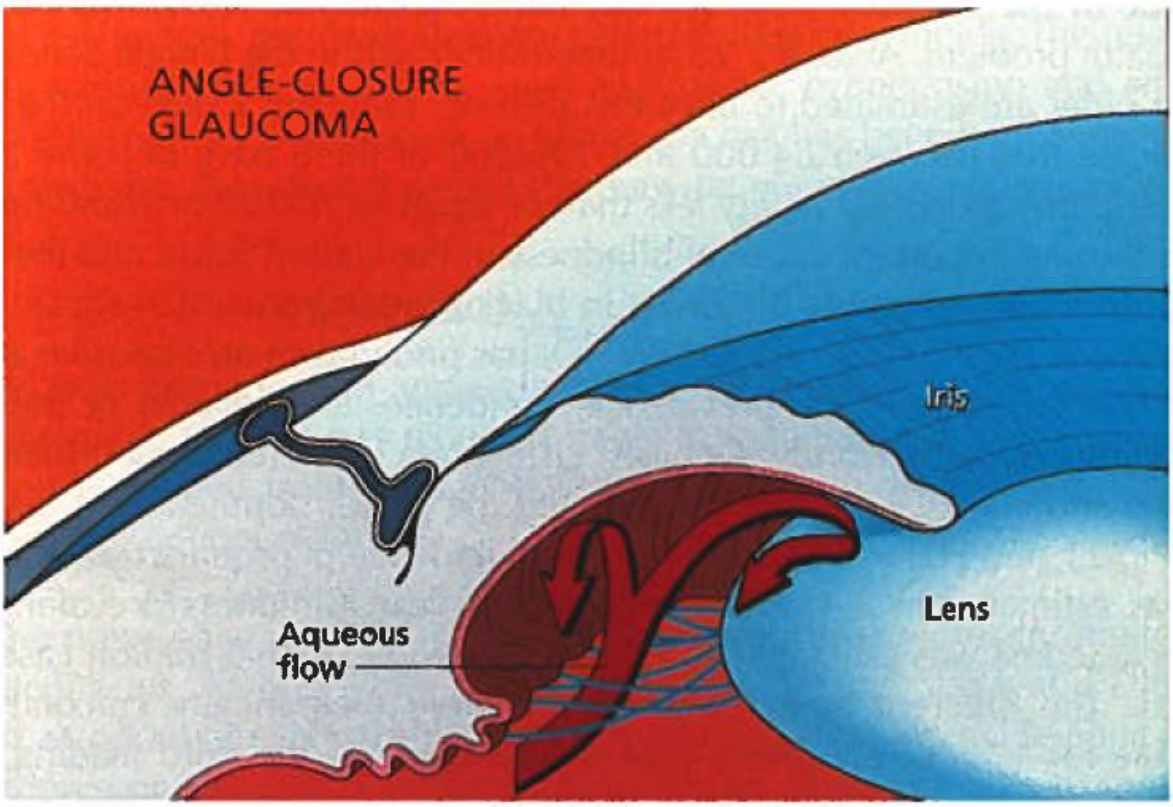


FIG I-3—Schematic of angle-closure glaucoma with pupillary block leading to peripheral iris obstruction of the trabecular meshwork.

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, ¶46.

D. Treatment of Glaucoma

Surgical attempts to treat glaucoma date back centuries and have often sought to decrease IOP by improving fluid drainage from the eye. Ex.1012, 4-5; Ex.1003, ¶47.

By the mid-1900's, Grant found that most resistance to outflow is caused by the TM and 75% of the resistance could be eliminated using an "ab interno"[2] approach to incise the TM. Ex.1007, 4; Ex.1011, 23. These findings spurred development of new surgical procedures that, well before 2003, focused on bypassing, disrupting, incising, and removing strips of TM tissue. Ex.1003, ¶48.

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, ¶50-51.

[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, ¶49.

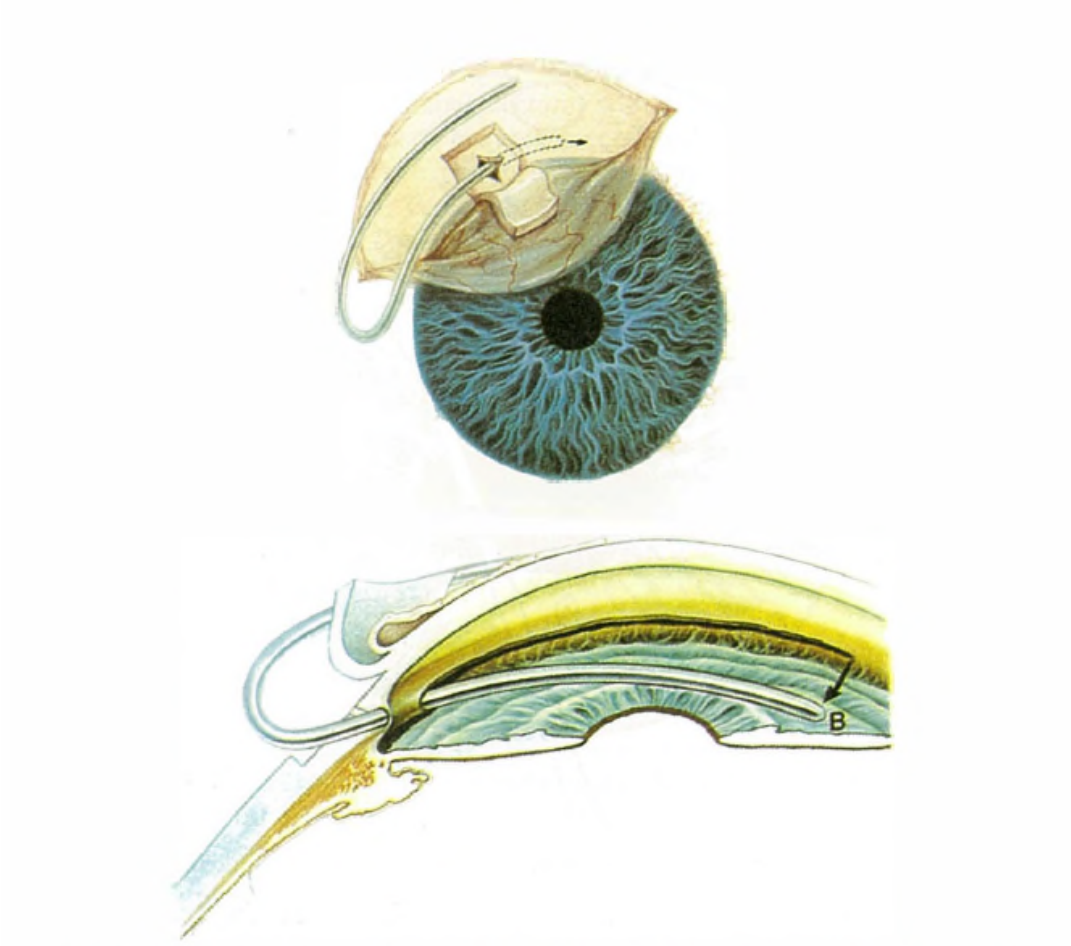


FIG VIII-13-Trabeculotomy. *Top,* Probe is gently passed along Schlemm's canal with little resistance for 6-10 mm. *Bottom,* By rotating the probe internally (8), the surgeon ruptures the trabeculum, and the probe appears in the anterior chamber with minimum bleeding. (Reproduced and modified with permission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

Trabeculectomy, described in the late 1960's, involves excising the TM. Ex.1011, 61-63. As shown below, trabeculectomy involves creating an exterior flap and ***excising*** (or removing) a portion of the TM, SC, and sclera underneath the flap to increase outflow. *Id.*; Ex.1003, ¶52.

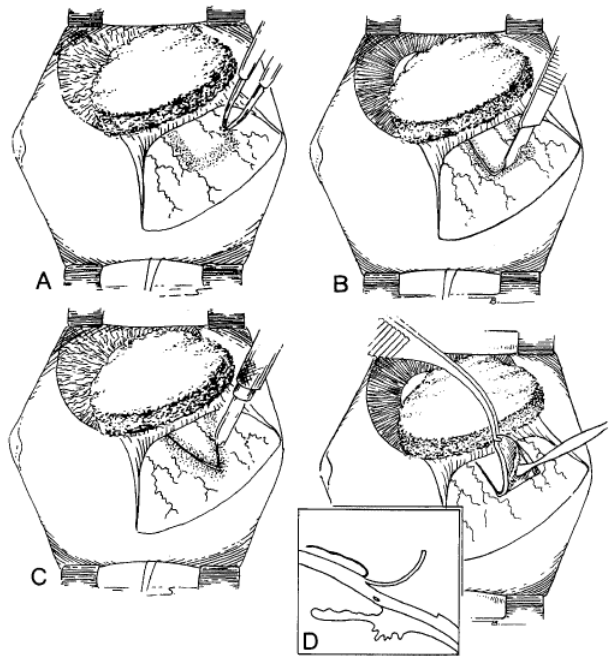


Figure 37.10. Trabeculectomy. A. Cauterization of area intended for margins of scleral flap. B. Margins of scleral flap outlined by partial-thickness incisions. C. Triangular scleral flap as an alternative technique. D. Dissection of scleral flap.

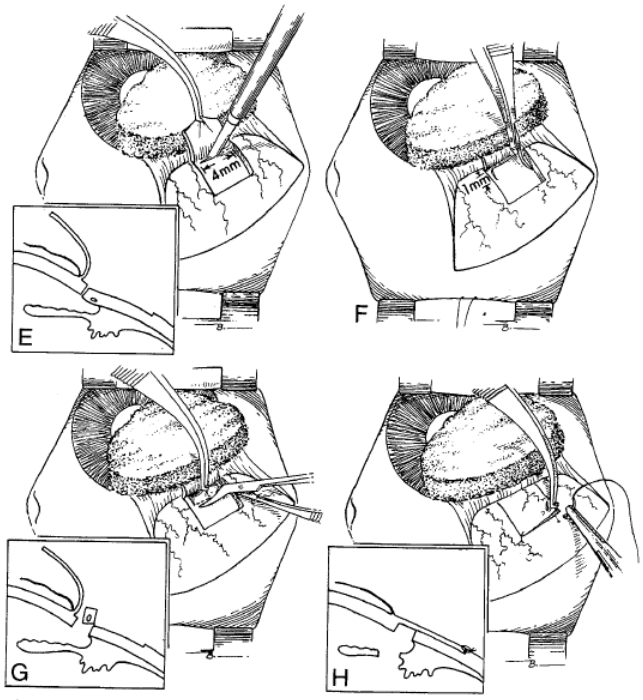


Figure 37.10. (cont'd) E. Anterior chamber entered just behind the hinge of the scleral flap. F. Completion of anterior and lateral margins of deep limbal incision with scissors. G. Flap of deep limbal tissue excised by cutting along scleral spur. H. Approximation of scleral flap. (Portions reprinted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

Ex.1011, 62-63.

2. Goniotomy

Goniotomy was introduced in the late 1930's. *Id.*, 51. As shown below, goniotomy is an "ab interno" procedure that involves penetrating the AC and creating a slit-like incision in the TM. *Id.*; Ex.1012, 51-52. A goniolens placed over the eye allows the surgeon to view the angle. Ex.1003, ¶¶53-55.

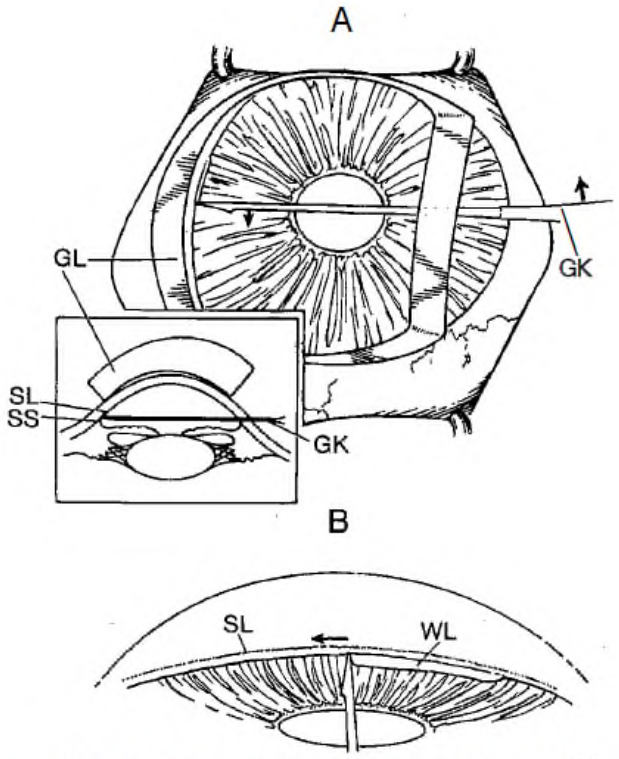


Figure 35.8. Goniotomy. A. With a surgical goniolens *(GL)* positioned on the cornea, a goniotomy knife *(GK)* is inserted through peripheral cornea and passed across the anterior chamber to the angle in the opposite quadrant. B. Under direct gonioscopic visualization, angle tissue is excised between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

Ex. 1011, 51.

3. "Excisional" Goniotomy

Despite success with these approaches, it was recognized well before 2003 that the slit-like opening these procedures create could close or scar over after surgery, blocking aqueous outflow. Ex.1007, 4 (traditional approaches "remove little tissue and allow filling in and scarring to occur with subsequent closure of the trabecular opening."); *see also* Ex.1006, 1:39-47; Ex.1014, 2; Ex.1003, ¶56. Techniques were developed to create larger and more permanent openings by removing strips of tissue to "avoid early reclosure" of the TM. Ex.1007, 4-5; Ex.1003, ¶56. These are referred to as "***excisional goniotomy***" procedures herein. Ex.1013, 11; Ex.1003, ¶¶56-57.

The '729 patent recognizes goniectomy was a known technique for treating glaucoma. Ex.1001, 1:36-65. Goniectomy is an "ab interno" procedure that involves excising and removing pieces of TM from the eye. *Id.*; Ex.1006, 5:55-6:45; Ex.1003, ¶58. 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, ¶58.

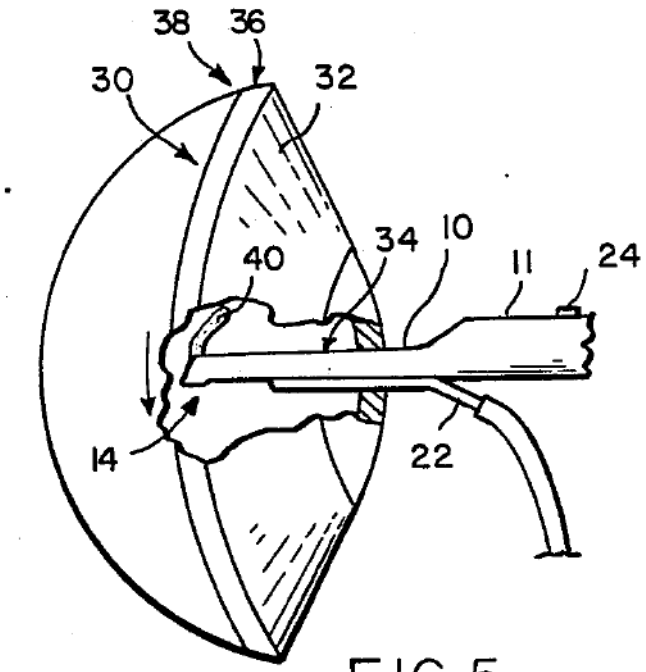


FIG.5

Quintana (Ex.1004) discloses a procedure for "stripping" and "achiev[ing] a section" of TM tissue. Ex.1004, 3, 4. Quintana sought to improve on techniques that incised TM by penetrating the AC with a needle having a tip bent 20-30°; introducing the needle tip into SC from within the AC; and "stripping" a section of TM tissue using the dual cutting edges at the needle tip. *Id*.; Ex.1003, ¶59.

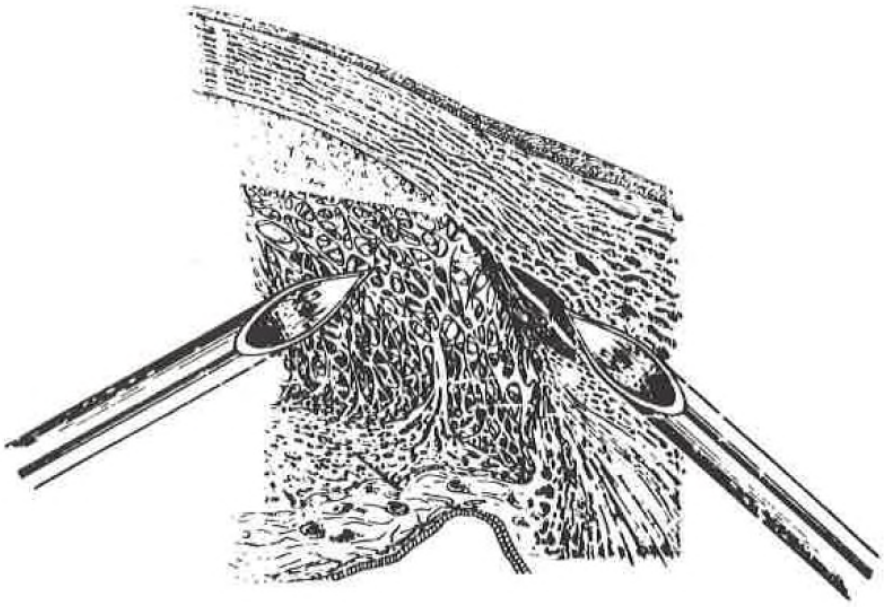


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

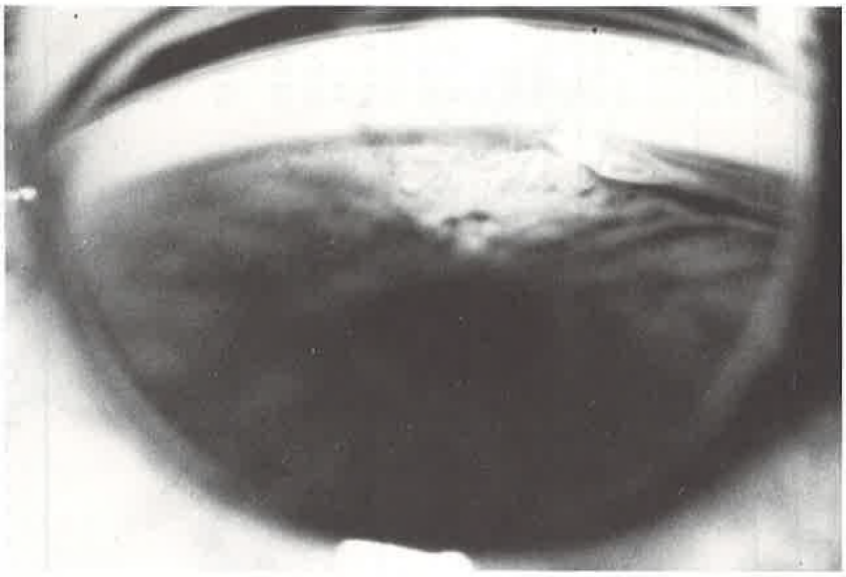


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

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, ¶60.

Clearly, 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, ¶61.

IV. The '729 Patent

A. Overview

The '729 patent discloses devices and methods for performing the well-known goniectomy procedure. Ex.1001, 1:21-2:37. The patent expressly ***admits*** that goniectomy procedures for ***removing strips of tissue from the eye were known***. *Id.*, 1:36-40; Ex.1003, ¶62. Neither its devices nor methods are valid over the prior art.

The patent claims a device that is effectively a needle with a bent tip. Ex.1003, ¶63. 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.

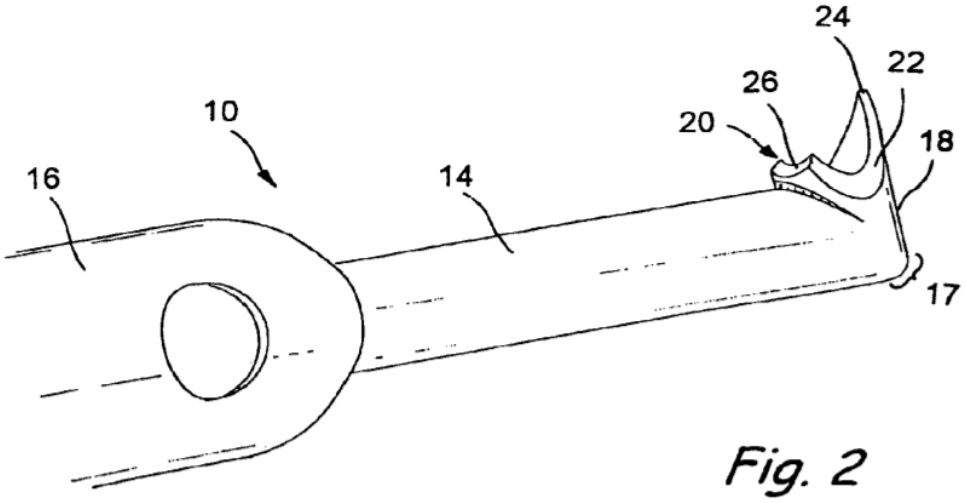


Fig. 2

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.*, 4:61-5:14; *see also id.*, Figs.3A-3D (below, showing "standard tubing" cut to form device); Ex.1003, ¶¶64-65.

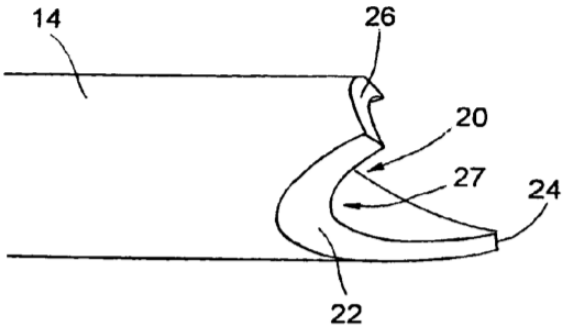


Fig. 3A

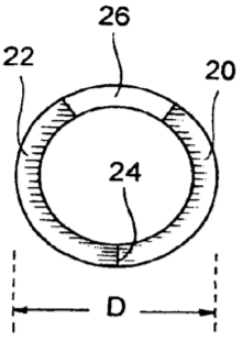


Fig. 3B

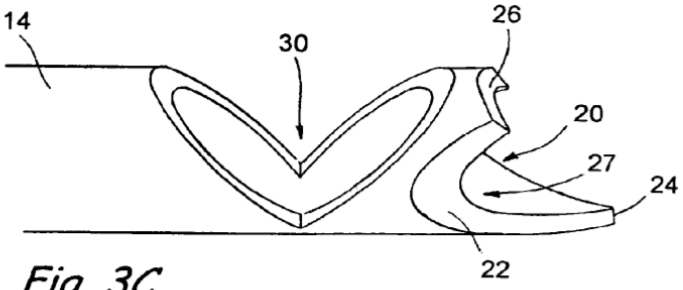


Fig. 3C

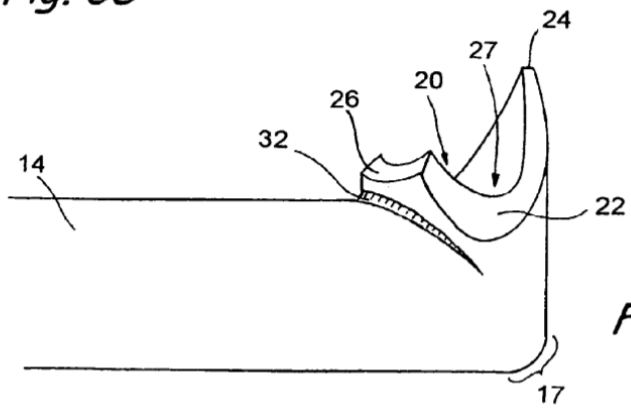


Fig. 3D

The patent also describes performing a goniectomy using the device in the exact same manner was well-known: inserting the device into the AC, advancing the tip 24 through SC, and cutting a strip of tissue from the TM. *Id.*, 5:28-6:24, Fig.4.

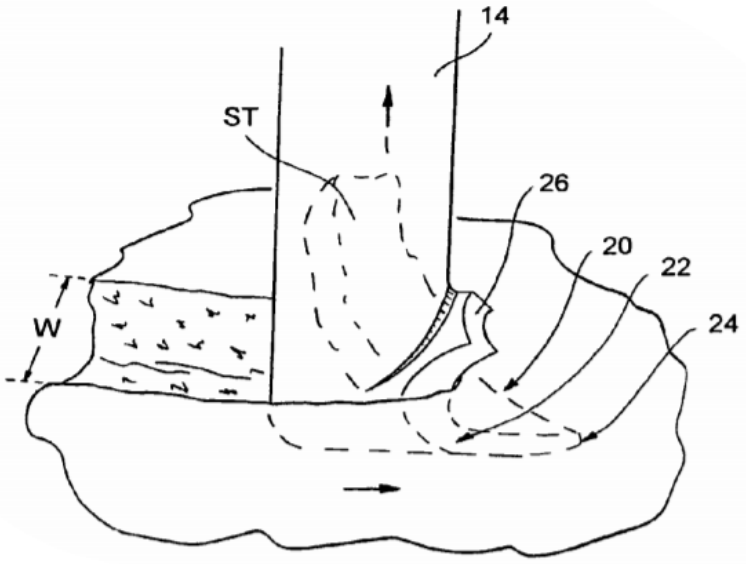


Fig. 4

This procedure had been performed for decades before 2003 to remove strips of TM. Ex.1003, ¶¶66-67. Importantly, the patent does not claim to have invented goniectomy and claim language related to that ***procedure is not a source of patentability***.

B. Prosecution History

The '729 patent issued from U.S. Application 14/481,754 ("the '754 application"), filed on September 9, 2014, and claims priority to U.S. Provisional Application 60,477,258, filed June 10, 2003. The '729 patent belongs to a large family and thus, only select portions of the prosecution histories are discussed.

1. '356 Application

The '754 application is a divisional of U.S. Application 13/159,356 ("the '356 application"), filed on June 13, 2011. 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

Originally-filed claim 1 of the '754 application was directed to an "ab interno method for using a device to form an opening in the TM of a patient's eye," which included, "obtaining a dual blade device which comprises . . . a distal protruding tip that extends at an angle of from 20 degrees to 90 degrees from a distal end of the shaft and is sized to be inserted in SC." Ex.1002, 31.

During an interview, the Examiner "suggested claim amendments to expedite prosecution." *Id.*, 315. A notice of allowance subsequently issued, which included an Examiner's amendment adding: "a distal protruding tip that extends ~~at an angle~~ from a distal end of the shaft <u>to form a bend or curve having an angle of at least 30 degrees, said distal protruding tip being</u> sized to be inserted in SC." *Id.*, 311-18. 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." *Id.*, 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.1005, 4:38-41, Figs. 2 (bottom view) and 3 (sectional side view).

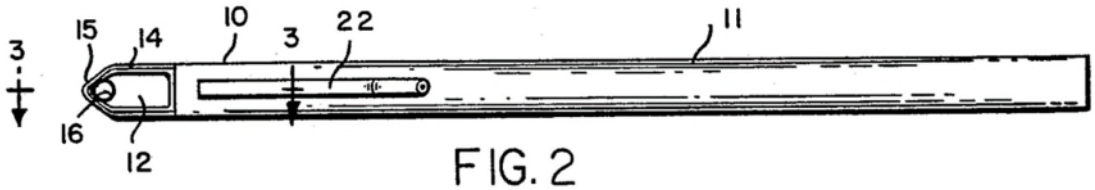


FIG. 2

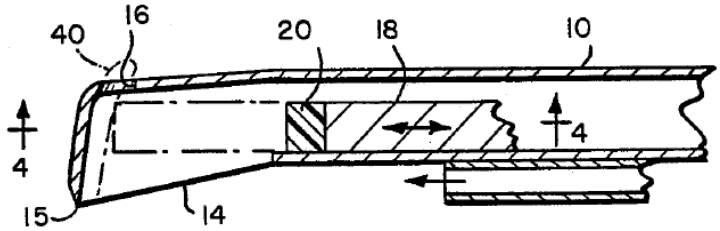


FIG. 3

Given the Examiner's finding that Lee 's device has "dual blades corresponding to the U-shape," a "dual blade device" is simply one with two edges for cutting. Ex.1003, ¶¶71-72.

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, ¶27.

D. Effective Filing Date

The '729 patent claims priority to the '258 provisional filed June 10, 2003. Because the prior art relied upon in this Petition published well before 2003, for this Petition alone NWM will assume a June 10, 2003 effective filing date for the '729 patent claims.

V. Claim Construction

In IPR proceedings filed after November 12, 2018, claims are construed under the standard used in civil actions under 35 U.S.C. §282(b). 37 C.F.R. §42.100(b). Except as noted below, Petitioner submits no terms require construction.[3]

A. "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, ¶74. The '729 patent uses these terms in this way to

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

describe the direction from which the TM is approached. In an "ab interno" procedure, the TM is approached from ***within*** the AC. Conversely, "ab externo" signifies approaching the TM through an opening made on the ***outside*** of the eye. *Id.*, ¶¶75-77.

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). Likewise, during prosecution, applicant explained "ab interno" requires approaching the TM from within the AC while "ab externo" involves making an incision on the eye's exterior directly into SC and removing TM through that incision. Ex.1019, 229-30, 264; Ex.1003, ¶¶78-80.

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, ¶81; Ex.1007, 2. Moreover, limiting "ab interno" to a specific entry point would violate claim differentiation. Claim 7 (dependent on claim 1) specifies forming an opening into the AC by "an incision through a cornea of the eye." "Ab interno" in claim 1 thus cannot be limited to openings through the cornea and instead must allow any opening into the AC. Ex.1003, ¶82. Accordingly, "ab interno" means approaching TM through the AC. *Id.*, ¶83.

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, cl.1; Ex.1003, ¶¶85-86.

The "needle cutter device" disclosed is effectively 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, the intrinsic record confirms that devices with U-shaped cutting edges, such as Lee's, are "dual blade" devices. Ex.1002, 320. "Dual blade devices" can thus encompass any device with generally spaced-apart cutting edges, including needle-like devices and devices such as Lee's. Ex.1003, ¶¶87-90.

VI. Detailed Explanation of Unpatentability

A. Ground 1: Quintana (Ex.1004) Anticipates Claims 1-4 and 7-9

1. Overview of Quintana

Quintana[4] describes an "ab interno" method for treating glaucoma. Ex.1004, 3. According to Quintana, "[i]ncreased resistance to the outflow of aqueous through the TM is the most accepted pathogenic mechanism in the majority of open-angle glaucomas" and therefore, "the rational treatment of the trabecular glaucomas should consist in opening the TM." *Id.* Quintana's technique "***achieves a section*** of the TM without damage to the external wall of SC." *Id.* (emphasis added); Ex.1003, ¶91.

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

[4] Quintana was not cited during prosecution of the '729 patent.

"stripped" from SC. *Id.* The needle advances 100-120° through SC. *Id.* The technique resulted in an IOP decrease in almost all cases. *Id.*, 3; Ex.1003, ¶92.

Quintana specifically indicates that the needle penetrates the AC "through the scleral side of the limbus . . . in order to run parallel to SC." Ex.1004, 4. Quintana did this to cause the needle to be roughly parallel to SC upon entry into the AC, given that SC is beneath the limbus in most patients. Ex.1003, ¶93. Penetrating the AC at or near the limbus would still have allowed the needle to run parallel to SC upon entry for the same reason. *Id.*

Quintana states the needle penetrates the AC on a "tangential approach." Ex.1004, 4. This means the needle tip approaches and enters the TM at a shallow angle to allow each cutting edge at the tip to separately cut the TM. Ex.1003, ¶94. 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).

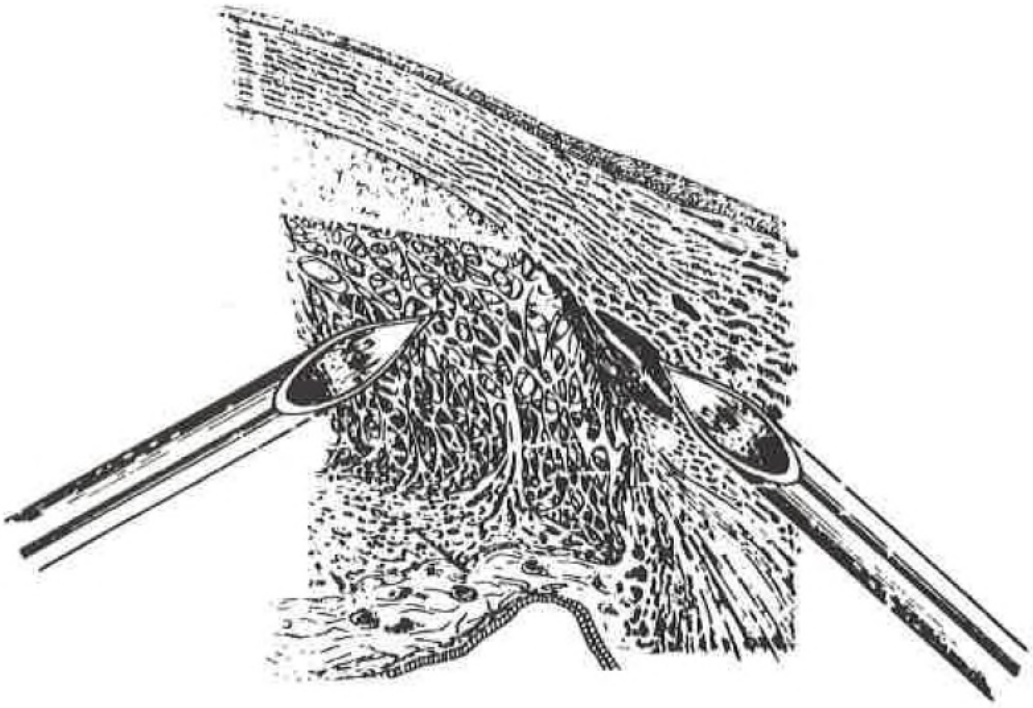
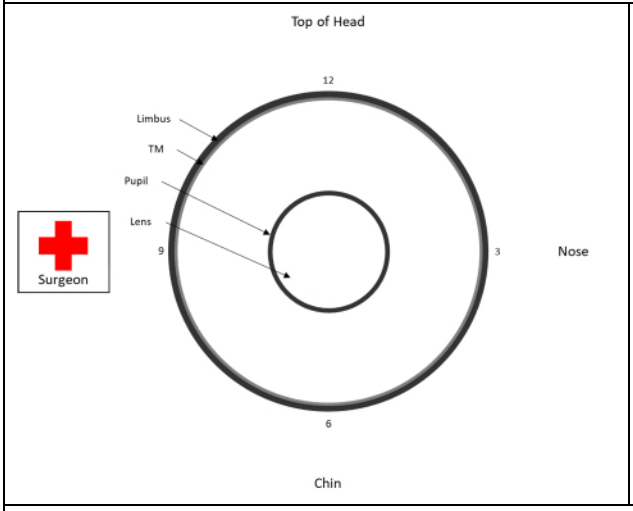
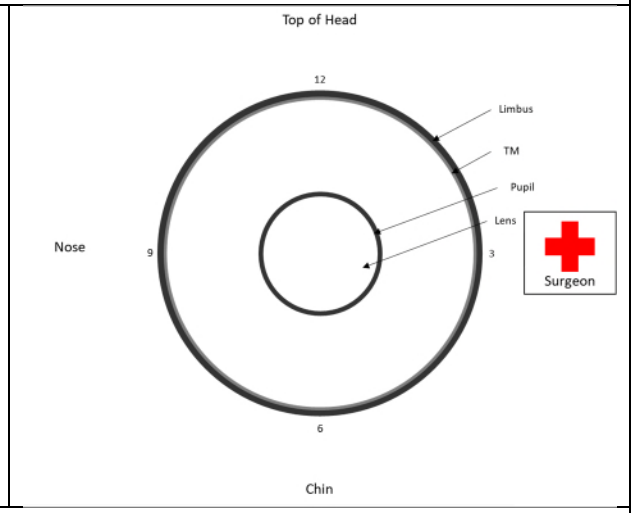
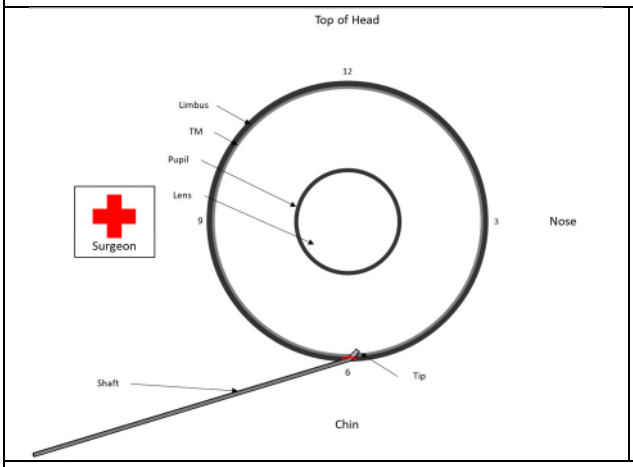
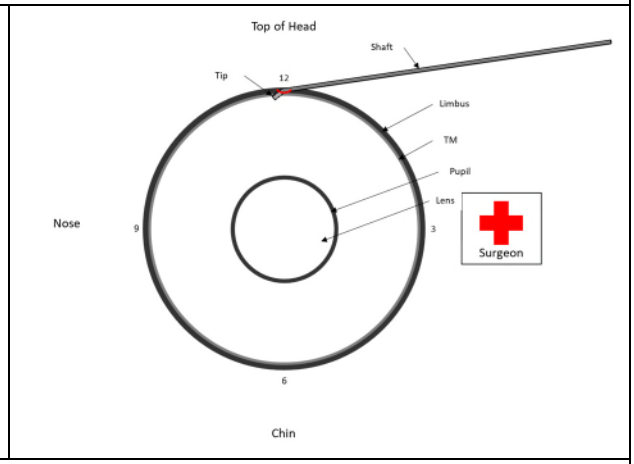
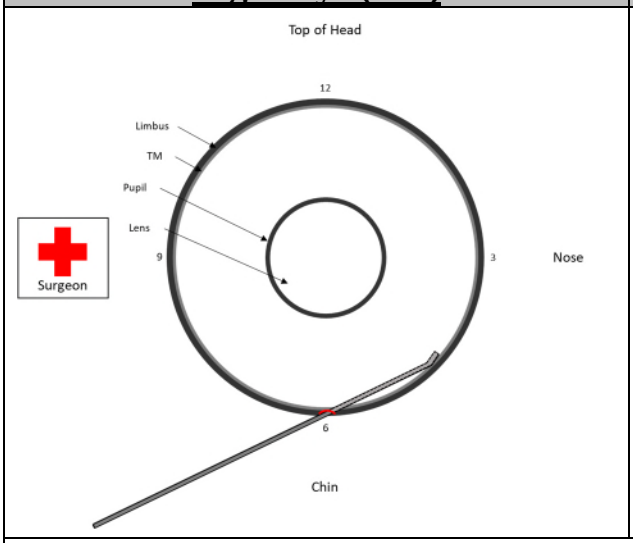
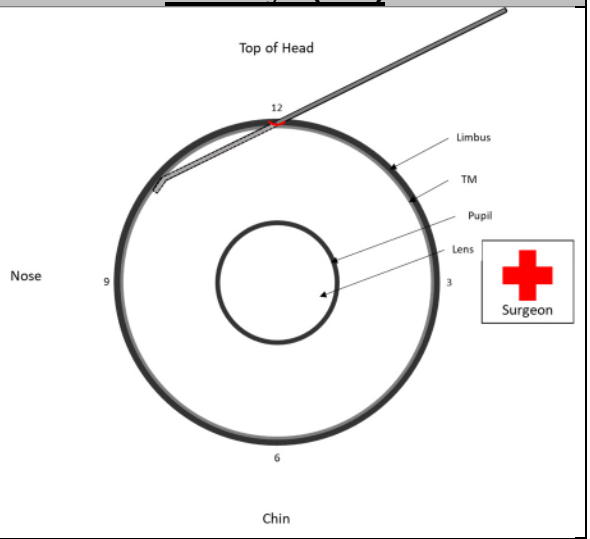


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

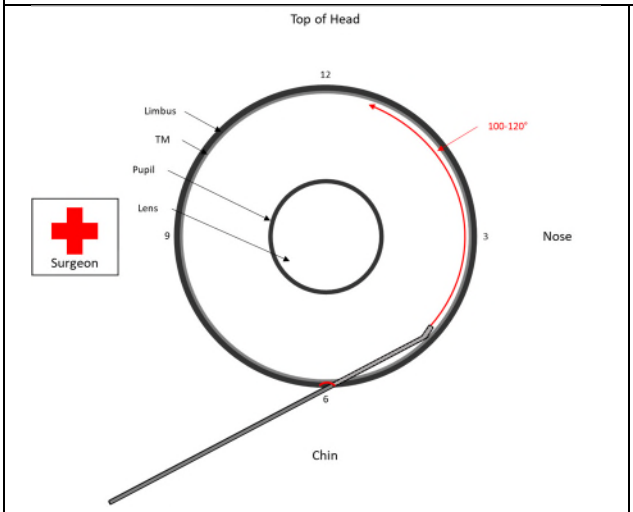
Ex.1004, 4.

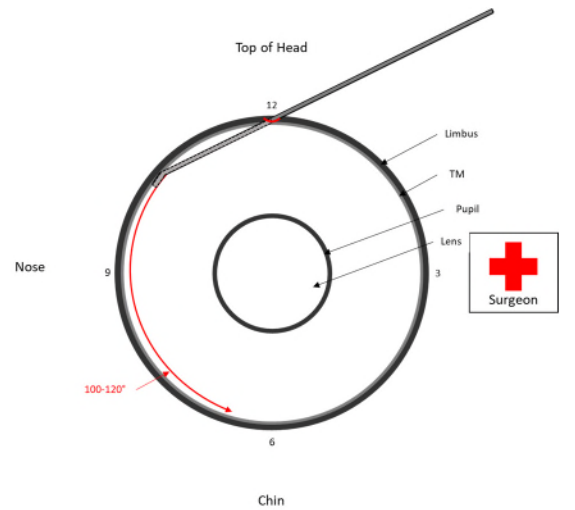
At the direction of NWM's expert, Dr. Peter Netland, illustrations depicting Quintana's procedure were prepared. Ex.1003, ¶95. The illustrations show a patient's right and left eye with the general location and progression of Quintana's needle throughout the procedure. *Id.*

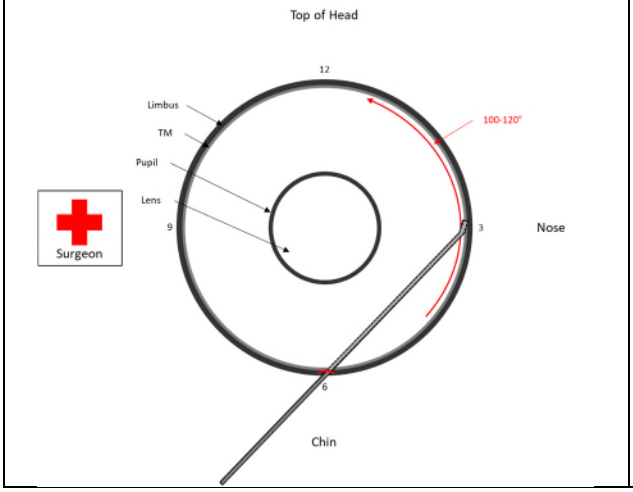
Right Eye (OD)	Left Eye (OS)
Surgeon positioned on temporal side of patient. Ex.1004, 3-4.	
	
"The needle penetrates the anterior chamber at 6 hours (right eye) or 12 hours (left eye) through the scleral side of the limbus." Id., 4.	
	
Needle tip introduced into SC with convexity of tip facing external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

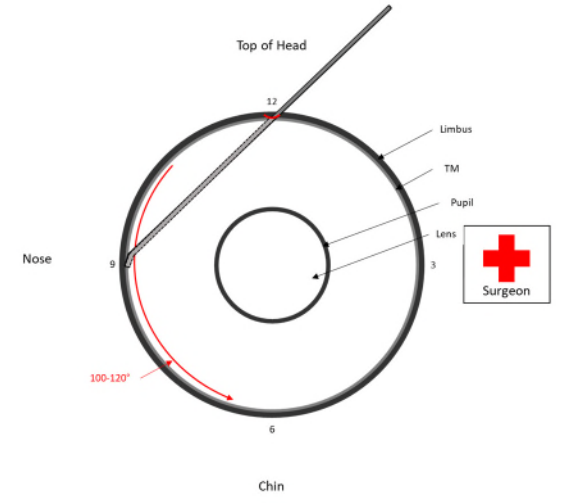
Right Eye (OD)	Left Eye (OS)
	

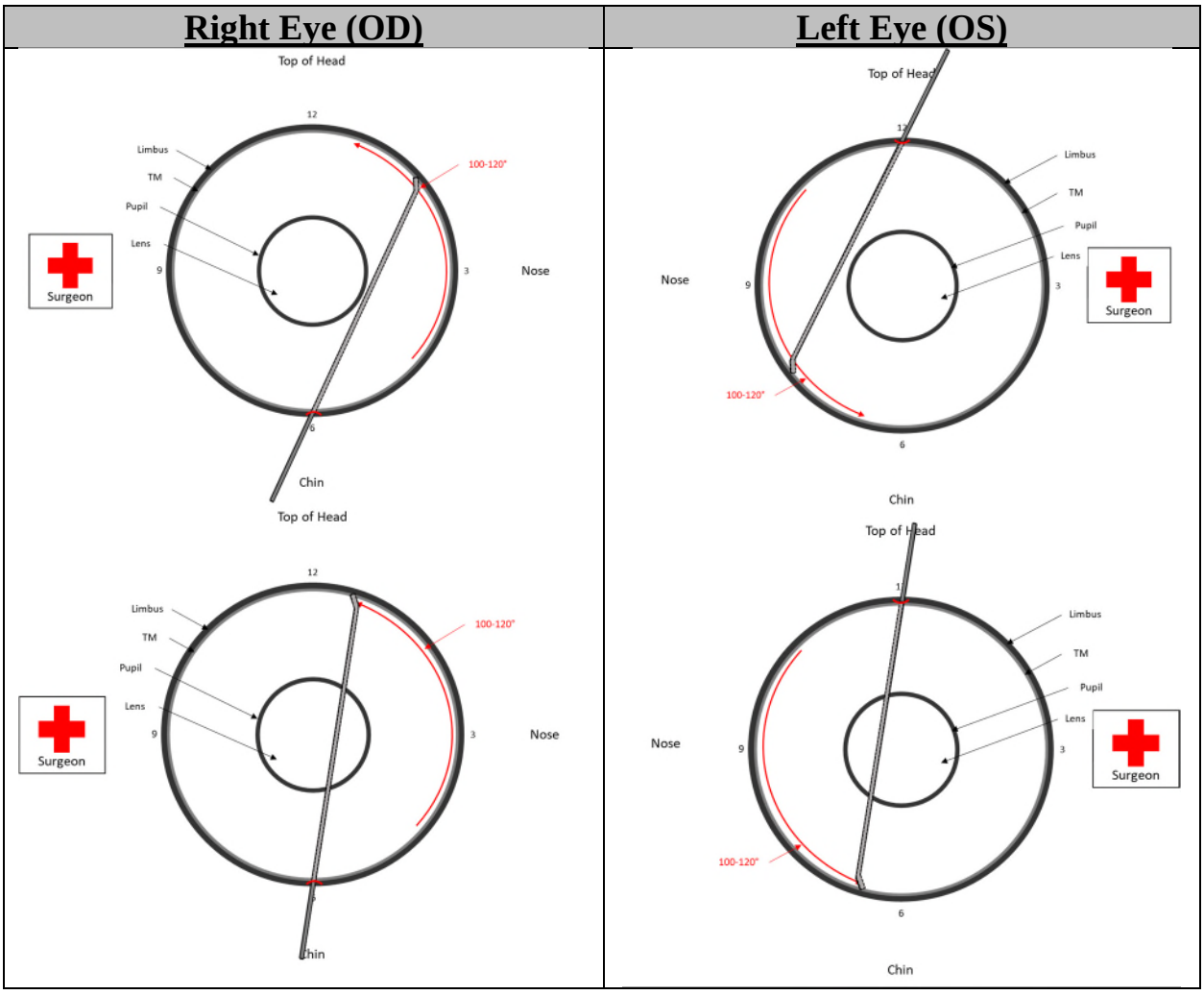
"A 100-120° trabeculotomy can be achieved." Id.











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

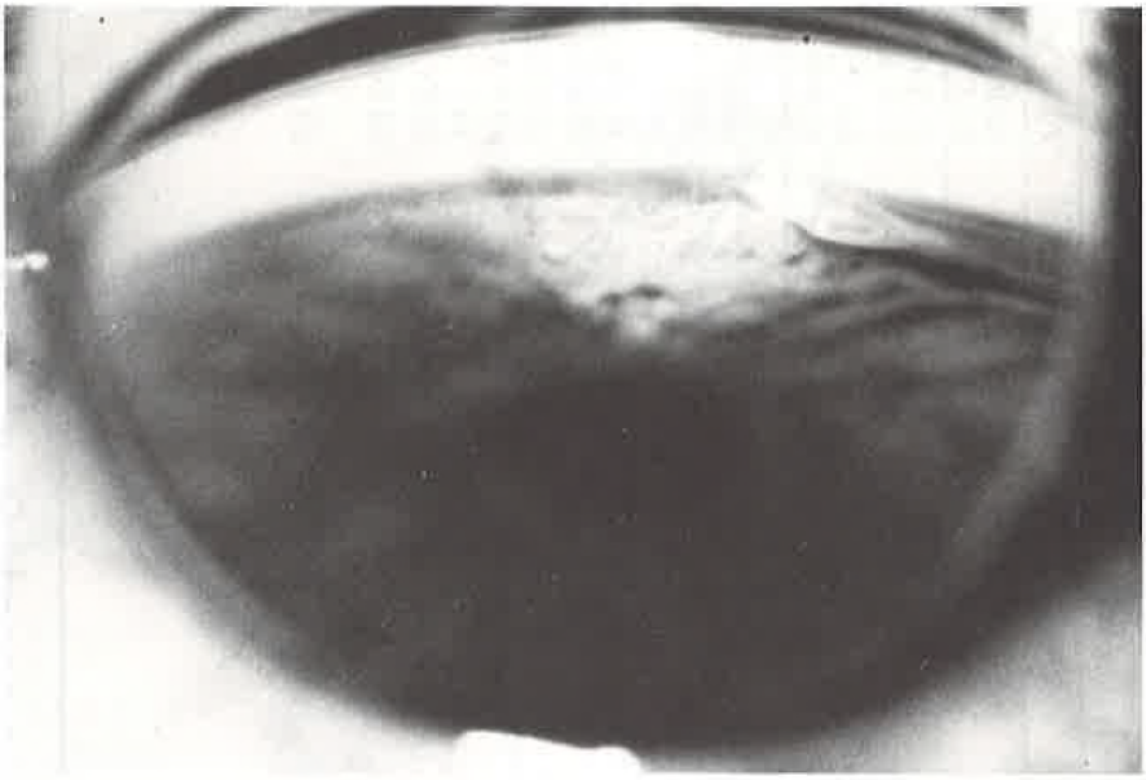
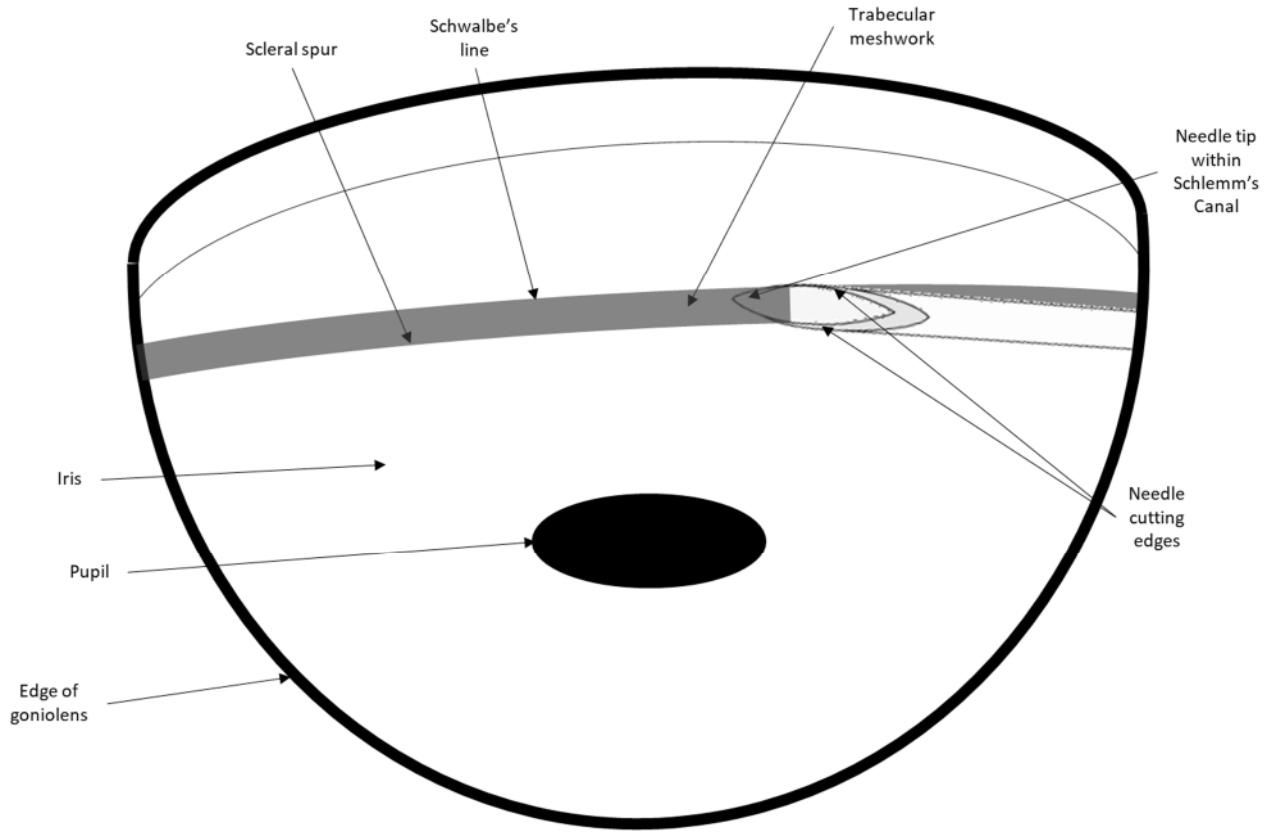


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

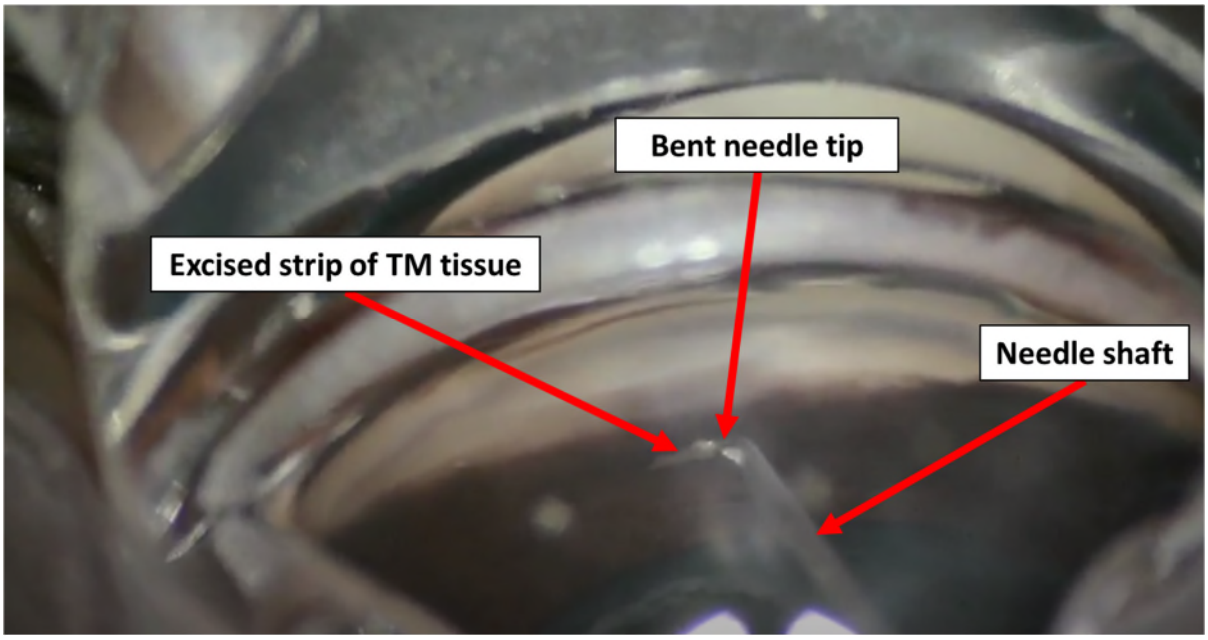
Id., Fig.2. To more clearly visualize Fig.2, the following schematic was prepared at Dr. Netland's direction. Ex.1003, ¶96.



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, ¶¶98-100. Not only is this demonstrated explicitly in Quintana, but Quintana's basic technique has since been used in similar surgical procedures to remove strips of TM from SC. *Id.* For example, Shute (Ex.1020) describes a procedure called "bent ab interno needle goniectomy" ("BANG") that involves, like Quintana, using a standard needle having a bent tip to "completely excise a segment of TM" and in which the needle's "cutting edges" create a "double blade" "capable of excising tissue en

bloc." Ex.1020, 1; Ex.1003, ¶98. Another surgeon posted a video online showing performance of the BANG procedure on a patient's eye, showing the tip of a standard needle being bent, entering the AC, being introduced through the TM into SC, and advancing through SC. Ex.1021; Ex.1003, ¶¶99-100. 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, ¶¶99-100.



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

2. Claim 1

a. Element 1.p

Quintana's procedure "achieves a ***section of the TM***" and the reference states "***the TM is <u>stripped</u> slowly, gently and easily from the canal's lumen*** towards the anterior chamber as the needle progresses in the angle." Ex.1004, 3, 4 (emphasis added). Figures 1 and 2 depict forming an opening in the TM of a patient's eye:

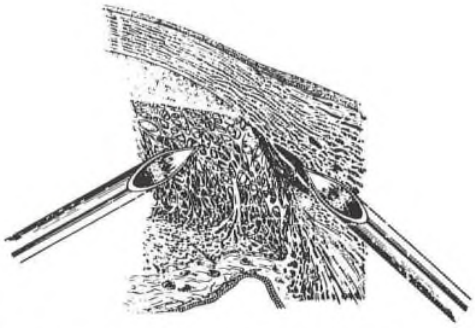


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

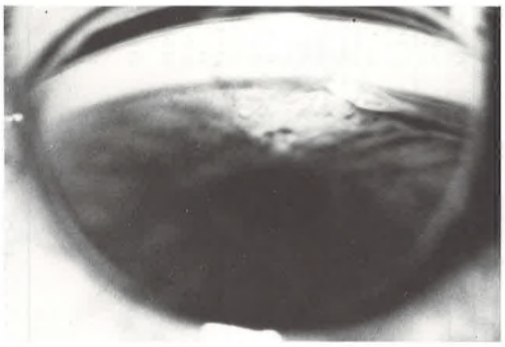


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

Id., Figs. 1-2; Ex.1003, ¶113.

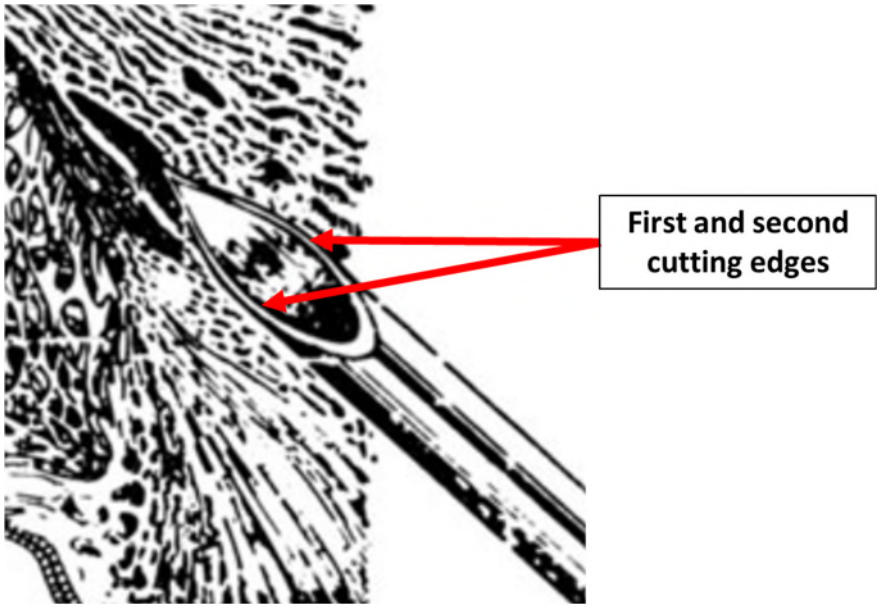
Quintana's procedure is "***ab interno***." Ex.1003, ¶114. As explained above, "ab interno" procedures are those in which the TM is approached from ***within*** the AC. *See supra*, §V.A. Quintana's procedure is "ab interno" because Quintana's needle approaches the TM from ***inside*** the eye ***within*** 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, ¶¶114-17.

A POSITA ***could not*** interpret Quintana's procedure as "ab externo." Ex.1003, ¶117. 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" would not indicate the procedure is "ab externo." Ex.1003, ¶118. Quintana explicitly states "[t]he needle ***penetrates the anterior chamber***" and approaches the TM from ***within*** the AC. Ex.1004, 4. Accordingly, Quintana discloses an "ab interno" procedure as claimed. Ex.1003, ¶¶118-19.

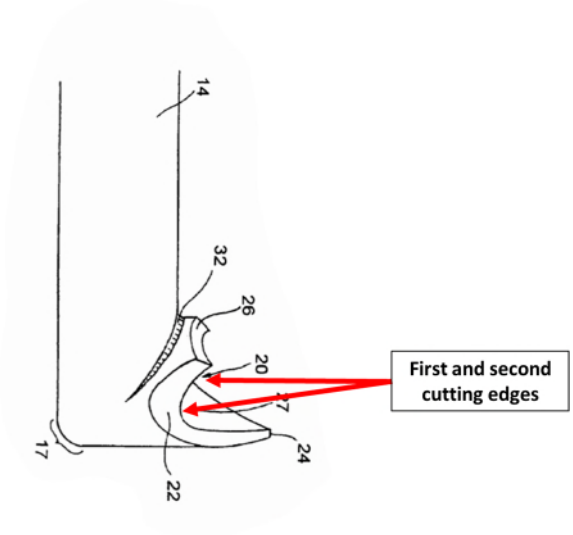
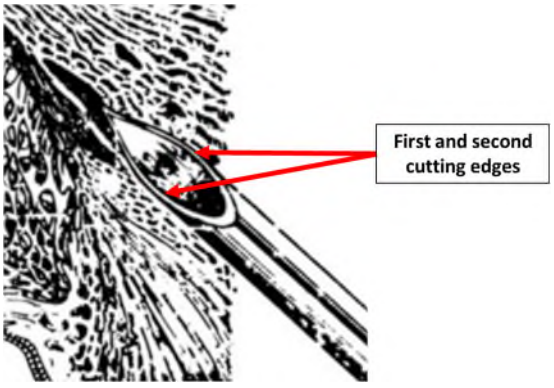
b. Element 1.a

Quintana teaches the claimed "dual blade device." Ex.1003, ¶120. Quintana uses a "trabeculotome [that] is a 0.4 x 15 mm needle, or an insulin-type needle" with the tip bent 20-30°. Ex.1004, 3.

A POSITA would understand Quintana's needle is a "dual blade device," which is simply a device with two cutting edges capable of cutting tissue. *See supra*, §V.B; Ex.1003, ¶121. As shown below, Quintana's needle has dual spaced-apart 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 '729 patent, as both have first and second cutting edges spaced apart on opposite sides of a needle tube:

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

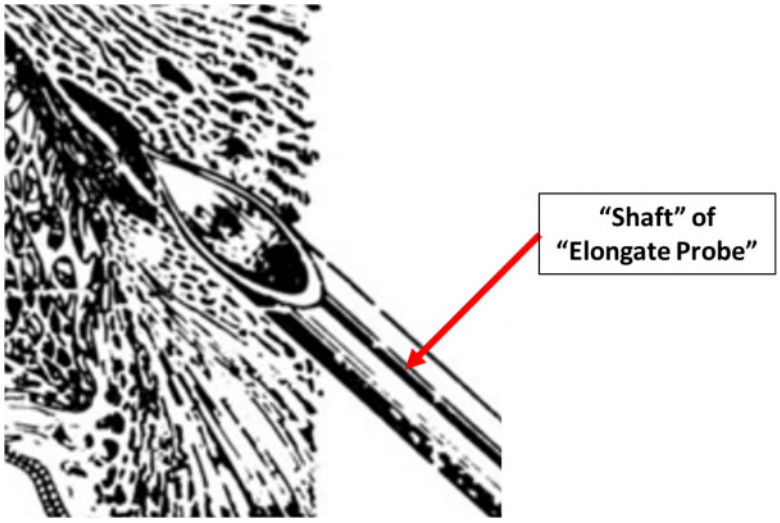
Ex.1003, ¶121. Quintana explains its cutting edges cut TM tissue. Ex.1004, 4. The "distal protruding tip" with "first and second cutting edges", *see infra*, §§VI.A.2.e, VI.A.2.g, is inserted into SC and used to "strip[]" the TM, which "achieves a section of the TM." Ex.1004, 3, 4. Because Quintana's needle has first and second cutting edges that cut tissue, the needle is a "dual blade device." Ex.1003, ¶122.

c. Element 1.a.1

Quintana states that "[t]he needle is ***inserted into a syringe***." Ex.1004, 3 (emphasis added). A POSITA would appreciate that syringes are intended to be grasped by a hand of a human operator. Ex.1003, ¶123.

d. Elements 1.a.2 and 1.a.2.i

Quintana's device is a needle inserted into a syringe, and thus the needle is an "elongate probe" that extends from the syringe or "elongate proximal portion." Ex.1004, 3; Ex.1003, ¶124. As shown below, the needle includes a shaft, *i.e.*, the needle tube.



Ex.1004, Fig.1 (annotated); Ex.1003, ¶124.

e. Elements 1.a.2.ii

The '729 patent states the "distal protruding tip" is "located on the bottom of the distal end of the cutting tube" and can be "configured and used to facilitate insertion of the device [] to its intended location" or "placed in an anatomical or man made groove or channel (e.g., SC of the eye) such that it will then advance through the channel or groove and guide the advancement and positioning of the remainder of the device." Ex.1001, 3:10-24, Fig.4 (below, "distal protruding tip 24").

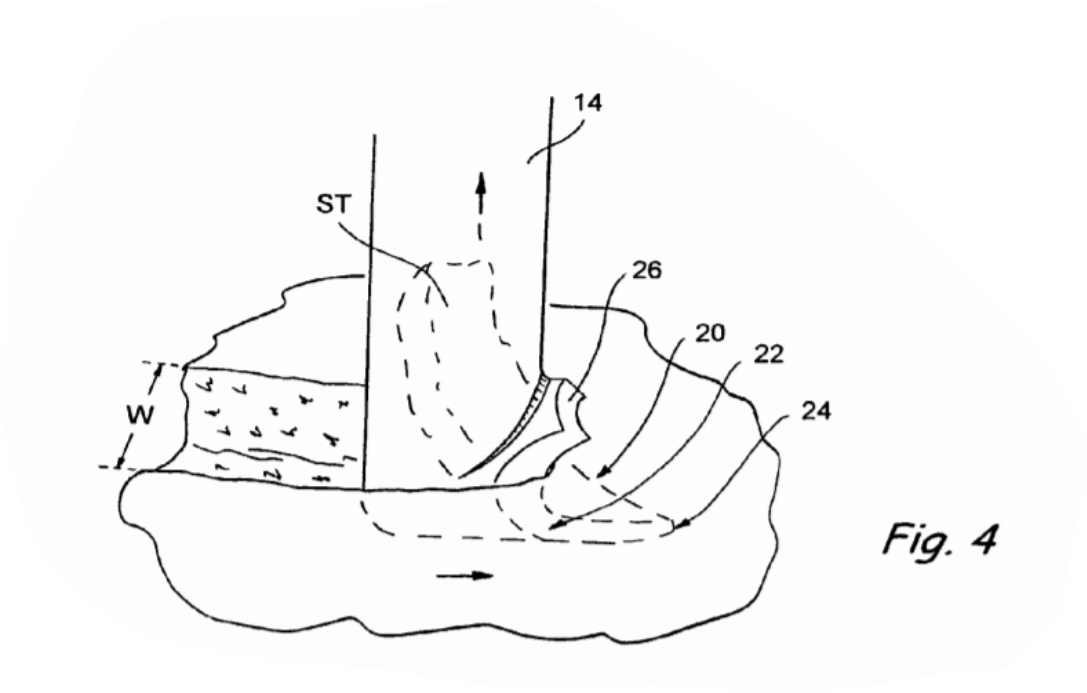
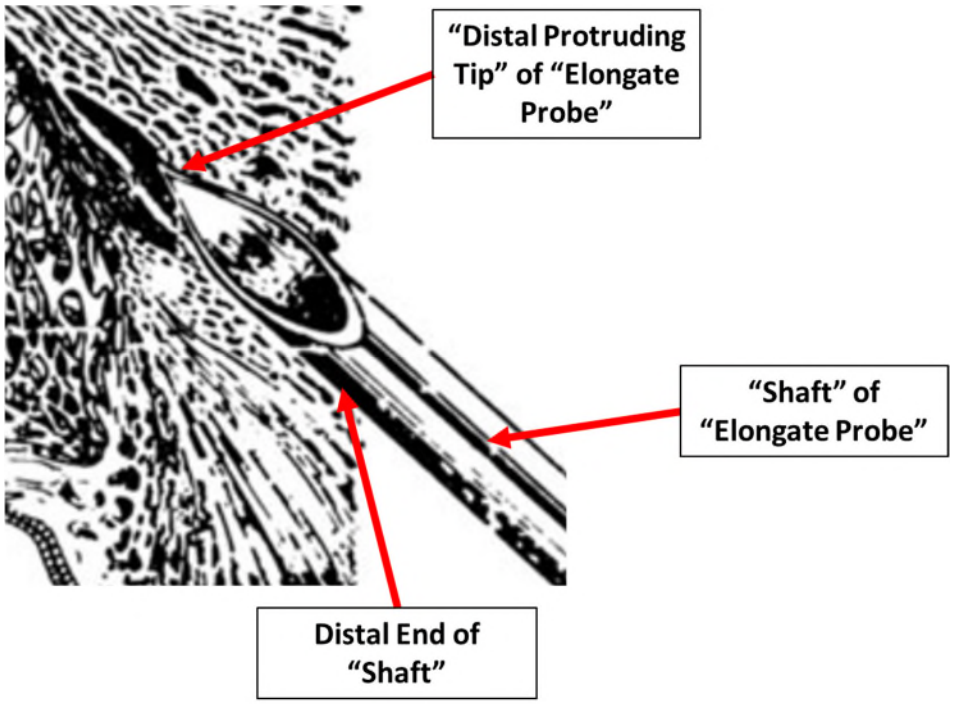


Fig. 4

As shown below, the point at the end of Quintana's needle that extends from the distal end of the shaft is a "distal protruding tip" as claimed. Ex.1003, ¶126.



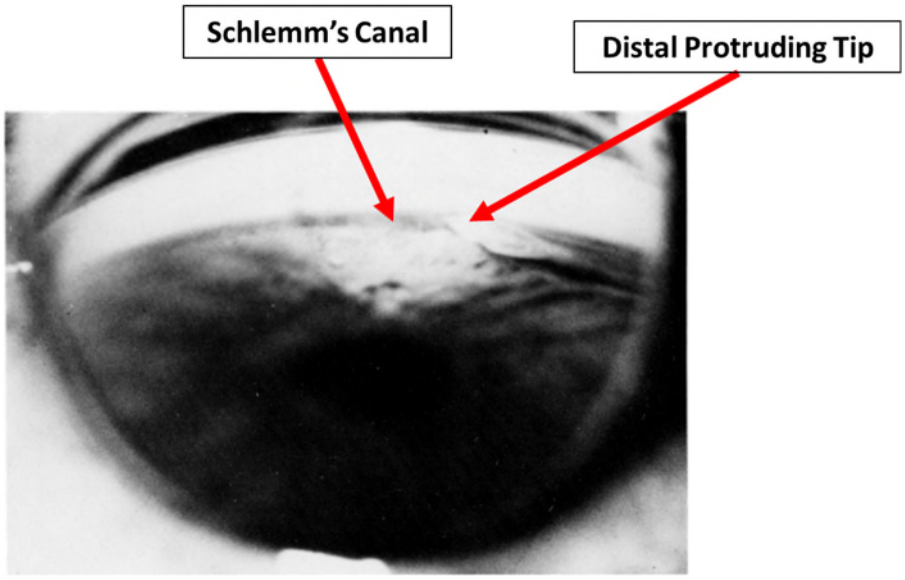
Ex.1004, Fig.1 (annotated). The figure also shows the "distal protruding tip" entering the SC through the TM such that it will guide the device through the canal. *Id.*, 4 ("Only the tip of the instrument is introduced into [SC], and the [TM] is stripped slowly, gently and easily from the canal's lumen towards the anterior chamber as the needle progresses in the angle."); Ex.1003, ¶126.

Quintana teaches that the needle "tip" is bent 20-30°, which Quintana explains is done so the convexity of the tip faces the external wall of SC such that the structure is not damaged.[5] Ex.1004, 3 ("we ***bend the tip 20-30°*** with a needle-holder"), 266 ("This is why we ***bend the tip*** and we point it towards the anterior chamber."). This bent portion of Quintana's needle, which includes the "distal protruding tip," forms a "bend or curve having an angle of at least 30 degrees" as claimed. Ex.1003, ¶127. *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).

[5] Quintana generally refers to the end of the needle, including the bent portion, as the "tip." Ex.1004, 3. As explained above, however, the "distal protruding tip" per the patent is the point 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.

f. Element 1.a.2.iii

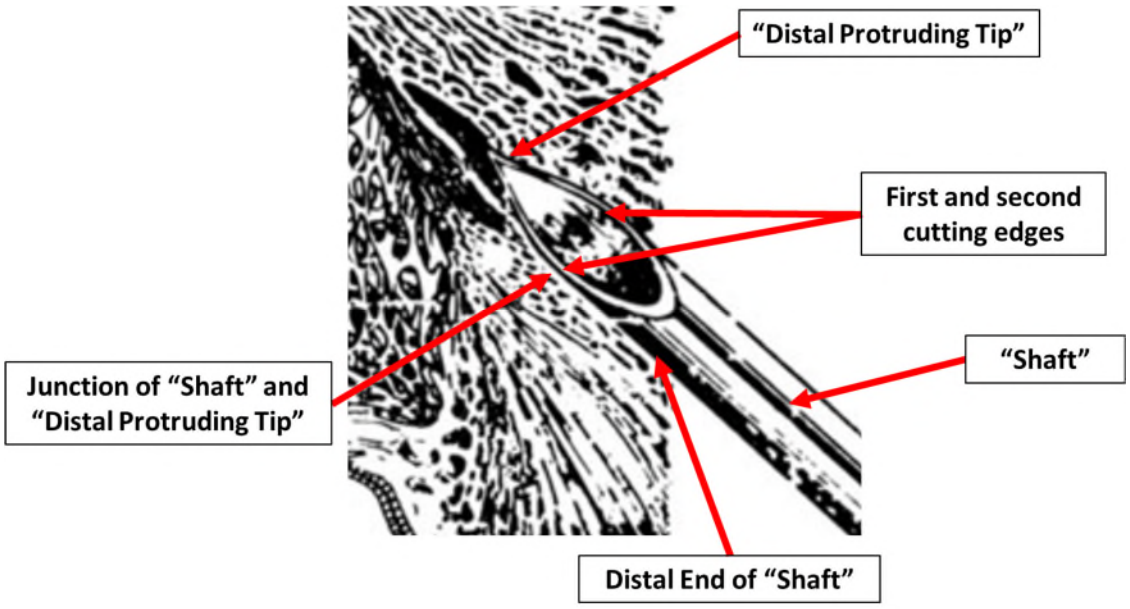
The "distal protruding tip" of Quintana's needle is "sized to be inserted in Schlemm's Canal." Quintana states that "***the tip of the instrument is introduced into SC***, and the TM is stripped slowly, gently and easily from the canal's lumen." Ex.1004, 4 (emphasis added). As shown below, the bent portion of Quintana's needle (including the "distal protruding tip") is inserted in SC:



Id., Fig.2 (annotated); Ex.1003, ¶128.

g. Element 1.a.2.iv

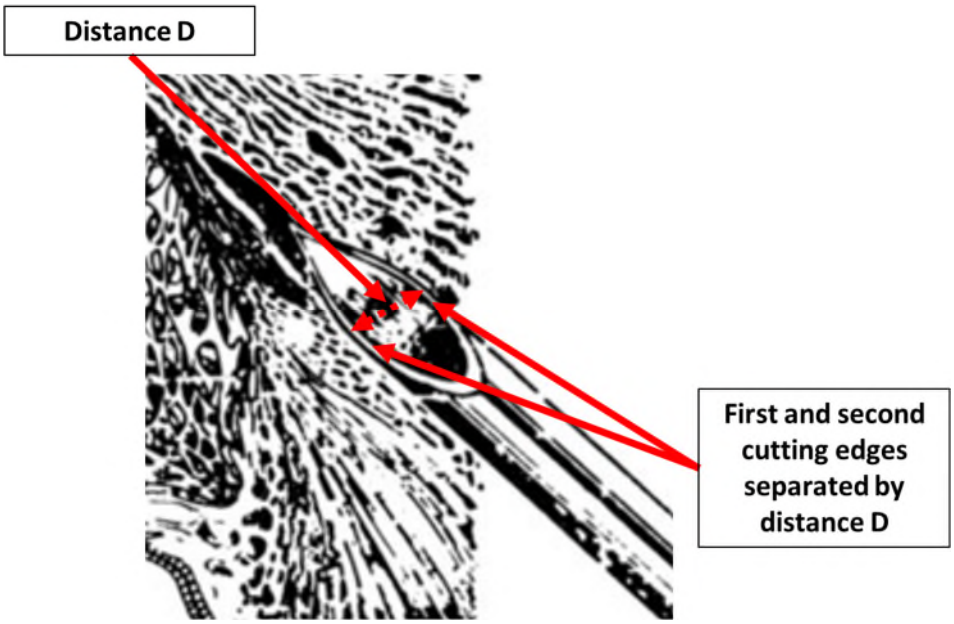
Quintana's needle has "first and second cutting edges." *See supra*, §VI.A.2.b. As shown below, Quintana's needle has two cutting edges on opposite sides of a tube.[6]



Ex.1004, Fig.1 (annotated); Ex.1003, ¶129. The figure also shows the "first and second cutting edges" are "located at a junction of the shaft and the distal protruding tip." Ex.1003, ¶129. The cutting edges are "formed at spaced-apart locations on the distal end of the shaft" because, as explained above, the cutting

[6] 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").

edges are located on opposite sides of the needle end. *Id*. Finally, as shown below, the "first and second cutting edges" of Quintana's needle are "separated by a distance D":



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

h. Element 1.b

Quintana discloses "forming an opening into an anterior chamber" because Quintana explicitly states "[t]he needle ***penetrates the anterior chamber*** at 6 hours (right eye) or 12 hours (left eye) through the *scleral* side of the limbus." Ex.1004, 4 (italics in original; bold emphasis added); Ex.1003, ¶131.

i. Element 1.c

Quintana explains that the needle (*i.e.*, the "elongate probe") penetrates the AC and explicitly states the needle "is progressively introduced in the angle." Ex.1004, 4. The "angle" is within the AC. Ex.1003, ¶132.

j. Element 1.d

Quintana indicates that "[t]he TM is incised with the tip of the needle" and the needle is "progressively introduced in the angle" such that "the tip of the instrument is introduced into Schlemm's canal." Ex.1004, 4. This indicates the needle tip (including the "distal protruding tip") is advanced through the AC, inserted through the TM, and positioned within SC. Ex.1003, ¶133. Quintana further states that the "TM is stripped" from SC "as the needle progresses in the angle." Ex.1004, 4. Figure 2 shows the "first and second cutting edges" contacting the TM and the caption explicitly indicates "[t]he tip of the needle strip[s]" the TM:

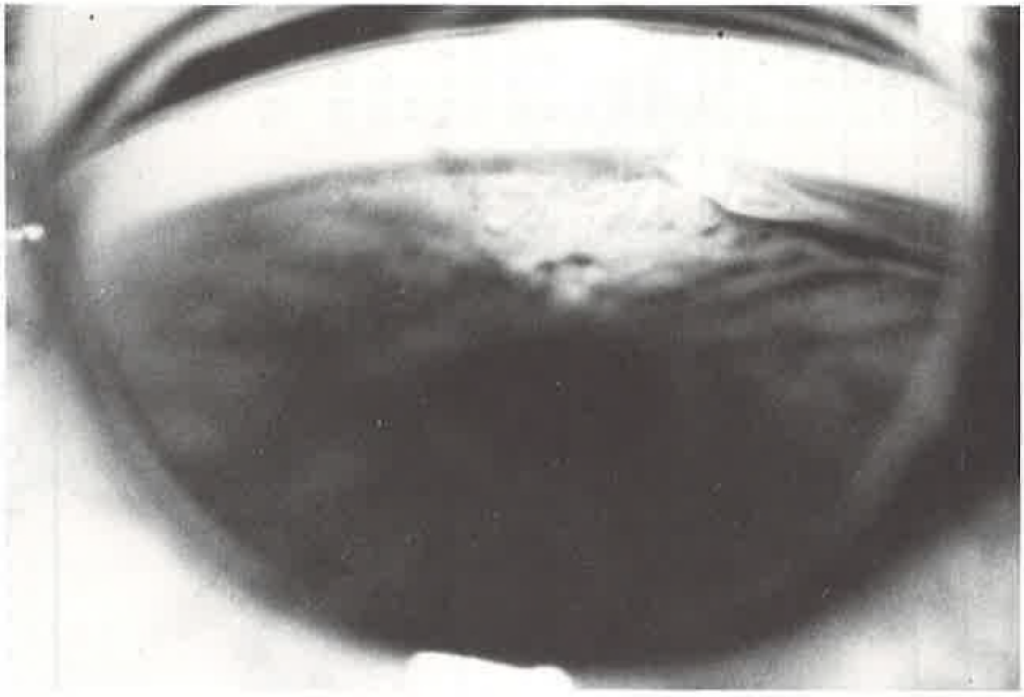


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

Id., Fig.2 (caption). Entering the TM through a cut with the needle's bent portion and then positioning it within SC, the "first and second cutting edges" would necessarily contact the TM. Ex.1003, ¶133.

Quintana's needle is advanced through the AC while the AC "is filled with fluid." Quintana states that "***[h]ealon can be injected at will at any time*** if the surgeon wants to deepen the angle. There is usually no chamber loss, but if this is the case, ***healon is injected***." Ex.1004, 4 (emphasis added). "Healon" is a viscoelastic fluid commonly used for ophthalmic procedures. *See, e.g.*, Ex.1011, 34-35, 51-52. Injecting a viscoelastic fluid within the AC would fill the AC with fluid. Ex.1003, ¶134. Quintana's statement that there is "no chamber loss" would also indicate to a POSITA that the AC remains filled with fluid (aqueous and/or viscoelastic fluid), further indicating the AC is "filled with fluid" as claimed. *Id.*, ¶135.

k. Element 1.f

Quintana explains that the needle tip is "progressively introduced" in the AC angle, that the "tip of the instrument is introduced into SC," and that the "TM is stripped . . . from the canal's lumen" as the needle "progresses in the angle." Ex.1004, 4. The "distal protruding tip" of the needle thus advances through SC, as claimed. Ex.1003, ¶136.

Quintana's statements that the "TM is stripped" and that the method "achieves a section of the TM" indicate that a "strip of tissue" is cut from the TM, as claimed. *Id.*; Ex.1004, 4. Quintana's needle has opposing cutting edges. Both edges contact the TM to create a strip of TM tissue, so a POSITA would understand that both cutting edges concurrently cut the TM. Ex.1003, ¶136. If the cutting edges did not concurrently cut the TM, Quintana would not have "achieve[d] a section of the TM," but would instead have created an incision as in traditional approaches. *Id.*; *see also id.*, ¶¶98-100.

The strip of tissue also necessarily has a width W that is "approximately equal to the distance D between the first and second cutting edges," because the first and second cutting edges of Quintana's needle strip the TM resulting in a strip having a width corresponding to the distance between the first and second cutting edges (as explained, "distance D"). *Id.*, ¶137.

3. Claim 2

Quintana discloses the limitations of claim 1. *See supra*, §VI.A.2. As explained, Quintana describes injecting healon during the procedure to "deepen the angle." Ex.1004, 4; Ex.1003, ¶139.

Quintana also teaches injecting healon "under controlled pressure" because its needle is inserted into a syringe filled with "healon" and the surgeon injects healon using the syringe—controlled pressure. Ex.1004, 3-4; Ex.1003, ¶140.

Further, a POSITA would appreciate the only way to infuse fluid into the eye during a surgical procedure is "under controlled pressure" because injecting liquid using "uncontrolled pressure" could lead to chamber loss (too much pressure) or extreme deepening of the chamber (too little pressure). Ex.1003, ¶140.

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, 1:39-45. 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, ¶144. For example, a 100° section of TM would be about 10.08mm in length, which is "about" 10mm as claimed (100°/360°=0.28; 28% of 36mm=10.08mm). *Id.* Quintana's explanation that a "100-120° trabeculotomy ***can be achieved***" would also indicate to a POSITA that shorter segments ranging from 0-10.08mm (or more) of TM are achieved. *Id.*

5. Claim 4

Quintana discloses the limitations of claim 1. *See supra*, §VI.A.2. And the '729 patent acknowledges removing a strip of TM from the patient's eye by goniectomy was known. *See* Ex.1001, 1:35-45. The patent also cites a prior art application (Baerveldt, Ex.1016), which describes a device that strips the TM and removes ablated tissues. *Id*., 1:60-65; Ex.1016, [0023]. Claim 4 does not cover a novel or nonobvious feature of the alleged invention.

Regardless, Quintana describes stripping the TM from SC, which "achieves a section of the TM." Ex.1004, 3, 4. A POSITA would interpret "achieving" a section of tissue to mean removing the tissue from the patient's body. Ex.1003, ¶147.

6. Claim 7

Quintana discloses the limitations of claim 1. *See supra*, §VI.A.2. Further, Quintana's procedure involves penetrating the AC with the needle "through the scleral side of the limbus." Ex.1004, 4. As discussed above, the "limbus" is part of the cornea. *See* Ex.1009, 4, 9, Fig.XXV-1 (below showing cornea zones including limbal zone including limbus).

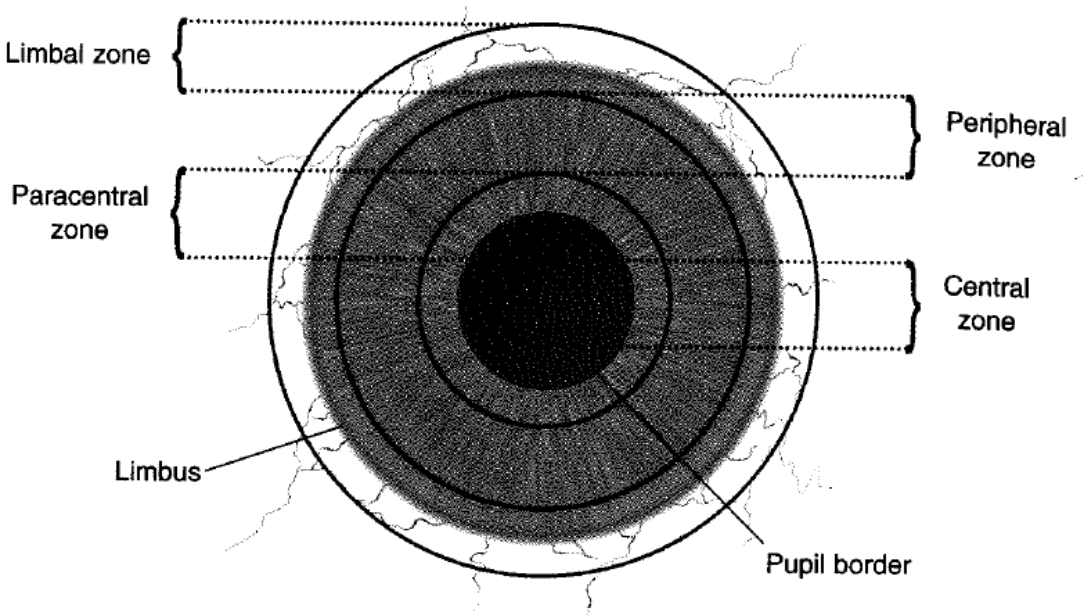


FIG XXV-1—Topographic zones of the cornea. (Illustration by Christine Gralapp.)

See also Ex.1007, 2 (describing "ab interno" procedure with instrument "inserted into the anterior chamber through a clear corneal incision at the temporal limbus."); Ex.1003, ¶¶35-36, 149. A POSITA would appreciate that penetrating the AC on the "scleral side of the limbus" is penetrating through the cornea because the limbus is within the cornea. Ex.1003, ¶149.

7. Claim 8

Quintana discloses the limitations of claim 1. *See supra*, §VI.A.2. Moreover, Quintana uses a "Swann lens," *i.e.*, a goniolens, for "angle visualization," which is inserted on the eye during the procedure. Ex.1004, 3-4. Quintana's disclosure of "inserting" the goniolens to involve positioning the device "on an anterior aspect of the eye" and performance of the procedure after insertion

of the device demonstrates the procedure is performed "under direct visualization." Ex.1003, ¶151.

8. Claim 9

Quintana discloses the limitations of claim 1, *see supra*, §VI.A.2, and the needle has a tip bent 20-30°, which is less than 90. Ex.1004, 3; Ex.1003, ¶153.

B. Ground 2: Quintana (Ex.1004) in View of the Knowledge of a POSITA Renders Obvious Claims 4-6 and 10

1. Claim 4

Quintana discloses the limitations of claim 1. *See* §VI.A.2. Further, the '729 patent acknowledges removing strips of TM from the patient's eye by goniectomy was known and cites prior art that describes a device for stripping and removing ablated TM tissue. Ex.1001, 1:35-45, 1:60-65; Ex.1015, [0023]. Thus, claim 4 does not cover a novel or nonobvious feature of the alleged invention.

If Quintana somehow does not explicitly disclose removing the strip from the patient's eye, it would have been obvious to do so. Ex.1003, ¶157. First, Quintana strips the TM from SC and it is obvious to remove the strip because leaving it within the eye could cause issues such as formation of scar tissue. Ex.1004, 4; Ex.1003, ¶157.

Second, it was well-known that portions of tissue left within the eye could block aqueous outflow, defeating the purpose of Quintana's disclosed procedure. Ex.1003, ¶158. Johnstone performed several procedures and found in one instance

a “flap” of TM tissue was left “that appeared to be capable of returning to its predissection position” following the procedure. Ex.1005, 8. Johnstone thus removed the “flap” to increase outflow. *Id.* Similarly, Jacobi’s “ab interno” procedure peeled TM tissue from the chamber angle, resulting in “strings” of TM tissue that Jacobi removed with an irrigation-aspiration probe. Ex.1007, 2. Given that the it was state of the art to remove strips or strings, a POSITA would have been motivated to remove strips of tissue from the patient’s eye after performing Quintana’s technique. Ex.1003, ¶158. Moreover, a POSITA would have known the tissue could be removed from the eye in a number of ways, including by Quintana’s needle itself or an irrigation-aspiration probe such as disclosed in Jacobi. *Id.* Other devices for removing tissue from the eye were also known, such as forceps. Ex.1018, 1-2.

Third, it was also known in the art to remove and collect strips of tissue for histological examination. Lee explains that “it would be useful to extract relatively large intact samples of undamaged TM and scar tissue and, perhaps, the surrounding tissue for histopathologic examination.” Ex.1006, 1:54-2:7, 3:50-57. A POSITA performing Quintana’s method would have been motivated to remove strips of tissue from the eye for the precise reason disclosed in Lee, *i.e.*, to provide specimens for histological examination. Ex.1003, ¶159.

2. Claim 5

Quintana in view of the knowledge of a POSITA renders obvious claim 4. *See supra*, §VI.B.1. Further, by 2003, it was well-known that portions of tissue remaining connected to the TM could return to their predissection positions or cause scar tissue to form, blocking outflow. Ex.1003, ¶161. Johnstone and Jacobi both recognized that their respective flaps or strings needed to be removed or risk blockage. *Id.*; Ex.1007, 2; Ex.1005, 8. Johnstone removed the "flap" specifically to aid outflow. Ex.1005, 8. Knowing portions of tissue remaining connected to the TM could block outflow, a POSITA performing Quintana's method would have been motivated to disconnect tissue remaining connected to the TM and remove the tissue from the eye, and would have expected success given the successful results of doing so in the prior art. Ex.1003, ¶162.

3. Claim 6

As explained for claim 5, a POSITA would have been motivated to disconnect and remove strips of tissue remaining connected to the TM to prevent blockages of aqueous outflow and would have done so using known "tissue severing apparatus." Ex.1003, ¶164. A POSITA would have known a "tissue severing apparatus" is any instrument capable of disconnecting a strip of tissue from the TM, such as: (a) Quintana's needle that strips TM tissue; (b) Jacobi's gonioscraper that could "peel" TM tissue by passing the device "in sweeping

movements" to disconnect tissue; (c) Jacobi's irrigation-aspiration probe, which could suction connected tissue and pull it (sever it) from the TM; or (d) Ferrari's forceps able to remove TM tissue in strings of varying length. *Id.* Given that each well-known instrument is capable of disconnecting tissue from the TM, a POSITA would appreciate that each could be used as the claimed "tissue severing apparatus." *Id.*, ¶165.

4. Claim 10

Quintana discloses the limitations of claim 9. *See supra*, §VI.A.8. Quintana's procedure uses a needle having a tip bent 20-30°. Ex.1004, 3. Quintana explicitly explains that by bending the tip, "the convexity of the tip" can be oriented to face the external wall of SC so that "this structure is not damaged." *Id.*, 4. It was also well-known to use devices having tips, points, or shafts bent at various angles to meet the needs of a given surgery. Ex.1003, ¶167. Johnstone discloses an "ab interno" procedure using "a cystotome with the point oriented at right angles to the shaft" that is 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").

For many reasons, it would have been obvious to modify Quintana's needle by bending the needle tip at different angles, such as the approximately 90 degrees disclosed in the prior art such as Johnstone. Ex.1003, ¶168. First, bending the tip of the needle to 90 degrees would have involved nothing more than combining prior art elements according to known methods or simple substitution to obtain predictable results—for example, combining Quintana's needle with Johnstone's bend. *Id.*

Second, it would have been obvious to try simple, straight-forward variations to Quintana's method, such as by bending the tip of Quintana's needle to different angles. *Id.*, ¶169. Given that there are a finite number of angles to bend the needle tip, a POSITA would have been motivated to try variations to expand or improve on Quintana's results including an angle of 90 degrees based on prior art such as Johnstone. *Id.* A POSITA would have expected success given the successful use of devices bent to different angles in the art such as Johnstone. *Id.*

Moreover, Quintana would not have dissuaded a POSITA from modifying the angle of the needle tip. 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 of the needle would have allowed for a number of different approaches and vice versa. Ex.1003, ¶170. In other words, the goal of Quintana's procedure was to strip TM

tissue from SC and doing so requires orienting the dual cutting edges of the needle to contact the TM tissue. 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.*

C. Ground 3: Quintana (Ex.1004) in View of Lee (Ex.1006) Renders Obvious Claims 1-4 and 7-9

As explained above, Quintana discloses all elements of claims 1-4 and 7-9 of the '729 patent (*see supra,* §VI.A). Nonetheless, to the extent the Board determines Quintana does not disclose an "ab interno" procedure or a "dual blade device" as required by claim 1, it would have been obvious to modify Quintana based on Lee to render claims 1-4 and 7-9 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, ¶101.

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, ¶102.

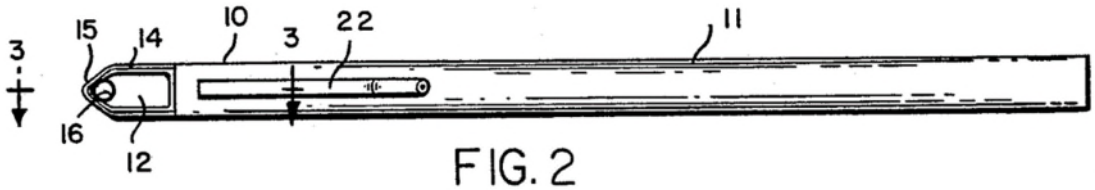


FIG. 2

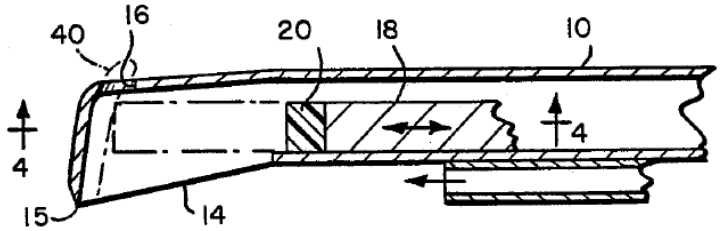


FIG. 3

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, ¶103. Lee was mentioned as the closest prior art during prosecution of 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 "achieves a section of the TM," forming an opening in the TM. Ex.1004, 4-5, Figs.1-2 (below).

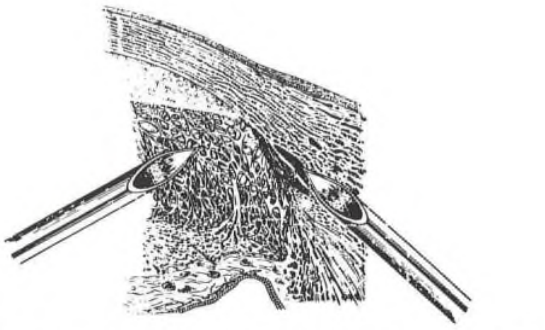


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

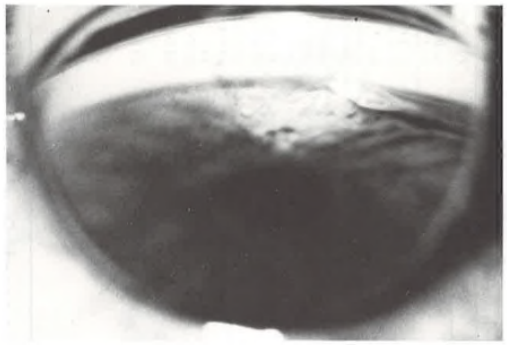


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

As clearly demonstrated above, Quintana's procedure is also "ab interno." *See supra*, §VI.A.2.a; Ex.1003, ¶172.

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 '729 patent itself. Ex.1001, 1:35-65, 5:19-26; *see also* Ex.1015, [0077-78]; Ex.1003, ¶¶173-74. 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 and is clearly ab interno. Ex.1003, ¶173.

Modifying Quintana's method to use an "ab interno" approach "through clear cornea about 1mm. anterior to the limbus" would have been obvious. *Id.*, ¶175. Quintana penetrated the AC "through the scleral side of the limbus," which is part of the cornea. Ex.1004, 4; Ex.1003, ¶175. 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 the needle is generally parallel to SC upon entry. Ex.1003, ¶175. 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). *Id.* A POSITA would have expected success given the successful procedures using alternate approaches in the prior art, including Lee. *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.*, ¶176. 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, ¶176.

b. Element 1.a

Quintana discloses this limitation. *See supra*, §VI.A.2.b. 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 trabecular glaucomas should consist in opening of the TM but that the results of the procedure potentially indicates "some kind of repair in the surgically damaged area." Ex.1004, 3, 8. A POSITA thus 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, ¶180. A POSITA would have recognized that one way of doing so would have been 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 merely incised the TM without tissue removal had limited success and that "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, ¶¶56, 181. 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 with dual cutting edges 14 can be 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).

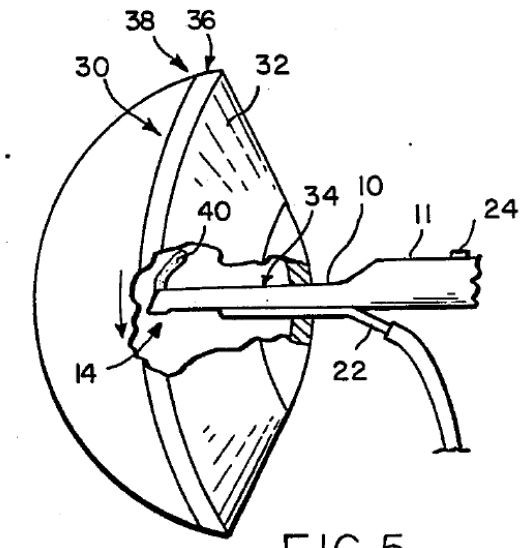


FIG.5

A POSITA would have found it obvious based on Lee to modify Quintana's by modifying (*e.g.*, sharpening) the needle 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, ¶¶181-82.

c. Element 1.a.1

Quintana discloses this limitation. *See supra*, §VI.A.2.c. Quintana states that "[t]he needle is inserted into a syringe," Ex.1004, 265, which a POSITA would understand are intended to be grasped by a hand of a human operator. Ex.1003, ¶183.

d. Elements 1.a.2 and 1.a.2.i

Quintana discloses this limitation. *See supra*, §VI.A.2.d. Quintana discloses a device in which a needle is inserted into a syringe, Ex.1004, 3, such that the needle is an "elongate probe" extending from the syringe or "elongate proximal portion" and has a shaft, *i.e.*, the tube of the needle. Ex.1003, ¶184.

e. Element 1.a.2.ii

Quintana discloses this limitation. *See supra*, §VI.A.2.e. Quintana's needle has a "distal protruding tip," which is the point at the end of the needle that extends from the distal end of the shaft and facilitates insertion of the tip into SC. Ex.1003, ¶185. Quintana's needle tip is bent 20-30°, Ex.1004, 4, forming a "bend or curve having an angle of at least 30 degrees" as claimed. Ex.1003, ¶185. *E.g.*, *Titanium Metals*, 778 F.2d at 775.

f. Element 1.a.2.iii

Quintana discloses this limitation. *See supra*, §VI.A.2.f. For example, Quintana discloses that the needle is "progressively introduced in the angle" and that "***the tip of the instrument is introduced into SC***." Ex.1004, 4 (emphasis added); Ex.1003, ¶186.

g. Element 1.a.2.iv

Quintana discloses this limitation. *See supra*, §VI.A.2.g. Quintana's needle has two cutting edges that are on opposite sides of the end of the tube (*i.e.*, "space-apart locations) and are located where the shaft meets the needle tip (*i.e.*, a

"junction of the shaft and the distal protruding tip"). Ex.1004, 4-5; Ex.1003, ¶187. If it is somehow determined Quintana does not disclose "first and second cutting edges," it would have been obvious to modify Quintana's needle by, for example, sharpening the cutting edges of the needle to create a "dual blade device" with "first and second cutting edges." *See supra*, §VI.C.2.b; Ex.1003, ¶188.

h. Element 1.b

Quintana discloses this limitation, s*ee supra*, §VI.A.2.h, as it explains the needle "penetrates the anterior chamber." Ex.1004, 4. Penetrating the AC would "form[] an opening into" the AC. Ex.1003, ¶189.

i. Element 1.c

Quintana discloses this limitation. *See supra*, §VI.A.2.i. It penetrates the AC with the needle and "progressively introduce[s]" it in the angle. Ex.1004, 4. The needle portion of Quintana's device, *i.e.*, the "elongate probe," is inserted through the opening created by penetrating the AC of the eye and into the AC. Ex.1003, ¶190.

j. Element 1.d

Quintana discloses this limitation. *See supra*, §VI.A.2.j. Quintana describes "progressively introduc[ing]" the needle portion of the device in the angle and inserting the tip into the TM (including the needle tip, *i.e.*, the "distal protruding tip"). Ex.1004, 4, Fig.2 (below). A POSITA would recognize that inserting the tip

through the TM would cause the "first and second cutting edges" near the tip to contact the TM. Ex.1003, ¶191.

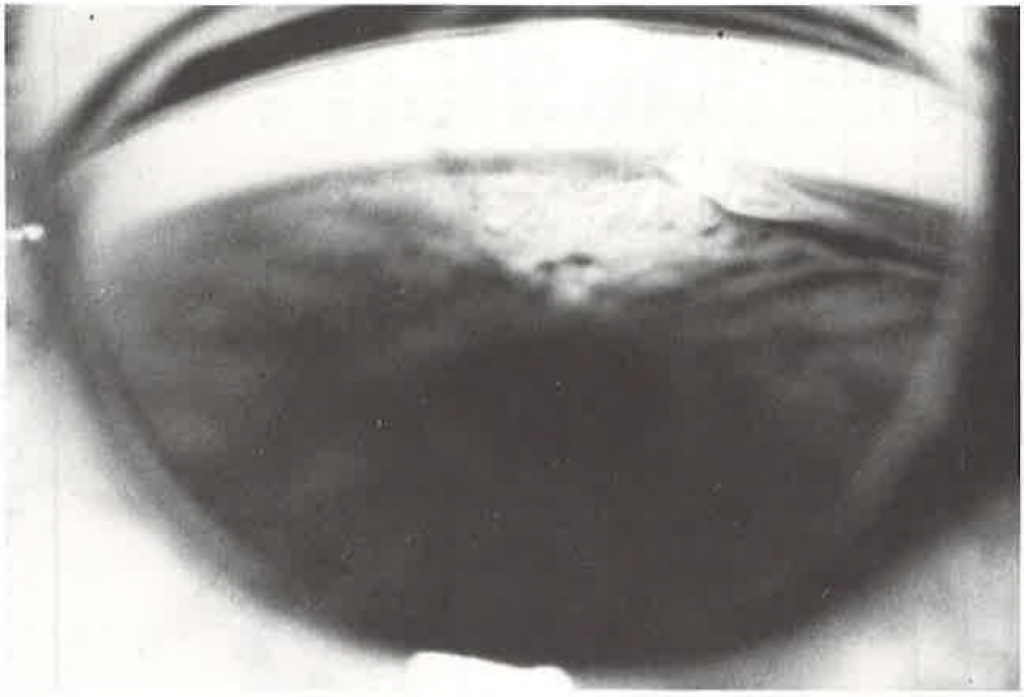


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

Ex.1004, Fig.2 (caption).

Additionally, Quintana indicates the surgeon can inject a viscoelastic fluid such as Healon to maintain a deep AC during surgery. *Id.*, 4; Ex.1011, 34-35, 51-52; Ex.1003, ¶192. The AC is thus filled with fluid, as claimed. Further, Lee also discloses maintaining fluid levels in the AC to protect the cornea and lens from injury, which would have motivated a POSITA performing Quintana's technique to do the same. Ex.1006, 5:6-15; Ex.1003, ¶192.

k. Element 1.f

Quintana discloses this limitation. *See supra*, §VI.A.2.k. The tip of Quintana's needle is "progressively introduced" in the angle, the "tip of the instrument is introduced into Schlemm's Canal," and the needle strips the TM from the canal. Ex.1004, 266. A POSITA would understand "stripping" the TM to "achieve[] a section of the TM" refers to cutting a "strip of tissue," and that achieving such a strip would require both the cutting edges of the needle to concurrently cut the TM. Ex.1003, ¶193; *see also id.*, ¶¶98-100. The strip of tissue would have a width W that corresponds to the distance between the cutting edges of the needle. *Id.*, ¶194.

3. Claim 2

Quintana and Lee disclose all the limitations of claim 1. *See supra*, §VI.C.2, with Quintana teaching injecting a viscoelastic fluid such as Healon to keep the AC filled, which must be "under controlled pressure" because a surgeon injects Healon via a syringe. Ex.1004, 4; Ex.1003, ¶196; *see supra*, §VI.A.3. Lee likewise discloses maintaining fluid levels in the AC to protect the cornea and lens from injury. A POSITA would be motivated to perform Quintana's method while maintaining fluid levels. Ex.1006, 5:6-15; Ex.1003, ¶196.

4. Claim 3

Quintana and Lee disclose all the limitations of claim 1. *See supra*, §VI.C.2. Not only does the '729 patent admit cutting a strip of TM with a length of about 2

to 10 millimeters was known in the art, Ex.1001, 1:39-45, 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 4

Quintana and Lee disclose all the limitations of claim 1. *See supra*, §VI.C.2. Not only does the '729 patent admit removing the strip of TM from the patient's eye was known and cite a prior art reference disclosing a device that strips the TM, Ex.1001, 1:35-45, 1:60-65; Ex.1015, [0023], "removing the strip of tissue from the patient's eye" would have been obvious based on Quintana and Lee. Quintana describes stripping TM from SC, Ex.1004, 4, and a POSITA would have known that leaving strips of tissue in the patient's eye could cause issues like blockage. Ex.1003, ¶203.

A POSITA also would have been motivated to remove the strips of tissue based on Lee, which discloses an excision device specifically to remove the tissue.

Ex.1006, 1:54-2:7, 3:50-57. It would have been obvious to a POSITA performing Quintana's method to remove strips of tissue for the precise reason disclosed in Lee, *i.e.*, avoid blockage and collect specimens for examination. Ex.1003, ¶204.

6. Claim 7

Quintana and Lee disclose all the limitations of claim 1. *See supra*, §VI.C.2. Quintana discloses penetrating the AC "through the scleral side of the limbus," Ex.1004, 266, which a POSITA would understand to include an incision through the cornea because the limbus is part of the cornea. *See* Ex.1009, 4, 9*;* Ex.1007, 2*;* Ex.1003, ¶¶35-36, 206.

Lee also discloses an incision into the AC through the clear cornea for introducing devices into the AC. Ex.1006, 6:14-27. For the reasons discussed above, it would have been obvious to perform Quintana's procedure by forming an opening through an incision in the cornea as disclosed by Lee. *See supra*, §VI.C.2.a; Ex.1003, ¶¶207-08.

7. Claim 8

Quintana and Lee disclose all the limitations of claim 1. *See supra*, §VI.C.2. Quintana uses a "Swann lens," *i.e.*, a goniolens, for "angle visualization," which is placed on the eye during the procedure. Ex.1004, 3-4. A POSITA would interpret Quintana's disclosure of "inserting" the goniolens to involve positioning the device

"on an anterior aspect of the eye" and performance of the procedure after placement so the eye is "under direct visualization." Ex.1003, ¶210.

8. Claim 9

Quintana and Lee disclose all the limitations of claim 1. *See supra*, §VI.C.2. Quintana's needle has the tip bent 20-30°, Ex.1004, 3, and all angles within that range are "less than approximately 90 degrees" as claimed. Ex.1003, ¶212.

D. Ground 4: Quintana (Ex.1004) in View of Lee (Ex.1006) and the Knowledge of a POSITA Renders Obvious Claims 4-6 and 10

Quintana in combination with the knowledge of a POSITA renders obvious claims 4-6 and 10 (*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 4-6 and 10 in combination with the knowledge of a POSITA alone, Quintana in combination with Lee (which renders obvious claims 1-4 and 7-9, *see supra*, §VI.C) further in combination with the knowledge of a POSITA would render obvious claims 4-6 and 10.

1. Claim 4

Quintana and Lee disclose all the limitations of claim 1. *See* §VI.C.2. The '729 patent acknowledges that removing strips of TM from the patient's eye by goniectomy was known and cites prior art that describes a device for stripping and

removing TM tissue. Ex.1001, 1:35-45, 1:60-65; Ex.1015, [0023]. In no way does claim 4 cover a novel or nonobvious feature of the alleged invention.

Regardless, removing the strip from the patient's eye would have been obvious based on Quintana and Lee in combination with the knowledge of a POSITA. Quintana's procedure strips the TM from SC and it was known that leaving the strip caused issues such as blockage. Ex.1004, 4. A POSITA would have found it obvious to remove the strip. Ex.1003, ¶¶216-17.

Other references acknowledged this problem and taught solutions. Johnstone found after performing a procedure that a "flap" of TM tissue was left "that appeared to be capable of returning to its predissection position." Ex.1005, 8. Johnstone thus removed the "flap," causing an increase in outflow in the majority of eyes. *Id.* Similarly, Jacobi peeled TM tissue from the chamber angle, resulting in "strings" of TM tissue that Jacobi removed with an irrigation-aspiration probe. Ex.1007, 2. The knowledge that portions of tissue remaining in the eye could block outflow would have motivated a POSITA to remove strips after performing Quintana's technique. Ex.1003, ¶217. A POSITA would have known tissue removal using any number of ways such as Quintana's needle itself or Jacobi's irrigation-aspiration probe. *Id.* Other prior art taught that forceps could be used in an "ab interno" procedure to remove TM tissue. Ex.1018, 1-2.

Finally, Lee explained that it was known to remove and collect strips of tissue for histological examination and to avoid scarring. Ex.1006, 1:54-2:7, 3:50-57. A POSITA performing Quintana's method would clearly have been motivated to remove strips of tissue from the eye based on Lee. Ex.1003, ¶218.

2. Claim 5

Quintana and Lee in view of the knowledge of a POSITA render obvious claim 4. *See supra*, §VI.D.1. It would have been obvious to disconnect and remove strips of tissue that remain connected to the TM. Ex.1003, ¶220. For instance, by 2003, it was well-known that outflow could be blocked via scarring or tissue could return to its predissection position. Ex.1005, 8; Ex.1003, ¶220. Johnstone thus removed a "flap," causing an increase in outflow. Ex.1005, 8. Similarly, Jacobi describes removing strings of tissue with an irrigation-aspiration probe. Ex.1007, 2. Knowing this, a POSITA performing Quintana's method would have been motivated to disconnect tissue and remove it from the eye. Ex.1003, ¶221. Moreover, the prior art provides explicit instructions on how to do so. *Id.*, ¶¶220-21.

3. Claim 6

Quintana and Lee in view of the knowledge of a POSITA also render obvious claim 5. *See supra,* §VI.B.3. As explained for claim 5, a POSITA would have been motivated to disconnect and remove strips of tissue and would have

done so using known "tissue severing apparatus." A POSITA would have known a "tissue severing apparatus" to be any instrument capable of disconnecting a strip of tissue from the TM. Ex.1003, ¶223. Any device able to cut tissue could be used such as: (a) Quintana's needle; (b) Jacobi's gonioscraper that could "peel" TM tissue; (c) Jacobi's irrigation-aspiration probe to suction/remove connected tissue; or (d) Ferrari's forceps to remove strings of TM. *Id.* Given that each instrument is capable of disconnecting tissue from the TM, a POSITA would appreciate that each could be used as the claimed "tissue severing apparatus." *Id.*, ¶¶223-24.

4. Claim 10

Quintana and Lee disclose all the limitations of claim 9. *See supra*, §VI.C.8. Quintana's procedure uses a needle having a tip bent 20-30° by a needle holder. Ex.1004, 3. Quintana explicitly explains "the convexity of the tip" can be oriented to face the external wall of SC so that "this structure is not damaged." *Id.*, 4. It was well-known to use devices having tips, points, or shafts bent at various angles to meet surgery needs. Ex.1003, ¶226. Johnstone discloses "a cystotome with the point oriented at right angles to the shaft," which was inserted through the TM into SC. Ex.1005, 2. The device's blunt surface faced the external wall of SC 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.

It would have been obvious to modify Quintana's needle by bending the needle tip at different angles, such as approximately 90 degrees as disclosed in the prior art like Johnstone. Bending the needle tip to 90 degrees would have involved nothing more than combining prior art elements according to known methods or simple substitution. Ex.1003, ¶227. A POSITA employing Quintana's method could have simply bent the needle to a 90-degree angle—with predictable results given Johnstone's disclosure. *Id.*, ¶¶227-28.

Quintana would not have dissuaded a POSITA from modifying the needle tip's angle. Quintana employs a tangential approach to access the AC angle but acknowledges that other approaches had been previously used. Ex.1004, 4. A POSITA would have understood that altering the angle of the bent portion of the needle would have allowed for different approaches. Ex.1003, ¶229. The goal of Quintana's procedure was to strip TM tissue from SC. Doing so requires orienting the needle's dual cutting edges to contact the TM tissue. If surgical requirements dictated a certain approach, the needle tip could be bent in a way that still allows the dual cutting edges to contact and strip the TM. For example, a POSITA would have known that angling the bent portion of Quintana's needle to approximately 90 degrees would allow for use of a perpendicular approach to orient the tip within the SC. *Id.* Thus, modifying the angle of the bent portion of Quintana's needle does not conflict with Quintana's method. *Id.*

E. Ground 5: Jacobi (Ex.1007) Anticipates Claims 1-4 and 7-8

1. Overview of Jacobi

Jacobi discloses an "ab interno" technique called "goniocurettage," which employs a "gonioscraper" device. Ex.1007, 1. According to Jacobi, in most cases of open-angle glaucoma, outflow resistance lies in the cribriform layer of the TM, and "simple disruption of the TM . . . removes little tissue and allows filling in and scarring to occur with subsequent closure of the trabecular opening." *Id.*, 1-2. Accordingly, Jacobi describes a new approach "to abrade rather than incise" the TM in order to "peel" off "strings of trabecular tissue." *Id.*, 2; Ex.1003, ¶¶104-05. 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 the claimed "bend or curve." Ex.1003, ¶106; *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, ¶107. Fig.2 below shows the procedure.

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

Ex.1007, Fig.2.

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

2. Claim 1

a. Element 1.p

Jacobi's procedure is a "method for forming an opening in TM of a patient's eye," as the procedure is aimed to "abrade rather than incise" the TM and resulted in "peel[ing]" off "strings of trabecular tissue" and "completely removed the TM and opened Schlemm's Canal, ensuring direct access into the anterior chamber."

Ex.1007, 1, 2; Ex.1003, ¶230. 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, ¶¶231-32. 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).

Id., Fig.2; Ex.1003, ¶231.

b. Element 1.a

Jacobi's gonioscraper is a "dual blade device." Ex.1003, ¶¶233-35. 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.1002, 320 (emphasis added); *see also* Ex.1006, 4:38-41, Figs. 2-3 (below).

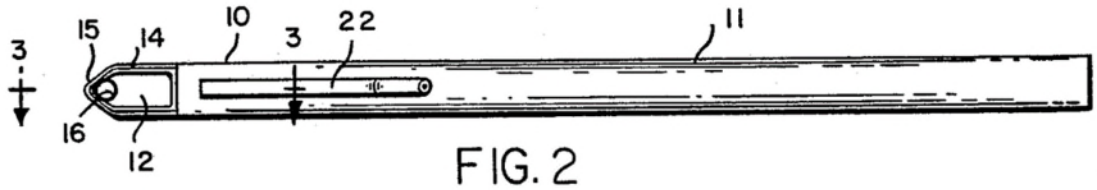


FIG. 2

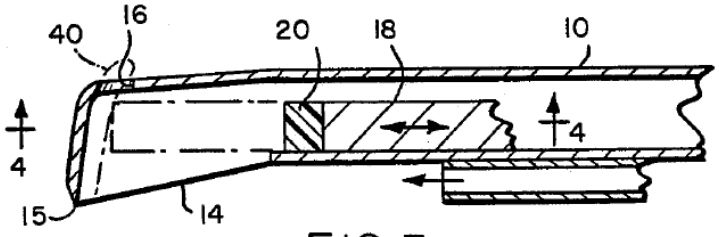


FIG. 3

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, 303; Ex.1002, 320; Ex.1003, ¶¶234-35.

c. Element 1.a.1

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 "an elongate proximal portion," the purpose of which is for grasping by an operator. Ex.1003, ¶236.

d. Element 1.a.2 and 1.a.2.i

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, ¶237. As shown below, the "convex-shaped arm" of Jacobi's device includes a shaft. *Id.*

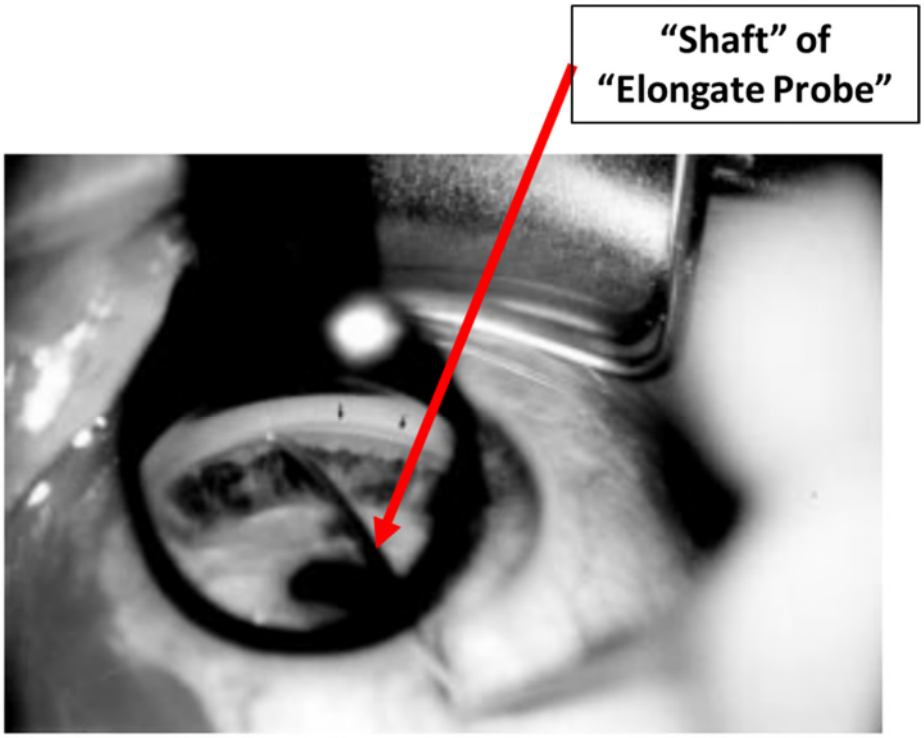


Figure 2 With the aid of an operating microscope and under gonioscopic control ab interno goniocurettage is performed. Following abrasion an irregular pattern of a glistening white band corresponding to the 'denuded' grey-white sulcus scleralis can be seen (black arrows).

Id.; Ex.1007, Fig.2 (annotated).

e. Element 1.a.2.ii

Jacobi's gonioscraper includes a tip that is "shaped as a tiny bowl with 300 µm diameter and with its edges sharpened." Ex.1007, 2. The bowl-shaped tip is a "distal protruding tip" that extends from a distal end of the shaft of the "convex-shaped arm." Ex.1003, ¶238.

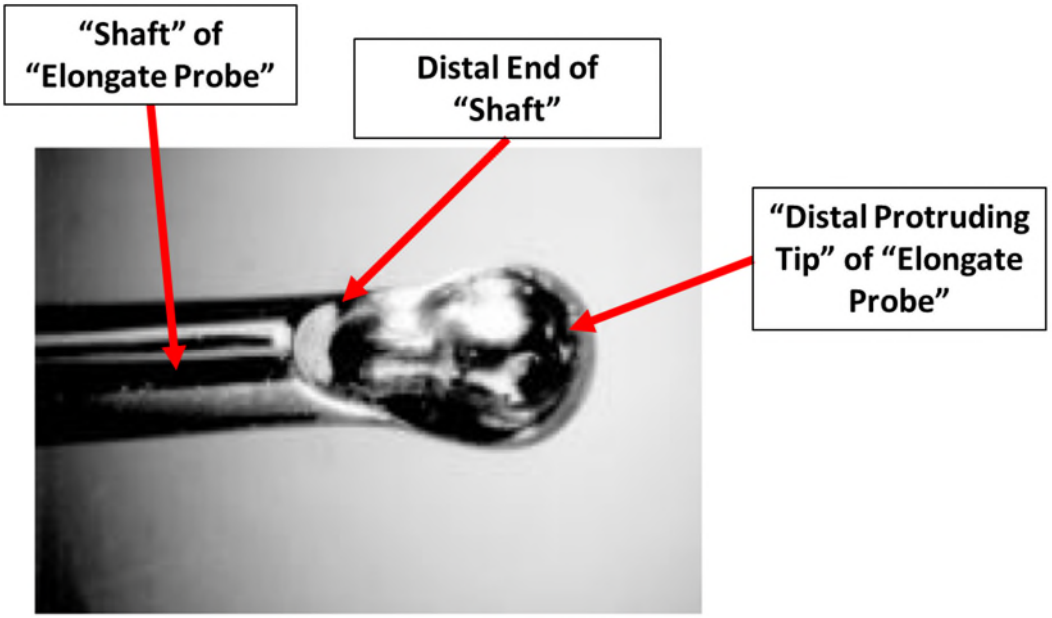


Figure 1 The tip of the 'gonioscraper'. The bowl is 300 µm in diameter with its edges sharpened.

Ex.1007, Fig.1 (annotated).

Jacobi's tip extends from the shaft "to form a bend or curve having an angle of at least 30 degrees" as claimed. Ex.1003, ¶239. As shown below, the shaft of Jacobi's device is bent to form an angle. *Id.*

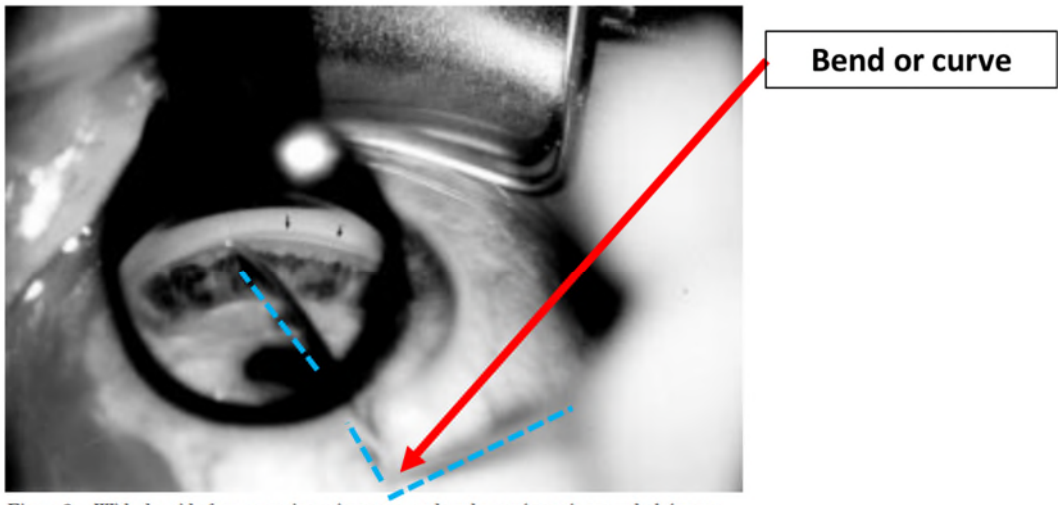
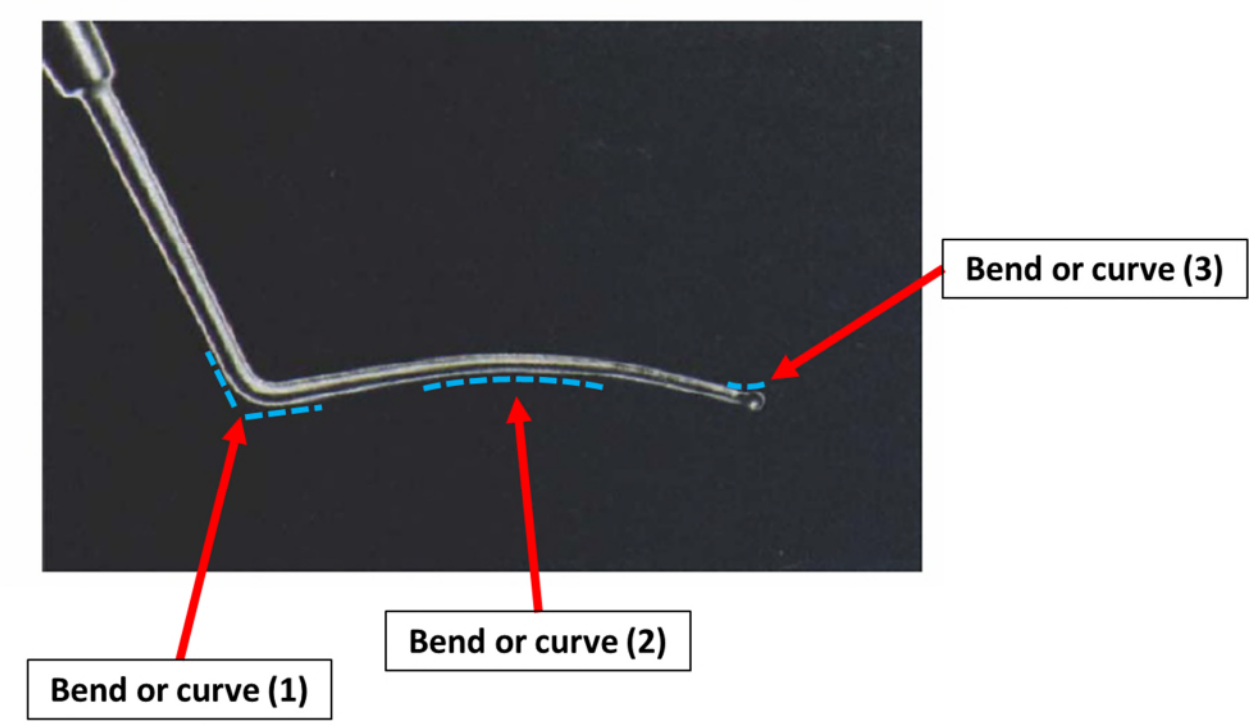


Figure 2 With the aid of an operating microscope and under gonioscopic control ab interno goniocurettage is performed. Following abrasion an irregular pattern of a glistening white band corresponding to the 'denuded' grey-white sulcus scleralis can be seen (black arrows).

Ex.1007, Fig.2 (annotated).

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: (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, ¶240.



Ex.1013, Fig.1(b) (annotated). A POSITA would appreciate that each of the "bends or curves" in the image above have "an angle of at least 30 degrees." Ex.1003, ¶240. Importantly, as shown in the image, the bowl-shaped tip (*i.e.*,

"distal 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. Ex.1003, ¶240.

f. Element 1.a.2.iii

The tip of Jacobi's device is "sized to be inserted in SC" as Jacobi reports that it "peel[ed]" TM tissue from SC. Ex.1007, 2. Figure 2 (below) shows the device within the AC with the tip directed against the TM within SC. Ex.1003, ¶241.

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

Id., Fig.2.

g. Element 1.a.2.iv

Jacobi's gonioscraper has "first and second cutting edges." *See supra*, §VI.E.2.b; Ex.1003, ¶242. As shown below, the device has a cutting edge on each lateral side of the bowl similar to Lee:

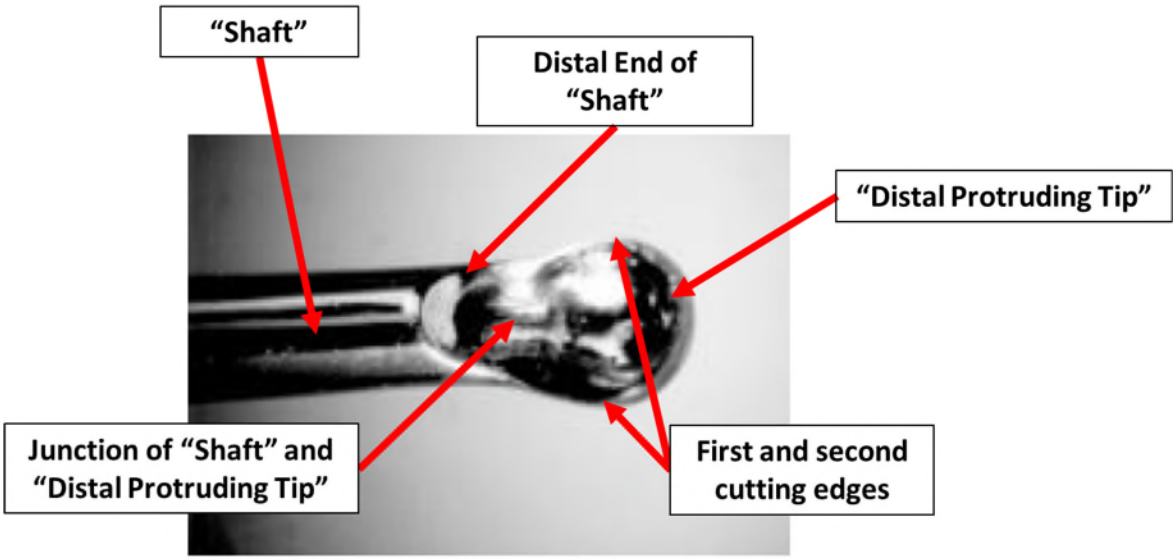


Figure 1 The tip of the 'gonioscraper'. The bowl is 300 μm in diameter with its edges sharpened.

Ex.1007, Fig.1 (annotated); Ex.1003, ¶242. Further, the cutting edges of Jacobi's gonioscraper are "located at a junction of the shaft and the distal protruding tip" because they are located where the shaft of the arm meets the bowl. Ex.1003, ¶243. The cutting edges are "formed at spaced-apart locations on the distal end of the shaft" because the cutting edges are located on opposite sides. *Id*. As shown in annotated Fig.1 below, the cutting edges are "separated by a distance D":

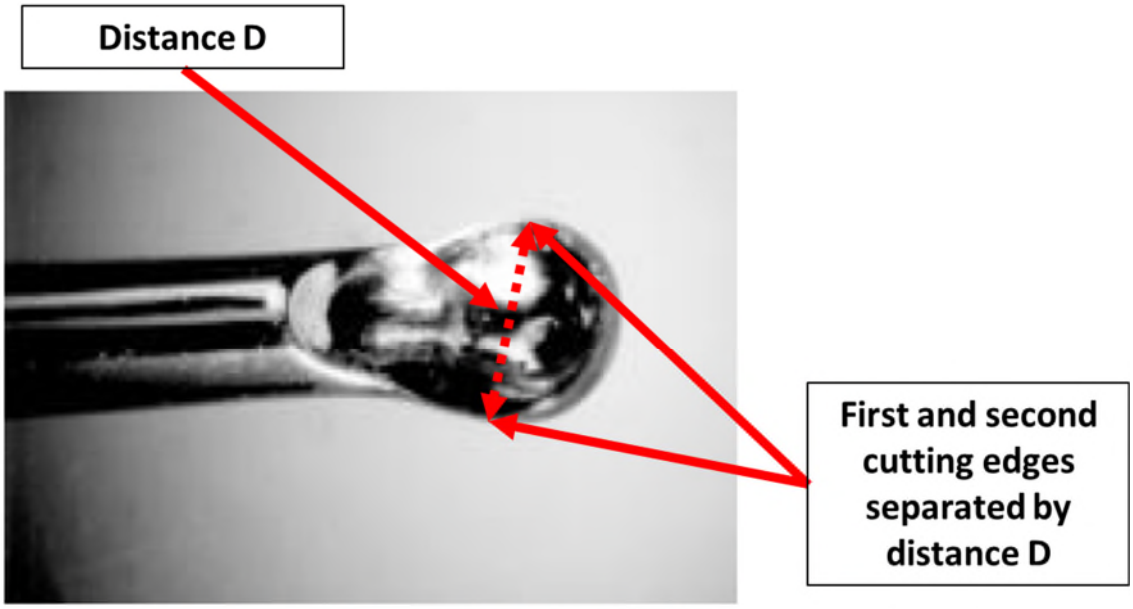


Figure 1 The tip of the 'gonioscraper'. The bowl is 300 µm in diameter with its edges sharpened.

Ex.1007, Fig.1 (annotated); Ex.1003, ¶244. As stated in Jacobi, the bowl has a diameter of 300µm and therefore, distance D is 300µm. Ex.1007, 2.

h. Element 1.b

Jacobi's gonioscraper was inserted into the AC "through a clear corneal incision at the temporal limbus." *Id.*, 2. Creating a "clear corneal incision" is "forming an opening" into the AC, as claimed. Ex.1003, ¶245.

i. Element 1.c

As shown in Fig.2, the convex-shaped arm of the gonioscraper, *i.e.*, the "elongate probe," is inserted into the AC. Ex.1003, ¶246.

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.

j. Element 1.d

According to Jacobi, "***[f]ollowing injection of viscoelastic, the 'gonioscraper' was inserted into the anterior chamber*** through a clear corneal incision at the temporal limbus and ***directed against the TM at the opposite side***." Ex.1007, 2 (emphasis added). Jacobi makes clear the gonioscraper is advanced through the AC "while the anterior chamber is filled with fluid." Ex.1003, ¶249. Figure 2 (above) shows the "distal protruding tip", *i.e.*, the bowl, in an "operative position" within SC. *Id.*, ¶247. The figure also shows the "distal protruding tip" and the first and second cutting edges, contacting the TM. *Id.*, ¶248; Ex.1007, 2. Jacobi also indicates goniocurettage requires "a deep and stable anterior chamber,"

which would indicate to a POSITA that the chamber is filled with fluid (viscoelastic or aqueous) so that it does not collapse. *Id*., 5; Ex.1003, ¶¶249-50.

k. Element 1.f

Jacobi describes directing the gonioscraper against the TM and passing the bowl through the angle to "peel" off TM. Ex.1007, 2. As shown in Figure 2, the bowl-like tip enters and advances through SC. *Id*.

The first and second cutting edges of the device concurrently cut a strip of tissue from the TM. Ex.1003, ¶251. Jacobi's purpose "was to abrade rather than incise" the TM to "peel" off "strings of trabecular tissue." Ex.1007, 2. This means Jacobi excises tissue rather than simply cutting a slit in the TM. Ex.1003, ¶251. Jacobi reports that "gonioscopically, ***strings of trabecular tissue could be observed intraoperatively to be removed by goniocurettage***." Ex.1007, 303. Peeling "strings of TM" tissue is cutting a "strip of tissue" from the TM as claimed. Ex.1003, ¶251. 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.

The strip of tissue would also have a width W that is "approximately equal to the distance D between the first and second cutting edges," because the first and

second cutting edges of Jacobi's device would cut the TM to create a strip having a width corresponding to the "distance D" (*i.e.*, 300µm) between the cutting edges. Ex.1003, ¶252.

3. Claim 2

Jacobi discloses the limitations of claim 1. *See supra*, §VI.E.2. Further, Jacobi performs the procedure "following injection of viscoelastic" and thus discloses keeping the AC filled with fluid while performing goniocurettage. Ex.1007, 2; Ex.1003, ¶254.

A POSITA would understand that Jacobi discloses injecting viscoelastic "under controlled pressure." As would be known to a POSITA, that the only way to inject viscoelastic would be by a surgeon under "controlled pressure because doing so under uncontrolled pressure could lead to chamber loss (too little pressure) or extreme deepening of the AC (too much pressure). Ex.1003, ¶255.

4. Claim 3

Jacobi discloses the limitations of claim 1. *See supra*, §VI.E.2. Further, the '729 patent admits that cutting a strip of TM with a length of about 2 to 10 millimeters was known in the art. *See* Ex.1001, 1:39-45. Thus, claim 3 does not cover a novel or nonobvious feature of the alleged invention.

In any event, Jacobi explains that "[g]oniocurettage was performed over 90-120° of the chamber angle circumference in all patients." Ex.1007, 4. A POSITA

would understand based on the circumference of SC (and thus, the TM), which is about 36mm, Ex.1010, 5, a 90° section of TM would equate to a section that is 9mm in length, which is within the claimed range (90°/360°=0.25; 25% of 36mm=9mm). Ex.1003, ¶¶258-59.

5. Claim 4

Jacobi discloses the limitations of claim 1. *See supra*, §VI.E.2. Further, the '729 patent admits that removing the strip of TM from the patient's eye was known and cites prior art describing a device that strips the TM. *See* Ex.1001, 1:35-45, 1:60-65; Ex.1016, [0023]. Claim 4 does not cover a novel or nonobvious feature of the alleged invention.

Nonetheless, Jacobi explicitly states that "[a]t the end of surgery the viscoelastic along with abraded trabecular debris were removed by means of an irrigation-aspiration probe." Ex.1007, 2. Jacobi thus discloses "removing the strip of tissue from the patient's eye." Ex.1003, ¶262.

6. Claim 7

Jacobi discloses the limitations of claim 1. *See supra*, §VI.E.2. Further, Jacobi explicitly indicates the device was inserted into the AC "through a clear corneal incision at the temporal limbus." Ex.1007, 2; Ex.1003, ¶264.

7. Claim 8

Jacobi discloses the limitations of claim 1. *See supra*, §VI.E.2. Jacobi additionally indicates that the procedure "was performed under direct visualisation

of the anterior chamber angle with an operating microscope and a surgical gonioscopy lens" and that successful treatment requires "[c]lear visualisation of the chamber angle structures by gonioscopy." Ex.1007, 2, 5. Visualization of the AC angle using a gonioscopy lens involves positioning the lens on an anterior aspect of the eye as claimed. Ex.1003, ¶266.

F. Ground 6: Jacobi (Ex.1007) in View of the Knowledge of a POSITA Render Obvious Claims 5-6 and 9-10

1. Claim 5

Jacobi discloses the limitations of claim 4. *See supra*, §VI.E.5. Jacobi teaches a procedure where the TM tissue is "abraded" to "peel" it from the TM, resulting in "strings of trabecular tissue" that were "removed by means of an irrigation-aspiration probe." Ex.1007, 2. Jacobi recognized that prior procedures often "allow[ed] filling in and scarring to occur with subsequent closure of the trabecular opening." *Id.* Thus, even if Jacobi does not explicitly state that the strings of TM tissue remained connected to the TM, a POSITA reviewing Jacobi would have known that any strings of tissue that did remain connected should be disconnected and removed. Ex.1003, ¶268.

Moreover, by 2003, it was well-known that portions of tissue remaining connected to the TM could return to their predissection positions or cause scar tissue to form. Ex.1003, ¶269. For example, Johnstone describes a "flap" of TM tissue was left "that appeared to be capable of returning to its predissection

position," which could block aqueous outflow. *Id.*; Ex.1005, 8. Johnstone removed the "flap," causing an increase in outflow in the majority of eyes. Ex.1005, 8. Given this knowledge that tissue remaining could block outflow, a POSITA would have been motivated to disconnect any strips of tissue that remained connected to the TM following Jacobi's procedure and to remove the disconnected strips of tissue from the patient's eye. Ex.1003, ¶269.

2. Claim 6

Jacobi in view of the knowledge of a POSITA render obvious claim 5. *See supra*, §VI.F.1. A POSITA would have been motivated to disconnect and remove strips of tissue remaining connected to the TM to prevent blockages of aqueous outflow, and would have done so using known "tissue severing apparatus." Ex.1003, ¶271. A POSITA would have known a "tissue severing apparatus" to be any instrument capable of disconnecting a strip of tissue from the TM. *Id.* As such, any device able to cut tissue could be used as a "tissue severing apparatus," such as: (a) Quintana's needle to "strip" TM tissue; (b) Jacobi's gonioscraper that could "peel" TM tissue; (c) Jacobi's irrigation-aspiration probe, which could suction tissue and sever it from the TM; or (d) Ferrari's forceps able to remove TM tissue in strings of varying length. *Id.* Given each instrument is capable of disconnecting tissue from the TM, a POSITA would appreciate that each could be used as the claimed "tissue severing apparatus." *Id.*

3. Claim 9

Jacobi discloses the limitations of claim 1. *See supra*, §VI.E.2. Further, as discussed, Jacobi's gonioscraper has several bends or curves. *Id.* It was also well-known in the art to use devices with portions bent at various angles to meet the needs of a given surgery. Ex.1003, ¶273. For example, Johnstone discloses an "ab interno" procedure using "a cystotome with the point oriented at right angles to the shaft" inserted through the TM into SC." Ex.1005, 2; *see also* Ex.1006, 4:49-54 (angle of device's cutting edges vary "depending on surgical requirements"). Quintana discloses a needle device with the tip bent 20-30°. Ex.1004, 3.

Based on the knowledge of a POSITA as informed by prior art references such as Quintana and Johnstone, it would have been obvious to alter the angle of one or more of the bends or curves in Jacobi's device. For example, it would have been a simple matter of combining prior art elements according to known methods or simple substitution of one known element for another to modify "bend or curve" (3), *see supra*, §VI.E.2, to an angle of less than approximately 90 degrees. Ex.1003, ¶274. Indeed, a POSITA would recognize the device's "bend or curve" could be substituted by, for example, Quintana's, with predictable results given the prior art's disclosure of positive results using devices having bends or curves of varying angles, including Johnstone and Quintana. *Id.*

A POSITA also would have found it obvious to try variations to the angle of the "bends or curves" in Jacobi's device, given there are a finite number of "bend or curve" angles that could be employed. *Id.*, ¶275. A POSITA would have been motivated to try variations to the angle, such as to have an angle of less than approximately 90 degrees based on the prior art including Quintana, in order to expand and/or improve upon Jacobi's results, and would have expected success given the successful use of devices with points and angles of varying degrees in the prior art. *Id.*

4. Claim 10

Jacobi in view of the knowledge of a person skilled in the art as informed by prior art references such as Johnstone and Quintana render obvious claim 9. *See supra*, §VI.F.3. Further, as discussed, Jacobi's gonioscraper has several bends or curves. *Id.* It was also 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, ¶277. For example, Johnstone discloses an "ab interno" procedure using "a cystotome with the point oriented at right angles to the shaft" inserted through the TM into SC." Ex.1005, 2; *see also* Ex.1006, 4:49-54 (angle of device's cutting edges vary "depending on surgical requirements"). Quintana discloses a needle device with the tip bent 20-30° by a needle holder. Ex.1004, 3.

Based on the knowledge of a POSITA as informed by prior art references such as Quintana and Johnstone, it would have been obvious to alter the angle of one or more of the bends or curves in Jacobi's device. For example, it would have been a simple matter of combining prior art elements according to known methods or simple substitution of one known element for another to modify "bend or curve" (3), *see supra*, §VI.E.2, to an angle of approximately 90 degrees. Ex.1003, ¶278. Indeed, a POSITA would recognize the device's "bend or curve" could be substituted by, for example, Johnstone's, with predictable results given the prior art's disclosure of positive results using devices having bends or curves of varying angles, including Johnstone and Quintana. *Id.*

A POSITA also would have found it obvious to try variations to the angle of the "bends or curves" in Jacobi's device, given there are a finite number of "bend or curve" angles that could be employed. *Id.*, ¶279. A POSITA would have been motivated to try variations to the angle, such as to have an angle of approximately 90 degrees based on the prior art including Johnstone, in order to expand and/or improve upon Jacobi's results, and would have expected success given the successful use of devices with points and angles of varying degrees in the prior art. *Id*.

VII. Conclusion

For the foregoing reasons, IPR of claims 1-10 of the '729 patent is respectfully requested.

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Respectfully submitted,

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Claim Appendix

Claim 1:

[1.p] An ab interno method for forming an opening in TM of a patient's eye, said method comprising the steps of:

[1.a] obtaining a dual blade device which comprises

[1.a.1] a) an elongate proximal portion sized to be grasped by a hand of a human operator and

[1.a.2] b) an elongate probe extending from the proximal portion, wherein the elongate probe comprises

[1.a.2.i] i) a shaft,

[1.a.2.ii] ii) a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees,

[1.a.2.iii] said distal protruding tip being sized to be inserted in Schlemm's Canal and

[1.a.2.iv] iii) first and second cutting edges located at a junction of the shaft and the distal protruding tip, said first and second cutting edges being formed at spaced-apart locations on the distal end of the shaft, said first and second cutting edges being separated by a distance D;

[1.b] forming an opening into an anterior chamber of the eye;

[1.c] inserting the elongate probe through the opening and into the anterior chamber;

[1.d] advancing the elongate probe through the anterior chamber, while the anterior chamber is filled with fluid, to an operative position where the distal protruding tip is positioned within SC and the first and second cutting edges are contacting the TM; and, thereafter

[1.e] causing the distal protruding tip to advance through a sector of SC with the first and second cutting edges concurrently cutting, from the TM, a strip of tissue having approximate width W, said approximate width W being

approximately equal to the distance D between the first and second cutting edges.

Claim 2:

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

[2.a] infusing fluid into the anterior chamber under controlled pressure to keep the anterior chamber filled with fluid during performance of the method.

Claim 3:

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

[3.a] the strip of tissue cut from the TM has a length of about 2 to 10 millimeters.

Claim 4:

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

[4.a] removing the strip of tissue from the patient's eye.

Claim 5:

[5.p] A method according to claim 4 wherein,

[5.a] after the first and second cutting edges have cut the strip of tissue from the TM, the strip of tissue remains connected to the TM and wherein the method further comprises the step of: disconnecting the strip of tissue such that it may be removed from the eye.

Claim 6:

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

[6.a] the disconnecting step comprises using a tissue severing apparatus to transect or sever the strip of tissue so as to disconnect it from the patient's body.

Claim 7:

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

[7.a] the step of forming an opening into the anterior chamber of the eye comprises forming an incision through a cornea of the eye.

Claim 8:

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

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

Claim 9:

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

[9.a] the angle is less than approximately 90 degrees.

Claim 10:

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

[10.a] the angle is approximately 90 degrees.

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 13928 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.

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing **PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 9,107,729** was served as of the below date via Federal Express on the following individuals:

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