

New World Medical, Inc.,  
v.  
MicroSurgical Technology, Inc. /  
The Regents of the Univ. of California

IPR2020-01573 (U.S. Patent 9,107,729)  
IPR2020-01711 (U.S. Patent 9,358,155)  
IPR2021-00017 (U.S. Patent 9,820,885)  
IPR2021-00065 (U.S. Patent 10,123,905)  
IPR2021-00066 (U.S. Patent 9,999,544)

Petitioner New World Medical, Inc.'s Demonstratives

Petitioner New World Medical, Inc., IPR Nos. 2020-01573,  
2020-01711, 2021-00017, 2021-00065, 2021-00066  
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE



NEW WORLD  
MEDICAL

Humanity's Vision Is Our Focus

# Petitioner's Evidence v. Patent Owner's Evidence

Petitioner's Evidence	Patent Owner's Evidence
<ul style="list-style-type: none"><li>• Quintana</li><li>• Jacobi</li><li>• Dr. Netland</li><li>• Testing</li></ul>	<ul style="list-style-type: none"><li>• Quintana's Affidavit</li> <li>• Dr. Condon</li></ul>

# Quintana Discloses All Elements

GONIOSCOPIC TRABECULOTOMY. FIRST RESULTS

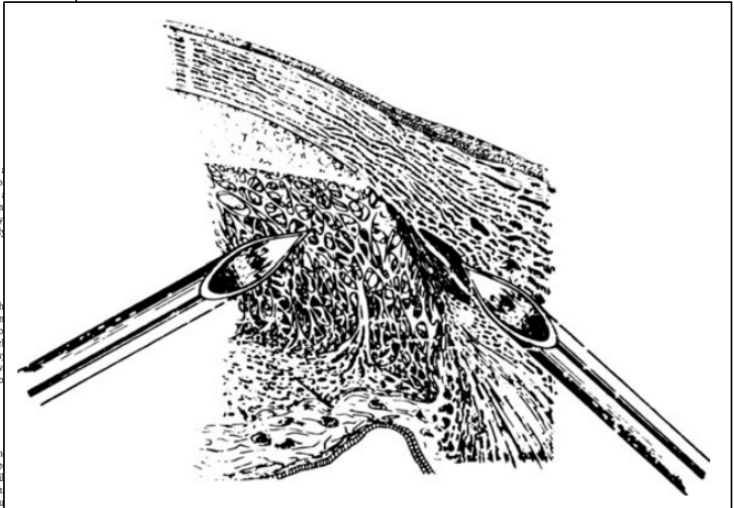
MANUEL QUINTANA  
(Barcelona, Spain)

## ABSTRACT

We describe a surgical method of goniotrabeculotomy which achieves a section of the trabecular meshwork without damage to the external wall of Schlemm's canal. Complications are minimal. A one year follow-up shows a fall of intraocular pressure in almost all cases. However, this effect is non-lasting and a slow rise in pressure occurs in most cases. Yet, medical therapy, if reinstated, achieves a better control than before the operation and usually can be less intense.

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A technique of trabeculotomy has been devised, which eliminates most of the presumed causes of failure of previous methods. The patient is operated under general anaesthesia; both eyes can be done at the same time. Pupil should be miotic. A coaxial operating microscope is necessary, with magnification of  $\times 10$ . We favour the Swann lens for angle visualisation. Our trabeculotome is a  $0.4 \times 15$  mm needle, or an inuline-type needle; we bend the tip  $20-30^\circ$  with a needle-holder; a factory-made needle (Moris, France) is even better. The needle is inserted into a syringe filled with "healon". "Modus operandi" is as in classical goniotomy (surgeon in the temporal side of the patient, patient's head rotated away from the surgeon, assistant holding

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E.L. Greve, W. Leydhecker & C. Raitini (eds.), Second European Glaucoma Symposium, Helsinki 1984.  
© 1985, Dr. W. Junk Publishers, Dordrecht. ISSN 0167-0106/85/4-0 Petitioner - New World Medical  
Ex. 1004, p. 3 of 9

Ex.1004, 3-4; see IPR2020-01573, Paper 1, 27, 36; IPR2020-01711, Paper 1, 31, 42; IPR2021-00017, Paper 1, 27, 36; IPR2021-00065, Paper 1, 30, 39; IPR2021-00066, Paper 1, 27-29, 36.

# Petitioner's Evidence v. Patent Owner's Evidence

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<ul style="list-style-type: none"><li>• Quintana</li><li>• Jacobi</li><li>• Dr. Netland</li><li>• Testing</li></ul>	<ul style="list-style-type: none"><li>• Quintana's Affidavit</li><li>• Dr. Condon</li></ul>

# Jacobi Discloses All Elements



302 *British Journal of Ophthalmology* 1997;81

**Technique of gonioscurettage: a potential treatment for advanced chronic open angle glaucoma**

Philipp C Jacobi, Thomas S Dietlein, Günter K Krieglstein

**Abstract**—To introduce a new concept of anterior chamber angle microsurgery, designed to scrape pathologically altered trabecular meshwork from the scleral sulcus as a potential treatment in primary open angle glaucoma.

**Methods**—Gonioscopically controlled ab interno abrasion of the trabecular meshwork was performed on six human eye banking eyes for morphological analysis. Thereafter, four eyes suffering from terminal glaucomatous optic nerve atrophy as a result of medically uncontrolled intraocular pressure were also treated by 'gonioscurettage'. The newly designed instrument resembles a modified cyclodialysis spatula with a bowl-shaped tip, 300 µm in diameter, and with its edges sharpened. The treatment zone comprised 4–6 clock hours of the chamber angle circumference.

**Results**—Microscopic examination of the treatment zone revealed that in addition to a complete disruption of the trabecular meshwork and internal wall of Schlemm's canal gonioscurettage also caused damage to intrascleral spaces. A splitting along the posterior wall of Schlemm's canal was also noted in one specimen. The clinical data of gonioscurettage also showed some promising results. Mean pre-treatment IOP averaged 40.7 (SD 9.8) mm Hg (range 32–61 mm Hg) and was significantly ( $p < 0.04$ ) reduced to 18.0 (4.2) mm Hg (12–22 mm Hg) after 6 months, representing an absolute decrease in IOP of 22.7 mm Hg and a mean decrease in IOP of 56%. Clinically significant hyphaema occurred in one eye, caused by iatrogenic trauma to a prominent chamber angle vessel. In three eyes a minor reflex of blood occurred at the treatment site. Flattened anterior chamber, or cyclodialysis were observed in those patients.

**Conclusion**—Morphological analysis of treated post-mortem eyes confirmed that gonioscurettage completely removed the trabecular meshwork and opened Schlemm's canal, ensuring direct access into the anterior chamber. In a small number of patients over a limited period of time this new surgical procedure resulted in a clinically significant pressure

reduction. However, longer term follow-up and a greater number of patients treated before this experimental procedure is applicable to eyes that will with conventional surgery.

(*Br J Ophthalmol* 1997;81:302–307)

Conventional glaucoma filtering surgery maintains of surgical treatment to intraocular pressure (IOP) in primary angle glaucoma.<sup>1</sup> There is a growing concern to perform surgery earlier in the course of glaucoma management.<sup>2</sup> However, increasing success rates, especially with the advent of antimetabolites, several remain, such as hyphaema, flat anterior chamber, and variable wound healing and conjunctival manipulation. In order to improve the success rate of filtering surgery, laser sclerostomy has recently become an alternative to conventional glaucoma surgery.<sup>3</sup> However, varying success of been reported using different laser eye techniques.<sup>4–7</sup> Based on the concept of minimal resistance to outflow of aqueous as a result of underdevelopment of the trabecular meshwork,<sup>8</sup> goniotomy,<sup>9</sup> ab externo iridotomy,<sup>10</sup> and trabeculotomy<sup>11</sup> have been recommended as surgical procedures in juvenile open angle glaucoma. In recent years, trabeculotomy has gained increasing interest among some glaucoma surgeons as a first choice surgical treatment of chronic open angle glaucoma.<sup>12</sup> Combined glaucoma and cataract surgery has been recommended as a surgical procedure in juvenile open angle glaucoma.<sup>13</sup> Based on transmission and scanning electron microscopy of trabeculotomy of various authors have suggested that cases of chronic open angle glaucoma with primary increase of outflow resistance the cribriform layer of the trabecular meshwork adjacent to the inner wall endothelium of Schlemm's canal.<sup>14</sup> Presuming that layers of the trabecular meshwork play a role in the pathology of primary angle glaucoma, incisional surgery (partial mechanical disruption (trabeculotomy) of the trabecular meshwork could then be a logical approach to medically uncontrolled angle glaucoma. Unfortunately, incision of the trabecular meshwork by trabeculotomy approach or punch holes with the Q-switched Nd:YAG

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P C Jacobi  
T S Dietlein  
G K Krieglstein

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Accepted for publication 14 December 1996

PEB00000



before surgery. Gonioabrasion was performed under direct visualisation of the anterior chamber angle with an operating microscope and a surgical gonioscopy lens. Following injection of viscoelastic, the 'gonioscraper' was inserted into the anterior chamber through a clear corneal incision at the temporal limbus and directed against the trabecular meshwork at the opposite side. In order to peel off trabecular meshwork the 'scraper' was lightly passed over 2–3 clock hours to either side at the nasal circumference of the anterior chamber angle in sweeping movements (Fig 2). Great care was taken to selectively pare uveal meshwork and not to traumatise adjacent intraocular structures, such as the corneal endothelium or the base of the iris. Gonioscopically, strings of trabecular tissue could be observed intraoperatively to be removed by gonioscurettage, leaving a 'denuded' grey-white scleral sulcus. At the end of surgery the viscoelastic along with abraded trabecular debris were removed by means of an irrigation-aspiration probe.

Ex.1007, 1-2; see IPR2020-01573, Paper 1, 74-76; IPR2020-01711, Paper 1, 75-78, 80; IPR2021-00017, Paper 1, 58-61; IPR2021-00065, Paper 1, 53-56; IPR2021-00066, Paper 1, 66-69.

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Petitioner New World Medical, Inc., IPR Nos. 2020-01573, 2020-01711, 2021-00017, 2021-00065, 2021-00066  
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

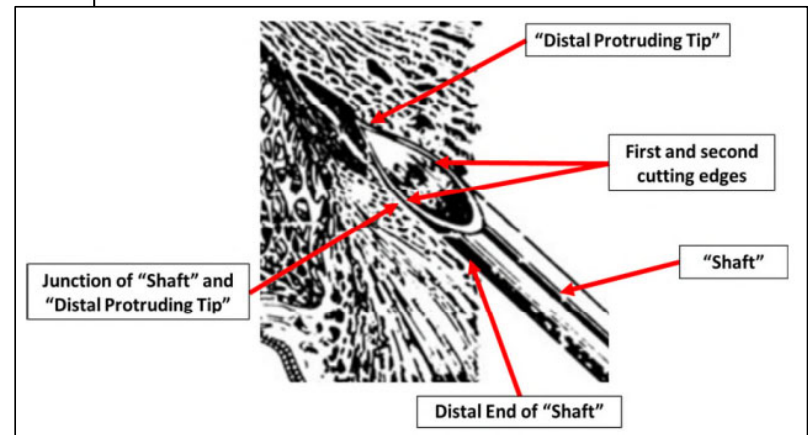
# Petitioner's Evidence v. Patent Owner's Evidence

Petitioner's Evidence	Patent Owner's Evidence
• Quintana 	• Quintana's Affidavit
• Jacobi 	
• Dr. Netland	• Dr. Condon
• Testing	

# Dr. Netland Confirms that Quintana Discloses All Elements

136. Quintana discloses “progressively introduc[ing]” the tip of the needle portion of the device in the angle of the anterior chamber. *Id.* Further, according to Quintana, “[o]nly *the tip of the instrument is introduced into Schlemm’s canal, and the TM is stripped slowly, gently and easily from the canal’s lumen* towards the anterior chamber as the needle progresses in the angle (Fig. 2).” *Id.*, 4 (emphasis added); *see also, id.*, 3 (“a surgical method of goniotrabeculotomy which *achieves a section of the trabecular meshwork* without damage to the external wall of Schlemm’s canal.”). In my opinion, Quintana’s disclosure of “stripping” the trabecular meshwork to “achieve[] a section of the trabecular meshwork” refers to excising or cutting a “strip of tissue” from the trabecular meshwork as claimed. Further, in order to create such a “strip of tissue,” both the “first and second cutting edges” of Quintana’s needle must be concurrently cutting the trabecular meshwork (otherwise, Quintana’s procedure would not have achieved a “section” of the trabecular meshwork, but instead would have merely created a slit-like opening in the trabecular meshwork).

UNITED STATES PATENT AND TRADEMARK OFFICE  
 THE PATENT TRIAL AND APPEAL BOARD  
 NEW WORLD MEDICAL, INC.,  
 Petitioner  
 v.  
 MICROSURGICAL TECH, INC.,  
 Patent Owner  
 PARTIES REVIEW OF U.S. PATENT NO. 9,107,729  
 Case No. IPR2020-01573  
 3 - DECLARATION OF DR. PETER NETLAND



IPR2020-01573 Ex.1003, ¶129, 136 (see Paper 1, 44, 47-48); see also IPR2020-01711, Ex.1003, ¶128, 135, (see Paper 1, 42-43, 47); IPR2021-00017, Ex.1003, ¶107, 115 (see Paper 1, 43-44, 47); IPR2021-00065, Ex.1003, ¶105, 112 (see Paper 1, 41, 4); IPR2021-00066, Ex.1003, ¶106, 112, (see Paper 1, 36, 41).

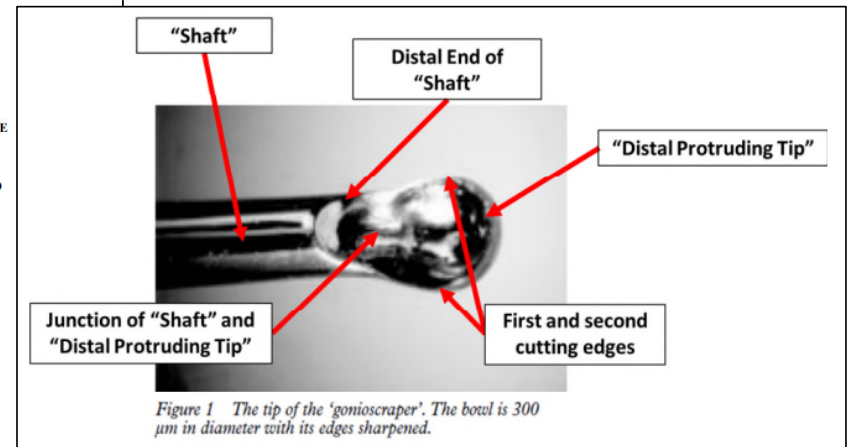
4850-5633-1210, v.1  
 Petitioner - New World Medical  
 Ex. 1003, p. 1 of 269

Petitioner New World Medical, Inc., IPR Nos. 2020-01573,  
 2020-01711, 2021-00017, 2021-00065, 2021-00066  
 DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

# Dr. Netland Confirms that Jacobi Discloses All Elements

anterior chamber angle to “peel off trabecular meshwork.” *Id.* Jacobi reports that “gonioscopically, *strings of trabecular tissue could be observed intraoperatively to be removed by gonioscurettage*, leaving a ‘denuded’ grey-white scleral sulcus.” *Id.* Persons of ordinary skill in the art would understand that “abrading” the trabecular meshwork to peel off “strings of trabecular meshwork” tissue refers to cutting a “strip of tissue” from the trabecular meshwork as claimed. Based on Jacobi’s stated disavowal of a simple incision, persons of ordinary skill in the art would further appreciate that in order to create such a “strip of tissue,” both the “first and second cutting edges” of Jacobi’s gonioscraper must be concurrently cutting the trabecular meshwork (otherwise, Jacobi’s procedure would not have achieved “strings” of trabecular meshwork tissue, but instead would have merely incised the trabecular meshwork to create a slit-like opening, which Jacobi explicitly sought to avoid).

INTELLLECTUAL PROPERTY AND TRADEMARK OFFICE  
 FEDERAL BUREAU OF INVESTIGATION  
 PATENT TRIAL AND APPEAL BOARD  
 WORLD MEDICAL, INC.,  
 Petitioner  
 v.  
 SURGICAL TECH., INC.,  
 Patent Owner  
 REVIEW OF U.S. PATENT NO. 9,107,729  
 Ex. No. IPR2020-01573  
 STATEMENT OF DR. PETER NETLAND






IPR2020-01573 Ex.1003, ¶1242, 251 (see Paper 1, 84, 87); see also IPR2020-01711, Ex.1003, ¶ 220, 231, 236, (see Paper 1, 80, 87, 90-91); IPR2021-00017, Ex.1003, ¶150, 156 (see Paper 1, 61, 64); IPR2021-00065, Ex.1003, ¶136, 141, (see Paper 1, 55-56, 57-58); IPR2021-00066, Ex.1003, ¶192, 198 (see Paper 1, 69, 72-73).

4850-5633-1210, v.1

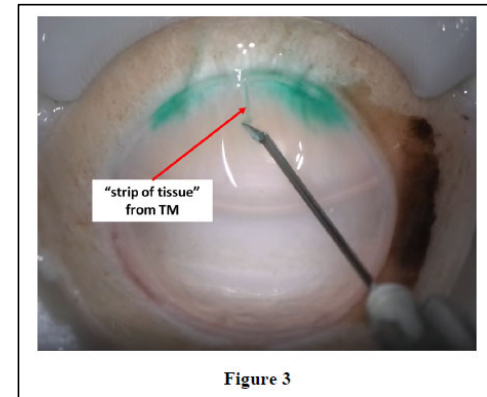
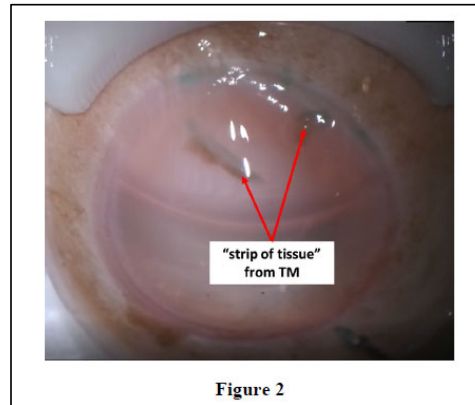
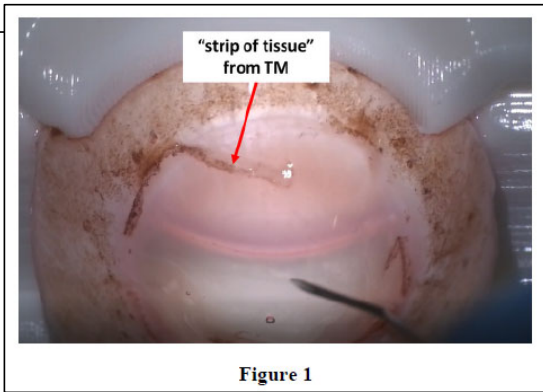
Petitioner - New World Medical  
 Ex. 1003, p. 1 of 289



# Petitioner's Evidence v. Patent Owner's Evidence

Petitioner's Evidence	Patent Owner's Evidence
• Quintana 	• Quintana's Affidavit
• Jacobi 	
• Dr. Netland 	• Dr. Condon
• Testing	

# Dr. Netland's Testing Provides Further Confirmation



v.  
MICROSURGICAL TECHNOLOGY, INC.,  
Patent Owner

Case No. IPR2020-01573

U.S. Patent No. 9,107,729

REPLY DECLARATION OF DR. PETER NEILSON





26. These results confirm my opinion that the surgical procedure described in the Quintana reference (Ex.1004) would have result in cutting "strips of tissue" from the trabecular meshwork, as well as my opinion that Patent Owner, Dr. Condon, and Dr. Quintana misinterpreted the disclosures of the Quintana reference (Ex.1004).

Petitioner - New World Medical  
Ex. 1030, p. 1 of 19  
New World Medical, Inc. v. MicroSurgical Tech., Inc., IPR2020-01573






Petitioner New World Medical, Inc., IPR Nos. 2020-01573,  
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DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Ex.1030, ¶¶17-26; Ex.1031-1033; see IPR2020-01573, Paper 35, 13-14; IPR2020-01711, Paper 27, 11-13; IPR2021-00017, Paper 26, 12-14; IPR2021-00065, Paper 24, 12-14; IPR2021-00066, Paper 25, 14-16.

# Petitioner's Evidence v. Patent Owner's Evidence

Petitioner's Evidence	Patent Owner's Evidence
• Quintana 	• Quintana's Affidavit
• Jacobi 	
• Dr. Netland 	• Dr. Condon
• Testing 	

# Petitioner's Evidence v. Patent Owner's Evidence

Petitioner's Evidence	Patent Owner's Evidence
• Quintana 	 • <del>Quintana's Affidavit</del>
• Jacobi 	
• Dr. Netland 	• Dr. Condon
• Testing 	

# Dr. Condon “Opines” on Invalidity...

267. In my opinion, according to the applicable legal standards as I understand them, a POSA reading the cited prior art in the Petition along with the general knowledge in the art would have concluded with a reasonable scientific certainty that Claims 1-10 of the '729 patent are not invalid, and specifically would have found that: (I) Claims 1-4 and 7-9 are not anticipated under 35 U.S.C. § 102 by Quintana (Ex. 1004); (II) Claims 4-6 and 10 are not rendered obvious under 35 U.S.C. § 103 by Quintana (Ex. 1004) in view of the knowledge of a person of ordinary skill in the art; (III) Claims 1-4 and 7-9 are not rendered obvious under 35 U.S.C. § 103 by Quintana (Ex. 1004) in view of Lee (Ex. 1006); (IV) Claims 4-6 and 10 are not rendered obvious under 35 U.S.C. § 103 by Quintana (Ex. 1004) in view of Lee (Ex. 1006) in further view of the knowledge of a person of ordinary skill in the art; (V) Claims 1-4 and 7-8 are not anticipated under 35 U.S.C. § 102 by Jacobi (Ex. 1007); and (VI) Claims 5-6 and 9-10 are not rendered obvious under 35 U.S.C. § 103 by Jacobi (Ex. 1007) in view of the knowledge of a person of ordinary skill in the art.

UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEW WORLD MEDICAL, INC.,  
Petitioner,

v.

MICROSURGICAL TECHNOLOGY, INC.,  
Patent Owner.

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

Filed: June 8, 2021

DECLARATION OF GARRY P. CONDON, M.D.  
IN SUPPORT OF PATENT OWNER'S RESPONSE

Patent Owner Ex. 2019-0001

IPR2020-01573, Ex.2019, ¶267 (see Paper 29, 12; Paper 35, 2; Paper 52, 10-11); see also IPR2020-01711, Ex.2019, ¶245 (see Paper 17, 13; Paper 27, 2; Paper 39, 10-12); IPR2021-00017, Ex.2019, ¶191 (see Paper 17, 10; Paper 26, 2; Paper 38, 10-12); IPR2021-00065, Ex.2019, ¶135 (see Paper 18, 10; Paper 24, 2; Paper 41, 10-11); IPR2021-00066, Ex.2019, ¶224 (see Paper 17, 12; Paper 25, 2; Paper 39, 10-11).

# ...But Dr. Condon Testified He Did Not Read or Understand the Patents

- Dr. Condon merely “**flipped through**” the ‘729 patent
  - Ex.1041, 176:2-4
- Dr. Condon “**didn’t drill down into [] the requirements** of the ‘729 patent”
  - Ex.1041, 214:13-15
- Dr. Condon “**would not be comfortable** telling [NWM’s counsel] what [is] required” in the patents at issue
  - Ex.1041, 214:21-22
- Dr. Condon testified he had “**not seen this before**” when given the Notice of Allowance from the ‘729 patent file history
  - Ex. 1042, 239:11-20
- Dr. Condon testified regarding the ‘905 patent: “**I don’t remember reading the whole thing**”
  - Ex.1042, 266:3-7
- Dr. Condon “**didn’t analyze [the ‘155 patent]** other than to look at ... the claim language.”
  - Ex.1042, 281:18-282:1

IPR2020-01573, Paper 35, 2-3; IPR2020-01711, Paper 27, 2-3;  
IPR2021-00017, Paper 26, 2-4; IPR2021-00065, Paper 24, 2-4;  
IPR2021-00066, Paper 25, 2-4.

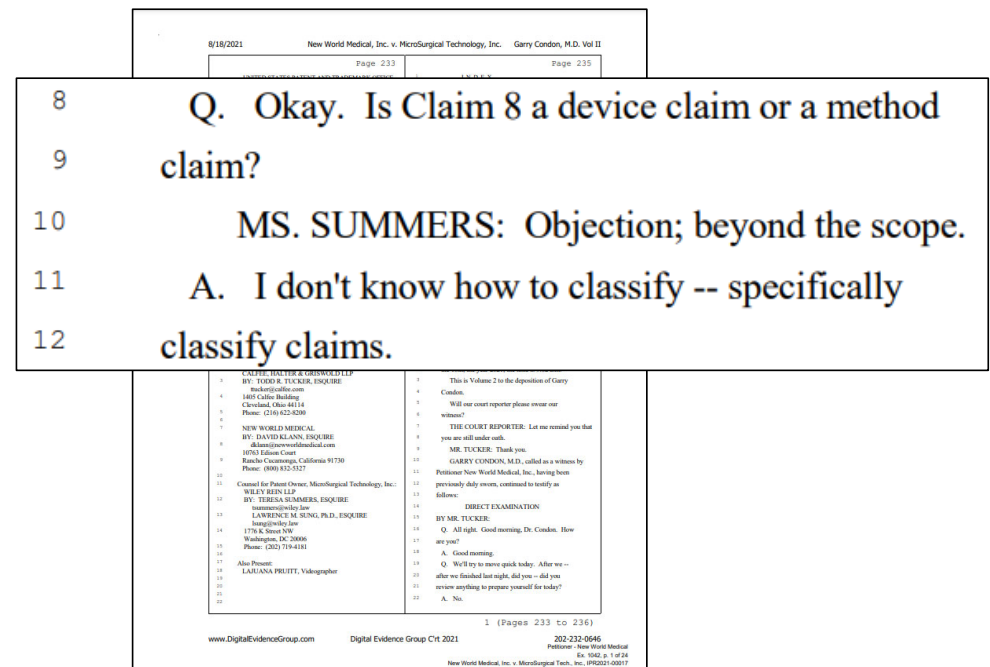
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Petitioner New World Medical, Inc., IPR Nos. 2020-01573,  
2020-01711, 2021-00017, 2021-00065, 2021-00066  
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

14

# ...And Dr. Condon Testified He Does Not Understand Patent Claims

- Dr. Condon testified he **cannot tell the difference between a device or method claim**
  - Ex.1042, 276:8-12
- Dr. Condon testified **“I don’t even know if I’m capable of dissecting that exact piece of information out of the claim”** when asked if claims require certain elements
  - Ex.1042, 257:4-9



# ...And Dr. Condon Testified He Does Not Understand Anticipation or Obviousness

- Dr. Condon testified he **“would have to say no”** and **“couldn’t explain it”** when asked if he has an **understanding of obviousness**
  - Ex.1042, 257:10-14
- Dr. Condon testified **“it’s not crystal clear to me”** when asked if he has an **understanding of anticipation**
  - Ex.1041, 178:10

IPR2020-01573, Paper 35, 2-3; IPR2020-01711, Paper 27, 2-3; IPR2021-00017, Paper 26, 2-4; IPR2021-00065, Paper 24, 2-4; IPR2021-00066, Paper 25, 2-4.

267. In my opinion, according to the applicable legal standards as I understand them, a POSA reading the cited prior art in the Petition along with the general knowledge in the art would have concluded with a reasonable scientific certainty that Claims 1-10 of the '729 patent are not invalid, and specifically would have found that: (I) Claims 1-4 and 7-9 are not anticipated under 35 U.S.C. § 102 by Quintana (Ex. 1004); (II) Claims 4-6 and 10 are not rendered obvious under 35 U.S.C. § 103 by Quintana (Ex. 1004) in view of the knowledge of a person of ordinary skill in the art; (III) Claims 1-4 and 7-9 are not rendered obvious under 35 U.S.C. § 103 by Quintana (Ex. 1004) in view of Lee (Ex. 1006); (IV) Claims 4-6 and 10 are not rendered obvious under 35 U.S.C. § 103 by Quintana (Ex. 1004) in view of Lee (Ex. 1006) in further view of the knowledge of a person of ordinary skill in the art; (V) Claims 1-4 and 7-8 are not anticipated under 35 U.S.C. § 102 by Jacobi (Ex. 1007); and (VI) Claims 5-6 and 9-10 are not rendered obvious under 35 U.S.C. § 103 by Jacobi (Ex. 1007) in view of the knowledge of a person of ordinary skill in the art.

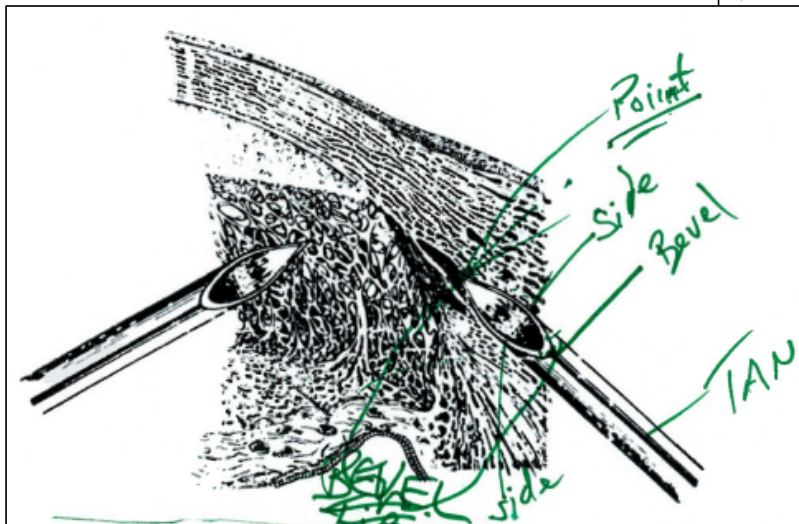
UNITED STATES PATENT AND TRADEMARK OFFICE  
THE PATENT TRIAL AND APPEAL BOARD  
NEW WORLD MEDICAL, INC.,  
Petitioner,  
v.  
SURGICAL TECHNOLOGY, INC.,  
Patent Owner.  
Case IPR2020-01573  
U.S. Patent No. 9,107,729  
Filed: June 8, 2021  
STATEMENT OF GARRY P. CONDON, M.D.  
PART OF PATENT OWNER'S RESPONSE  
Patent Owner Ex. 2019-0001

IPR2020-01573 Ex.2019, ¶1267 (see Paper 29, 12; Paper 35, 2; Paper 52, 10-11) see also IPR2020-01711, Ex.2019, ¶1245 (see Paper 17, 13; Paper 27, 2; Paper 39, 10-12); IPR2021-00017, Ex.2019, ¶1191 (see Paper 17, 10; Paper 26, 2; Paper 38, 10-12); IPR2021-00065, Ex.2019, ¶135 (see Paper 18, 10; Paper 24, 2; Paper 41, 10-11); IPR2021-00066, Ex.2019, ¶1224 (see Paper 17, 12; Paper 25, 2; Paper 39, 10-11).

Petitioner New World Medical, Inc., IPR Nos. 2020-01573,  
2020-01711, 2021-00017, 2021-00065, 2021-00066  
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE



# Dr. Condon's Testimony and Annotated Figure Demonstrate Quintana's Needle Is a "Dual Blade Device"



The diagram shows a cross-section of a needle with several handwritten annotations in green ink: 'Point' at the tip, 'Side Bevel' along the upper edge, 'TAN' at the bottom edge, and 'Back side' at the lower edge. The needle is shown penetrating a cross-section of tissue.

New World Medical, Inc. v. MicroSurgical Technology, Inc. Garry Condon, M.D.	
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UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD	INDEX Tuesday, August 17, 2021
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DATE TAKEN: Tuesday, August 17, 2021 TIME: 9:04 a.m. - 8:11 p.m. EXAM: Eastern Daylight Time PLACE: Telephony Station by Video Services 202 South Western Ave. Savannah, Georgia 30238	Page 4
DESCRIPTION OF THE VIDEO: Video before SUSAN D. WASELINSKI, RFE, CRE, CMRS, CRC, FRC - Realtime System Administrator -	EXHIBIT A CONT (Checklist to accompany) GARRY CONDON, M.D. DEPOSITION EXHIBITS PAGE Condon Exhibit 8 Block of Medical Dictionary 75 Page 19 - "needle" Medical Dictionary Condon Exhibit 9 Oxford Medical Dictionary 78 Page 19 - "needle" 2021-00017 through 1 2021-00065 through 1 Condon Exhibit 6 Clinical Research Impression Memorandum of Dr. Richard Chappin Condon Exhibit 9 Affidavit, Testimony of Deposition Condon Exhibit 10 Deposition of Garry P. Condon, M.D., in Support of Patent Nos. 9,077,729, 9,336,175, 9,820,895, 10,226,065, 10,999,344 10,226,065 through 11 10,226,065 through 11 Condon, M.D., in Support of Patent Nos. 9,077,729, 9,336,175, 9,820,895, 10,226,065, 10,999,344 10,226,065 through 11
DIGITAL EVIDENCE GROUP 1700 Rosslyn, DC, Suite 402 Washington, D.C. 20009 (202) 572-0646	1 (Pages 1 to 4)
APPEARANCES Counsel for Respondent, New World Medical, Inc.: CALLEE HALTER & GREWOLD LLP BY: TUCKER, TUCKER, ESQUIRE tucker@ttt.com 4000 Cahoon Building Cleveland, Ohio 44114 Phone: (216) 425-2500	www.DigitalEvidenceGroup.com Digital Evidence Group Cyt 2021 202-232-0646 Petitioner, New World Medical Ex. 1046, p. 17 of 98 New World Medical, Inc. v. MicroSurgical Tech., Inc. IPR2020-01711
NEW WORLD MEDICAL BY: DAVID KLANN, ESQUIRE dklann@newworldmedical.com 10700 Eureka Court Rancho Cucamonga, California 91750 Phone: (909) 812-5222	
Counsel for Petitioner, MicroSurgical Technology, Inc.: WILEY KEENE LLP BY: TERESA WILMARES, ESQUIRE twilmares@wke.com Law Offices by Law 1774 K Street, N.W. Washington, DC 20006 Phone: (202) 774-4411	
Also Present: LARIANA FRUITI, Videographer	

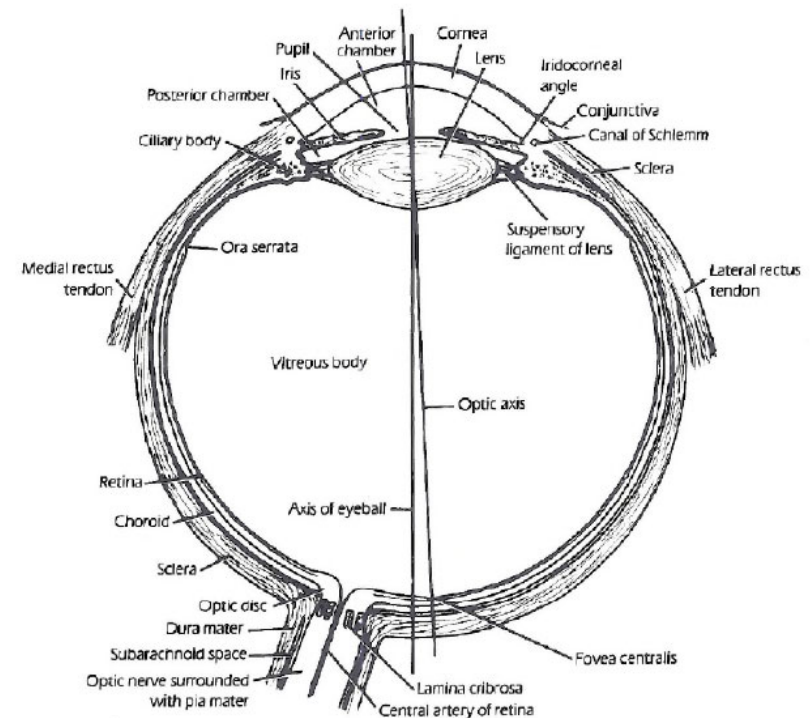
Ex.1043, 192; see IPR2020-01573, Paper 35, 17-18; IPR2020-01711, Paper 27, 15; IPR2021-00017, Paper 26, 16; IPR2021-00065, Paper 24, 16-17; IPR2021-00066, Paper 25, 18.

# Petitioner's Evidence v. Patent Owner's Evidence

Petitioner's Evidence	Patent Owner's Evidence
<ul style="list-style-type: none"><li>• Quintana ✓</li></ul>	<ul style="list-style-type: none"><li>• <del>Quintana's Affidavit</del></li></ul>
<ul style="list-style-type: none"><li>• Jacobi ✓</li></ul>	
<ul style="list-style-type: none"><li>• Dr. Netland ✓</li></ul>	<ul style="list-style-type: none"><li>• Dr. Condon ?</li></ul>
<ul style="list-style-type: none"><li>• Testing ✓</li></ul>	

# Eye Anatomy and Glaucoma

- Human eye has three chambers including **anterior chamber** (“AC”)
- Aqueous humor in AC normally drains through **trabecular meshwork** (“TM”) into **Schlemm’s Canal** (“SC”)
- Increased resistance to aqueous humor outflow across TM-SC causes increased **intraocular pressure** (“IOP”)
- Elevated IOP was known to be primary risk factor for **glaucoma**



Ex.1008, 9; see IPR2020-01573, Paper 1, 5; IPR2021-01711, Paper 1, 5; IPR2021-00017, Paper 1, 5; IPR2021-00065, Paper 1, 5; IPR2021-00066, Paper 1, 5.

IPR2020-01573, Paper 1, 4-18; IPR2020-01711, Paper 1, 4-18; IPR2021-00017, Paper 1, 4-18; IPR2021-00065, Paper 1, 4-18; IPR2021-00066, Paper 1, 4-19.

Ex.1046, p. 19 of 98

Petitioner New World Medical, Inc., IPR Nos. 2020-01573,  
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DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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# Treatment of Glaucoma

- Known by mid-1900's that most outflow resistance caused by TM
- Procedures (*e.g.*, goniotomy, trabeculotomy) developed to incise TM
- Recognized well before 2003 that incision could close/scar over, blocking outflow
- Led to development of procedures and devices to create larger and more permanent openings in TM

IPR2020-01573, Paper 1, 4-18; IPR2020-01711, Paper 1, 4-18; IPR2021-00017, Paper 1, 4-18; IPR2021-00065, Paper 1, 4-18; IPR2021-00066, Paper 1, 4-19.

Ex.1046, p. 20 of 98

Petitioner New World Medical, Inc., IPR Nos. 2020-01573, 2020-01711, 2021-00017, 2021-00065, 2021-00066  
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

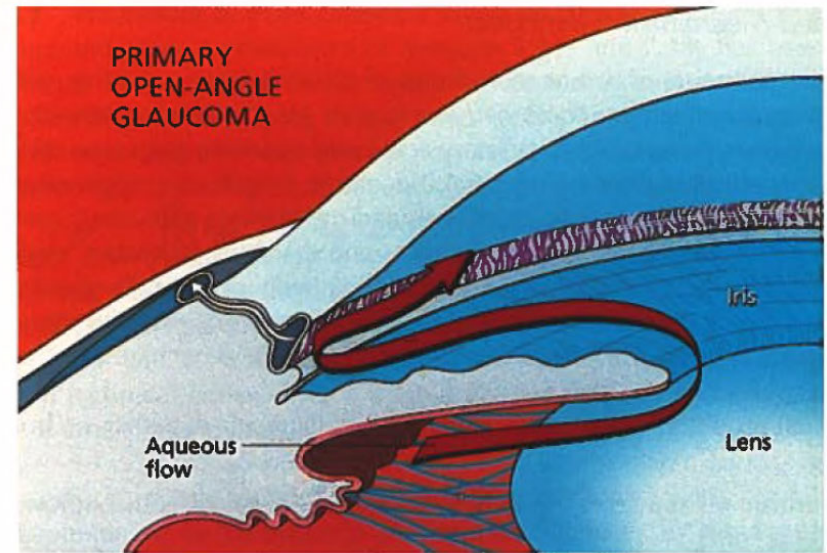


FIG 1-2—Schematic of open-angle glaucoma with resistance to aqueous outflow through the trabecular meshwork–Schlemm's canal system in the absence of gross anatomic obstruction. Small white arrow shows normal path of outflow and indicates that resistance in this illustration is relative, not total.

Ex.1012, 10; see IPR2020-01573, Paper 1, 9; IPR2021-01711, Paper 1, 9; IPR2021-00017, Paper 1, 9; IPR2021-00065, Paper 1, 9; IPR2021-00066, Paper 1, 9.

# Procedures and Devices for Treating Glaucoma Were Well-Known

## '729 Patent

One surgical procedure wherein a strip of tissue of a known width is removed from an anatomical location within the body of a patient is an ophthalmological procedure used to treat glaucoma. This ophthalmological procedure is sometimes referred to as a goniotomy. In a goniotomy procedure, a device that is operative to cut or ablate a strip of tissue of approximately 2-10 mm in length and about 50-200 µm in width is inserted into the anterior chamber of the eye and used to remove a full thickness strip of tissue from the trabecular meshwork. The trabecular meshwork is a loosely organized,

IPR2020-01573, Ex.1001, 1:35-45 (see Paper 1, 18); see also IPR2020-01711, Ex.1001, 1:23-2:37 (see Paper 1, 18); IPR2021-00017, Ex.1001, 1:25-2:40 (see Paper 1, 18); IPR2021-00065, Ex.1001, 2:25-37 (see Paper 1, 18).

## '544 Patent

The surgical instrument is used to perform a goniotomy procedure, by removing a portion of the trabecular meshwork consisting of the pigmented trabecular meshwork, allowing free access of aqueous from the anterior chamber through to the scleral portion of Schlemm's canal that contains the endothelial cells and most importantly the collector channels that lead back to the episcleral venous system.

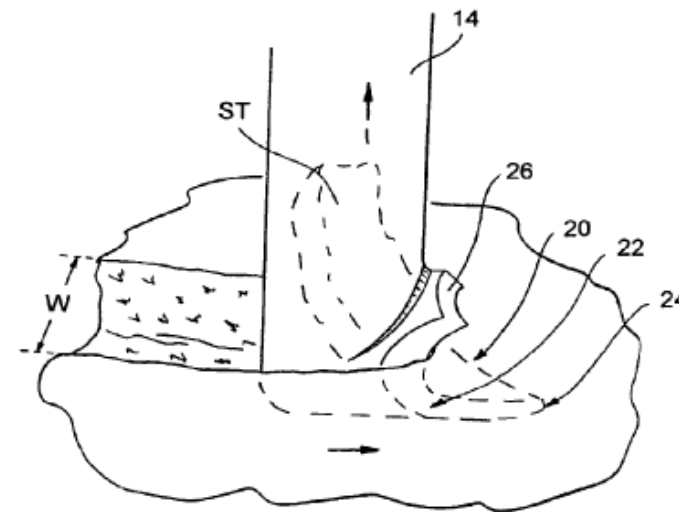
IPR2021-00066, Ex.1001, 5:6-26 (see Paper 1, 19).

# The Patents Claim a Bent Needle

One example of a **needle cutter device 10** of the present invention is shown in FIGS. 1-4. This needle cutter device **10** generally comprises an elongate cutting tube **14** that has a distal end and a lumen **27** that opens through an opening in the distal end. First and second cutting edges **20, 22** are formed on generally opposite edges of the distal end of the cutting tube **14**. These first and second cutting edges **20, 22** are separated by a distance **D**, as shown in the distal end view of FIG. 3B. In

FIGS. 3A-3D show an example of a **method for manufacturing the cutting tube 14 from standard tubing (e.g., stainless steel hypodermic tubing)**. Initially, the distal end of a tube is cut to form the lateral cutting edges **20, 22**, the protruding tip **24** and the blunt top edge **26**. Thereafter, if it is desired to have

or curve(s) in the cutting tube **14**. Likewise, if it is desired to have one or more bends or curves in the cutting tube **14**, the tube **14** may be directly bent to form said curves or bends without the use of angular cut outs(s) **30**. It may be appreci-



IPR2020-01573, Ex.1001, 3:3-43, 4:61-5:14, Fig.4 (see Paper 1, 18-21); see also IPR2020-01711, Ex.1001, 3:3-43, 4:60-5:12, Fig.4 (see Paper 1, 18-21); IPR2021-00017, Ex.1001, 3:6-49, 4:66-5:18, Fig.4 (see Paper 1, 18-21); see also generally IPR2021-00065, Ex.1001, 6:63-7:7, 11:20-13:19 (see Paper 1, 18-20); IPR2021-00066, Paper 1, 19-21 .


# Provisional Establishes Patents Cover Bent Needle

**GONIECTOMY DEVICE  
Development History**

Disease and Invention    Project Review    Regulatory Plan

***Bladed Goniectomy***  
***Design Criteria***

1. Based on the bent surgical needle used originally.
2. Sharp pointed footplate to cut the meshwork.
3. Shape of the footplate allows the blade to be guided along the Schlemms canal.




NeoMedix

**GONIECTOMY DEVICE  
Development History**

Disease and Invention    Project Review    Regulatory Plan

***Mechanical Dual Cutting Goniectomy***

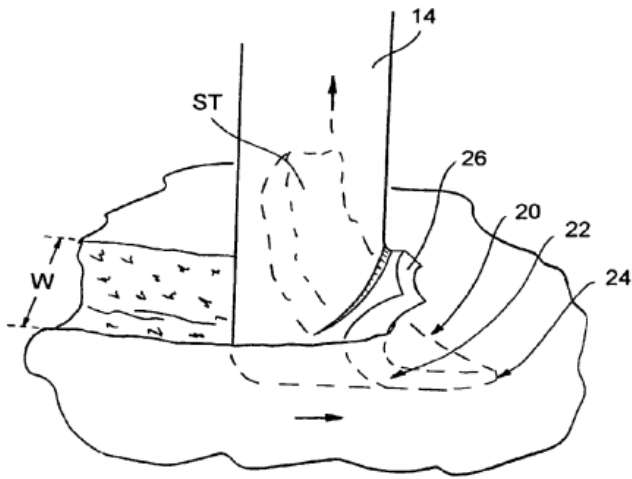
1. Distal sides of tube facets form the cutting blades.
2. Means to separate a strip of meshwork.



NeoMedix

Ex.1039, 12-13; see IPR2020-01573, Paper 35, 6-7, 16; IPR2020-01711, Paper 27, 6, 14; IPR2021-00017, Paper 26, 6-7, 15; IPR2021-00065, Paper 24, 6-7.

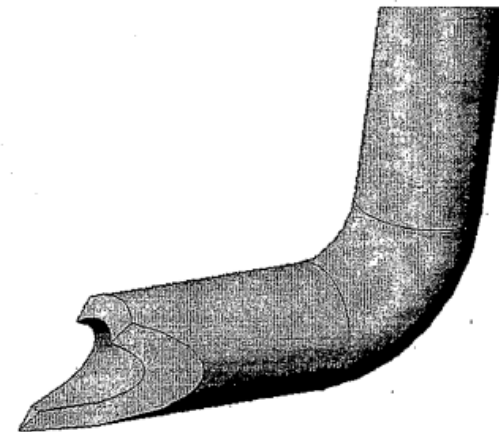
# Patents Include Provisional's Bent Needle



*Fig. 4*

'729/'155/'885 Patent Fig. 4

IPR2020-01573, Ex.1001, Fig.4 (see Paper 1, 21; Paper 35, 6-7, 16);  
IPR2020-01711, Ex.1001, Fig.4 (see Paper 1, 21; Paper 27, 6, 14);  
IPR2021-00017, Ex.1001, Fig.4 (see Paper 1, 21; Paper 26, 6-7, 15).



'258 Provisional

Ex.1039, 13; see IPR2020-01573, Paper 35, 6-7, 15-16; IPR2020-01711, Paper 27, 6, 14; IPR2021-00017, Paper 26, 6-7, 15; IPR2021-00065, Paper 24, 6-7.



# Invalidity Grounds

'729 Patent IPR2020-01573	'155 Patent IPR2020-01711	'885 Patent IPR2021-00017	'905 Patent IPR2021-00065	'544 Patent IPR2021-00066
<ol style="list-style-type: none"> <li>1. §102: Quintana</li> <li>2. §103: Quintana / POSITA</li> </ol>	<ol style="list-style-type: none"> <li>1. §102: Quintana</li> <li>2. §103: Quintana / POSITA</li> </ol>	<ol style="list-style-type: none"> <li>1. §102: Quintana</li> <li>2. §103: Quintana / POSITA</li> </ol>	<ol style="list-style-type: none"> <li>1. §102: Quintana</li> <li>2. §103: Quintana / POSITA</li> </ol>	<ol style="list-style-type: none"> <li>1. §102: Quintana</li> <li>2. §103: Quintana / POSITA</li> </ol>
<ol style="list-style-type: none"> <li>3. §103: Quintana / Lee</li> <li>4. §103: Quintana / Lee / POSITA</li> </ol>	<ol style="list-style-type: none"> <li>3. §103: Quintana / Lee</li> <li>4. §103: Quintana / Lee / POSITA</li> </ol>			
<ol style="list-style-type: none"> <li>5. §102: Jacobi</li> <li>6. §103: Jacobi / POSITA</li> </ol>	<ol style="list-style-type: none"> <li>5. §103: Jacobi / POSITA</li> </ol>	<ol style="list-style-type: none"> <li>3. §103: Jacobi / POSITA</li> </ol>	<ol style="list-style-type: none"> <li>3. §103: Jacobi / POSITA</li> </ol>	<ol style="list-style-type: none"> <li>3. §103: Jacobi / POSITA</li> </ol>

# Quintana: Limited Number of Issues Remaining in Dispute That Overlap Across Patents

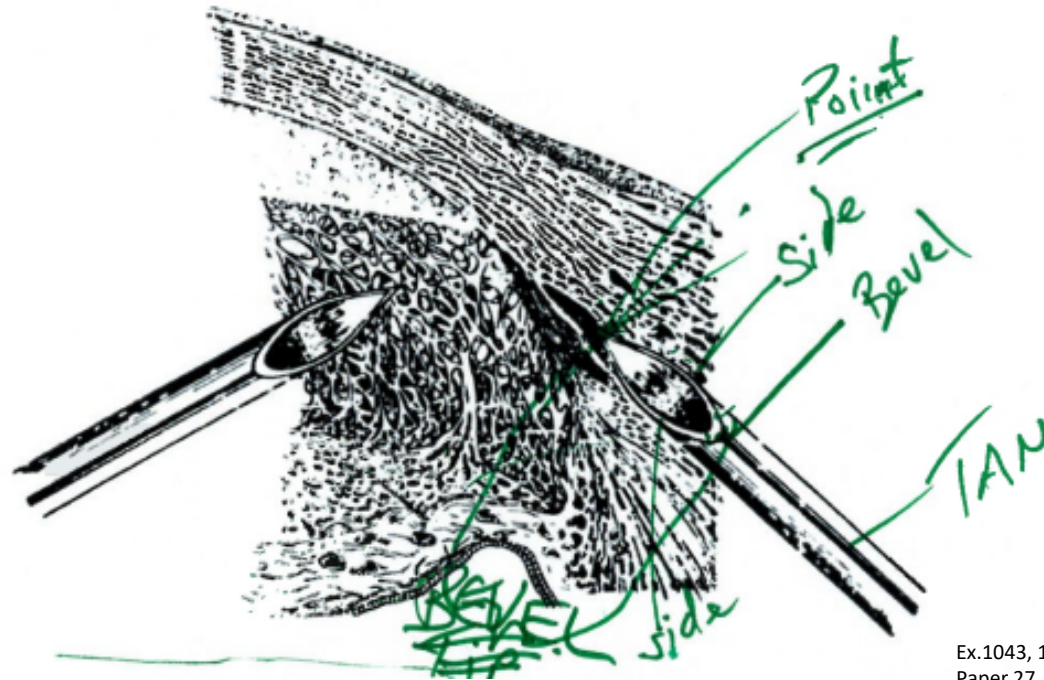
## '729 / '155 / '885 / '905 Patents

- **creating a “strip” of TM** ('729, cl.1 / '155, cl.1 / '885, cl.1 / '905, cl.1)
- **“dual blade device”** ('729, cl.1 / '155, cl.1)
  - “cutting edges” ('885, cl.1)
  - “knife blades” ('905, cl.1)
  - “contacting” TM ('729, cl.1 / '155, cl.1 / '885, cl.1)
  - “concurrently” cutting ('729, cl.1)
- **“ab interno”** ('729, cl.1 / '155, cl.1)
- **“bend or curve”** ('729, cl.1 / '155, cl.1)
- **“blunt protruding tip” and “blunt top edge”** ('155, cl.1)
- **“platform”** ('885, cl.1)
- **“protector member”** ('905, cl.1)

## '544 Patent

- **creating an “opening” in TM** ('544, cl.1)
- **“ab interno”** ('544, cl.4)
- **“foot member”** ('544, cl.1)

# Quintana (Ex.1004) Invalidates the Challenged Claims



Ex.1043, 192; see IPR2020-01573, Paper 35, 17; IPR2020-01711, Paper 27, 15; IPR2021-00017, Paper 26, 16; IPR2021-00065, Paper 24, 16-17; IPR2021-00066, Paper 25, 18.

# Quintana Discloses Creating a “Strip” of TM (’729, cl.1 / ’155, cl.1 / ’885, cl.1 / ’905, cl.1)

- Quintana (Ex.1004) discloses:
  - improvement on prior techniques that failed due to reclosure/scarring of incision
  - “achiev[ing] a section” of TM
  - “stripping” TM
  - “remaining cells can enlarge”
- Dr. Netland confirms Quintana creates/removes “strips” of TM (Ex.1003)
- Dr. Netland’s additional testing confirms Quintana discloses “strips” of TM (Ex.1030)

# Quintana's "Key Concern" Was Improving on Prior Techniques That Incised TM

Increased resistance to the outflow of aqueous through the trabecular meshwork is the most accepted pathogenic mechanism in the majority of open-angle glaucomas ("trabecular glaucomas"). Thus, the rational treatment of the trabecular glaucomas should consist in opening the trabecular meshwork (TM). This has been attempted since the last century (11, 12; 13) and many times later on (1, 2, 4, 5, 8, 9), but all the techniques described so far have failed (3, 10) despite the in vitro evidence (6, 7) of the effectiveness of trabeculotomy.

\*\*\*

A technique of trabeculotomy has been devised, which eliminates most of the presumed causes of failure of previous methods. The patient is operated

Ex.1004, 3; see IPR2020-01573, Paper 1, 16, Paper 35, 8-9; IPR2020-01711, Paper 1, 16, Paper 27, 7-8; IPR2021-00017, Paper 1, 16, Paper 26, 8; IPR2021-00065, Paper 1, 16, Paper 24, 8; IPR2021-00066, Paper 1, 16, Paper 25, 11.

CULOTOMY. FIRST RESULTS

EL QUINTANA  
(Barcelona, Spain)

ABSTRACT

of goniotrabeculotomy which achieves a work without damage to the external wall of the eye are minimal. A one year follow-up shows a success in most cases. However, this effect is not permanent in most cases. Yet, medical therapy, should be controlled before the operation and usually

INTRODUCTION

flow of aqueous through the trabecular meshwork is the most accepted pathogenic mechanism in the majority of open-angle glaucomas. Thus, the rational treatment of the trabecular glaucomas should consist in opening the trabecular meshwork. This has been attempted since the last century (11, 12, 13) and many times later on (1, 2, 4, 5, 8, 9), but all the techniques described so far have failed (3, 10) despite the in vitro evidence (6, 7) of the effectiveness of trabeculotomy.

MATERIAL AND METHODS

A technique of trabeculotomy has been devised, which eliminates most of the presumed causes of failure of previous methods. The patient is operated under general anaesthesia; both eyes can be done at the same time. Pupils should be miotic. A coaxial operating microscope is necessary, with magnification of x 10. We favour the Swann lens for angle visualisation. Our trabeculotome is a 0.4 x 15 mm needle, or an insulin-type needle; we bend the tip 20-30° with a needle-holder; a factory-made needle (Moriz, France) is even better. The needle is inserted into a syringe filled with "healon". "Modus operandi" is as in classical goniotomy (surgeon in the temporal side of the patient, patient's head rotated away from the surgeon, assistant holding

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E.L. Greve, W. Leydhecker & C. Raitta (eds.), Second European Glaucoma Symposium, Helsinki 1984.  
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Petitioner - New World Medical  
Ex. 1004, p. 3 of 9

Petitioner New World Medical, Inc., IPR Nos. 2020-01573, 2020-01711, 2021-00017, 2021-00065, 2021-00066  
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

# Spencer and Becker Show Incising TM Does Not Work

*Symposium: Microsurgery of the Outflow Channels*  
 ' ' '  
 CLINICAL RESEARCH  
 BERNARD BECKER, MD  
 STEVEN M. PODOS, MD  
 and  
 CARL F. ASSEFF, MD

MD, unpublished data). Unfortunately, most observers found that the increased outflow facility was temporary. This may have been a consequence of regeneration, healing over, and scarring of the trabecular opening or of damage to the outer wall of Schlemm's canal.

Support provided by 100-5-10004, St. Louis 63110 (Dr. Becker).  
 This investigation was supported in part by grants EY08091 and EY08016 from the National Eye Institute.  
 Presented at the Seventeenth Annual Meeting of the American Academy of Ophthalmology and Otolaryngology, Las Vegas, Nev., Sept. 29-30, 1971.  
 405  
 Petitioner - New World Medical  
 Ex. 1035, p. 2 of 8  
 New World Medical, Inc. v. MicroSurgical Tech., Inc. IPR2020-01573

## Becker (Ex.1035)

Ex.1035, 2; see IPR2020-01573, Paper 35, 8-9; IPR2020-01711, Paper 27, 7-8; IPR2021-00017, Paper 26, 8; IPR2021-00065, Paper 24, 8; IPR2021-00066, Paper 25, 11.

*Symposium: Microsurgery of the Outflow Channels*  
 ' ' '  
 CLINICAL RESEARCH

tation, iris adhesions, or scarring of the excised tissue resulting from previous inflammation, injury, or surgical treatment. The degree of scarring in some specimens has been sufficient to completely obliterate Schlemm's canal, and one may infer from this that the likelihood of producing an opening into Schlemm's canal in such eyes is quite small. Conversely, the presence of un-

Petitioner - New World Medical  
 Ex. 1036, p. 2 of 10  
 New World Medical, Inc. v. MicroSurgical Tech., Inc. IPR2020-01573

## Spencer (Ex.1036)

Ex.1036, 5-6; see IPR2020-01573, Paper 35, 8-9; IPR2020-01711, Paper 27, 7-8; IPR2021-00017, Paper 26, 8; IPR2021-00065, Paper 24, 8; IPR2021-00066, Paper 25, 11.

Petitioner New World Medical, Inc., IPR Nos. 2020-01573, 2020-01711, 2021-00017, 2021-00065, 2021-00066  
 DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

# Dr. Condon Did Not Review Becker or Spencer

9 Q. When you gave your opinion on Quintana, you  
 10 did not review Becker?  
 11 A. That's correct.

20 Q. Okay. And I've handed you Spencer,  
 21 Number 10, and you did not consider this, correct?  
 22 A. I've not reviewed this.

IPR2020-01573, Ex.1041, 91:9-11, 132:20-22; IPR2020-01711, Ex.1041, 91:9-11, 132:20-22; IPR2021-00017, Ex.1041, 91:9-11, 132:20-22; IPR2021-00065, Ex.1041, 91:9-11, 132:20-22; IPR2021-00066, Ex.1041, 91:9-11, 132:20-22.

8/17/2021 New World Medical, Inc. v. MicroSurgical Technology, Inc. Garry Condon, M.D.	
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	6 EXAMINER: DEB M. TUCKER 7
	7
	8 EXHIBITS
	9 (Amended Verdict)
	10 GARRY CONDON, M.D. DEPOSITION EXHIBITS PAGE
	11 Condon Exhibit 1 Petitioner Notice of
	12 Deposition of Garry P.
	13 Condon, M.D.
	14 Condon Exhibit 2 Declaration of Garry P.
	15 Condon, M.D., in Support of
	16 Patent Owner's Response
	17 U.S. Patent No. 9,187,729
	18 Patent Owner Exhibit
	19 2019-0001 through 175
	20 Condon Exhibit 3 United States Patent
	21 No. 10,137,729 B2
	22 Condon Exhibit 4 Osteonagon Tablets (mms),
	23 First Round
	24 Manual Ostium
	25 Petitioner New World Medical
	26 Exhibit 1004, Page 1 through 9
	27 Condon Exhibit 5 Amendment Accompanying Notice
	28 of Appeal
	29 Application No. 13/175,156
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1 APPEARANCES	1 EXHIBITS, CONT
2 Counsel for Petitioner, New World Medical, Inc.:	2 (Amended Verdict)
3 TUCKER, ESQUIRE	3 GARRY CONDON, M.D. DEPOSITION EXHIBITS PAGE
4	4 Condon Exhibit 1 "Osteonagon Medical Dictionary" 71
5	5 Patent Owner Exhibit
6	6 Condon Exhibit 7 "Osteonagon Medical Dictionary" 71
7	7 - Page 65 - "Invasive"
8	8 Patent Owner Exhibit
9	9 Condon Exhibit 8
10	10 Condon Exhibit 9 "Clinical Research -
11	11 Symposium: Microsurgery of
12	12 the Outflow Channel"
13	13 Condon Exhibit 10 Declaration of Garry P.
14	14 Condon, M.D., in Support of
15	15 Patent Owner's Response
16	16 Case IPR2020-01711, U.S.
17	17 Patent No. 9,187,729
18	18 Patent Owner Exhibit
19	19 2019-0001 through 145
20	20 Condon Exhibit 11 Declaration of Garry P.
21	21 Condon, M.D., in Support of
22	22 Patent Owner's Response
23	23 Case IPR2020-01573
24	24 U.S. Patent No. 9,187,729
25	25 Patent Owner Exhibit
26	26 2019-0001 through 145
27	27
28	28
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32	32
17 Also Present:	18
19 LARIANA PHILLIP, Videographer	20
21	21
22	22
	1 (Pages 1 to 4)
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	202-232-0646
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# Quintana's Procedure Results in "Strip" of TM

We describe a surgical method of goniotrabeculotomy which achieves a section of the trabecular meshwork without damage to the external wall of Schlemm's canal. Complications are minimal. A one year follow-up shows a

introduced in the angle. Only the tip of the instrument is introduced into Schlemm's canal, and the TM is stripped slowly, gently and easily from the canal's lumen towards the anterior chamber as the needle progresses in the angle (Fig. 2). Since the convexity of the tip is facing the external wall of the

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

Ex.1004, 3-5; see IPR2020-01573, Paper 1, 27, 33, 37, 47-48; IPR2020-01711, Paper 1, 31, 37, 42-43; IPR2021-00017, Paper 1, 27, 33, 36-37; IPR2021-00065, Paper 1, 30, 36, 39; IPR2021-00066, Paper 1, 27, 33, 36-37.

## GONIOSCOPIC TRABECULOTOMY. FIRST RESULTS

MANUEL QUINTANA  
(Barcelona, Spain)

### ABSTRACT

We describe a surgical method of goniotrabeculotomy which achieves a section of the trabecular meshwork without damage to the external wall of Schlemm's canal. Complications are minimal. A one year follow-up shows a fall of intraocular pressure in almost all cases. However, this effect is non-lasting and a slow rise in pressure occurs in most cases. Yet, medical therapy, if reinstated, achieves a better control than before the operation and usually can be less intense.

### INTRODUCTION

Increased resistance to the outflow of aqueous through the trabecular meshwork is the most accepted pathogenic mechanism in the majority of open-angle glaucomas ("trabecular glaucomas"). Thus, the rational treatment of the trabecular glaucomas should consist in opening the trabecular meshwork (TM). This has been attempted since the last century (11, 12, 13) and many times later on (1, 2, 4, 5, 8, 9), but all the techniques described so far have failed (3, 10) despite the in vitro evidence (6, 7) of the effectiveness of trabeculotomy.

### MATERIAL AND METHODS

A new method of trabeculotomy has been devised, which eliminates most of the causes of failure of previous methods. The patient is operated under general anaesthesia; both eyes can be done at the same time. Pupils are dilated with atropine. A coaxial operating microscope is necessary, with magnification  $\times 10$ . We favour the Swann lens for angle visualisation. Our instrument is a 0.4  $\times$  15 mm needle, or an insulin-type needle; we bend it with a needle-holder; a factory-made needle (Morie, France) is used. The needle is inserted into a syringe filled with "healon". The "modus operandi" is as in classical goniotomy (surgeon in the temporal side of the patient, patient's head rotated away from the surgeon, assistant holding

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E. L. Gravo, W. Leyshock & C. Raitis (eds.), Second European Glaucoma Symposium, Helsinki 1984.  
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# “Remaining Cells” Means Tissue Was Excised

GONIOSCOPIC TRABECULOTOMY. FIRST RESULTS

MANUEL QUINTANA  
*(Barcelona, Spain)*

ABSTRACT

not damaged. But the remaining cells can enlarge, as do the corneal endothelial cells, and this is the subject of our present research; complete repair

increase resistance to the outflow of aqueous through the trabecular meshwork is the most accepted pathogenic mechanism in the majority of open-angle glaucomas ("trabecular glaucomas"). Thus, the rational treatment of the trabecular glaucomas should consist in opening the trabecular meshwork (TM). This has been attempted since the last century (11, 12, 13) and many times later on (1, 2, 4, 5, 8, 9), but all the techniques described so far have failed (3, 10) despite the in vitro evidence (6, 7) of the effectiveness of trabeculotomy.

#### MATERIAL AND METHODS

A technique of trabeculotomy has been devised, which eliminates most of the presumed causes of failure of previous methods. The patient is operated under general anaesthesia; both eyes can be done at the same time. Pupils should be miotic. A coaxial operating microscope is necessary, with magnification of x 10. We favour the Swann lens for angle visualisation. Our trabeculotome is a 0.4 x 15 mm needle, or an insulin-eye needle; we bend the tip 20-30° with a needle-holder; a factory-made needle (Moris, France) is even better. The needle is inserted into a syringe filled with "healon". "Modus operandi" is as in classical goniotomy (surgeon in the temporal side of the patient, patient's head rotated away from the surgeon, assistant holding

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E.L. Oliver, W. Leydhecker & C. Raitta (eds.), Second European Glaucoma Symposium, Helsinki 1984.  
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Ex. 1004, p. 3 of 9

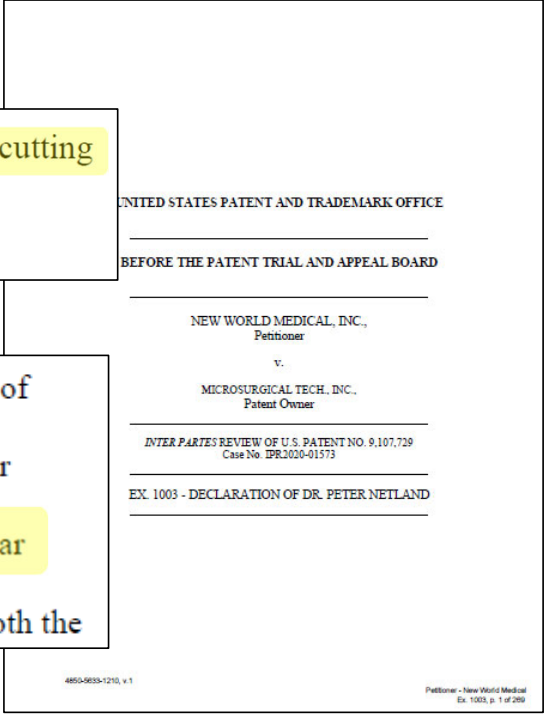
Ex.1004, 8; see IPR2020-01573, Paper 35, 10-11; IPR2020-01711, Paper 27, 9; IPR2021-00017, Paper 26, 10; IPR2021-00065, Paper 24, 10; IPR2021-00066, Paper 25, 12.

# Dr. Netland Confirms Quintana Explicitly Discloses Excising “Strip” of TM

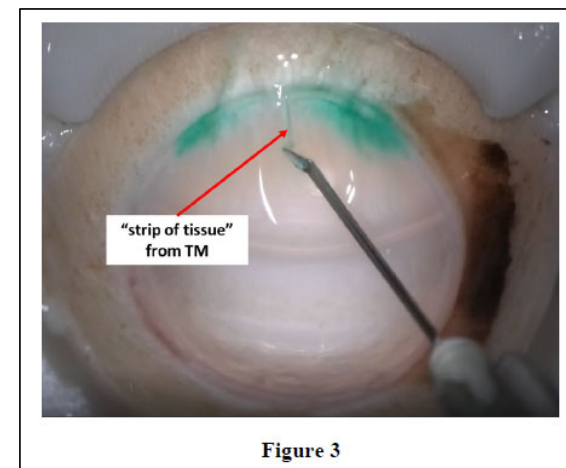
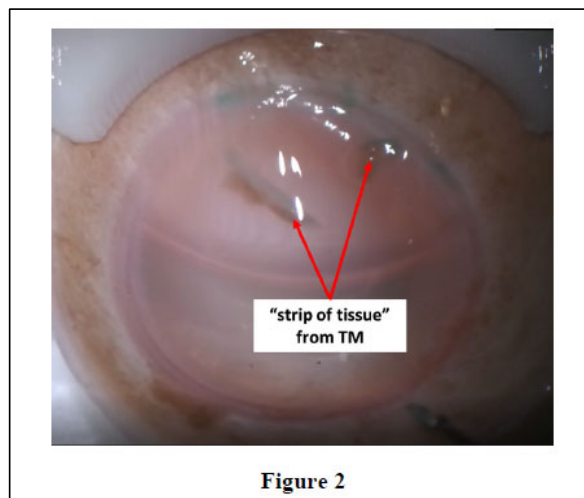
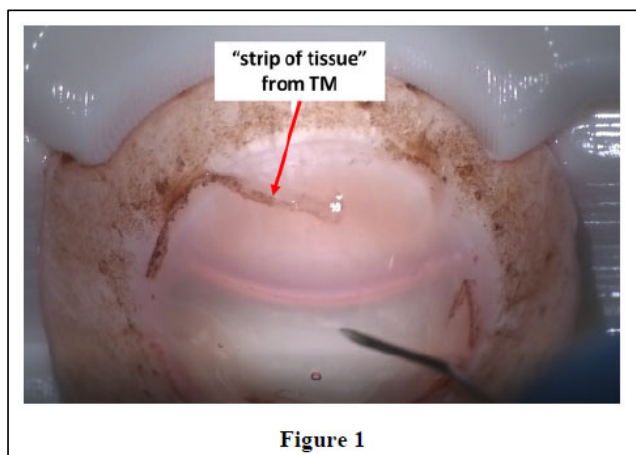
98. Quintana’s procedure would without question have resulted in cutting “strips of tissue” from the TM. Not only do Quintana’s explicit disclosures

external wall of Schlemm’s canal.”). In my opinion, Quintana’s disclosure of “stripping” the trabecular meshwork to “achieve[] a section of the trabecular meshwork” refers to excising or cutting a “strip of tissue” from the trabecular meshwork as claimed. Further, in order to create such a “strip of tissue,” both the

IPR2020-01573, Ex.1003, ¶198, 136 (see Paper 1, 47-48); see also IPR2020-01711, Ex.1003, ¶104, 127-128 (see Paper 1, 42-43); IPR2021-00017, Ex.1003, ¶184, 96-97 (see Paper 1, 36-37); IPR2021-00065, Ex.1003, ¶188, 100-101 (see Paper 1, 37, 39, 48); IPR2021-00066, Ex.1003, ¶193, 106-107 (see Paper 1, 34, 36-37).



# Dr. Netland's Testing Confirms Quintana Obtained "Strips" of TM



Ex.1030, ¶17-26; Ex.1031-1033; see IPR2020-01573, Paper 35, 13-14; IPR2020-01711, Paper 27, 11-13; IPR2021-00017, Paper 26, 12-14; IPR2021-00065, Paper 24, 12-14; IPR2021-00066, Paper 25, 14-16.

# Patent Owner Reimagines Quintana

- Dr. Condon admits Quintana’s procedure could leave TM on needle tip thereby admitting removal of TM
- Patent Owner wrongly equates Quintana’s use of terms “section” and “stripping” with “incising” or “opening”
- Quintana’s “key concern” was improving on prior techniques that failed due to reclosure of incision (and Patent Owner ignores Spencer and Becker)

IPR2020-01573, Paper 35, 13.

Ex.1046, p. 36 of 98

Petitioner New World Medical, Inc., IPR Nos. 2020-01573,  
2020-01711, 2021-00017, 2021-00065, 2021-00066  
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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# Patent Owner Mistakenly Equates “Section” and “Stripping” with “Incising”

<p>1. “Section” in <i>Quintana</i> means “incising” or “opening”</p> <p>Quintana describes “a surgical method of goniotrabeculotomy which achieves a section of the trabecular meshwork without damage to the external wall of Schlemm’s canal.” Ex. 1004 at 3 (Abstract). A POSA would have understood Quintana’s use of “section” in this sentence to mean incising or opening the TM, not creating and removing a strip of TM, as Petitioner erroneously asserts. Ex. 2019 ¶32.</p>	<p style="text-align: right;">Paper 29</p> <p style="text-align: center;">UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD</p> <p style="text-align: center;">NEW WORLD MEDICAL, INC., Petitioner,</p> <p style="text-align: center;">v.</p> <p style="text-align: center;">MICROSURGICAL TECHNOLOGY, INC., Patent Owner.</p> <p style="text-align: center;">Case IPR2020-01573 U.S. Patent No. 9,107,729</p> <p style="text-align: center;">Filed: June 8, 2021</p> <p style="text-align: center;">PATENT OWNER RESPONSE PURSUANT TO 37 C.F.R. § 42.120</p>
<p>Quintana’s use of the words “stripped” and “stripping” in these sentences refers to cutting or tearing the TM to move it away from the lumen of Schlemm’s Canal while avoiding injury to the external wall, which was Quintana’s key concern. See Ex. 1004 at 4 (“This is why we bend the tip and we point it towards</p>	

IPR2020-01573, Paper 29, 14, 18; see also IPR2020-01711, Paper 17, 15, 18-19; IPR2021-00017, Paper 17, 12, 16; IPR2021-00065, Paper 18, 12, 16; IPR2021-00066, Paper 17, 19-20, 23.

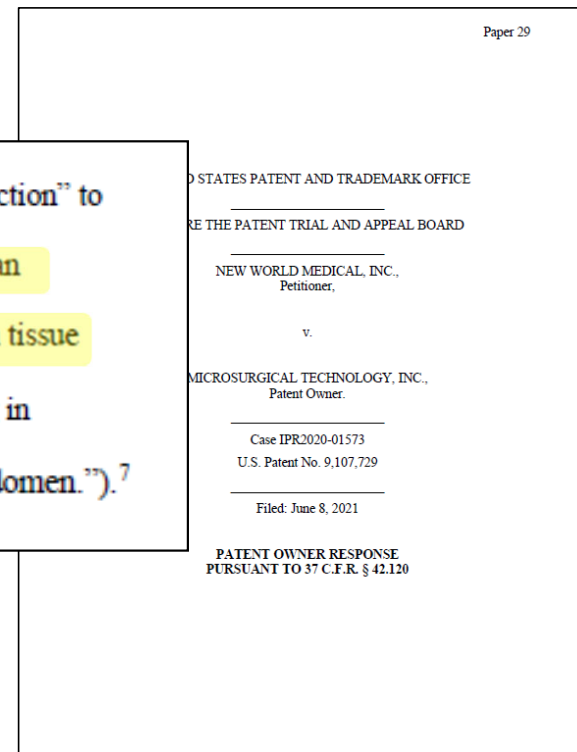
# “Section” Cannot Mean Incise or Opening

<p>GONIOSCOPIC TRABECULOTOMY. FIRST RESULTS</p>	<p>MANUEL QUINTANA <i>(Barcelona, Spain)</i></p> <p>ABSTRACT</p> <p>method of goniotrabeculotomy which achieves a ir meshwork without damage to the external wall of lications are minimal. A one year follow-up shows a ure in almost all cases. However, this effect is non- n pressure occurs in most cases. Yet, medical therapy, a better control than before the operation and usually</p>	
<p>INTRODUCTION</p> <p>Increased resistance to the outflow of aqueous through the trabecular meshwork is the most accepted pathogenic mechanism in the majority of open-angle glaucomas (“trabecular glaucomas”). Thus, the rational treatment of the trabecular glaucomas should consist in <u>opening the trabecular meshwork</u> (TM). This has been attempted since the last century (11, 12, 13) and many times later on (1, 2, 4, 5, 8, 9), but all the techniques described so far have failed (3, 10) despite the in vitro evidence (6, 7) of the effectiveness of trabeculotomy.</p>	<p>INTR</p> <p>the outflow pted pathoge trabecular glau as should con empted since 5, 8, 9), but the in vitro</p>	<p>lens. <u>The TM is incised with the tip of the needle.</u> From now on, and with the concavity of the tip <i>towards</i> the surgeon, the trabeculotome is progressively introduced in the angle. Only the tip of the instrument is introduced into Schlemm’s canal, and the TM is stripped slowly, gently and easily from the canal’s lumen towards the anterior chamber as the needle progresses in the angle (Fig. 2). Since the convexity of the tip is facing the external wall of the canal, this structure is not damaged. This is why we bend the tip and we point <u>it towards the anterior chamber.</u></p>
<p>MATERIAL</p> <p>A technique of trabeculotomy has b presumed causes of failure of pre under general anaesthesia; both ey should be miotic. A coaxial operat fication of x10. We favour the trabeculotome is a 0,4 x 15 mm net the tip 20–30° with a needle-holder even better. The needle is inserted into a syringe filled with “healon”. “Modus operandi” is as in classical goniotomy (surgeon in the temporal side of the patient, patient’s head rotated away from the surgeon, assistant holding</p> <p>265</p> <p><small>E.L. Greve, W. Leydhecker &amp; C. Raina (eds.), Second European Glaucoma Symposium, Helsinki 1984. © 1985, Dr. W. Junk Publishers, Dordrecht, ISBN 978-94-010-8954-0</small></p> <p>Petitioner - New World Medical Ex. 1004, p. 3 of 9</p>	<p>Ex.1004, 3, 4; see IPR2020-01573, Paper 35, 9; IPR2020-01711, Paper 27, 8; IPR2021-00017, Paper 26, 9; IPR2021-00065, Paper 24, 9; IPR2021-00066, Paper 25, 11-12.</p>	

# Patent Owner's Definitions of "Section" Prove Quintana Excises a Strip of TM

refer to incising, not excising, TM. *See, e.g.*, Ex. 2023 at 605 (defining "section" to mean "1. an act of cutting. 2. a cut surface. 3. a segment or subdivision of an organ."); Ex. 2024 at 519 (defining "section" to mean "(1) A thin slice of a tissue specimen taken for examination under a microscope. (2) The act of cutting in surgery; for example, an abdominal section is done to explore the abdomen.").<sup>7</sup>

IPR2020-01573, Paper 29, 14-15; *see also* IPR2020-01711, Paper 17, 15; IPR2021-00017, Paper 17, 13; IPR2021-00065, Paper 18, 12-13; IPR2021-00066, Paper 17, 20.





# “Stripping” Cannot Mean Cutting TM to Move TM Away From SC

- Quintana would not merely move TM tissue because it could fall back into place, contrary to goal
  - IPR2020-01573, Paper 35, 11; IPR2020-01711, Paper 27, 10; IPR2021-00017, Paper 26, 10; IPR2021-00065, Paper 24, 10; IPR2021-00066, Paper 25, 13.
- Quintana states that TM is stripped “from the canal’s lumen **toward the anterior chamber**” —would not refer to stripping “toward” if it simply meant incising
  - IPR2020-01573, Paper 35, 11-12; IPR2020-01711, Paper 27, 10; IPR2021-00017, Paper 26, 11; IPR2021-00065, Paper 24, 11; IPR2021-00066, Paper 25, 13.

# Patent Owner Offers No Definition of “Stripping” Because It Means “Removing”

**Modified Goniotomy for Inflammatory Glaucoma**  
**Histologic Evidence for the Mechanism of Pressure Reduction**  
 Jonathan Hirschler, MD, E. Barry Davis

• A modified goniotomy (trabeculodialysis) was performed on both eyes of a 23-year-old woman who had glaucoma secondary to seroid uveitis. One month after trabeculodialysis, a cataract extraction was performed on one eye and a histologic specimen was obtained from the area of the filtration angle that was previously incised. Successful control of intraocular pressure has been maintained in both eyes for 18 months following trabeculodialysis. By light and electron microscopic examination, there was a

ludialysis) be applied to inflammatory glaucoma. He reported an encouraging but small series of modified goniotomies performed on patients with uveitis who were aphakic. Because of its simplicity, easy repeatability, and seeming lack of inflammatory response, the procedure was thought to be well suited for treating inflammatory glaucoma. In a recent article, Hokinis et al<sup>1</sup> reviewed their experience with the surgical treatment of inflammatory glaucoma and also re-

glaucoma became medically uncontrol- lable, and trabeculodialysis was performed on both eyes. One month later, a cataract extraction was performed on one eye, and a histologic specimen was obtained from the trabecular meshwork, incised by the trabeculodialysis (Fig 1).

**REPORT OF A CASE**

In July 1974, facial numbness, pain around the mouth, red eyes, lymphadenopathy, and night sweats developed in a 23-year-old woman. A final diagnosis

ation of successful goniotomy in primary infantile glaucoma has not been established either, even though it has been the preferred procedure for many years.<sup>2</sup>

This case report describes a 23-year-old woman who had seroid uveitis, secondary glaucoma, and cataracts. Over a two-year period, the secondary

rects, mild cell and flare in the anterior chamber, and some cells in the vitreous. Scattered periferical anterior synechiae were seen gonioscopically in the filtration angles. The angle discs showed early glaucomatous cupping, but no rim loss was noted. There was no evidence of periphle- latic. Visual fields showed a shallow paracentral defect superiorly in the right eye. The visual field of the left eye was full.

years ago, that goniotomy (trabecu-

Accepted for publication May 21, 1975.  
 From the Department of Ophthalmology, Bascom Palmer Eye Institute, University of Miami School of Medicine.  
 Reprint requests to Department of Ophthalmology, Bascom Palmer Eye Institute, University of Miami School of Medicine, PO Box 363600, Miami, FL 33136 (Dr Hirschler).

884 Arch Ophthalmol—Vol 98, April 1980

Modified Goniotomy—Hirschler & Davis  
 Petitioner - New World Medical

**STRIPPING OF DESCMET'S MEMBRANE IN CATARACT EXTRACTION\***  
 BY Harold G. Scheie, M.D.

**Stripping of Descemet's membrane to a lesser degree is not rare. Strips of Descemet's membrane, which appear as curly tags of transparent tissue, can often be seen along the inner aspect of corneal incisions or perforations of any type. More extensive separation of**

**A trabeculodialysis procedure, stripping away the nasal trabecular sheets, was performed through a temporal approach on the right eye on Dec 7, 1976.**

been stripped by a cyclodialysis spatula during cyclodialysis. The edema can progress to painful bullous keratopathy with discomfort and loss of vision. Separation of Descemet's membrane from the cornea occurs rarely following rupture of Descemet's membrane with contusion of the eyeball. It may be seen associated with ruptures of Descemet's membrane in infantile glaucoma. Descemet's membrane may separate from the cornea at the rupture sites to form a shelf in the anterior chamber, and occasionally it may separate completely from the cornea between two parallel ruptures forming a ribbon-like bridge or reduplication across the anterior chamber. Reduplication of Descemet's membrane has been seen during keratoplasty for scarring due to severe chemical burns of the cornea. It is possible that corneal edema and changes in corneal metabolism allow retraction of Descemet's membrane from the corneal stroma.

Extensive stripping of Descemet's membrane with cataract extraction has been mentioned in the literature only twice. Weve<sup>1</sup> reported

\*From the Department of Ophthalmology, Hospital of the University of Pennsylvania, Philadelphia General Hospital, Veterans Administration Hospital, and the Children's Hospital of Philadelphia.

Tr. Am. Ophth. Soc., vol. 62, 1964

Petitioner - New World Medical  
 New World Medical, Inc. v. Microsurgical Tech., Inc., IPR2020-01573

Ex.1037, 2; see IPR2020-01573, Paper 35, 11; IPR2020-01711, Paper 27, 10; IPR2021-00017, Paper 26, 10-11; IPR2021-00065, Paper 24, 10-11; IPR2021-00066, Paper 25, 13.

Petitioner New World Medical, Inc., IPR Nos. 2020-01573, 2020-01711, 2021-00017, 2021-00065, 2021-00066  
 DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Ex.1038, 1; see IPR2020-01573, Paper 35, 11; IPR2020-01711, Paper 27, 10; IPR2021-00017, Paper 26, 10-11; IPR2021-00065, Paper 24, 10-11; IPR2021-00066, Paper 25, 13.

# Unsurprising Quintana Suggested Study of “In Vivo” Behavior of “Sectioned” TM Given Desire to Eliminate Scarring/Reclosure of TM

<p>In conclusion, our results show that goniotrabeculectomy, although highly successful in the first postoperative month, is in the end a partially successful procedure. Further studies are necessary to disclose the “in vivo” behaviour of the <u>sectioned trabecular meshwork</u>.</p>	<p style="text-align: center;">GONIOSCOPIC TRABECULOTOMY. FIRST RESULTS</p> <p>which achieves a external wall of blow-up shows a his effect is non-medical therapy,</p> <p>if reinstated, achieves a better control than before the operation and usually can be less intense.</p> <p style="text-align: center;">INTRODUCTION</p> <p>Increased resistance to the outflow of aqueous through the trabecular meshwork is the most accepted pathogenic mechanism in the majority of open-angle glaucomas (“trabecular glaucomas”). Thus, the rational treatment of the trabecular glaucomas should consist in opening the trabecular meshwork (TM). This has been attempted since the last century (11, 12, 13) and many times later on (1, 2, 4, 5, 8, 9), but all the techniques described so far have failed (3, 10) despite the in vitro evidence (6, 7) of the effectiveness of trabeculectomy.</p>
<p>We describe a surgical method of goniotrabeculectomy which <u>achieves a section of the trabecular meshwork</u> without damage to the external wall of Schlemm’s canal. Complications are minimal. A one year follow-up shows a</p>	<p style="font-size: small;">E.L. Green, W. Leydecker &amp; C. Raitta (eds.), Second European Glaucoma Symposium, Helsinki 1984. © 1985, Dr. W. Junk Publishers, Dordrecht. ISBN 978-94-010-8924-0 Petitioner - New World Medical Ex. 1004, p. 3 of 9</p>

Ex.1004, 3, 8; see IPR2020-01573, Paper 35, 10-11; IPR2020-01711, Paper 27, 9; IPR2021-00017, Paper 26, 10; IPR2021-00065, Paper 24, 10; IPR2021-00066, Paper 25, 12.

Petitioner New World Medical, Inc., IPR Nos. 2020-01573, 2020-01711, 2021-00017, 2021-00065, 2021-00066  
 DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

# “Remaining Cells” Means Tissue Was Excised

GONIOSCOPIC TRABECULOTOMY. FIRST RESULTS  
MANUEL QUINTANA  
*(Barcelona, Spain)*  
ABSTRACT

not damaged. But the remaining cells can enlarge, as do the corneal endothelial cells, and this is the subject of our present research; complete repair

increase resistance to the outflow of aqueous through the trabecular meshwork is the most accepted pathogenic mechanism in the majority of open-angle glaucomas ("trabecular glaucomas"). Thus, the rational treatment of the trabecular glaucomas should consist in opening the trabecular meshwork (TM). This has been attempted since the last century (11, 12, 13) and many times later on (1, 2, 4, 5, 8, 9), but all the techniques described so far have failed (3, 10) despite the in vitro evidence (6, 7) of the effectiveness of trabeculotomy.

#### MATERIAL AND METHODS

A technique of trabeculotomy has been devised, which eliminates most of the presumed causes of failure of previous methods. The patient is operated under general anaesthesia; both eyes can be done at the same time. Pupils should be miotic. A coaxial operating microscope is necessary, with magnification of x 10. We favour the Swann lens for angle visualisation. Our trabeculotome is a 0.4 x 15 mm needle, or an insulin-eye needle; we bend the tip 20-30° with a needle-holder; a factory-made needle (Moris, France) is even better. The needle is inserted into a syringe filled with "healon". "Modus operandi" is as in classical goniotomy (surgeon in the temporal side of the patient, patient's head rotated away from the surgeon, assistant holding

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E.L. Greve, W. Leydhecker & C. Raitis (eds.), Second European Glaucoma Symposium, Helsinki 1984.  
© 1985, Dr. W. Junk Publishers, Dordrecht. ISBN 978-94-010-8934-0 Petitioner - New World Medical  
Ex. 1004, p. 3 of 9

Ex.1004, 8; see IPR2020-01573, Paper 35, 10-11; IPR2020-01711, Paper 27, 9; IPR2021-00017, Paper 26, 10; IPR2021-00065, Paper 24, 10; IPR2021-00066, Paper 25, 12.

# Quintana Discloses Creating an “Opening” in TM (‘544, cl.1)

- ‘544 Patent claims require “[a] device useable to create an opening in the trabecular meshwork”
  - IPR2021-00066, Ex.1001, cl.1 (see Paper 1, 20).
- Other patents require creating/removing “strips” of TM
  - IPR2020-01573, Ex.1001, cl.1 (see Paper 1, 47-48); IPR2020-01711, Ex.1001, cl.1 (see Paper 1, 40-43); IPR2021-00017, Ex.1001, cl.1 (see Paper 1, 36); IPR2021-00065, Ex.1001, cl.2 (see Paper 1, 50-52).
- Patent Owner admits ‘544 patent does not require creating/removing “strips” of TM
  - IPR2021-00066, Paper 17, 2 n.1.

# Patent Owner and Dr. Condon Admit Quintana Discloses Creating an “Opening” in the TM

Paper 17

UNITED STATES PATENT AND TRADEMARK OFFICE

1. “Section” in Quintana means “incising” or “opening”

Quintana describes “a surgical method of goniotrabeclotomy which achieves a section of the trabecular meshwork without damage to the external wall of Schlemm’s canal.” Ex. 1004 at 3 (Abstract). A POSA would have understood Quintana’s use of “section” in this sentence to mean incising or opening the TM.

Filed: June 15, 2021

PATENT OWNER RESPONSE  
PURSUANT TO 37 C.F.R. § 42.120

IPR2021-00066, Paper 17, 19; *see also* IPR2020-01573, Paper 29, 14; IPR2020-01711, Paper 17, 15; IPR2021-00017, Paper 17, 12; IPR2021-00065, Paper 18, 12.

Ex.1046, p. 46 of 98

33. In its Abstract, Quintana describes “a surgical method of goniotrabeclotomy which achieves a *section* of the trabecular meshwork without damage to the external wall of Schlemm’s canal.” Ex. 1004 at 3 (emphasis added). In my opinion, a POSA would have understood Quintana’s reference to “section” in this sentence to mean incising or opening the TM, as opposed to creating or removing a strip of TM.

DECLARATION OF GARRY P. CONDON, M.D.  
IN SUPPORT OF PATENT OWNER RESPONSE

Patent Owner Ex. 2019-0001

IPR2021-00066, Ex.2019, ¶33 (*see* Paper 17, 20); *see also* IPR01573, Ex.2019, ¶32 (*see* Paper 29, 14); IPR2020-01711, Ex.2019, ¶32 (*see* Paper 17, 15); IPR2021-00017, Ex.2019, ¶31 (*see* Paper 17, 12); IPR2021-00065, Ex.2019, ¶31 (Paper 18, 12).

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Petitioner New World Medical, Inc., IPR Nos. 2020-01573, 2020-01711, 2021-00017, 2021-00065, 2021-00066  
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Quintana Discloses a “Dual Blade Device” (‘729, cl.1 / ‘155, cl.1) / “Cutting Edges” (‘885, cl.1) / “Knife Blades” (‘905, cl.1) / “Contacting” TM (‘729, cl.1 / ‘155, cl.1 / ‘885, cl.1 / ‘905, cl.1) / “Concurrently” Cutting (‘729, cl.1)

- Board construed terms according to plain and ordinary meaning
- Patents claim a bent needle—if patented device has two cutting edges so too does Quintana
- Patent Owner and Dr. Condon admit Quintana’s needle has two “sides”
- Patent Owner and Dr. Condon admit sides are blades that cut TM
- Patent Owner and Dr. Condon concede sides cut TM and thus must necessarily “contact” the TM

# Board Gave “Dual Blade Device” and “Knife Blades” Plain and Ordinary Meaning

Trials@uspto.gov  
571.272.7822

Paper 22  
Date: March 11, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE PATENT TRIAL AND APPEAL BOARD

The language “dual blade device” is readily understandable on its face; *dual* refers to two, and *blade*, in context, refers to a cutting part. The

IPR2020-01573  
Patent 9,107,729 B2

Before JAMES A. TARTAL, ROBERT A. POLLOCK, and  
RYAN H. FLAX, *Administrative Patent Judges*.  
FLAX, *Administrative Patent Judge*.

DECISION  
Granting Institution of *Inter Partes* Review  
35 U.S.C. § 314

IPR2020-01573, Paper 22, 17; *see also* IPR2020-01711,  
Paper 11, 13; IPR2021-00017, Paper 11, 13.  
Ex.1046, p. 48 of 98

Trials@uspto.gov  
571.272.7822

Paper 11  
Date: March 16, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEW WORLD MEDICAL, INC.,  
Petitioner,

v.

MICROSURGICAL TECHNOLOGY, INC.,  
Patent Owner.

IPR2021-00065  
Patent 10,123,905 B2

The claim language “knife blades” is readily understandable on its face; *knife* refers to a cutting instrument, and *blades*, in context, refers to plural cutting parts. The evidence of record does not indicate that this term

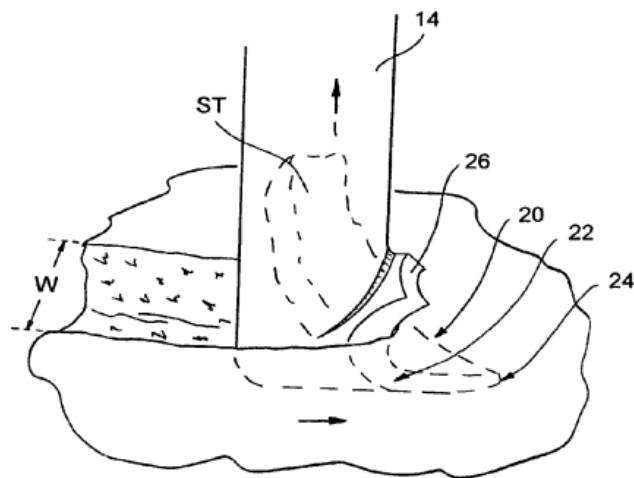
DECISION  
Granting Institution of *Inter Partes* Review  
35 U.S.C. § 314

IPR2021-00065, Paper 11, 16.

Petitioner New World Medical, Inc., IPR Nos. 2020-01573,  
2020-01711, 2021-00017, 2021-00065, 2021-00066  
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE



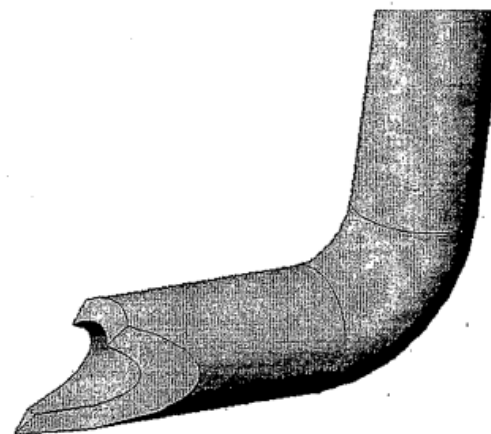
# Patented Device Is a Bent Needle



*Fig. 4*

## '729/'155/'885 Patent Fig. 4

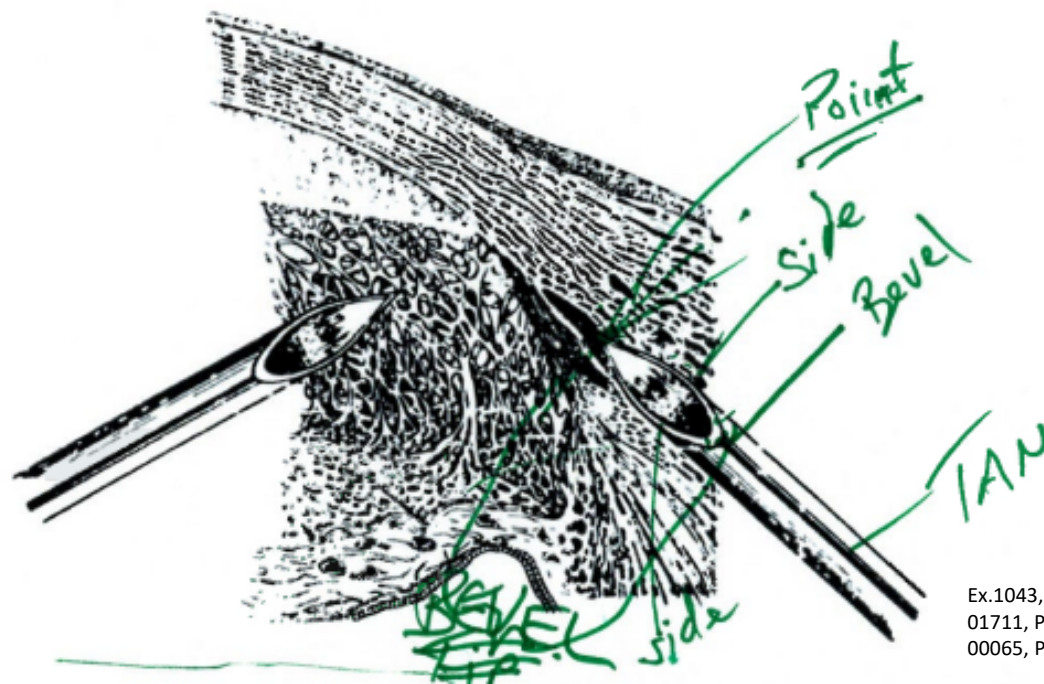
IPR2020-01573, Ex.1001, Fig.4 (see Paper 1, 21; Paper 35, 6-7, 16);  
IPR2020-01711, Ex.1001, Fig.4 (see Paper 1, 21; Paper 27, 6, 14);  
IPR2021-00017, Ex.1001, Fig.4 (see Paper 1, 21; Paper 26, 6-7, 15).



## '258 Provisional

Ex.1039, 13; see IPR2020-01573, Paper 35, 6-7, 15-16; IPR2020-01711, Paper 27, 6, 14; IPR2021-00017, Paper 26, 6-7, 15; IPR2021-00065, Paper 24, 6-7.

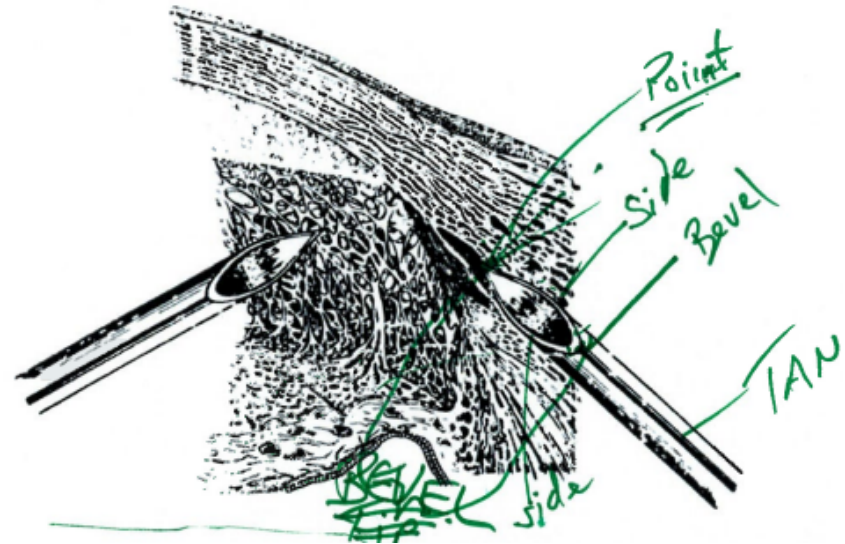
# Dr. Condon's Testimony and Annotated Figure Demonstrate Quintana's Needle Has Two Cutting Parts and Thus Meets the Board's Constructions



Ex.1043, 192; see IPR2020-01573, Paper 35, 17-18; IPR2020-01711, Paper 27, 15; IPR2021-00017, Paper 26, 16; IPR2021-00065, Paper 24, 16-17; IPR2021-00066, Paper 25, 18.

# Dr. Condon's Testimony and Annotated Figure Demonstrate Quintana's Needle Has Two Cutting Parts and Thus Meets the Board's Constructions

- **“dual blade device”**
  - “dual refers to two, and blade in context, refers to a cutting part”(IPR2020-01573, Paper 22, 17)
- **“knife blades”**
  - “knife refers to a cutting instrument, and blades, in context, refers to plural cutting parts”(IPR2020-00065, Paper 11, 16)



Ex.1043, 192; see IPR2020-01573, Paper 35, 17-18; IPR2020-01711, Paper 27, 15; IPR2021-00017, Paper 26, 16; IPR2021-00065, Paper 24, 16-17; IPR2021-00066, Paper 25, 18.

# Patent Owner's Argument Is Semantics

Paper 29

UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE PATENT TRIAL AND APPEAL BOARD

1003 ¶94 (emphasis added). If anything, the beveled sides of the Quintana device tip merely act alongside the sharp point as part of a single blade to allow the tip to create a slit-like incision in the TM. Ex. 2019 ¶23. Nothing supports Petitioner's mischaracterization of the beveled sides of the Quintana device tip as two distinct cutting edges.

PATENT OWNER RESPONSE  
PURSUANT TO 37 C.F.R. § 42.120

IPR2020-01573, Paper 29, 22; *see also* IPR2020-01711, Paper 17, 22-23; IPR2021-00017, Paper 17, 20; IPR2021-00065, Paper 18, 20; IPR2021-00066, Paper 17, 27.  
Ex.1046, p. 52 of 98

Petitioner New World Medical, Inc., IPR Nos. 2020-01573, 2020-01711, 2021-00017, 2021-00065, 2021-00066  
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

22. In my opinion, a POSA would have understood the Quintana trabeculotome, other than its needle tip bend, to be the same as an unbent standard hypodermic needle, the tip of which has a single bevel with a sharp point and sides.

23. In my opinion, a POSA would have determined that the beveled sides of the Quintana trabeculotome, like those of a standard hypodermic needle, may act alongside the sharp point as part of a single blade to allow the needle to create a slit-like incision in the TM. A POSA reading Quintana would not have found the

Patent Owner Ex. 2019-0001

IPR2020-01573, Ex.2019, ¶22-23 (*see* Paper 29, 21-22); *see also* IPR2020-01711, ¶22-23 (*see* Paper 17, 22-23); IPR2021-00017, Ex.2019, ¶22-23 (*see* Paper 17, 20); IPR2021-00065, Ex.2019, ¶22 (*see* Paper 18, 20); IPR2021-00066, Ex.2019, ¶22 (*see* Paper 17, 27). 52

# Patent Owner Bases Argument on Mischaracterization of Dr. Netland's Testimony

- Patent Owner repeatedly argues needles have a single blade based on statement in Dr. Netland's declaration:
  - “Petitioner admits that a standard hypodermic needle tip has a single bevel with a sharp point to facilitate tissue penetration by incision. See Ex. 1003 ¶94 (‘an unbent needle tip would have acted as a **single blade** to allow the needle to create a **slit-like incision** in the trabecular meshwork.’) (emphasis added)”
    - *e.g.*, IPR2020-01573, Paper 29, 9; *see also* IPR2021-01711, Paper 17, 10; IPR2021-00017, Paper 17, 8; IPR2021-00065, Paper 18, 7; IPR2021-00066, Paper 17, 8.

# Dr. Netland’s Statement Refers to “Perpendicular” Approach—Not Quintana’s “Tangential” Approach

94. Quintana also specifies that the needle penetrates the anterior chamber at 6 or 12 o’clock to allow for a “tangential approach.” *Id.* By this tangential approach, persons of ordinary skill in the art would have understood Quintana to mean that the tip of the needle with the 20-30° bend approaches and enters the trabecular meshwork at a very shallow angle. This would have allowed the opposing edges at the end of the needle to contact and to each separately cut the trabecular meshwork. In this orientation, the opposing edges would serve as separate cutting edges to allow the needle to excise a strip of tissue from the trabecular meshwork. By contrast, a perpendicular approach used in classic goniotomy techniques would have been understood to mean that the tip of a needle approaches and enters the trabecular meshwork at a roughly 90-degree angle. This would have allowed only the very tip of the needle to contact the trabecular meshwork. In this orientation, an unbent needle tip would have acted as a single blade to allow the needle to create a slit-like incision in the trabecular meshwork. This is shown in Fig. 1 below, which shows Quintana’s tangential approach (on the right) and the perpendicular approach used in classic goniotomy techniques (on the left).

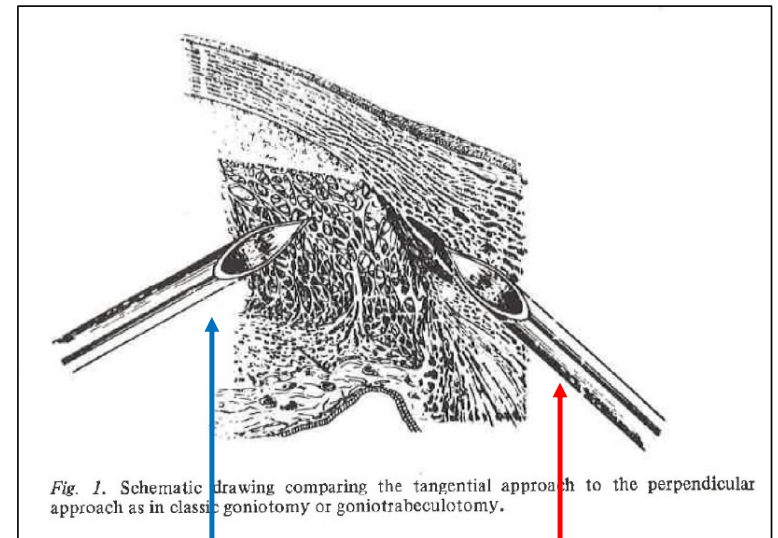


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

Ex.1004, 4; see IPR2020-01573, Paper 1, 28-29; IPR2020-01711, Paper 1, 32-33; IPR2021-00017, Paper 1, 28-29; IPR2021-00065, Paper 1, 31-32; IPR2021-00066, Paper 1, 28-29.

IPR2020-01573, Ex.1003, ¶94 (see Paper 1, 28-29); see also IPR2020-01711, Ex.1003, ¶100 (see Paper 1, 32-33); IPR2021-00017, Ex.1003, ¶80 (see Paper 1, 28-29); IPR2021-00065, Ex.1003, ¶84 (see Paper 1, 31-32); IPR2021-00066, Ex.1003, ¶89 (see Paper 1, 28-29).

Petitioner New World Medical, Inc., IPR Nos. 2020-01573, 2020-01711, 2021-00017, 2021-00065, 2021-00066  
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

# Dr. Condon Testified the Sides “Contact” TM, Consequently Admitting the “Cutting Edges Are Contacting the TM” as Claimed

7 So where the sides end, I mean, at the  
 8 point, we're talking -- are we talking microns here?  
 9 Is it possible that, you know, where the side meets  
 10 the point, that that contacts the trabecular  
 11 meshwork? I'll give you that it's possible and  
 12 could -- may assist in creating that tearing away of  
 13 the trabecular meshwork from its insertion point,  
 14 much as what I saw in the photograph.

Ex.1041, 181:7-14; see IPR2020-01573, Paper 35, 16-17, 20-21; IPR2020-01711, Paper 27, 14-15, 18-19; IPR2021-00017, Paper 26, 15-16, 20-21; IPR2021-00065, Paper 24, 15-16, 19, 20; IPR2021-00066, Paper 25, 10, 16-17.

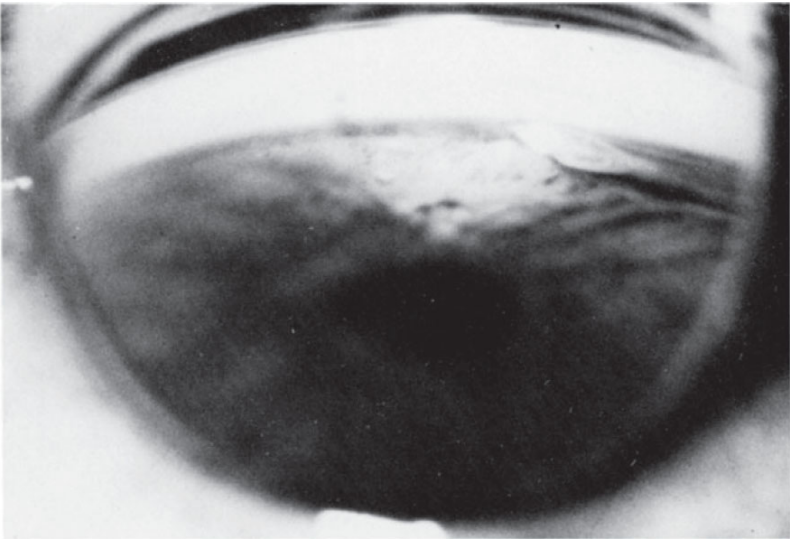
8/17/2021 New World Medical, Inc. v. MicroSurgical Technology, Inc. Gerry Condon, M.D.	
Page 1	Page 2
UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD New World Medical, Inc. Petitioner vs. MicroSurgical Technology, Inc. Respondent (Case No. IPR2020-01573) (Case No. IPR2020-01711) (Case No. IPR2020-01712) (Case No. IPR2020-01713) (Case No. IPR2020-01714) (Case No. IPR2020-01715) (Case No. IPR2020-01716) (Case No. IPR2020-01717) (Case No. IPR2020-01718) (Case No. IPR2020-01719) (Case No. IPR2020-01720) (Case No. IPR2020-01721) (Case No. IPR2020-01722) (Case No. IPR2020-01723) (Case No. IPR2020-01724) (Case No. IPR2020-01725) (Case No. IPR2020-01726) (Case No. IPR2020-01727) (Case No. IPR2020-01728) (Case No. IPR2020-01729) (Case No. IPR2020-01730) (Case No. IPR2020-01731) (Case No. IPR2020-01732) (Case No. IPR2020-01733) (Case No. IPR2020-01734) (Case No. IPR2020-01735) (Case No. IPR2020-01736) (Case No. IPR2020-01737) (Case No. IPR2020-01738) (Case No. IPR2020-01739) (Case No. IPR2020-01740) (Case No. IPR2020-01741) (Case No. IPR2020-01742) (Case No. IPR2020-01743) (Case No. IPR2020-01744) (Case No. IPR2020-01745) (Case No. IPR2020-01746) (Case No. IPR2020-01747) (Case No. IPR2020-01748) (Case No. IPR2020-01749) (Case No. IPR2020-01750) (Case No. IPR2020-01751) (Case No. IPR2020-01752) (Case No. IPR2020-01753) (Case No. IPR2020-01754) (Case No. IPR2020-01755) (Case No. IPR2020-01756) (Case No. IPR2020-01757) (Case No. IPR2020-01758) (Case No. IPR2020-01759) (Case No. IPR2020-01760) (Case No. IPR2020-01761) (Case No. IPR2020-01762) (Case No. IPR2020-01763) (Case No. IPR2020-01764) (Case No. IPR2020-01765) (Case No. IPR2020-01766) (Case No. IPR2020-01767) (Case No. IPR2020-01768) (Case No. IPR2020-01769) (Case No. IPR2020-01770) (Case No. IPR2020-01771) (Case No. IPR2020-01772) (Case No. IPR2020-01773) (Case No. IPR2020-01774) (Case No. IPR2020-01775) (Case No. IPR2020-01776) (Case No. IPR2020-01777) (Case No. IPR2020-01778) (Case No. IPR2020-01779) (Case No. IPR2020-01780) (Case No. IPR2020-01781) (Case No. IPR2020-01782) (Case No. IPR2020-01783) (Case No. IPR2020-01784) (Case No. IPR2020-01785) (Case No. IPR2020-01786) (Case No. IPR2020-01787) (Case No. IPR2020-01788) (Case No. IPR2020-01789) (Case No. IPR2020-01790) (Case No. IPR2020-01791) (Case No. IPR2020-01792) (Case No. IPR2020-01793) (Case No. IPR2020-01794) (Case No. IPR2020-01795) (Case No. IPR2020-01796) (Case No. IPR2020-01797) (Case No. IPR2020-01798) (Case No. IPR2020-01799) (Case No. IPR2020-01800)	I N D E X Volume 1 Tuesday, August 17, 2021 PAGE Called by the Petitioner: EXAMINATION BY MR. TUCKER..... 7 E X H I B I T S (Number in Italic) GARRY CONDON, M.D. DEPOSITION EXHIBITS PAGE Condon Exhibit 1 Petitioner's Notice of 9 Dependence of Claim F Condon, M.D. Condon Exhibit 2 Declaration of Gary F. 11 Condon, M.D., in Support of Petitioner's Response U.S. Patent No. 9,107,759 Patent Owner Exhibit 2019-061 through 171 Condon Exhibit 3 United States Patent 14 No. US 9,107,759 B2 Condon Exhibit 4 Oculogrip Technologies, 22 Inc. Patent Patent Owner Exhibit Petitioner New World Medical Exhibit 1004, Page 1 through 5 Condon Exhibit 5 Amended Accompanying Notice 31 of Appeal Application No. 15/195,356 Page 2 Page 4 EXHIBIT A CONT GARRY CONDON, M.D. DEPOSITION EXHIBITS PAGE Condon Exhibit 4 Study Medical Dictionary 71 Page 713 - "tear" Patent Owner Exhibit 2019-061 through 171 Condon Exhibit 7 Oculogrip Medical Dictionary 78 - "tear" Patent Owner Exhibit 2019-061 through 171 Condon Exhibit 8 Clinical Research - 88 Support: Neurography of the Oculoflex Channels Ronald Jackson, M.D., et al. Condon Exhibit 9 Histologic Evaluation of 131 Microsurgical Oculogrip Technologies Support: Microsurgery of the Oculoflex Channels William H. Swann, MD Condon Exhibit 10 Declaration of Gary F. 172 Condon, M.D., in Support of Petitioner's Response Case IPR2020-01573, IPR Patent No. 9,151,151 Patent Owner Exhibit 2019-061 through 149 Condon Exhibit 11 Declaration of Gary F. 173 Condon, M.D., in Support of Petitioner's Response Case IPR2020-01573, U.S. Patent No. 9,107,759 Patent Owner Exhibit 2019-061 through 145 1 (Pages 1 to 4) www.DigitalEvidenceGroup.com Digital Evidence Group C/T 2021 202-232-0646 Petitioner - New World Medical Ex. 1041, p. 1 of 96 New World Medical, Inc. v. MicroSurgical Tech., Inc., IPR2020-01573

# Quintana Explicitly States the Tip Contacts the TM

GONIOSCOPIC TRABECULOTOMY. FIRST RESULTS

MANUEL QUINTANA  
*(Barcelona, Spain)*

lens. The TM is incised with the tip of the needle. From now on, and with the concavity of the tip *towards* the surgeon, the trabeculotome is progressively introduced in the angle. Only the tip of the instrument is introduced into Schlemm's canal, and the TM is stripped slowly, gently and easily from the canal's lumen towards the anterior chamber as the needle progresses in the angle (Fig. 2). Since the convexity of the tip is facing the external wall of the canal, this structure is not damaged. This is why we bend the tip and we point it towards the anterior chamber.



MATERIAL AND METHODS

A technique of trabeculotomy has been devised, which presumed causes of failure of previous methods. This is done under general anaesthesia; both eyes can be done at the same time. A coaxial operating microscope is used with a magnification of  $\times 10$ . We favour the Swann lens for an trabeculotomy; it is a 0.4  $\times$  15 mm needle, or an insulated needle with the tip 20–30° with a needle-holder; a factory-made needle is even better. The needle is inserted into a syringe. "Modus operandi" is as in classical goniotomy (surgeon of the patient, patient's head rotated away from the surgeon).

Ex. 1004, p. 3 of 9

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

Ex.1004, 4-5; see IPR2020-01573, Paper 1, 36-48; IPR2020-01711, Paper 1, 40-43; IPR2021-00017, Paper 1, 36-46; IPR2021-00065, Paper 1, 39-48; IPR2021-00066, Paper 1; 36-44.



# Claims Do Not Require “Distinct” Cutting Edges

meshwork.”) (emphasis added). To be sure, the dual blade device of the  
Challenged Claims must have two distinct cutting edges, no more and no less. The

IPR2020-01573, Paper 29, 25; *see also* IPR2020-01711, Paper 17, 26; IPR2021-00017, Paper 17, 23-24; IPR2021-00065, Paper 18, 23.

Paper 29

UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE PATENT TRIAL AND APPEAL BOARD

Filed: June 8, 2021

PATENT OWNER RESPONSE  
PURSUANT TO 37 C.F.R. § 42.120

# Reading “Distinct” Into Claim Is Inconsistent with Intrinsic Record

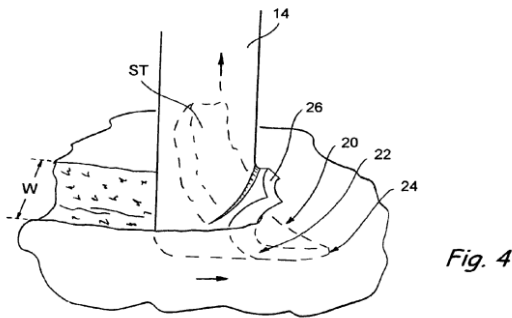


Fig. 4

## '729/'155/'885 Patent Fig. 4

IPR2020-01573, Ex.1001, Fig.4 (see Paper 1, 21; Paper 35, 6-7, 16);  
 IPR2020-01711, Ex.1001, Fig.4 (see Paper 1, 21; Paper 27, 6, 14);  
 IPR2021-00017, Ex.1001, Fig.4 (see Paper 1, 21; Paper 26, 6-7, 15).

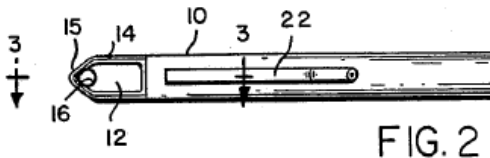


FIG. 2

## Lee (Ex.1006), Fig.2

Ex. 1006, Fig.2; see IPR2020-01573 Paper 1, 22-23, 78-79; IPR2020-01711, Paper 1, 22-23, 69, 78-79; IPR2021-00017, Paper 1, 22-26, 66-68; IPR2021-00065, Paper 1, 59-62; IPR2021-00066, Paper 1, 80.

Ex.1046, p. 58 of 98

<b>Notice of Allowability</b>		Application No. 1481,354	Applicant(s) SOPHENSEN, ET AL.
		Examiner AMY R. WEISBERG	Art Unit 2734
		Priority Number	File Date
			File

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address—  
 All claims being allowed, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included  
 herewith (or previously mailed), a Notice of Allowance (PTOL 85) or other appropriate communication will be mailed in due course. THIS  
 NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative  
 of the Office or upon petition by the applicant. See 37 CFR 1.315 and 1.316.

This communication is responsive to the amendment filed 8/8/15.  
 A declaration (if applicable) under 37 CFR 1.156(a) was/were filed on \_\_\_\_\_.

The Patent Prosecution  
 Information, please see  
 page application from the  
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 at least past the back of  
 Note the  
 REAL.  
 present  
 reasons for Allowance  
 (if amendment)

of Paper No. Mail Date 20150314  
 Petitioner - New World Medical  
 Ex. 1002, p. 316 of 499

The closest prior art includes Lee USP 4,900,300 which teaches a method of excising a piece of tissue from the anterior chamber angle (trabecular meshwork and the inner wall of Schlemm's Canal) utilizing a device with a U-shaped cutting edge (14) which has dual blades corresponding to the U-shape. However Lee fails to teach a device comprising a shaft and 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. It would not have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Lee to include using a device with a shaft and 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.

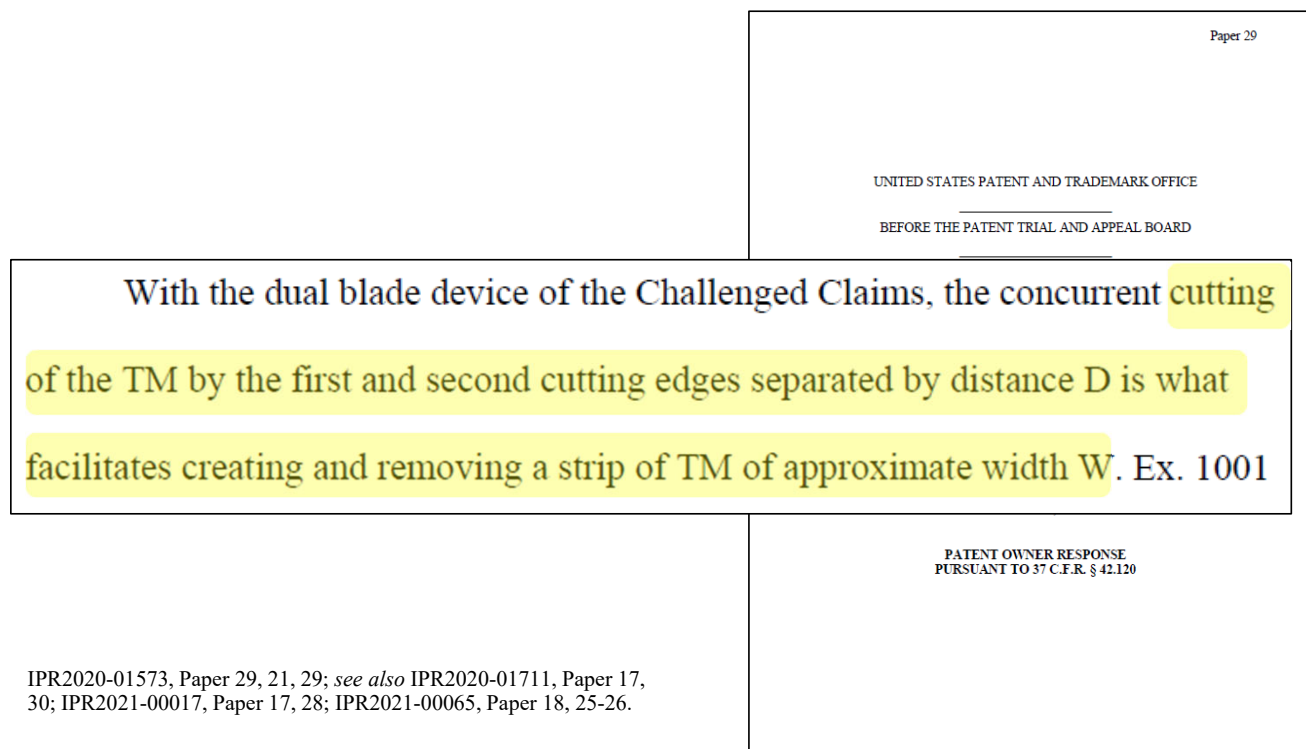
IPR2020-01573, Ex.1002, 320-21 (see Paper 1, 22-23, 78-79); see also Ex.1022, 320-21; IPR2020-01711, Paper 1, 22-23, 27, 78-79; IPR2021-00017, Paper 1, 22-23, 66; IPR2021-00065, Paper 1, 59-60.

# Dr. Condon Testifies Claims Do Not Require “Uniform” Width Strip

8/18/2021      New World Medical, Inc. v. MicroSurgical Technology, Inc.      Garry Condon, M.D. Vol II Page 233      Page 235	
5      Q. Again, I'm not asking a measurement. I'm 6      just asking conceptually, the width is approximately 7      the distance between the cutting edges, correct? 8      A. Yes. I would expect that by this 9      description, a strip of tissue I'm going to say 10      would be uniform with W, approximately equal to the 11      distance between the first and second cutting edges. 12      I'm reading right from the claim. 13      Q. Okay. Well, where does it say uniform, 14      Dr. Condon, in the claim? 15      A. I'm saying uniform.	22      Q. Let me ask another way. When you read the 1      claim, do you believe it requires a uniform width 2      for the strip? 3      MS. SUMMERS: Objection; beyond the scope. 4      A. I can't read the claim and say specifically, 5      again, the width, but equal to the distance between 6      the first and second cutting edges kind of defines 7      the width. 8      Q. Right, but focused on -- focusing on 9      uniform, it says -- 10      A. Uniform is not there.
www.DigitalEvidenceGroup.com      Digital Evidence Group Ctr 2021      1 (Pages 233 to 236) 202-232-0646 Petitioner - New World Medical File: 002_21 of 24 New World Medical, Inc. v. MicroSurgical Tech., Inc., IPR2020-01573	

Ex.1042, 253:-254:10; see IPR2020-01573, Paper 35, 20-21; IPR2020-01711, Paper 27, 19; IPR2021-00017, Paper 26, 21; IPR2021-00065, Paper 24, 20.

# “Defined Width” Strip Is Simply Result of Cutting TM by Cutting Edges



IPR2020-01573, Paper 29, 21, 29; *see also* IPR2020-01711, Paper 17, 30; IPR2021-00017, Paper 17, 28; IPR2021-00065, Paper 18, 25-26.

# Quintana Discloses “Ab Interno” Procedure (‘729, cl.1 / ‘155, cl.1 / ‘544, cl.4)

- Board construed “ab interno” according to plain and ordinary meaning
  - IPR2020-01573, Paper 22, 17; IPR2020-01711, Paper 11, 13; IPR2021-00066, Paper 10, 20-21.
- Plain and ordinary meaning of “ab interno” is “from the inside”
  - IPR2020-01573, Paper 29, 31; IPR2020-01711, Paper 17, 35; IPR2021-00066, Paper 17, 31.
- Dr. Condon admits Quintana’s needle enters anterior chamber and is directed to TM from within anterior chamber
  - Ex.1041, 139:20-140:15, 147:9-18; see IPR2020-01573, Paper 35, 22; IPR2020-01711, Paper 27, 22; IPR2021-00066, Paper 25, 20.
- Quintana explicitly discloses that needle “penetrates the anterior chamber” and shows needle within anterior chamber in Fig. 2
  - Ex.1004, 4-5; see IPR2020-01573, Paper 1, 27-37; IPR2020-01711, Paper 1, 41-43; IPR2021-00066, Paper 1, 36-47.

# “Ab Interno” Means “From the Inside”

Paper 29

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

art at the time of filing of the ‘729 patent. Persons of ordinary skill in the art would have understood the term ‘ab interno’ to generally mean *from the inside* and would have understood the term ‘ab externo’ to generally mean *from the outside.*”

Ex. 1003 ¶74 (emphasis in original). Patent Owner agrees with these definitions.<sup>10</sup>

PATENT OWNER AGREES  
PURSUANT TO 37 C.F.R. § 42.120

IPR2020-01573, Paper 29, 31; *see also* IPR2020-01711, Paper 17, 35; IPR2021-00066, Paper 17, 31.

# Dr. Condon Testifies Quintana’s Needle Enters the Anterior Chamber and Is Redirected Back to the TM on the Opposite Side—an “Ab Interno” Procedure

- Surgical procedure can be both “ab interno” and “ab externo” is same sitting
  - Ex.1041, 141:11-142:2; *see* IPR2020-01573, Paper 35, 22; IPR2020-01711, Paper 27, 22; IPR2021-00066, Paper 25, 20.
- Quintana’s needle is eventually within the anterior chamber (even under hypothetical alternate view)
  - Ex.1041, 139:20-140:15; *see* IPR2020-01573, Paper 35, 22; IPR2020-01711, Paper 27, 22; IPR2021-00066, Paper 25, 20.
- Once inside the anterior chamber, Quintana’s needle is “redirected back” to the TM on the other side
  - Ex.1041, 147:9-18; *see* IPR2020-01573, Paper 35, 22; IPR2020-01711, Paper 27, 22; IPR2021-00066, Paper 25, 20.

# Quintana Explicitly Discloses and Shows an “Ab Interno” Procedure

GONIOSCOPIC TRABECULOTOMY. FIRST RESULTS

MANUEL QUINTANA  
(Barcelona, Spain)

the vertical recti). The needle penetrates the anterior chamber at 6 hours (right eye) or 12 hours (left eye) through the scleral side of the limbus; this is in order to run parallel to Schlemm’s canal. Penetration at 6 or 12 hours allows a *tangential* approach (Fig. 1) to the angle; this avoids the pupillary field and the convexity of the lens. Penetration is carried on under direct control, to avoid the prismatic effect of the gonioleins. Once the needle is in the anterior chamber, the gonioleins is inserted, held with the surgeon’s left hand. A drop of “healon” is a good wetting agent between cornea and gonioleins. The TM is incised with the tip of the needle. From now on, and with the concavity of the tip towards the surgeon, the trabeculotome is progressively introduced in the angle. Only the tip of the instrument is introduced into Schlemm’s canal, and the TM is stripped slowly, gently and easily from the canal’s lumen towards the anterior chamber as the needle progresses in the angle (Fig. 2). Since the convexity of the tip is facing the external wall of the canal, this structure is not damaged. This is why we bend the tip and we point it towards the anterior chamber.

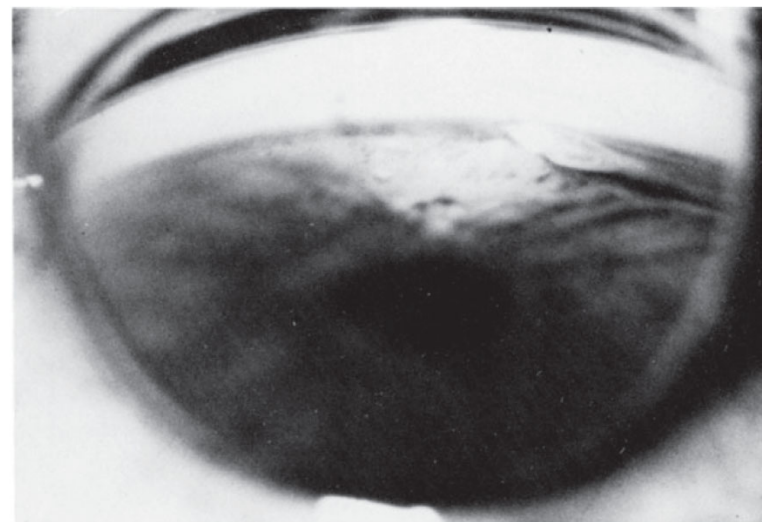


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

Ex.1004, 4-5; see IPR2020-01573, Paper 1, 27-37; IPR2020-01711, Paper 1, 41-43; IPR2021-00066, Paper 1, 36-47.

E. J. Orve, W. Leydhecker & C. Raitta (eds.), Second European Glaucoma Symposium  
© 1985, Dr. W. Junk Publishers, Dordrecht. ISBN 978-94-010-8934-0

Petitioner - New World Medical  
Ex. 1004, p. 3 of 9

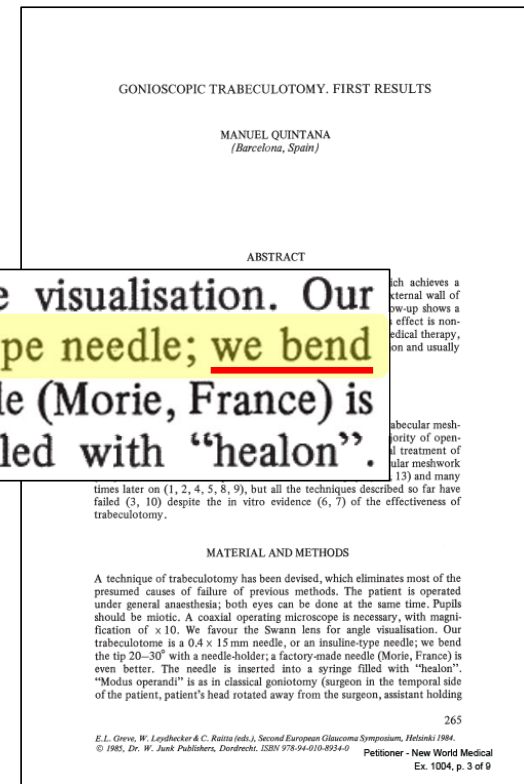
Ex.1046, p. 64 of 98

Petitioner New World Medical, Inc., IPR Nos. 2020-01573,  
2020-01711, 2021-00017, 2021-00065, 2021-00066  
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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# Quintana Discloses a “Bend or Curve” (‘729, cl.1 / ‘155, cl.1)



Ex.1004, 3; see IPR2020-01573, Paper 1, 42; IPR2020-01711, Paper 1, 40, 45-46.

# Quintana Discloses a “Blunt Protruding Tip” and a “Blunt Top Edge” (“155, cl.1)

- Patent claims a bent needle (“needle cutter device”)—if patented device has “blunt” tip, so too does Quintana
  - IPR2020-01711, Ex.1001, 6:6-11, Fig.4 (see Paper 1, 20-21); IPR2020-01711, Ex.1004, 4 (see Paper 1, 44-56).
- Dr. Netland testifies patent does not define “blunt” and that tip is used to penetrate the TM
  - IPR2020-01711, Ex.1042, 281:5-282:9 (see Paper 27, 20 n.9).
- Dr. Netland confirms Quintana’s needle performs same function as tip of patented device
  - IPR2020-01711, Ex.1003, ¶132 (see Paper 1, 45).
- Dr. Condon admits Dr. Netland is correct
  - IPR2020-01711, Ex.1042, 281:5-282:9 (see Paper 27, 20 n.9).

# Patent Claims Cover a Bent Needle With a Point

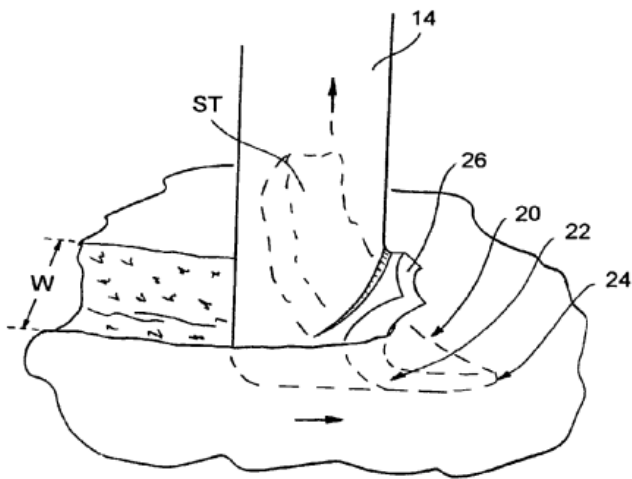
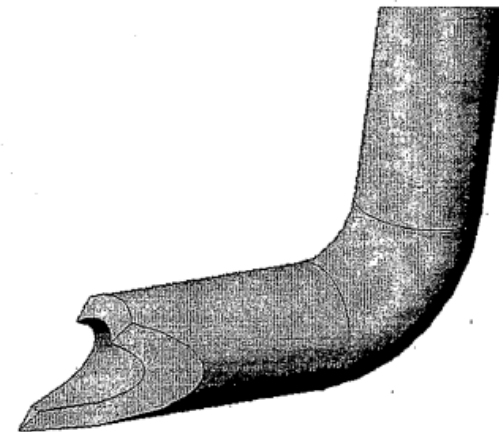


Fig. 4

## '729/'155/'885 Patent Fig. 4

IPR2020-01573, Ex.1001, Fig.4 (see Paper 1, 21; Paper 35, 6-7, 16);  
IPR2020-01711, Ex.1001, Fig.4 (see Paper 1, 21; Paper 27, 6, 14);  
IPR2021-00017, Ex.1001, Fig.4 (see Paper 1, 21; Paper 26, 6-7, 15).



## '258 Provisional

Ex.1039, 13; see IPR2020-01573, Paper 35, 6-7, 15-16; IPR2020-01711, Paper 27, 6, 14; IPR2021-00017, Paper 26, 6-7, 15; IPR2021-00065, Paper 24, 6-7.

# Embodiments Covered by Claims and Quintana's Needle Do the Exact Same Thing—Penetrate TM

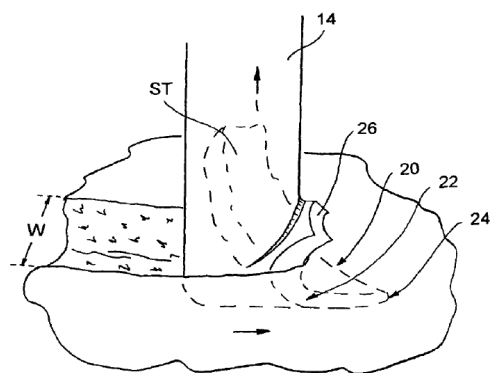
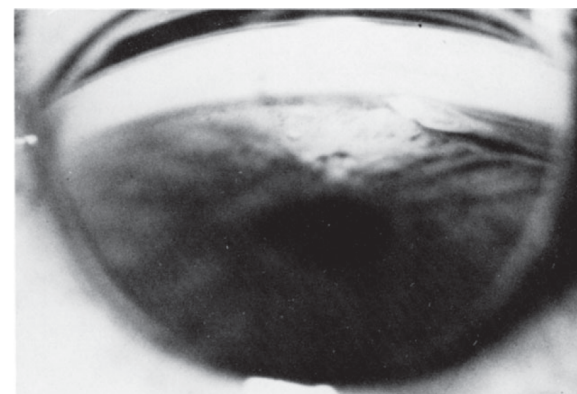


Fig. 4



removed. Under direct visualization, the device **10** is advanced until the distal tip of the cutter tube **14** is positioned adjacent to the trabecular meshwork at the location where the strip **ST** is to be removed. Thereafter, the protruding tip **24** is advanced through the trabecular meshwork and into Schlemm's Canal.

IPR2020-01711, Ex.1001, 6:6-11, Fig.4 (see Paper 1, 20-21).

lens. The TM is incised with the tip of the needle. From now on, and with the concavity of the tip towards the surgeon, the trabeculotome is progressively introduced in the angle. Only the tip of the instrument is introduced into Schlemm's canal, and the TM is stripped slowly, gently and easily from the canal's lumen towards the anterior chamber as the needle progresses in the angle (Fig. 2). Since the convexity of the tip is facing the external wall of the

IPR2020-01711, Ex.1004, 4, Fig.2 (see Paper 1, 44-56).

# Dr. Netland Confirms Patented Device and Quintana’s Needle Do the Exact Same Thing— Penetrate the TM

132. Quintana’s needle has a “blunt protruding tip” because, like the “blunt protruding tip” of the ‘155 patent’s “needle cutter device,” it is located on the bottom of the distal end of the needle tube, is used to facilitate insertion of the tip through the trabecular meshwork into Schlemm’s Canal, and guides the needle as it is advanced through Schlemm’s Canal. Ex.1001 (‘155 patent), 3:10-24; Ex.1004 (Quintana), 4. As shown in annotated Fig. 1 below, the portion of Quintana’s

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RIAL AND APPEAL BOARD

MEDICAL, INC.,  
itioner

V.

CAL TECH, INC.,  
Owner

F.U.S. PATENT NO. 9,358,155  
R2020-01711

N OF DR. PETER NETLAND

IPR2020-01711, Ex.1003, ¶132 (see Paper 1, 45).

4817-8365-1789, v.1

Petitioner - New World Medical  
Ex. 1003, p. 1 of 276

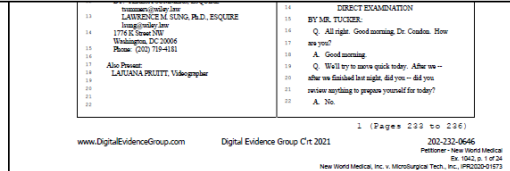
# Dr. Condon Testifies Patent Provides No Indication How to Measure Bluntness or Sharpness

8/18/2021 New World Medical, Inc. v. MicroSurgical Technology, Inc. Garry Condon, M.D. Vol II	
5 Q. Does the '155 patent give any indication how	Page 233 Page 235
6 to determine or measure bluntness?	1 ADEMARC OFFICE
7 MS. SUMMERS: Objection; form, outside the	2 APPEAL BOARD
8 scope.	3 I N D E X
9 A. You know, in the interest of time, I'm not	4 Volume 2
10 going to read this while we're sitting here, but to	5 Wednesday, August 18, 2021
11 my recollection and -- I don't remember anything in	6 WITNESS PAGE
12 the '155 specifying how to measure bluntness. I	7 Called by the Petitioner
13 don't know what bluntness refers to in any of these	8 EXAMINATION BY MR. TUCKER 236
14 documents, the "ness." Blunt is just not sharp.	9 E X H I B I T S
15 Q. Okay.	10 (Attached to transcript)
16 A. So bluntless -- bluntness would be not	11 GARRY
17 sharpness. I'm not sure I can put it any better.	12 Condon E
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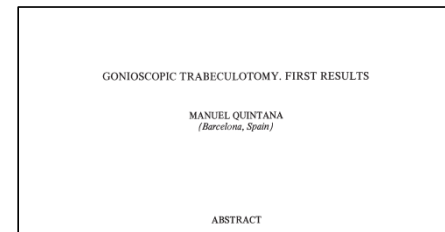
# Dr. Condon Concedes a “Blunt” Tip Can Penetrate TM



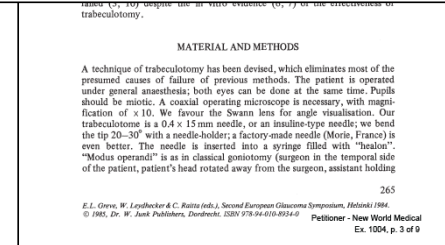
14 A. Can a blunt protruding tip penetrate  
 15 trabecular meshwork?  
 16 Q. Yes.  
 17 A. I would say it could, depending on the  
 18 specific construction of that blunt tip, so it would  
 19 have to be -- it can be a blunt tip and penetrate  
 20 trabecular meshwork.



IPR2021-01711, Ex.1042, 279:15-20 (see Paper 27, 20).

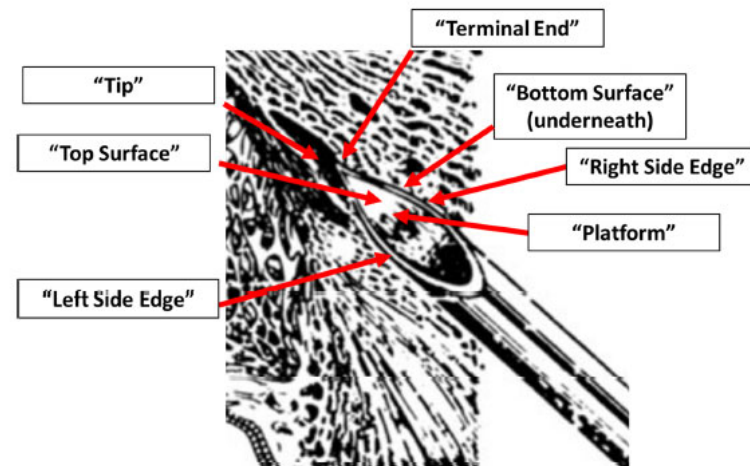
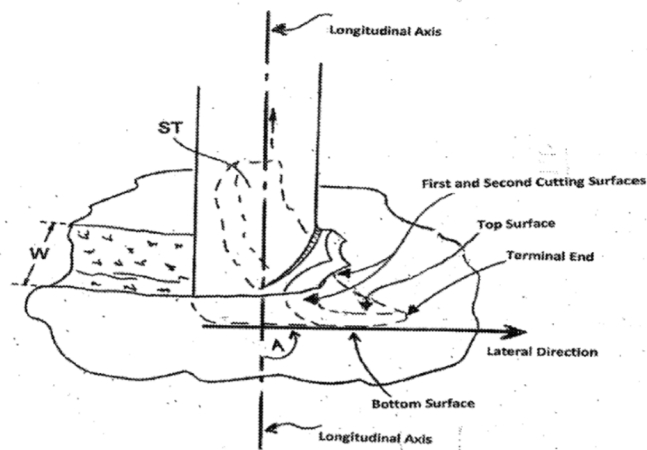


lens. The TM is incised with the tip of the needle. From now on, and with the concavity of the tip towards the surgeon, the trabeculotome is progressively introduced in the angle. Only the tip of the instrument is introduced into Schlemm's canal, and the TM is stripped slowly, gently and easily from the canal's lumen towards the anterior chamber as the needle progresses in the angle (Fig. 2). Since the convexity of the tip is facing the external wall of the



IPR2020-01711, Ex.1004, 4 (see Paper 1, 44-56).

# Quintana Discloses a “Platform” (‘855, cl.1)



‘729/’155/’885 Patent Fig. 4  
(annotated by applicant during prosecution)

IPR2020-01711, Ex.1002, 199 (see Paper 1, 23-24); IPR2021-00017, Ex.1023, 199 (see Paper 1, 23-24).

Quintana (Ex.1004),  
Fig.1 (annotated)

IPR2021-00017, Ex.1004, 4 (see Paper 1, 41; Paper 26, 22-23).





# Quintana Discloses a “Protector Member” (‘905, cl.1)

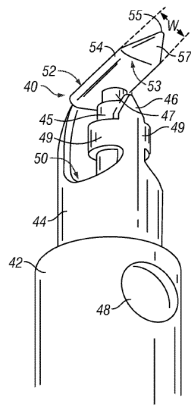
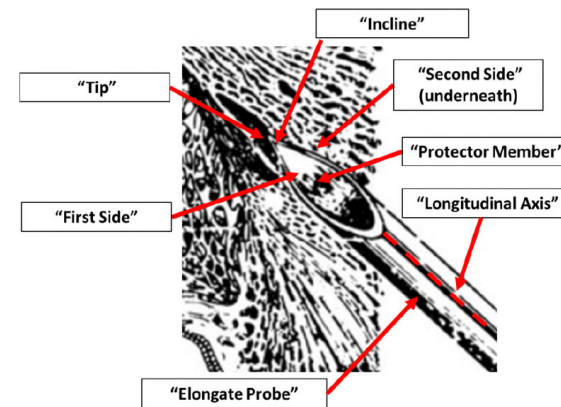


FIG. 5A

The device 10 further comprises a protector 24 having a first side located adjacent to the cutting or ablating apparatus, and a second side located on a distal-most portion of the device 10. The protector 24 is structured and designed to preventing damage to tissue located near the tissue to be cut. For example, the protector 24 is designed to protect or prevent any substantial damage to surfaces of Schlemm’s canal while the device 10 is being utilized to cut portions of the trabecular meshwork during a goniotomy procedure.

IPR2021-00065, Ex.1001, 9:9-17, Fig.5A (see Paper 1, 19-20).



angle (Fig. 2). Since the convexity of the tip is facing the external wall of the canal, this structure is not damaged. This is why we bend the tip and we point it towards the anterior chamber.

IPR2021-00065, Ex.1004, 4 (see Paper 1, 41-42, Paper 24, 20-22); see also IPR2021-00066, Ex.1004, 4 (see Paper 1, 40-43; Paper 25, 7-9).

# Quintana's Needle Tip Serves Same Purpose as "Protector Member"

Paper 18

UNITED STATES PATENT AND TRADEMARK OFFICE

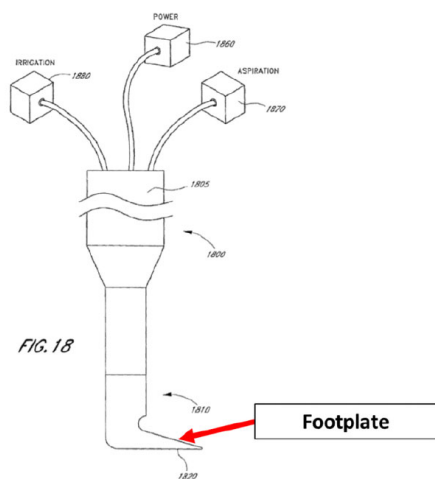
describes protector member 24. And with respect to the Quintana device, **avoiding** injury to the external wall of Schlemm's Canal is attributed only to the "convexity of the tip" of the bent standard hypodermic needle. Quintana therefore does not disclose a protector member, and the only portion of the Quintana device that serves a similar intended purpose is the "convexity of the tip," which is created by

TRIAL AND APPEAL BOARD  
LD MEDICAL, INC.,  
Petitioner,  
v.  
AL TECHNOLOGY, INC.,  
Text Owner.  
PR2021-00065  
ment No. 10,123,905  
June 8, 2021  
OWNER RESPONSE  
TO 37 C.F.R. § 42.120

IPR2021-00065, Paper 18, 27, Paper 24, 22;  
*see also* IPR2021-00066, Paper 17, 15.

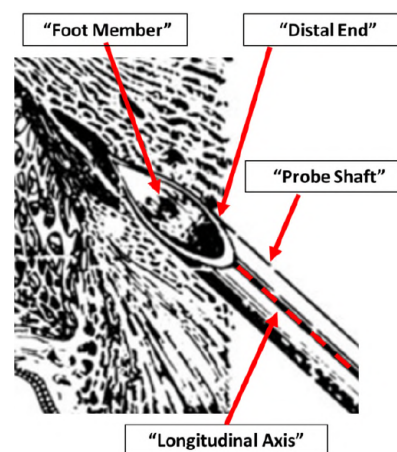
Petitioner New World Medical, Inc., IPR Nos. 2020-01573,  
2020-01711, 2021-00017, 2021-00065, 2021-00066  
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

# Quintana Discloses a “Foot Member” (‘544, cl.1)



cylindrical shape, be provided. The probe tip **1810** further comprises a footplate **1820**, protecting endothelial cells and collector channels lining the scleral wall of Schlemm’s canal. The footplate **1820** also serves as a guide in Schlemm’s canal. The sharpened end of the footplate is used to penetrate the trabecular meshwork.

IPR2021-00066, Ex.1001, 13:53-58, Fig.18 (see Paper 1, 38-39).



angle (Fig. 2). Since the convexity of the tip is facing the external wall of the canal, this structure is not damaged. This is why we bend the tip and we point it towards the anterior chamber.

IPR2021-00066, Ex.1004, 4 (see Paper 1, 40-43; Paper 25, 7-9); see also IPR2021-00065, Ex.1004, 4 (see Paper 1, 41-42, Paper 24, 20-22).

# Obviousness Based on Quintana (Ex.1004) and Lee (Ex.1006) ('729 Grounds 3-4 / '155 Grounds 3-4)

- **“ab interno”** ('729 cl.1 / '155 cl.1)
  - Lee discloses “ab interno” procedure
    - IPR2020-01573, Paper 1, 58-60; IPR2020-01711, Paper 1, 15, 63-67.
  - Obvious to modify Quintana’s procedure by altering penetration site
    - IPR2020-01573, Paper 1, 60; IPR2020-01711, Paper 1, 66-67.
- **“dual blade device”** ('729 cl.1 / '155 cl.1)
  - Lee discloses “dual blade device”
    - IPR2020-01573 Paper 1, 15-16, 57-58; IPR2020-01711, Paper 1, 15-16, 62-65.
  - Obvious to modify Quintana’s needle by sharpening edges
    - IPR2020-01573 Paper 1, 61-62; IPR2020-01711 Paper 1, 64-66.
- **“blunt protruding tip”** and **“blunt top edge”** ('155 cl.1)
  - Lee discloses protruding tip that is “softly rounded” “in order to avoid damage to the outer wall of Schlemm’s Canal”
    - IPR2020-01711, Paper 1, 68-69 (citing Ex.1006, 4:38-48, Fig.2).
  - Obvious to modify Quintana’s tip based on Lee to avoid damaging SC
    - *Id.*

# Quintana Obviousness Grounds ('729 Grounds 2-4 / '155 Grounds 2-4 / '885 Ground 2 / '905 Ground 2 / '544 Ground 2)

- Patent Owner repeats generic arguments across obviousness grounds
- Patent Owner wrongly contends no motivation for modifying prior art but fails to address all arguments in NWM's petitions
- No explanations how proposed modifications to Quintana's needle would reduce effectiveness/increase SC injury risk
- Patent Owner fails to rebut *prima facie* obviousness

IPR2020-01573, Paper 29, 30-45; IPR2020-01711, Paper 17, 39-50; IPR2021-00017, Paper 17, 30-34; IPR2021-00065, Paper 18, 29-31; IPR2021-00066, Paper 17, 34-39.

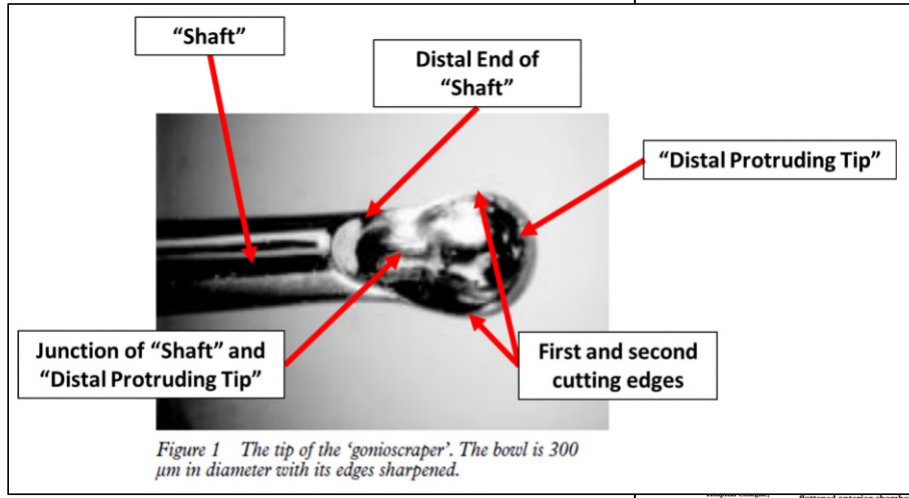
# Jacobi (Ex.1007) Invalidates the Challenged Claims



Ex.1007, Fig.1; *see* IPR2020-01573, Paper 1, 75-85; IPR2020-01711, Paper 1, 75-98; IPR2021-00017, Paper 1, 58-67; IPR2021-00065, Paper 1, 53-69; IPR2021-00066, Paper 1, 66-74.

# Jacobi's Discloses a "Dual Blade Device" ('729, cl.1 / '155, cl.1) / "Cutting Edges" ('885, cl.1) / "Knife Blades" ('905, cl.1)

302  
 British Journal of Ophthalmology 1997;81:302-307  
 Technique of gonioscurettage: a potential treatment for advanced chronic open angle glaucoma



Dierlein, Günter K Kriegstein  
 Concept of antere-  
 surgery, de-  
 sically altered  
 the scleral sul-  
 in primary  
 controlled ab-  
 blecular mechi-  
 six human eye  
 gical analysis.  
 rize from ter-  
 nerve atrophy  
 uncontrolled  
 also treated by  
 only designed  
 modified cyclo-  
 set-shaped tip,  
 with its edges  
 at some concs  
 the chamber  
 reduction. However, longer term  
 and a greater number of patients  
 wanted before this experiment  
 dore is applicable to eyes that  
 well with conventional surgery.  
 (Br J Ophthalmol 1997;81:302-307)  
 Conventional glaucoma filtering sur-  
 mainstay of surgical treatment to  
 intracular pressure (IOP) in post-  
 angle glaucoma.<sup>1-3</sup> There is a growing  
 perform surgery earlier in the  
 glaucoma management.<sup>4</sup> However,  
 increasing success rates, especially in  
 of adjuvant antimetabolites, several  
 remain, such as hyphaema, flat ante-  
 ber, and variable wound healing re-  
 constrictal manipulation. In order  
 the latter, various techniques have be-  
 gined that minimize constrictal dis-  
 improve the success rate of filtrate  
 Laser sclerotomy has recently become  
 alternative to conventional glaucoma  
 surgery.<sup>5</sup> However, varying success  
 been reported using different laser or  
 techniques.<sup>6-10</sup> Based on the concep-  
 tual resistance to outflow of aqueous  
 as a result of maldevelopment of the  
 meshwork,<sup>11</sup> goniotomy,<sup>12</sup> ab extri-  
 culotomy,<sup>13</sup> and trabeculopuncture<sup>14</sup>  
 been recommended as surgical pro-  
 choice in juvenile open angle glau-  
 recent years, trabeculotomy has  
 increasing interest among some glau-  
 gons as a first choice surgical treat-  
 chronic open angle glaucoma,<sup>15</sup>  
 combined glaucoma and cataract sur-  
 Based on transmission and scan-  
 tron microscopy of trabeculotomy,<sup>16</sup>  
 various authors have suggested that  
 cases of chronic open angle glaucoma  
 the primary increase of outflow resistance lies in  
 the cribriform layer of the trabecular mesh-  
 work adjacent to the inner wall endothelium of  
 Schlemm's canal.<sup>17-19</sup> Presuming that the outer  
 layers of the trabecular meshwork play the key  
 role in the pathology of primary open angle  
 glaucoma, incisional surgery (goniotomy) or  
 mechanical disruption (trabeculotomy) of the  
 trabecular meshwork could then be a valid surgi-  
 cal approach to medically uncontrolled open  
 angle glaucoma. Unfortunately, simple disrup-  
 tion of the trabecular meshwork with the  
 trabeculotomy approach or punching small  
 holes with the Q-switched Nd:YAG laser

was designed. The 'gonioscraper' consists of a small handle and a slightly convex-shaped arm for intraocular use and very much resembles a cyclodialysis spatula. However, the tip of the instrument is shaped as a tiny bowl with 300 μm diameter and with its edges sharpened (Fig 1). In order to abrade clockwise and anticlockwise the scoop is angulated vertically at 90 degrees to the left and right, respectively.

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 11 December 1996  
 flattened anterior chamber, or cyclodialy-  
 sis were observed in these patients.  
 Conclusion—Morphological analysis of  
 treated postmortem eyes confirmed  
 that gonioscurettage completely removed  
 the trabecular meshwork and opened  
 Schlemm's canal, ensuring direct access  
 into the anterior chamber. In a small  
 number of patients over a limited period  
 of time this new surgical procedure re-  
 sulted in a clinically significant pressure  
 Petitioner - New World Medical  
 Ex. 1007, p. 1 of 6

Ex. 1007, 2, Fig.1; see IPR2020-01573, Paper 1, 77-85; IPR2020-01711, Paper 1, 77-88; IPR2021-00017, Paper 1, 61-72; IPR2021-00065, Paper 1, 56-62.



# Jacobi's Aim Was to Remove Rather Than Cut TM

302 *British Journal of Ophthalmology* 1997;81:302-307

**Technique of gonioscurettage: a potential treatment for advanced chronic open angle glaucoma**

Philipp C Jacobi, Thomas S Dietlein, Günter K Kriegstein

**Abstract**  
**Aim**—To introduce a new concept of anterior chamber angle microsurgery, designed to scrape pathologically altered trabecular meshwork from the scleral sulcus as a potential treatment in primary open angle glaucoma.  
**Methods**—Gonioscopically controlled ablativum abrasion of the trabecular meshwork was performed on six human eye banking eyes for morphological analysis. Thereafter, four eyes suffering from terminal glaucomatous optic nerve atrophy as a result of medically uncontrolled intracranial pressure were also treated by 'gonioscurettage'. The newly designed instrument resembles a modified cyclo-dialysis spatula with a bow-shaped tip, 300 µm in diameter, and with its edges sharpened. The treatment zone comprised 4–6 clock hours of the chamber angle circumference.  
**Results**—Microscopic examination of the treatment zones revealed that in addition to a complete disruption of the trabecular meshwork and internal wall of Schlemm's canal gonioscurettage also caused damage to intracanalicular septa. A splitting along the posterior wall of Schlemm's canal was also noted in one specimen. The clinical data of gonioscurettage also showed some promising results. Mean pretreatment IOP averaged 40.7 (SD 8.5) mm Hg (range 22–51 mm Hg) and was significantly ( $p<0.05$ ) reduced to 18.0 (4.2) mm Hg (12–21 mm Hg) after 6 months, representing an absolute decrease in IOP of 22.7 mm Hg and a mean decrease in IOP of 56%. Clinically significant hyphemas occurred in one eye, caused by iatrogenic trauma to a prominent chamber angle vessel. In three eyes a minor reflux of blood occurred at the treatment site. However, no hypotony, choroidal effusion, flattened anterior chamber, or cyclo-dialysis were observed in these patients.  
**Conclusions**—Morphological analysis of treated postmortem eyes confirmed that gonioscurettage completely removed the trabecular meshwork and opened Schlemm's canal, ensuring direct access into the anterior chamber. In a small number of patients over a limited period of time this new surgical procedure resulted in a clinically significant pressure

reduction. However, and a greater number of eyes treated before there is applicability well with conventional surgery.  
 Conventional glaucoma management. However, despite increasing success rates, especially with the use of adjuvant antimetabolites, several problems remain, such as hyphema, flat anterior chamber, and variable wound healing response to conjunctival manipulation. In order to avoid the latter, various techniques have been investigated that minimise conjunctival dissection to improve the success rate of filtration surgery. Laser sclerostomy has recently become a viable alternative to conventional glaucoma filtration surgery. However, despite being reported as techniques, it is still not clear as a result of mild meshwork, gonioscurettage, and it has been recommended choice in juvenile increasing interest in chronic open angle glaucoma. Based on transillumination microscopy various authors have reported cases of chronic primary increase of the cribriform lamina work adjacent to Schlemm's canal, layers of the trabecular meshwork, and the trabecular meshwork. This surgical approach to angle glaucoma filtration of the trabecular meshwork with the

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 Accepted for publication 11 December 1996

Petitioner - New World Medical  
 Ex-1007, p. 1 of 6

the opposite side. In order to peel off trabecular meshwork the 'scraper' was lightly passed over 2–3 clock hours to either side at the nasal circumference of the anterior chamber angle in sweeping movements (Fig 2). Great care was

due to glaucoma absolutum. The aim of the surgical procedure was to abrade rather than incise uveal meshwork; this novel method, therefore, is termed gonioscurettage. A descrip-

base of the iris. Gonioscopically, strings of trabecular tissue could be observed intraoperatively to be removed by gonioscurettage, leaving a 'denuded' grey-white scleral sulcus. At the end of surgery the viscoelastic along with abraded trabecular debris were removed by means of an irrigation-aspiration probe.

Ex. 1007, 1-2; see IPR2020-01573, Paper 1, 74-88; IPR2020-01711, Paper 1, 75-97; IPR2021-00017, Paper 1, 58-72; IPR2021-00065, Paper 1, 53-64; IPR2021-00066, Paper 1, 68-78.

Petitioner New World Medical, Inc., IPR Nos. 2020-01573, 2020-01711, 2021-00017, 2021-00065, 2021-00066  
 DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

# The '729's Notice of Allowance Confirms that a U-Shaped Cutting Edge is "Dual Blade"

Notice of Allowability	Application No. 1449,754	Applicant(s) SØRENSEN ET AL.	
	Examiner AMY R. WEISBERG	Art Unit 3734	AA (Patent Inventor to File Date) No

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address—  
All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included  
herein or previously mailed, a Notice of Allowance (PTOL 80) or other appropriate communication will be mailed in due course. THIS

The closest prior art includes Lee USP 4,900,300 which teaches a method of excising a piece of tissue from the anterior chamber angle (trabecular meshwork and the inner wall of Schlemm's Canal) utilizing a device with a U-shaped cutting edge (14) which has dual blades corresponding to the U-shape. However Lee fails to teach a device comprising a shaft and 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. It would not have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Lee to include using a device with a shaft and 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.

U.S. PATENT DOCUMENTS

3,942,051	11/1975	Taylor	404/2
4,041,591	11/1977	Bohler, Jr.	404/2
4,042,512	11/1977	Robinson	404/2
4,230,346	7/1980	Baskin	328/2
4,320,151	11/1980	Knechtling et al.	328/2
4,577,820	7/1986	Morisset	404/2
4,652,943	4/1987	Byde	404/2

Notice of Allowability  
Part of Paper No. Mail Date 20150514  
Petitioner - New World Medical  
Ex. 1002, p. 316 of 409

United States Patent [19] [11] Patent Number: 4,900,300  
Lee [45] Date of Patent: Feb. 13, 1990

4,889,000 8/1987 Thompson 404/2

[54] SURGICAL INSTRUMENT

[76] Inventor: David Lee

[21] Appl. No.: 318,139

[22] Filed: Feb. 2, 1984

[51] Int. Cl. A61B 1/00

[52] U.S. Cl. 606.1

[53] Field of Search: 606.1

U.S. PATENT DOCUMENTS

3,942,051	11/1975	Taylor	404/2
4,041,591	11/1977	Bohler, Jr.	404/2
4,042,512	11/1977	Robinson	404/2
4,230,346	7/1980	Baskin	328/2
4,320,151	11/1980	Knechtling et al.	328/2
4,577,820	7/1986	Morisset	404/2
4,652,943	4/1987	Byde	404/2

The forward end of shaft 10 comprises a parabolic, bowl-like cavity 12 having a sharpened rim which creates a single, more or less U-shaped cutting edge 14 integral with the sides of shaft 10. The cutting edge is

FIG. 3

FIG. 2

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Ex. 1006, p. 1 of 11

IPR2020-01573, Ex.1002, 320-21 (see Paper 1, 22-23, 78-79); see also IPR2020-01711, Ex.1022, 320-21 (see Paper 1, 22-23, 27, 78-79); IPR2021-00017, Ex.1022 (see Paper 1, 22-23, 66); IPR2021-00065, Ex.1022, 320-21 (see Paper 1, 59-60).

Ex. 1006, 4:38, Fig.2, Fig.3; see IPR2020-01573, Paper 1, 22-23, 78-79; IPR2020-01711, Paper 1, 22-23, 69, 78-79; IPR2021-00017, Paper 1, 22-26, 66-68; IPR2021-00065, Paper 1, 59-62; IPR2021-00066, Paper 1, 80.

# Patent Owner Admits “Defined Width” Strip Is Simply Result of Cutting Edges

With the dual blade device of the Challenged Claims, the concurrent cutting of the TM by the first and second cutting edges separated by distance D is what facilitates creating and removing a strip of TM of approximate width W. Ex. 1001

Paper 29

UNITED STATES PATENT AND TRADEMARK OFFICE

INTERPARTY PATENT TRIAL AND APPEAL BOARD

WORLD MEDICAL, INC.,  
Petitioner.

v.

LOGICAL TECHNOLOGY, INC.,  
Patent Owner.

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

Filed: June 8, 2021

PATENT OWNER RESPONSE  
PURSUANT TO 37 C.F.R. § 42.120

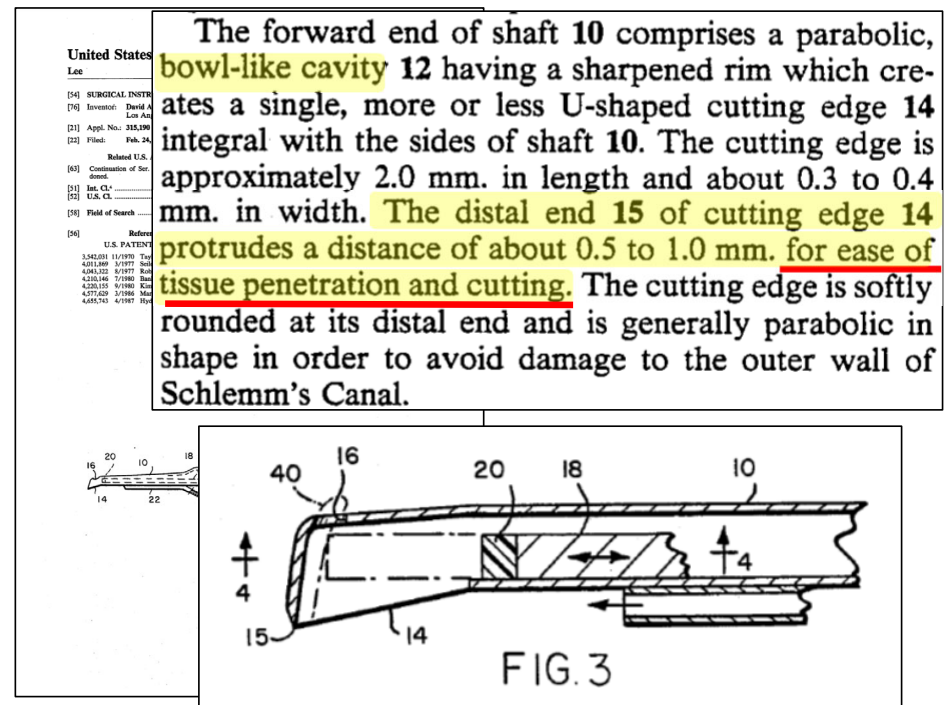
IPR2020-01573, Paper 29, 29; *see also* IPR2020-01711, Paper 17, 30; IPR2021-00017, Paper 17, 28; IPR2021-00065, Paper 18, 25-26.

# Obvious to Modify Jacobi So TM Passes Over “Protector Member” Before Contacting the “Knife Blades” (‘905, cl.1)



Ex.1007, Fig.1; see IPR2020-01573, Paper 1, 75-85; IPR2020-01711, Paper 1, 75-98; IPR2021-00017, Paper 1, 58-67; IPR2021-00065, Paper 1, 53-69; IPR2021-00066, Paper 1, 66-74.

Ex.1046, p. 84 of 98



IPR2021-00065, Ex.1006, 4:38-48, Fig.3 (see Paper 1, 61-62).

Petitioner New World Medical, Inc., IPR Nos. 2020-01573, 2020-01711, 2021-00017, 2021-00065, 2021-00066  
 DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

84

# Jacobi Discloses a “Bend or Curve” (‘729, cl.1 / ‘155, cl.1)

302 *British Journal of Ophthalmology* 1997;81:302-307

Technique of gonioscurettage: a potential treatment for advanced chronic open angle glaucoma

Philipp C Jacobi, Thomas S Dietlein, Günter K Kriegstein

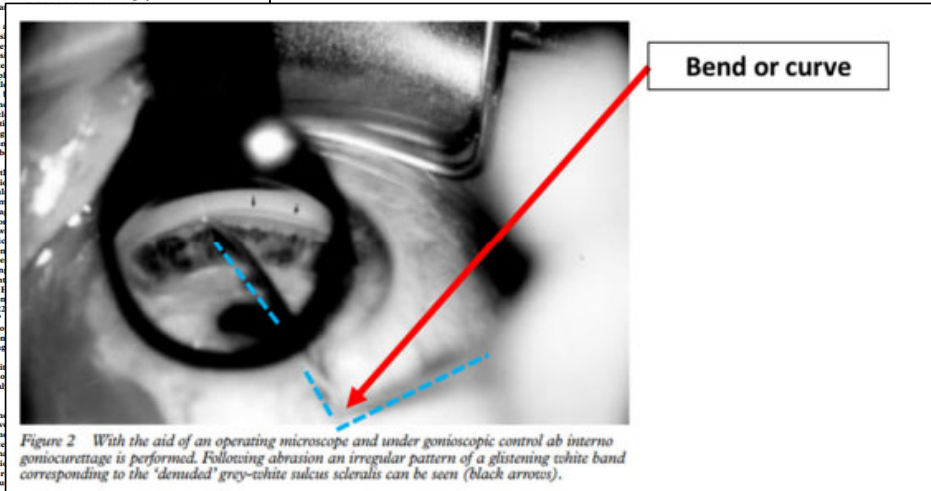
**Abstract**—To introduce a new concept of anterior chamber angle microsurgery, designed to scrape pathologically altered trabecular meshwork from the scleral sulcus as a potential treatment in primary open angle glaucoma.

**Methods**—Gonioscopically controlled ab interno abrasion of the trabecular meshwork was performed on six human enucleating eyes for morphological analysis. Thereafter, four eyes suffering from incipient glaucomatous optic nerve atrophy as a result of medically uncontrolled intraocular pressure were also treated with gonioscurettage. The newly designed instrument resembles a modified cyclodialysis spatula with a boat-shaped tip 80 µm in diameter, and with its edge sharpened. The treatment zone comprised 4–5 clock hours of the chamber angle circumference.

**Results**—Microscopic examination of the treatment zone revealed that in addition to a complete disruption of the trabecular meshwork and internal wall of Schlemm's canal gonioscurettage also caused damage to intracommissural septa. A splitting of the posterior wall of Schlemm's canal was also noted in one specimen. The clinical data of gonioscurettage also showed some promising results. Mean pretreatment IOP averaged 46.7 (SD 8.5) mm Hg (range 32–51 mm Hg) and was significantly ( $p < 0.001$ ) reduced to 38.8 (4.2) mm Hg (32–42 mm Hg) after 6 months, representing an absolute decrease in IOP of 7.9 mm Hg and a mean decrease in IOP of 56%. Clinically significant hyphaema occurred in one eye, caused by intraoperative trauma to a prominent chamber angle vessel. In three eyes a minor reflex blood occurred at the treatment site. However, no hypotony, choroidal effusion, flattened anterior chamber, or cyclodialysis were observed in these patients.

**Conclusion**—Morphological analysis of treated postmortem eyes confirms that gonioscurettage completely removes the trabecular meshwork and opens Schlemm's canal, ensuring direct access into the anterior chamber. In a small number of patients over a limited period of time this new surgical procedure resulted in a clinically significant pressure reduction. However, longer term follow up and a greater number of patients are warranted before this experimental procedure is applicable to eyes that would do well with conventional surgery.

was designed. The ‘gonioscraper’ consists of a small handle and a slightly convex-shaped arm for intraocular use and very much resembles a cyclodialysis spatula. However, the tip of the instrument is shaped as a tiny bowl with 300 µm diameter and with its edges sharpened (Fig 1). In order to abrade clockwise and anticlockwise the scoop is angulated vertically at 90 degrees to the left and right, respectively.



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 Accepted for publication 11 December 1996

Petitioner - New World Medical  
 Ex. 1007, p. 1 of 6

Ex.1007, 2, Fig.2; see IPR2020-01573, Paper 1, 79-86; IPR2020-01711, Paper 1, 81-85; IPR2021-00017, Paper 1, 61-62; IPR2021-00065, Paper 1, 56-57; IPR2021-00066, Paper 1, 71-76.

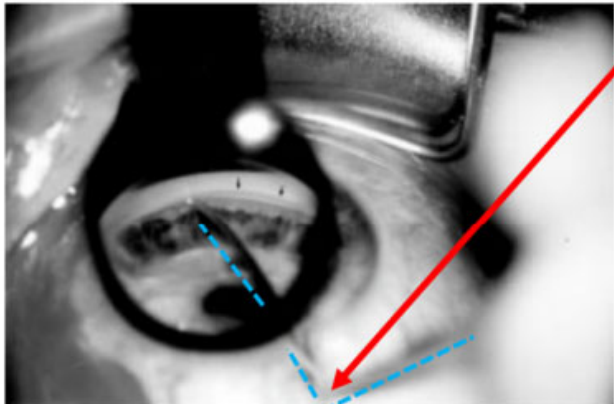
# Other Images of Jacobi's Gonioscraper Include the Bend

302 *British Journal of Ophthalmology* 1997;81:302-307

**Technique of gonioscurettage: a potential treatment for advanced chronic open angle glaucoma**

Philipp C Jacobi, Thomas S Dietlein, Günter K Krieglstein

**Abstract**  
**Aim**—To introduce a new concept of anterior chamber angle microsurgery, designed to scrape pathologically altered trabecular meshwork from the scleral sulcus reduction. However, longer term follow up and a greater number of patients are warranted before this experimental procedure is applicable to eyes that would do well with conventional surgery.



Bend or curve

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

Petitioner - New World Medical  
Ex. 1007, p. 1 of 6

Ex.1007, Fig.2; see IPR2020-01573, Paper 1, 79-86; IPR2020-01711, Paper 1, 81-85; IPR2021-00017, Paper 1, 61-62; IPR2021-00065, Paper 1, 56-57; IPR2021-00066, Paper 1, 71-76.

302 *British Journal of Ophthalmology* 1997;81:302-307

**Technique of gonioscurettage: a potential**

Bend or curve (1)

Bend or curve (2)

Bend or curve (3)

**mm Hg and a mean decrease in IOP of 56%. Clinically significant hyphaema occurred in one eye, caused by iatrogenic trauma to a prominent chamber angle vessel. In three eyes a minor reflux of blood occurred at the treatment site. However, no hypotony, choroidal effusion, flattened anterior chamber, or cyclodialysis were observed in these patients.**

**Conclusion**—Morphological analysis of treated postmortem eyes confirmed that gonioscurettage completely removed the trabecular meshwork and opened Schlemm's canal, ensuring direct access into the anterior chamber. In a small number of patients over a limited period of time this new surgical procedure resulted in a clinically significant pressure

Based on transmission and scanning electron microscopy of trabeculotomy specimens various authors have suggested that in most cases of chronic open angle glaucoma the primary increase of outflow resistance lies in the cribriform layer of the trabecular meshwork adjacent to the inner wall endothelium of Schlemm's canal.<sup>1-3</sup> Presuming that the outer layers of the trabecular meshwork play the key role in the pathology of primary open angle glaucoma, incisional surgery (goniotomy) or mechanical disruption (trabeculotomy) of the trabecular meshwork could then be a valid surgical approach to medically uncontrolled open angle glaucoma. Unfortunately, simple disruption of the trabecular meshwork with the trabeculotomy approach or punching small holes with the Q switched Nd:YAG laser

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 Accepted for publication 11 December 1996.

Petitioner - New World Medical  
Ex. 1007, p. 1 of 6

Petitioner New World Medical, Inc., IPR Nos. 2020-01573, 85; IPR2021-00017, Paper 1, 85, 80-84; IPR2021-00066, Paper 1, 75-76.

2020-01711, 2021-00017, 2021-00065, 2021-00066

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

# Dr. Condon Admitted Jacobi Has A Bend

11 A. So in a cyclodialysis spatula, the **convex**  
 12 **bend** starts at the part of the instrument that's  
 13 outside the eye and then **extends in a gentle curve,**  
 14 **and there is a picture of that curve in Jacobi 2000,**  
 15 I believe.  
 16 Q. Ah. Okay.  
 17 A. So just to cut to the quick on it, that's  
 18 the curve that is a convex curve.

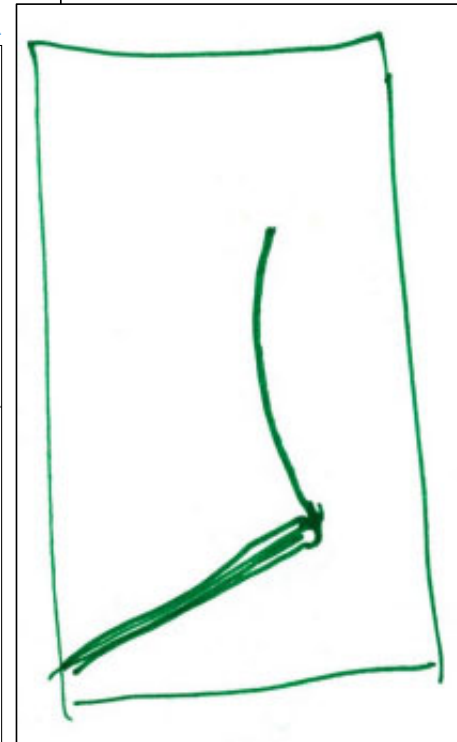
16 A. It's fine. So -- (indicating.) So --  
 17 Q. Okay. That's the handle?  
 18 A. **There is the curved bend.**  
 19 Q. So the curved -- the curved bend, some  
 20 portion of this will enter the eye and this handle  
 21 out here is outside the eye?

1 A. Yes.

Ex.1041, 189:11-191:1; see IPR2020-01573, Paper 35, 25; IPR2020-01711, Paper 27, 24.

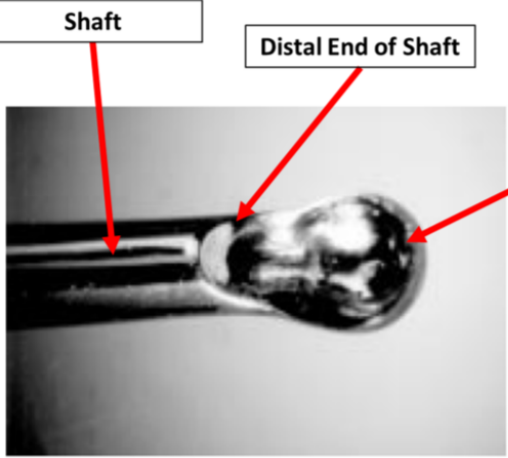
8/17/2021 New World Medical, Inc. v. MicroSurgical Technology, Inc. Garry Condon, M.D.

Page 1	Page 3
UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD	I N D E X
New World Medical, Inc., Petitioner	Volume 1
MicroSurgical Technology, Inc., Patent Owner	Tuesday, August 17, 2021
Case Nos. IPR2020-01573; IPR2020-01711; IPR2021-00017; IPR2021-00065; IPR2021-00066	WITNESS PAGE
U.S. Patent Nos. 9,107,729; 9,328,155; 9,820,885; 10,123,905; 9,999,544	Called by the Petitioner:
VIDEOTAPED DEPOSITION OF GARRY CONDON, M.D. Volume 1	EXAMINATION BY MR. TUCKER..... 7
DATE TAKEN: Tuesday, August 17, 2021	EXHIBITS
TIME: 9:04 a.m. - 4:13 p.m.	(Attached to transcript)
Eastern Daylight Time	GARRY CONDON, M.D. DEPOSITION EXHIBITS PAGE
PLACE: Embassy Suites by Hilton Sarasota	Condon Exhibit 1 Petitioner's Notice of Deposition of Garry P. Condon, M.D. 9
202 North Tamiami Trail Sarasota, Florida 34236	Condon Exhibit 2 Declaration of Garry P. Condon, M.D., in Support of Patent Owner's Response U.S. Patent No. 9,107,729 Patent Owner Exhibit 2019-0001 through 171 11
Examination of the witness taken before: SUSAN D. WASILEWSKI, RPR, CRR, CMRS, CRC, FPR - Realtime Systems Administrator -	Condon Exhibit 3 United States Patent No. US 9,107,729 R2 14
DIGITAL EVIDENCE GROUP 1750 M Street, NW, Suite 812 Washington, D.C. 20036 (202) 232-0646	Condon Exhibit 4 Gonioscopic Tuberculosis, 22 First Results Manual Quinitas Petitioner New World Medical Exhibit 1004, Page 1 through 9 Condon Exhibit 5 Amendment Accompanying Notice of Appeal 35 Application No. 13/159,356
Page 2	Page 4
APPEARANCES	EXHIBITS, CONT
Counsel for Petitioner, New World Medical, Inc.: CALFEY, HALTER & GRESHOLD LLP BY: TODD R. TUCKER, ESQUIRE tucker@calfe.com 1405 Calfee Building Cleveland, Ohio 44114 Phone: (216) 622-8200	(Attached to transcript) GARRY CONDON, M.D. DEPOSITION EXHIBITS PAGE Condon Exhibit 6 Black's Medical Dictionary - 71 Page 59, "Sector" Patent Owner Exhibit 2023-0001 through 3
NEW WORLD MEDICAL BY: DAVID KLANN, ESQUIRE d.klann@newworldmedical.com 10763 Edison Court Rancho Cucamonga, California 91730 Phone: (800) 832-5327	Condon Exhibit 7 DeLia's Medical Dictionary 78 - Page 605, "Sector" Patent Owner Exhibit 2022-0001 through 8 Condon Exhibit 8 Clinical Research - 88 Symposium: Microsurgery of the Outflow Channels Bernard Becker, MD, et al.
Counsel for Patent Owner, MicroSurgical Technology, Inc.: WILEY REIN LLP BY: TERESA SIMMERS, ESQUIRE tsimmers@wileylaw.com LAWRENCE M. SUNG, PH.D., ESQUIRE lsung@wileylaw.com 1776 K Street NW Washington, DC 20006 Phone: (202) 719-4181	Condon Exhibit 9 Histologic Evaluation of Microsurgical Glaucoma Techniques Symposium: Microsurgery of the Outflow Channels William H. Spencer, MD Condon Exhibit 10 Declaration of Garry P. Condon, M.D., in Support of Patent Owner's Response Case IPR2020-01711, U.S. Patent No. 9,358,155 Patent Owner Exhibit 2019-0001 through 169
Also Present: LAKUANA PRUITT, Videographer	Condon Exhibit 11 Declaration of Garry P. Condon, M.D., in Support of Patent Owner's Response Case IPR2021-00066 U.S. Patent No. 9,999,544 Patent Owner Exhibit 2019-0001 through 145



Ex.1043, 824; see IPR2020-01573, Paper 35, 25; IPR2020-01711, Paper 27, 24.

# Jacobi Discloses a “Blunt Protruding Tip” and a “Blunt Top Edge” (“155, cl.1)



**Shaft**

**Distal End of Shaft**

**Blunt Protruding Tip**

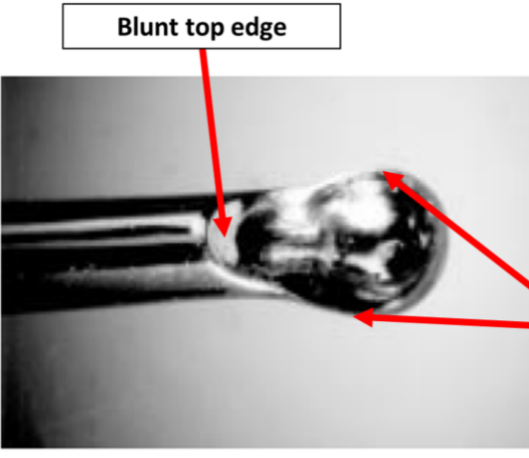
302 British Journal of Ophthalmology 1997;81:302-307

**Technique of gonioscurettage: a potential treatment for advanced chronic open angle glaucoma**

Philipp C. Jacobi, Thomas S. Dietlein, Günter K. Kr.

**Abstract**  
*Aim*—To introduce a new concept of anterior chamber angle microsurgery, designed to scrape pathologically altered trabecular meshwork from the scleral sulcus as a potential treatment in primary open angle glaucoma.  
*Methods*—Gonioscopically controlled ab interno abrasion of the trabecular meshwork was performed on six human eye banking eyes for morphological analysis. Thereafter, four eyes suffering from terminal glaucomatous optic nerve atrophy as a result of medically uncontrolled intraocular pressure were also treated by 'gonioscurettage'. The newly designed instrument resembles a modified cyclo-diastis spatula with a bowl-shaped tip 300 µm in diameter, and with its edges sharpened. The treatment zone comprised 4–5 clock hours of the chamber angle circumference.  
*Results*—Microscopic examination of the treatment zone revealed that in addition to a complete disruption of the trabecular meshwork and internal wall of Schlemm's canal gonioscurettage also caused damage to intracanalicular septa. A splitting along the posterior wall of Schlemm's canal was also noted in one specimen. The clinical data of gonioscurettage also showed some promising results. Mean pretreatment IOP averaged 46.7 (SD 8.5) mm Hg (range 32–51 mm Hg) and was significantly ( $p<0.04$ ) reduced to 18.0 (4.2) mm Hg (1.2–22 mm Hg) after 6 months, representing an absolute decrease in IOP of 22.7 mm Hg and a mean decrease in IOP of 56%. Clinically significant hyphaema occurred in one eye, caused by iatrogenic trauma to a prominent chamber angle vessel. In three eyes a minor reflux of blood occurred at the treatment site. However, no hypotony, choroidal effusion, flattened anterior chamber, or cyclodialysis were observed in these patients.  
*Conclusion*—Morphological analysis of treated postmortem eyes confirmed that gonioscurettage completely removed the trabecular meshwork and opened Schlemm's canal, ensuring direct access into the anterior chamber. In a small number of patients over a limited period of time this new surgical procedure resulted in a clinically significant pressure reduction.

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 Accepted for publication 11 December 1996.



**Blunt top edge**

**First and second lateral cutting edges**

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

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

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 0168-5539/97/8103-0302\$05.00/0  
 DOI: 10.1054/bjoo.1997.8103.302

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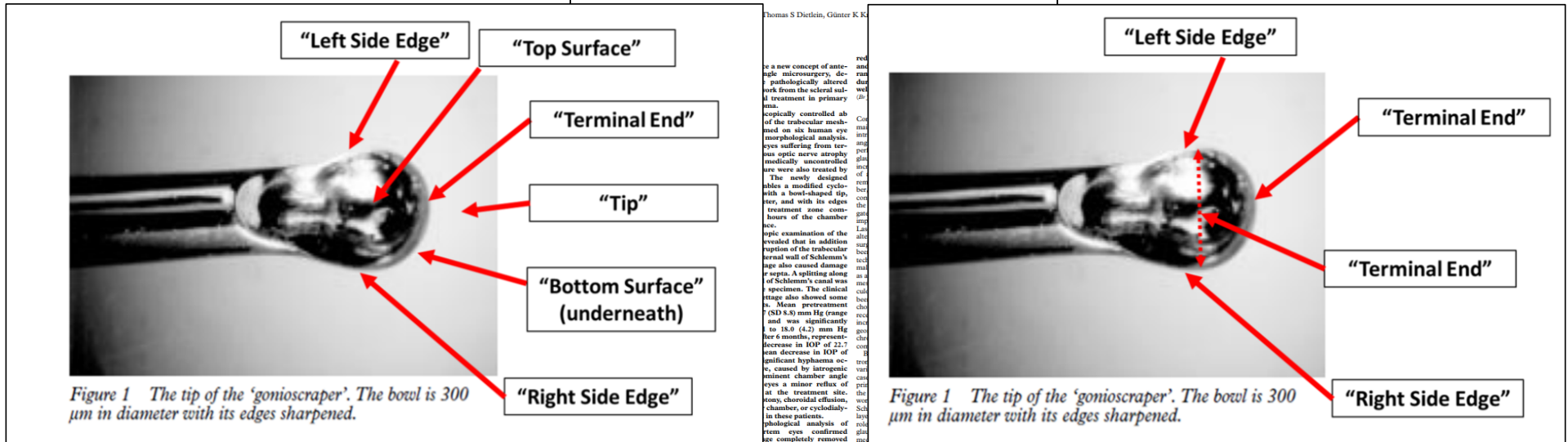
IPR2020-01711, Ex.1007, Fig.1 (see Paper 1, 83).

IPR2020-01711, Ex.1007, (see Paper 1, 91).



# Jacobi Discloses a “Platform” as Claimed (‘885, cl.1)

302  
 British Journal of Ophthalmology 1997;81:302-307  
 Technique of gonioscurettage: a potential treatment for advanced chronic open angle glaucoma



Thomas S Dietlein, Günter K K...  
 is a new concept of ante-  
 angle microsurgery, de-  
 pathologically altered  
 work from the scleral sul-  
 treatment in primary  
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 scopically controlled ab-  
 of the trabecular mesh-  
 on six human eye  
 morphological analysis,  
 eyes suffering from ter-  
 sus optic nerve atrophy  
 medically uncontrolled  
 ure were also treated by  
 The newly designed  
 sibles a modified cyclot-  
 with a bowl-shaped tip,  
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 revealed that in addition  
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 lernal wall of Schlemm's  
 age also caused damage  
 r septa. A splitting along  
 of Schlemm's canal was  
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 Mean pretreatment  
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 to 18.0 (4.2) mm Hg  
 her 6 months, represent-  
 increase in IOP of 22.7  
 lean decrease in IOP of  
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 ce, caused by iatrogenic  
 nherent chamber angle  
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 stony, choroidal effusion,  
 chamber, or cyclodialysis  
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 phological analysis of  
 tem eyes confirmed  
 be completely removed  
 the trabecular meshwork and opened  
 Schlemm's canal, ensuring direct access  
 into the anterior chamber. In a small  
 number of patients over a limited period  
 of time this new surgical procedure re-  
 sulted in a clinically significant pressure

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 11 December 1996  
 the trabecular meshwork could then be a valid sur-  
 gical approach to medically uncontrolled open  
 angle glaucoma. Unfortunately, simple disrupt-  
 ion of the trabecular meshwork with the  
 trabeculotomy approach or punching small  
 holes with the Q-switched Nd:YAG laser  
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IPR2021-00017, Ex.1007, Fig.1 (see Paper 1, 64).

IPR2021-00017, Ex.1007, Fig.1 (see Paper 1, 65).

# Jacobi Discloses a “Protector Member” (‘905, cl.1) and a “Foot Member” (‘544, cl.1)

the opposite side. In order to peel off trabecular meshwork the ‘scraper’ was lightly passed over 2–3 clock hours to either side at the nasal circumference of the anterior chamber angle in sweeping movements (Fig 2). **Great care was taken to selectively pare uveal meshwork and not to traumatise adjacent intraocular structures,** such as the corneal endothelium or the base of the iris. Gonioscopically, strings of

Ex.1007, 2; see IPR2021-00065, Paper 1, 57; IPR2021-00066, Paper 1, 83.

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33–51 mm Hg) and was significantly (p<0.04) reduced to 18.0 (4.2) mm Hg (13–22 mm Hg) after 6 months, representing an absolute decrease in IOP of 22.7 mm Hg and a mean decrease in IOP of 56%. Clinically significant hyphaema occurred in one eye, caused by iatrogenic trauma to a prominent chamber angle vessel. In three eyes a minor reflux of blood occurred at the treatment site. However, no hypotony, choroidal effusion, flattened anterior chamber, or cyclodialysis were observed in these patients.

**Conclusion**—Morphological analysis of treated postmenstrual eyes confirmed that gonioscraze completely removed the trabecular meshwork and opened Schlemm’s canal, ensuring direct access into the anterior chamber. In a small number of patients over a limited period of time this new surgical procedure resulted in a clinically significant pressure

reduction. However, and a greater number of patients must be included before the procedure is applicable well with conventional (Dr J Ophthalmol 1997; 12: 100–102)

Conventional glaucoma surgery of surgically reducing intraocular pressure in angle glaucoma. However, despite increasing success rates, especially with the use of adjunct antimetabolites, several remain, such as hyphaema, flat anterior chamber, and variable wound healing. In order to minimise conjunctival manipulation, various techniques have been suggested that minimise conjunctival dissection and improve the success rate of filtration surgery. Laser sclerostomy has recently been recommended as an alternative to conventional glaucoma surgery. However, varying success has been reported using different laser techniques. Based on the conceptual choice in juvenile open angle glaucoma as a result of maldevelopment of the trabecular meshwork, goniotomy, ab externo, and trabeculopuncture have been recommended as surgical choices in juvenile open angle glaucoma. Based on transmission and scanning electron microscopy of trabeculotomy, various authors have suggested that primary increase of outflow resistance in the cribriform layer of the trabecular meshwork adjacent to the inner wall of Schlemm’s canal. Presuming the role of the trabecular meshwork in the pathology of primary glaucoma, incisional surgery (goniotomy) and mechanical disruption (trabeculotomy) of the trabecular meshwork could then be a logical approach to medically unresponsive angle glaucoma. Unfortunately, simultaneous removal of the trabecular meshwork and Schlemm’s canal by goniotomy or trabeculotomy approach or puncture with the Q switched Nd

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IPR2021-00065, Ex.1007, Fig.1 (see Paper 1, 58).

IPR2021-00066, Ex.1007, Fig.1 (see Paper 1, 73).

# Jacobi Discloses Creating a “Strip” of TM (‘729, cl.1 / ‘155, cl.1 / ‘885, cl.1 / ‘905, cl.1) and Creating an “Opening” in TM (‘544, cl.1)

302 *British Journal of Ophthalmology*

Technique of gonioscurettage: a potential treatment for advanced chronic open angle glaucoma

Philipp C Jacobi, Thomas S Dietlein, Günter K Kriegstein

**Abstract**—To introduce a new concept of anterior chamber angle microsurgery, designed to scrape pathologically altered trabecular meshwork from the scleral sulcus as a potential treatment in primary open angle glaucoma.

**Methods**—Gonioscopically controlled anterior abrasion of the trabecular meshwork was performed on six human eye banking eyes for morphological analysis. Thereafter, four eyes suffering from terminal glaucomatous optic nerve atrophy as a result of medically uncontrolled intraocular pressure were also treated by ‘gonioscurettage’. The newly designed instrument resembles a modified cyclo-diastasis spatula with a hook-shaped tip, 300 µm in diameter, and with its edges sharpened. The treatment zone comprised 4–5 clock hours of the chamber angle circumference.

**Results**—Microscopic examination of the treatment zone revealed that in addition to a complete disruption of the trabecular meshwork and internal wall of Schlemm’s canal gonioscurettage also caused damage to intertrabecular septa. A splitting along the posterior wall of Schlemm’s canal was also noted in one specimen. The clinical data of gonioscurettage also showed some promising results. Mean pre-treatment IOP averaged 40.7 (SD 8.8) mm Hg (range 35–51 mm Hg) and was significantly (p<0.05) reduced to 33.0 (4.2) mm Hg (15–52 mm Hg) after 6 months, representing an absolute decrease in IOP of 22.7 mm Hg and a mean decrease in IOP of 50%. Clinically significant hypohemias occurred in one eye, caused by iatrogenic trauma to a prominent chamber angle vessel. In three eyes a minor reflex of blood occurred at the treatment site. However, no hypotony, choroidal effusion, flattened anterior chamber, or cyclodialysis were observed in these patients.

**Conclusion**—Morphological analysis of treated post-mortem eyes confirmed that gonioscurettage completely removed the trabecular meshwork and opened Schlemm’s canal, ensuring direct access into the anterior chamber. In a small number of patients over a limited period of time this new surgical procedure resulted in a clinically significant pressure reduction. However, long and a greater number of treated before this exposure is applicable to eyes well with conventional surgery.

Conventional glaucoma filtering surgery is the mainstay of surgical treatment to control intraocular pressure (IOP) in primary open angle glaucoma.<sup>1</sup> There is a growing trend to perform surgery earlier in the course of glaucoma management.<sup>2</sup> However, despite increasing success rates, especially with the use of adjunct antimetabolites, several problems remain, such as hypotonia, flat anterior chamber, and variable wound healing response to conjunctival manipulation. In order to avoid the latter, various techniques have been investigated that minimise conjunctival dissection to improve the success rate. Laser sclerostomy has been recommended as an alternative to conventional surgery.<sup>3</sup> However, varying results have been reported using different techniques.<sup>4–7</sup> Based on its minimal resistance to outflow as a result of maldevelopment of the trabecular meshwork,<sup>8</sup> goniotomy,<sup>9</sup> and trabeculectomy have been recommended as a first choice in juvenile open angle glaucoma, trabeculectomy increasing interest among ophthalmologists as a first choice in chronic open angle glaucoma and combined glaucoma and cataract surgery.

Based on transmission electron microscopy of rat eyes various authors have suggested that a primary increase of outflow resistance in the trabecular meshwork adjacent to the inner wall of Schlemm’s canal may be a pathogenic mechanism in the pathogenesis of glaucoma, instead of mechanical disruption (or tearing) of the trabecular meshwork and subsequent approach to medical treatment of glaucoma. Interruption of the trabecular meshwork by a trabeculectomy approach holds with the Q value

the opposite side. In order to peel off trabecular meshwork the ‘scraper’ was lightly passed over 2–3 clock hours to either side at the nasal circumference of the anterior chamber angle in sweeping movements (Fig 2). Great care was

base of the iris. Gonioscopically, strings of trabecular tissue could be observed intraoperatively to be removed by gonioscurettage, leaving a ‘denuded’ grey-white scleral sulcus. At the end of surgery the viscoelastic along with abraded trabecular debris were removed by means of an irrigation-aspiration probe.

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due to glaucoma absolutum. The aim of the surgical procedure was to abrade rather than incise uveal meshwork; this novel method, therefore, is termed gonioscurettage. A descrip-

Ex. 1007, 1-2; see IPR2020-01573, Paper 1, 74-88; IPR2020-01711, Paper 1, 75-97; IPR2021-00017, Paper 1, 58-72; IPR2021-00065, Paper 1, 53-64; IPR2021-00066, Paper 1, 68-78.

Petitioner New World Medical, Inc., IPR Nos. 2020-01573, 2020-01711, 2021-00017, 2021-00065, 2021-00066  
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

# Petitioner Has Shown By Preponderance of the Evidence That the Challenged Claims of the '729, '155, '885, 905, and '544 Patents Are Unpatentable

Petitioner's Evidence	Patent Owner's Evidence
<ul style="list-style-type: none"><li>• Quintana ✓</li></ul>	<ul style="list-style-type: none"><li>• <del>Quintana's Affidavit</del></li></ul>
<ul style="list-style-type: none"><li>• Jacobi ✓</li></ul>	
<ul style="list-style-type: none"><li>• Dr. Netland ✓</li></ul>	<ul style="list-style-type: none"><li>• Dr. Condon ?</li></ul>
<ul style="list-style-type: none"><li>• Testing ✓</li></ul>	

# Claim Appendix

# '729 Patent, Claim 1

[1.p] An ab interno method for forming an opening in trabecular meshwork 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 Schlemm's Canal and the first and second cutting edges are contacting the trabecular meshwork; and, thereafter

[1.e] causing the distal protruding tip to advance through a sector of Schlemm's Canal with the first and second cutting edges concurrently cutting, from the trabecular meshwork, 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.

# '155 Patent, Claim 1

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

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

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

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

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

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

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

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

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

[1.i] the blunt protruding tip being further sized to fit within Schlemm's Canal of the human eye and, when so positioned, to be advanceable through Schlemm's Canal with trabecular meshwork tissue passing over its top surface and into contact with the first and second lateral cutting edges.

# '885 Patent, Claim 1

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

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

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

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

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

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

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

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

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



# '905 Patent, Claim 1

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

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

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

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

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

# '544 Patent, Claim 1

[1.p] A device useable to create an opening in the trabecular meshwork of the eye comprising:

[1.a] an elongate surgical instrument comprising a probe shaft having a distal end and a longitudinal axis; and

[1.b] a foot member which comprises a platform on the distal end of the probe shaft, said platform having a tip, an upper side, a lower side and being set at an angle relative to the longitudinal axis of the probe shaft;

[1.c] wherein the foot member is insertable, tip first, from a position within the anterior chamber, through the trabecular meshwork, and into Schlemm's Canal such that the lower side is next to the scleral wall of Schlemm's Canal and the upper side is next to the trabecular meshwork; and

[1.d] wherein, after being so inserted in Schlemm's Canal, the foot member is then advancable, tip first, through Schlemm's Canal to facilitate performance of a surgical procedure using the surgical instrument.