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

NEW WORLD MEDICAL
Humanity's Vision Is Our Focus

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	

Quintana Discloses All Elements

GONIOSCOPIC TRABECULOTOMY. FIRST RESULTS

MANUEL QUINTANA
(Barcelona, Spain)

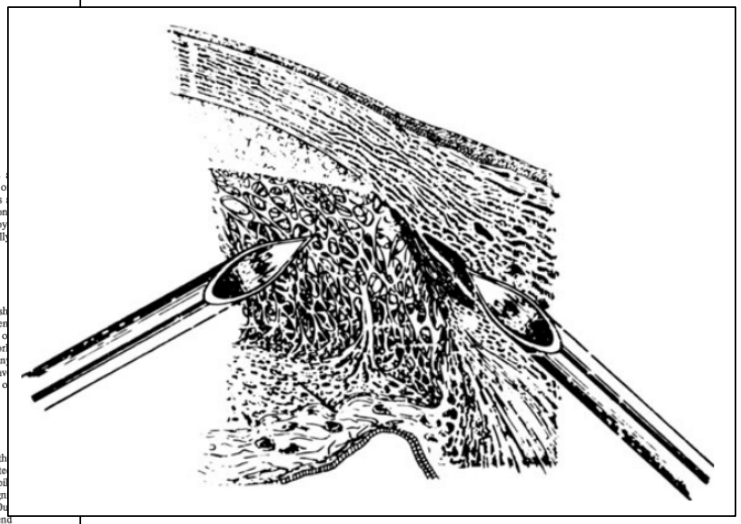
ABSTRACT

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 reinstituted, achieves a better control than before the operation and usually can be less intense.

A technique of trabeculotomy has been devised, which eliminates most of th presumed causes of failure of previous methods. The patient is operate under general anaesthesia; both eyes can be done at the same time. Pupi should be miotic. A coaxial operating microscope is necessary, with magn fication of ×10. We favour the Swann lens for angle visualisation. O trabeculotome is a 0.4 × 15 mm needle, or an insuline-type needle; we bend the tip 20–30° with a needle-holder; a factory-made needle (Morie, 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

265

E.L. Greve, W. Leydhecker & C. Raitta (eds.), Second European Glaucoma Symposium, Helsinki 1984.

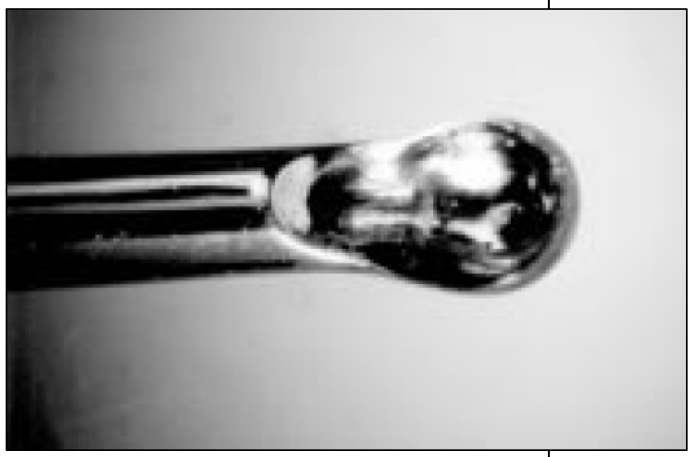


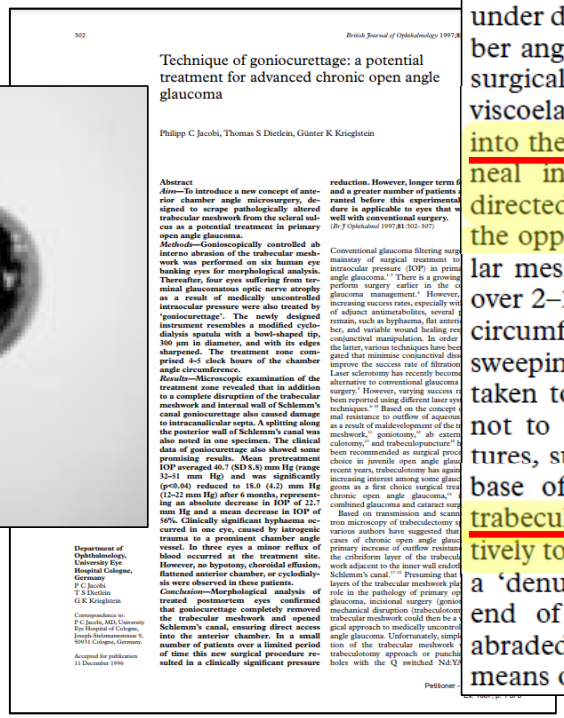
Ex.1004, 3-4; *see* IPR2020-01573, Paper 1, 27, 36; IPR2020-01711, Paper 1, 31, 42; IPR2021-00017, Paper 1, 27, 36; IPR2021-00065, Paper 1, 30, 39; IPR2021-00066, Paper 1, 27-29, 36.

Petitioner's Evidence v. Patent Owner's Evidence

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

Jacobi Discloses All Elements





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

Philipp C Jacobi, Thomas S Dietlein, Günter K Krieglstein

Abstract

***Aims*—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 'goniocurettage'. 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 4–5 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 goniocurettage 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 goniocurettage also showed some promising results. Mean pretreatment IOP averaged 40.7 (SD 8.8) mm Hg (range 32–51 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 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 goniocurettage 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 f and a greater number of patients ranted before this experimental dure is applicable to eyes that well with conventional surgery.**

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 goniocurettage, 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.

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).

STATES PATENT AND TRADEMARK OFFICE

THE PATENT TRIAL AND APPEAL BOARD

NEW WORLD MEDICAL, INC.,
Petitioner

v.

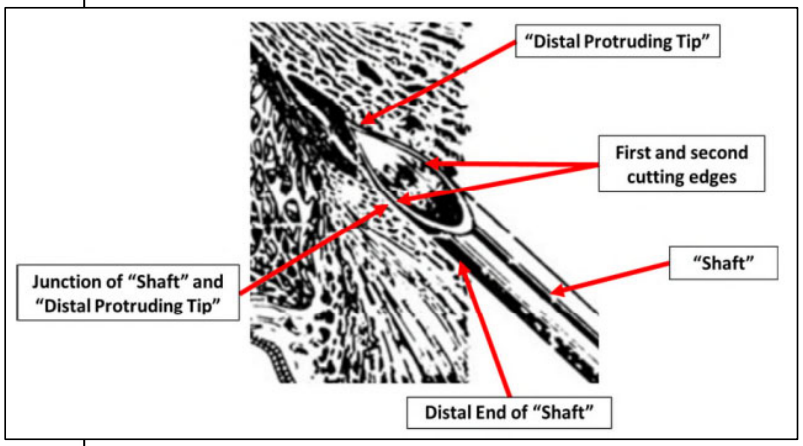
MICROSURGICAL TECH., INC.,
Patent Owner

R PARTES REVIEW OF U.S. PATENT NO. 9,107,729
Case No. IPR2020-01573

3 - DECLARATION OF DR. PETER NETLAND

4850-5633-1210, v.1

Petitioner - New World Medical
Ex. 1003, p. 1 of 269



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).

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 goniocurettage***, 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).

TENT AND TRADEMARK OFFICE

NT TRIAL AND APPEAL BOARD

ORLD MEDICAL, INC.,
Petitioner

v.

SURGICAL TECH., INC.,
Patent Owner

IEW OF U.S. PATENT NO. 9,107,729
e No. IPR2020-01573

ATION OF DR. PETER NETLAND

4850-5633-1210, v.1

Petitioner - New World Medical
Ex. 1003, p. 1 of 269

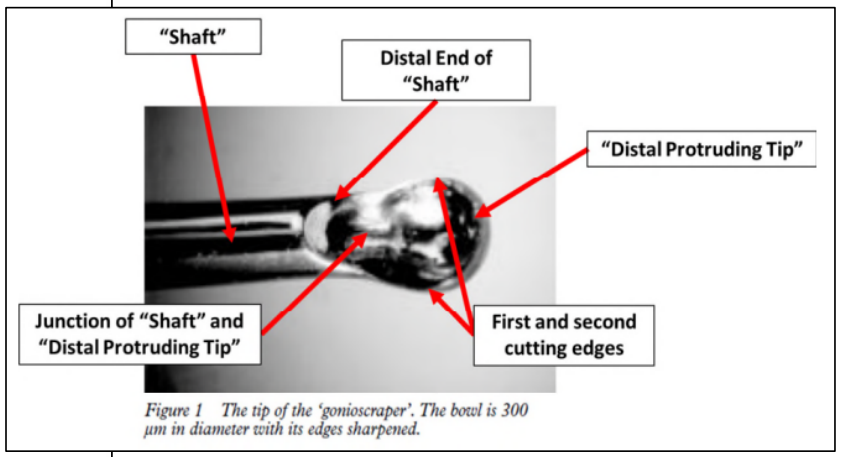


Figure 1 The tip of the 'gonioscraper'. The bowl is 300 μm in diameter with its edges sharpened.

IPR2020-01573 Ex.1003, ¶242, 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).

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

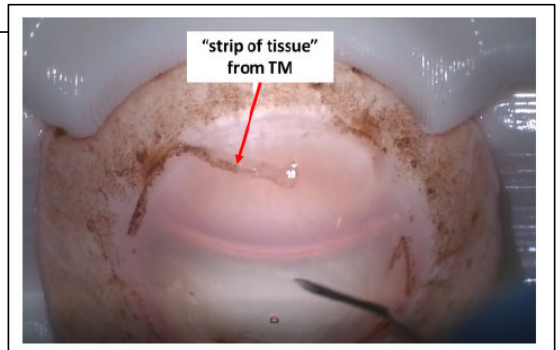


Figure 1

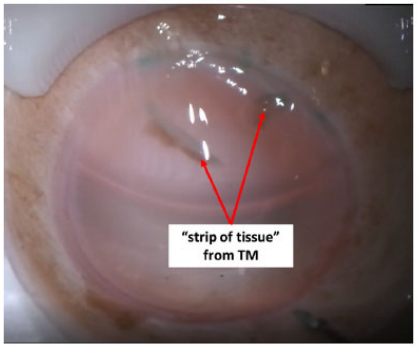


Figure 2

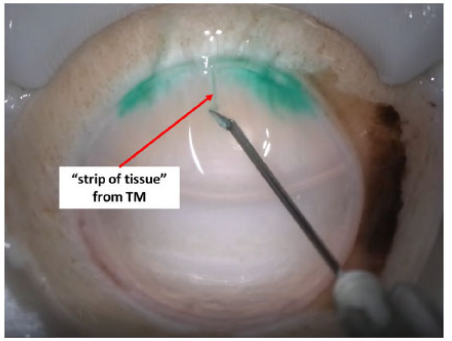


Figure 3

v.

MICROSURGICAL TECHNOLOGY, INC.,
Patent Owner

Case No. IPR2020-01573

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

REPLY DECLARATION OF DR. PETER NETLA

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

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.

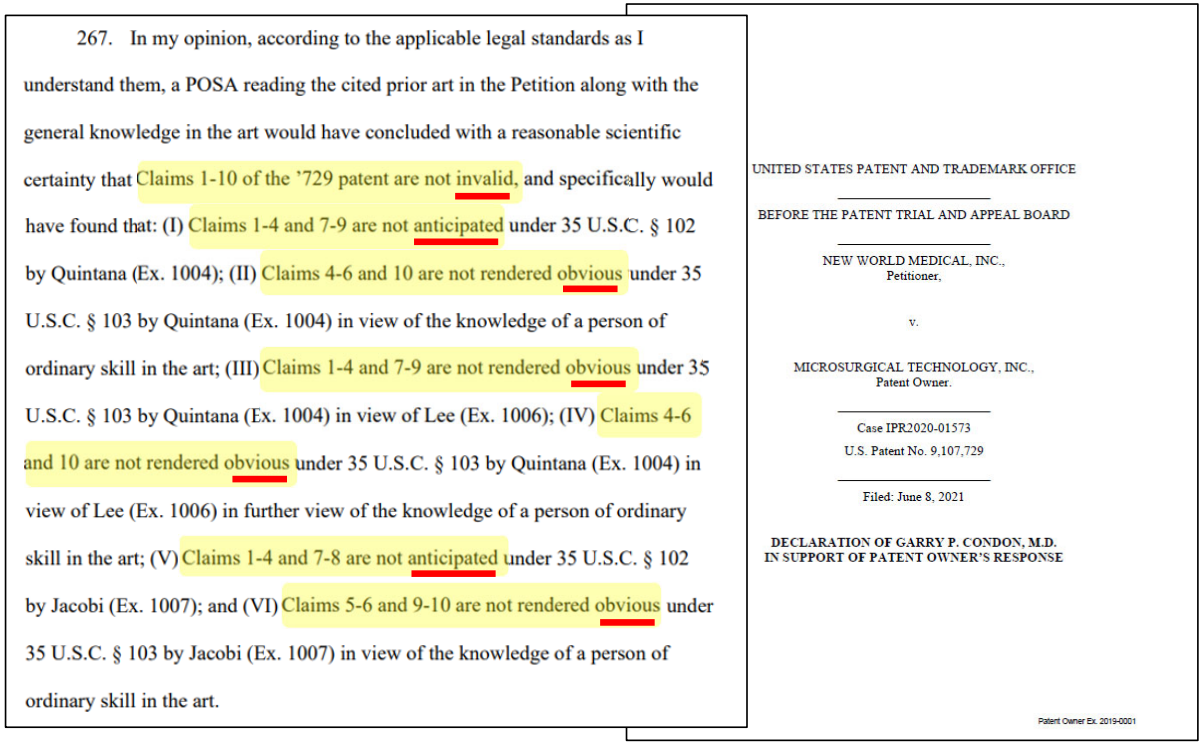
Petitioner's Evidence v. Patent Owner's Evidence

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 ✓	✗ • ~~Quintana's Affidavit~~
• 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

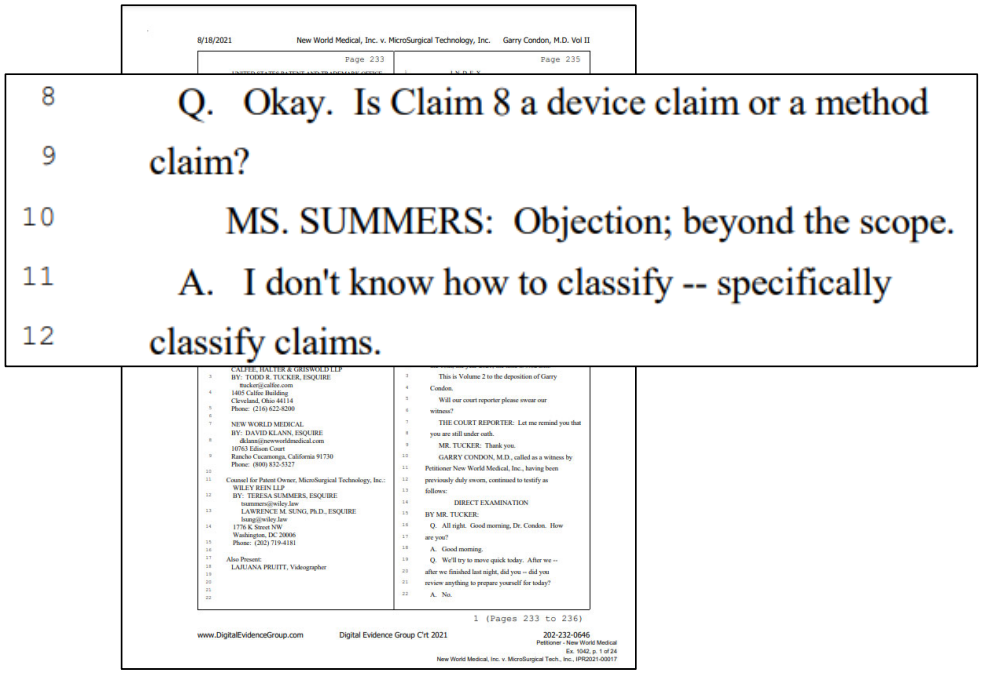
- Dr. Condon merely "**flipped through**" the '729 patent
  - Ex.1041, 176:2-4
- Dr. Condon "**didn't drill down into [] the requirements** of the '729 patent"
  - Ex.1041, 214:13-15
- Dr. Condon "**would not be comfortable** telling [NWM's counsel] what [is] required" in the patents at issue
  - Ex.1041, 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.

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

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



8/18/2021 New World Medical, Inc. v. MicroSurgical Technology, Inc. Garry Condon, M.D. Vol II

Page 233 Page 235

8 Q. Okay. Is Claim 8 a device claim or a method
9 claim?
10 MS. SUMMERS: Objection; beyond the scope.
11 A. I don't know how to classify -- specifically
12 classify claims.

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Also Present:
LAJUANA PRUITT, Videographer

This is Volume 2 to the deposition of Garry Condon.
Will our court reporter please swear our witness?
THE COURT REPORTER: Let me remind you that you are still under oath.
MR. TUCKER: Thank you.
GARRY CONDON, M.D., called as a witness by Petitioner New World Medical, Inc., having been previously duly sworn, continued to testify as follows:

DIRECT EXAMINATION

BY MR. TUCKER:
Q. All right. Good morning, Dr. Condon. How are you?
A. Good morning.
Q. We'll try to move quick today. After we -- after we finished last night, did you -- did you review anything to prepare yourself for today?
A. No.

1 (Pages 233 to 236)

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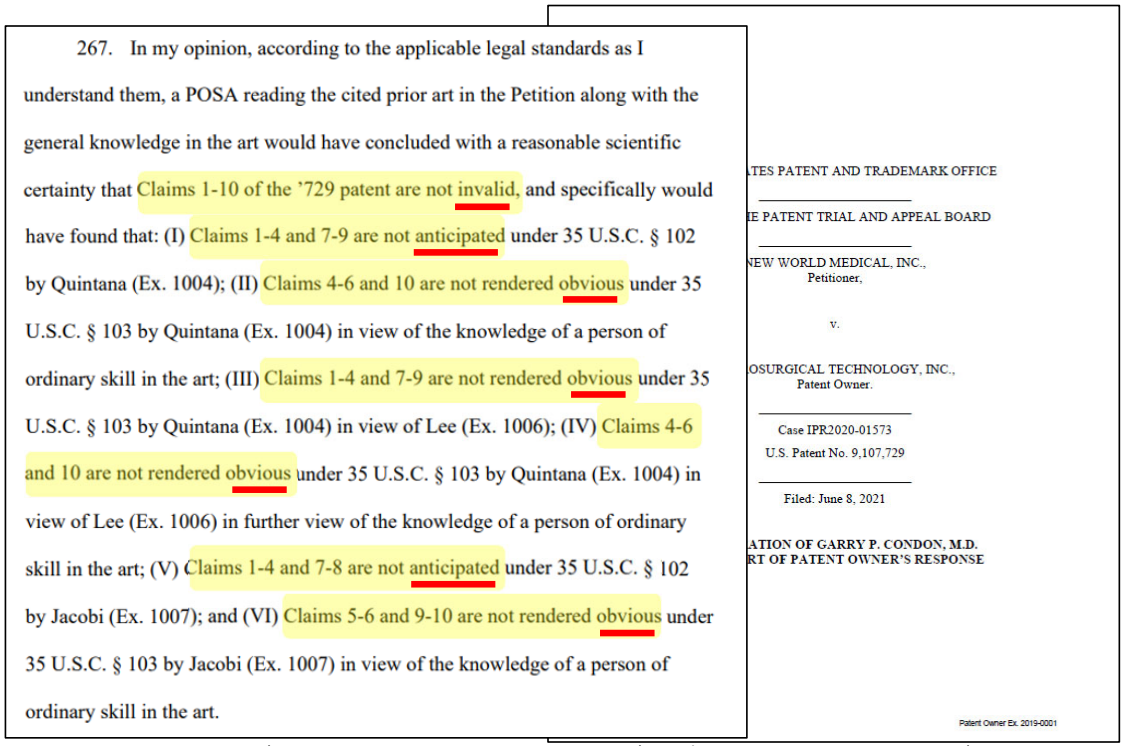
Petitioner - New World Medical
Ex. 1042, p. 1 of 24
New World Medical, Inc. v. MicroSurgical Tech., Inc., IPR2021-00017

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.

…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.

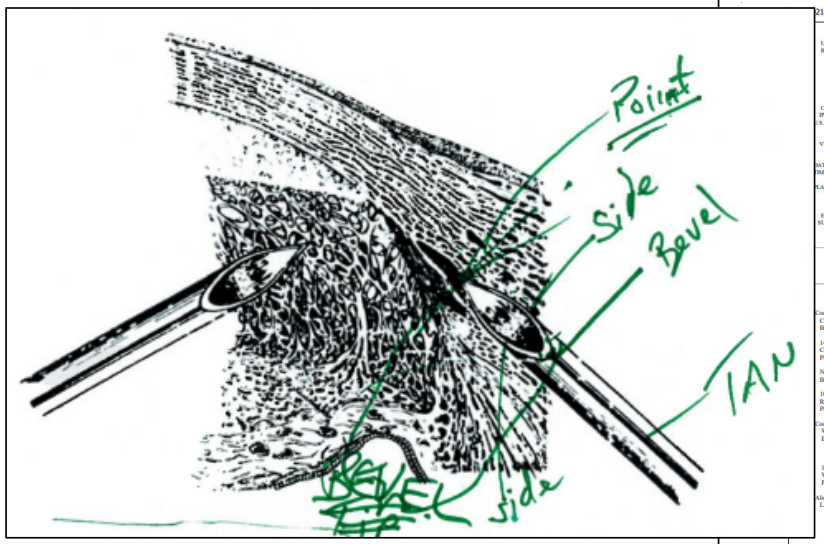


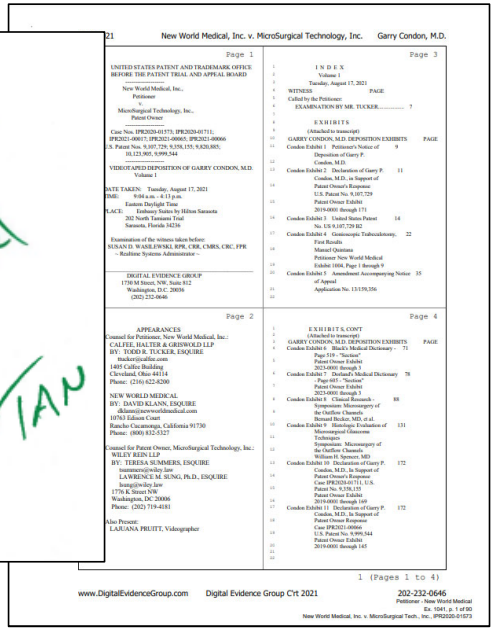
267. In my opinion, according to the applicable legal standards as I understand them, a POSA reading the cited prior art in the Petition along with the general knowledge in the art would have concluded with a reasonable scientific certainty that Claims 1-10 of the '729 patent are not invalid, and specifically 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.

…TES PATENT AND TRADEMARK OFFICE
…E PATENT TRIAL AND APPEAL BOARD
…NEW WORLD MEDICAL, INC.,
Petitioner,
v.
…OSURGICAL TECHNOLOGY, INC.,
Patent Owner.
Case IPR2020-01573
U.S. Patent No. 9,107,729
Filed: June 8, 2021
…ATION OF GARRY P. CONDON, M.D.
…RT 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).

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




21 New World Medical, Inc. v. MicroSurgical Technology, Inc. Garry Condon, M.D.

Page 1

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

VIDEOTAPED DEPOSITION OF GARRY CONDON, M.D.
Volume I

DATE TAKEN: Tuesday, August 17, 2021
TIME: 9:04 a.m. - 4:13 p.m.
Eastern Daylight Time
PLACE: Embassy Suites by Hilton Sarasota
202 North Tamiami Trail
Sarasota, Florida 34236

Examination of the witness taken before:
SUSAN D. WASIELEWSKI, RPR, CRR, CMRS, CRC, FPR
~ Realtime Systems Administrator ~

DIGITAL EVIDENCE GROUP
1730 M Street, NW, Suite 812
Washington, D.C. 20036
(202) 232-0646

Page 2

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I N D E X
Volume I
Tuesday, August 17, 2021

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EXHIBITS CONT
(Attached to transcript)

1 (Pages 1 to 4)

www.DigitalEvidenceGroup.com Digital Evidence Group C'rt 2021 202-232-0646

Petitioner - New World Medical
Ex. 1041, p. 1 of 90
New World Medical, Inc. v. MicroSurgical Tech., Inc., IPR2020-01573

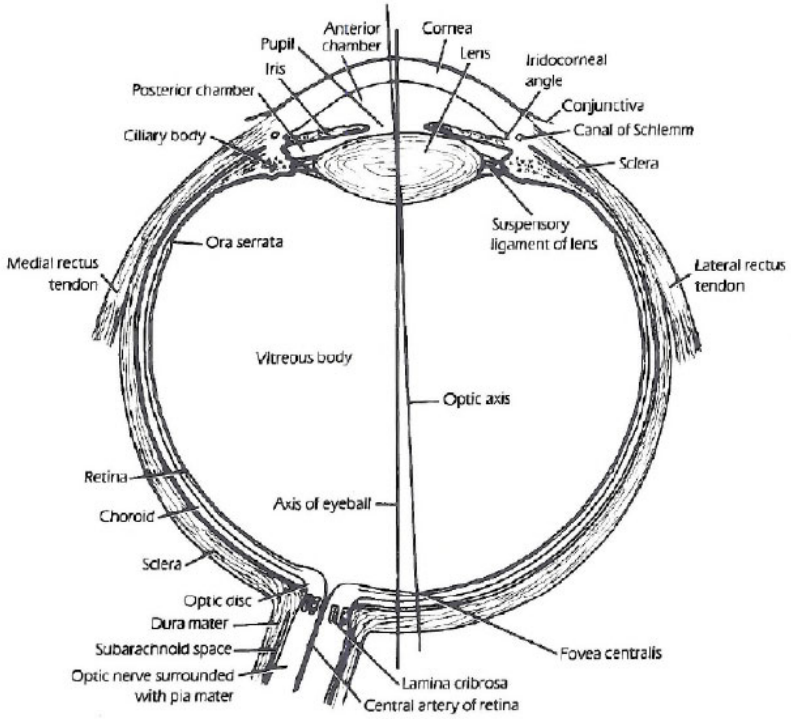
Ex.1043, 192; *see* IPR2020-01573, Paper 35, 17-18; IPR2020-01711, Paper 27, 15; IPR2021-00017, Paper 26, 16; IPR2021-00065, Paper 24, 16-17; IPR2021-00066, Paper 25, 18.

Petitioner's Evidence v. Patent Owner's Evidence

Petitioner's Evidence	Patent Owner's Evidence
• Quintana ✓	✗ • ~~Quintana's Affidavit~~
• Jacobi ✓	
• Dr. Netland ✓	? • Dr. Condon
• Testing ✓	

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.

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

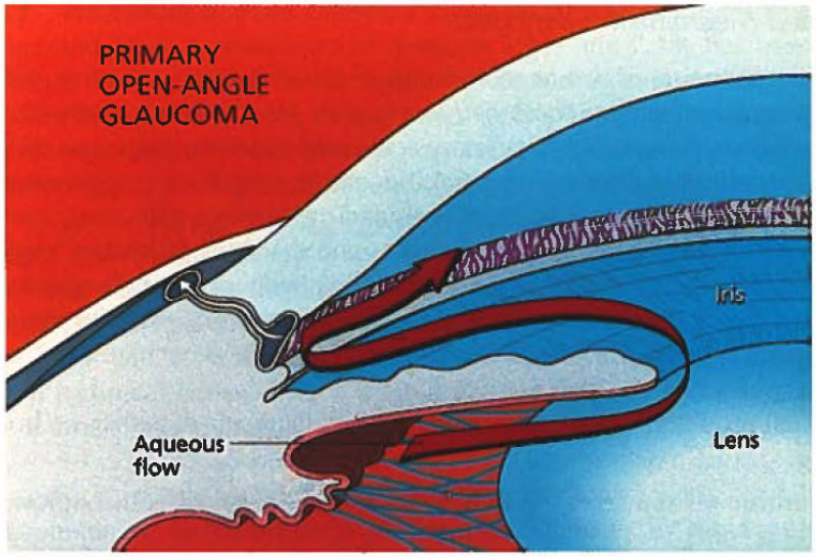


FIG I-2—Schematic of open-angle glaucoma with resistance to aqueous outflow through the trabecular meshwork–Schlemm's canal system in the absence of gross anatomic obstruction. Small white arrow shows normal path of outflow and indicates that resistance in this illustration is relative, not total.

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.

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.

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 refered to as a goniectorny. In a goniectorny 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 loosly 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 goniectomy 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. **3**B. 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-

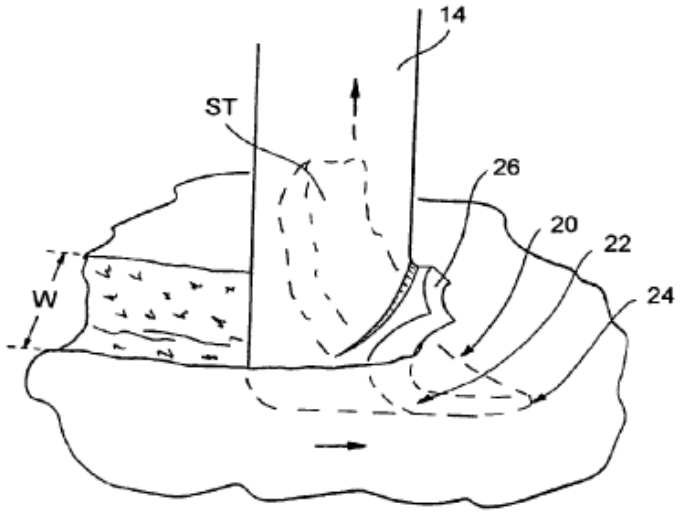
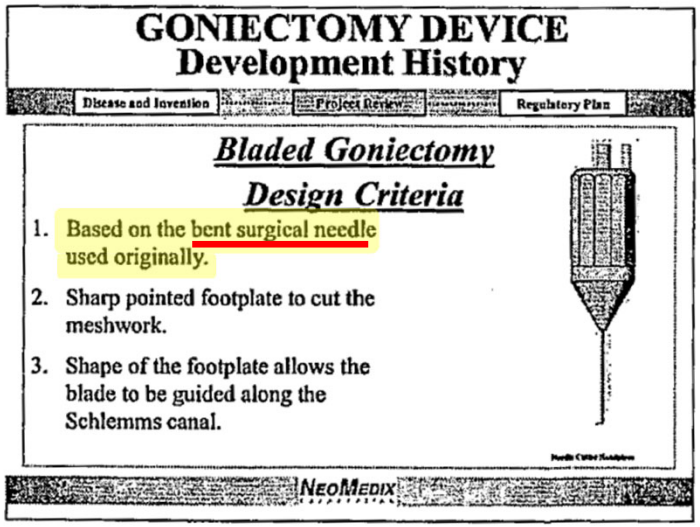
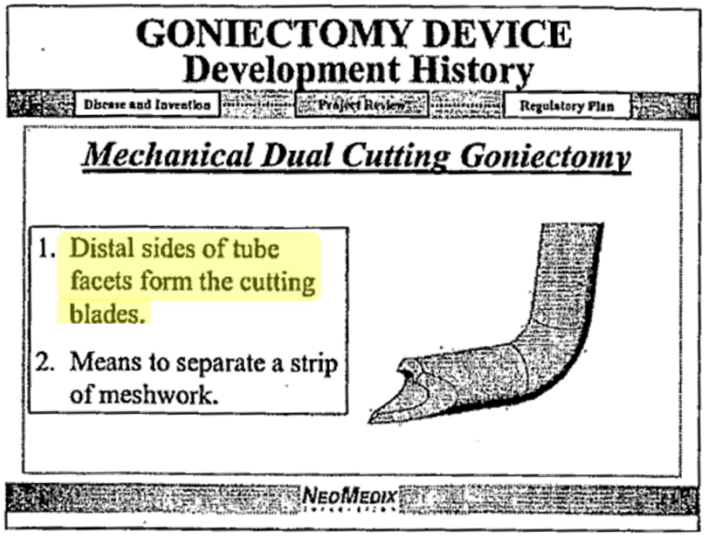


Fig. 4

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





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

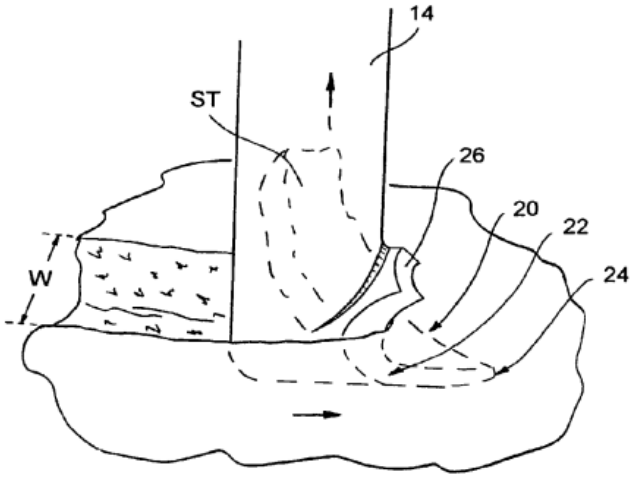
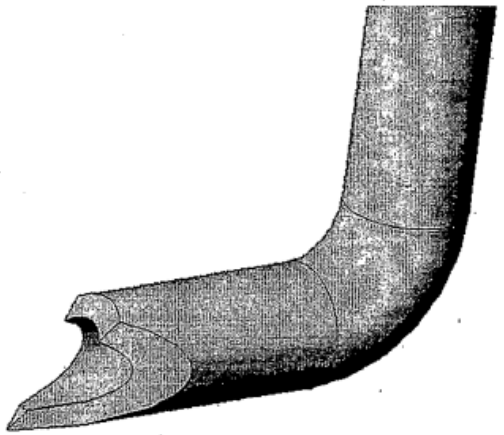


Fig. 4



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

'258 Provisional

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).

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
1. §102: Quintana 2. §103: Quintana / POSITA	1. §102: Quintana 2. §103: Quintana / POSITA	1. §102: Quintana 2. §103: Quintana / POSITA	1. §102: Quintana 2. §103: Quintana / POSITA	1. §102: Quintana 2. §103: Quintana / POSITA
3. §103: Quintana / Lee 4. §103: Quintana / Lee / POSITA	3. §103: Quintana / Lee 4. §103: Quintana / Lee / POSITA			
5. §102: Jacobi 6. §103: Jacobi / POSITA	5. §103: Jacobi / POSITA	3. §103: Jacobi / POSITA	3. §103: Jacobi / POSITA	3. §103: Jacobi / POSITA

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

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

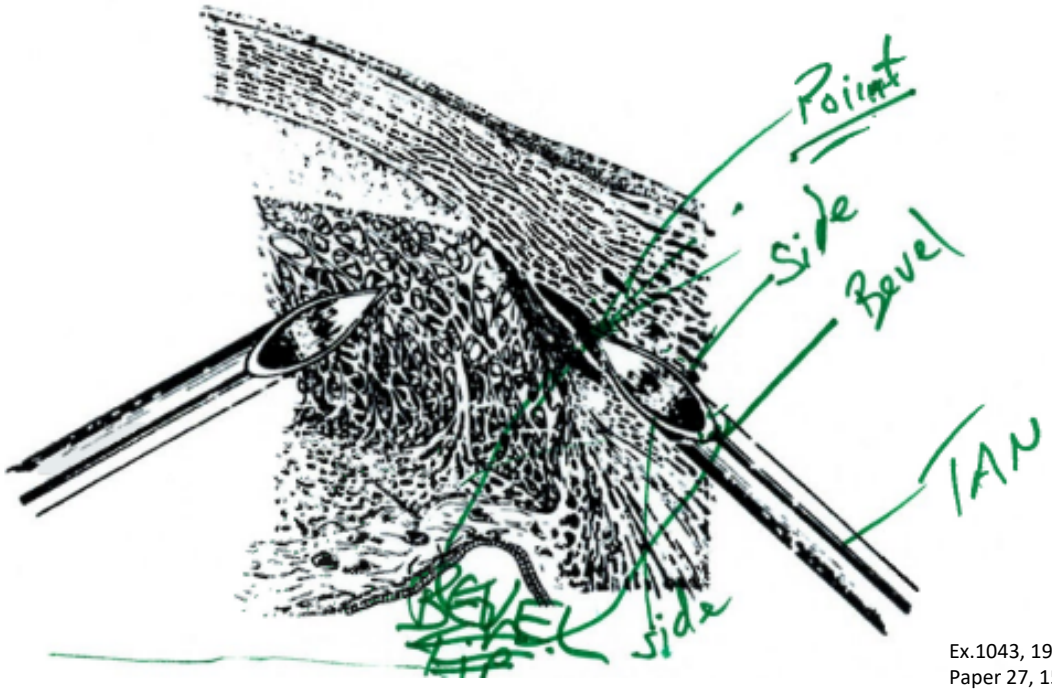
‘729 / ‘155 / ‘885 / ‘905 Patents

- **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)

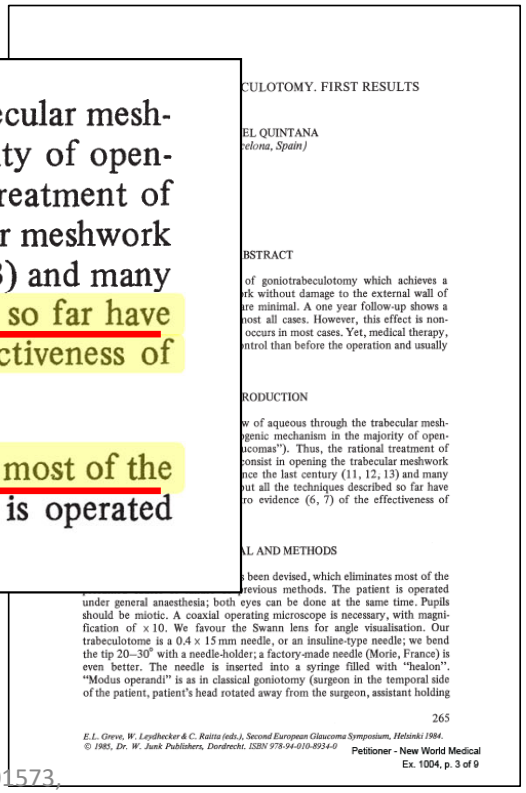
Quintana's "Key Concern" Was Improving on Prior Techniques That Incised TM

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
elona, Spain)

BSTRACT

of goniotrabeculotomy which achieves a rk without damage to the external wall of re minimal. A one year follow-up shows a ost all cases. However, this effect is non- occurs in most cases. Yet, medical therapy, ntrol than before the operation and usually

RODUCTION

w of aqueous through the trabecular mesh- genic mechanism in the majority of open- ucomas"). Thus, the rational treatment of consist in opening the trabecular meshwork nce the last century (11, 12, 13) and many ut all the techniques described so far have ro evidence (6, 7) of the effectiveness of

AL AND METHODS

s been devised, which eliminates most of the revious 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 insuline-type needle; we bend the tip 20–30° with a needle-holder; a factory-made needle (Morie, 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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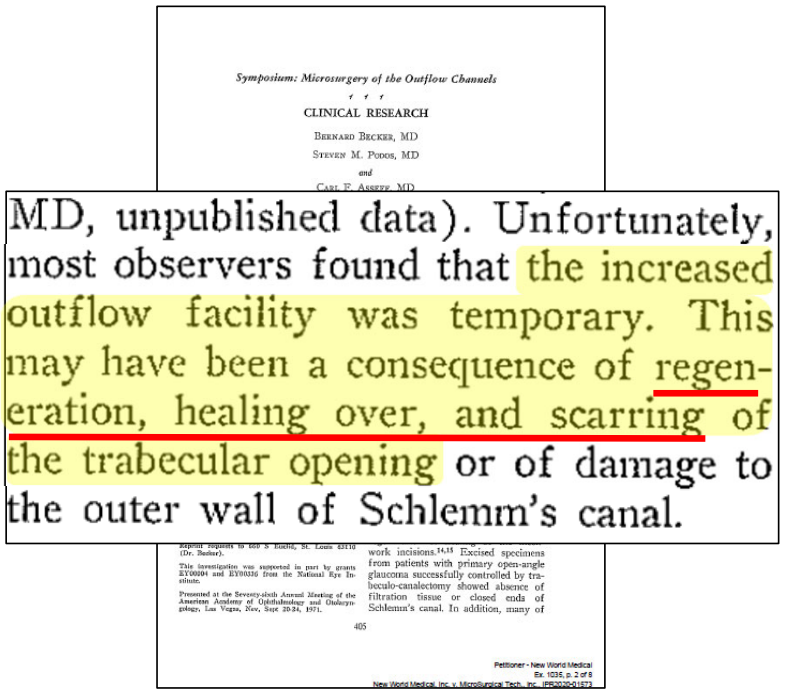
E.L. Greve, W. Leydhecker & C. Raitta (eds.), Second European Glaucoma Symposium, Helsinki 1984.
© 1985, Dr. W. Junk Publishers, Dordrecht. ISBN 978-94-010-8934-0

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

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.

work incisions.[14,15] Excised specimens from patients with primary open-angle glaucoma successfully controlled by trabeculo-canalectomy showed absence of filtration tissue or closed ends of Schlemm's canal. In addition, many of

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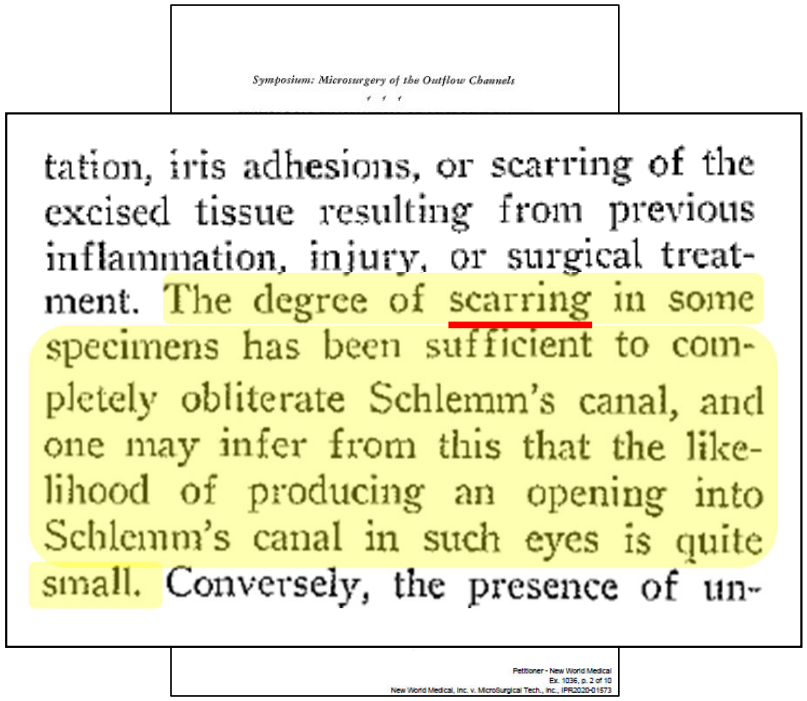
New World Medical, Inc. v. MicroSurgical Tech., Inc., IPR2020-01573

Becker (Ex.1035)



Symposium: Microsurgery of the Outflow Channels

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.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.

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.

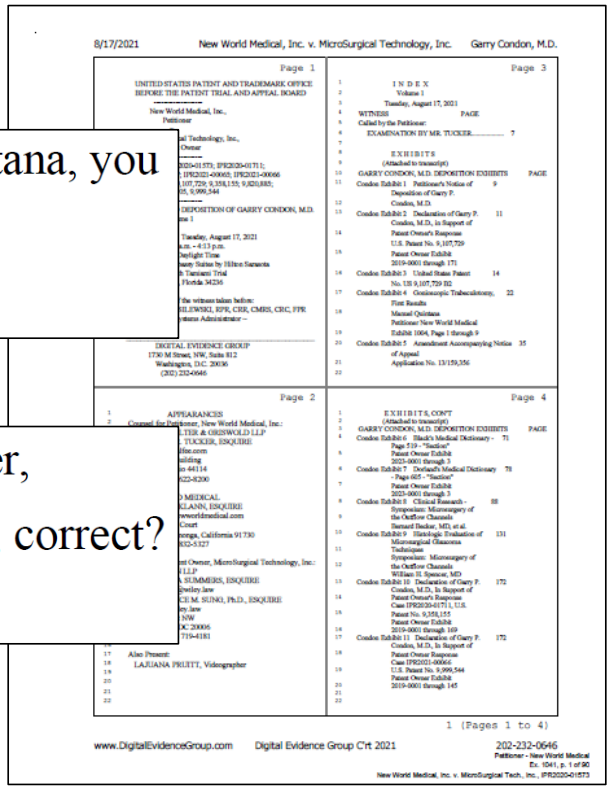
Dr. Condon Did Not Review Becker or Spencer

Q. When you gave your opinion on Quintana, you did not review Becker?

A. That's correct.

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

A. I've not reviewed this.


8/17/2021 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

New World Medical, Inc.,
Petitioner

DEPOSITION OF GARRY CONDON, M.D.

DIGITAL EVIDENCE GROUP
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(202) 232-0646

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TUCKER, ESQUIRE
Counsel for Patent Owner, MicroSurgical Technology, Inc.:
SUMMERS, ESQUIRE
Also Present:
LAJUANA PRUETT, Videographer

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Condon Exhibit 11 Declaration of Garry P. Condon, M.D. In Support of Patent Owner Response Case IPR2021-00066 U.S. Patent No. 9,999,544 Patent Owner Exhibit 2019-9001 through 145 172

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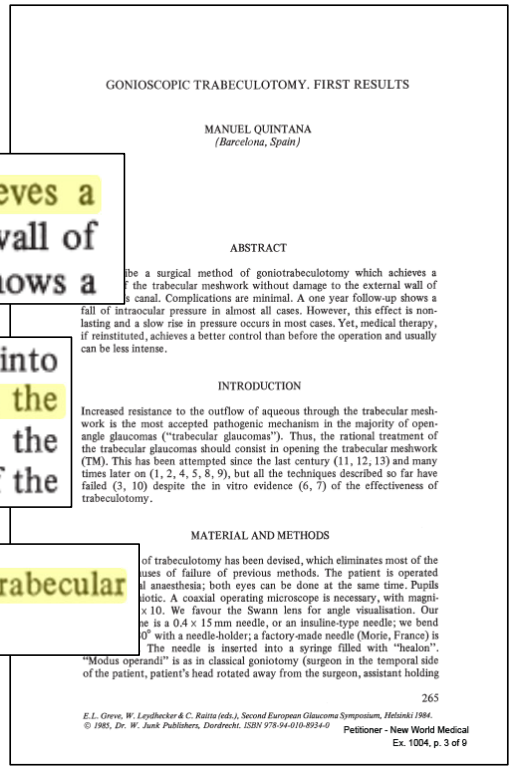
IPR2020-01573, Ex.1041, 91:9-11, 132:20-22; IPR2020-01711, Ex.1041, 91:9-11, 132:20-22; IPR2021-00017, Ex.1041, 91:9-11, 132:20-22; IPR2021-00065, Ex.1041, 91:9-11, 132:20-22; IPR2021-00066, Ex.1041, 91:9-11, 132:20-22.

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.



GONIOSCOPIC TRABECULOTOMY. FIRST RESULTS

MANUEL QUINTANA
(Barcelona, Spain)

ABSTRACT

...be a surgical method of goniotrabeculotomy which achieves a ...f the trabecular meshwork without damage to the external wall of ...l 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 reinstituted, 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

...of trabeculotomy has been devised, which eliminates most of the ...uses of failure of previous methods. The patient is operated ...l anaesthesia; both eyes can be done at the same time. Pupils ...iotic. A coaxial operating microscope is necessary, with magni-... x 10. We favour the Swann lens for angle visualisation. Our ...e is a 0.4 x 15 mm needle, or an insuline-type needle; we bend ...0° with a needle-holder; a factory-made needle (Morie, France) is ... 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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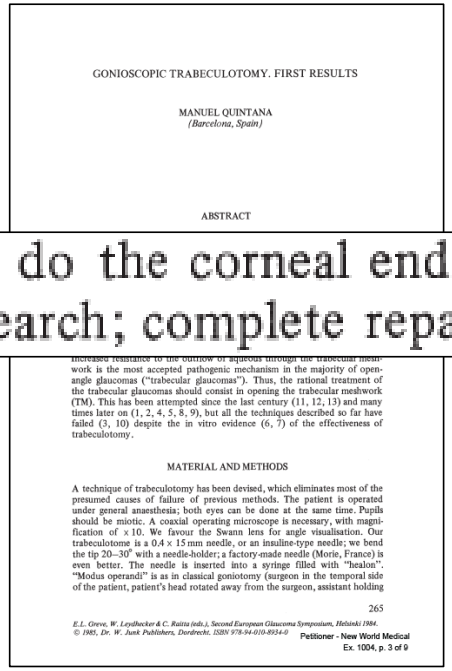
Ex.1004, 3-5; *see* IPR2020-01573, Paper 1, 27, 33, 37, 47-48; IPR2020-01711, Paper 1, 31, 37, 42-43; IPR2021-00017, Paper 1, 27, 33, 36-37; IPR2021-00065, Paper 1, 30, 36, 39; IPR2021-00066, Paper 1, 27, 33, 36-37.

“Remaining Cells” Means Tissue Was Excised

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



GONIOSCOPIC TRABECULOTOMY. FIRST RESULTS

MANUEL QUINTANA
(Barcelona, Spain)

ABSTRACT

work 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 insuline-type needle; we bend the tip 20–30° with a needle-holder; a factory-made needle (Morie, 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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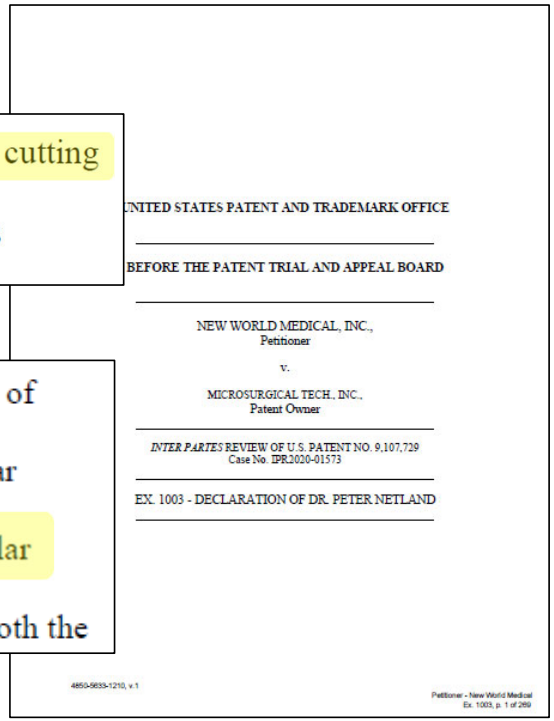
Petitioner - New World Medical
Ex. 1004, p. 3 of 9

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


UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEW WORLD MEDICAL, INC.,
Petitioner

v.

MICROSURGICAL TECH., INC.,
Patent Owner

INTER PARTES REVIEW OF U.S. PATENT NO. 9,107,729
Case No. IPR2020-01573

EX. 1003 - DECLARATION OF DR. PETER NETLAND

IPR2020-01573, Ex.1003, ¶98, 136 (*see* Paper 1, 47-48); *see also* IPR2020-01711, Ex.1003, ¶104, 127-128 (*see* Paper 1, 42-43); IPR2021-00017, Ex.1003, ¶84, 96-97 (*see* Paper 1, 36-37); IPR2021-00065, Ex.1003, ¶88, 100-101 (*see* Paper 1, 37, 39, 48); IPR2021-00066, Ex.1003, ¶93, 106-107 (*see* Paper 1, 34, 36-37).

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

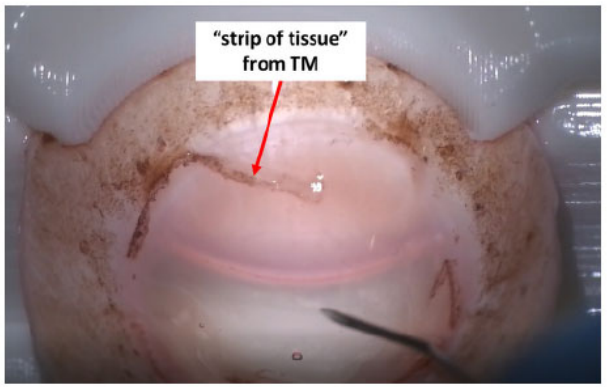


Figure 1

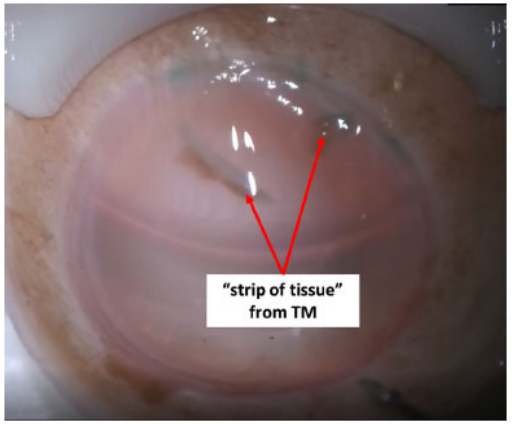


Figure 2

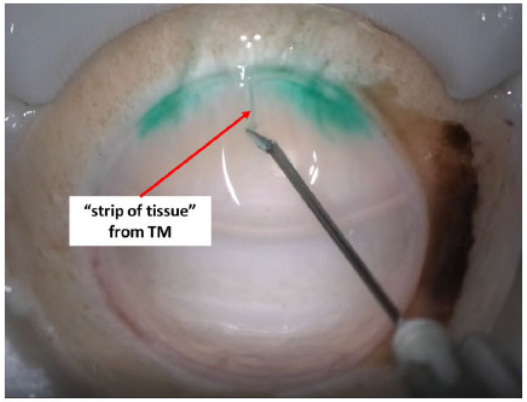


Figure 3

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

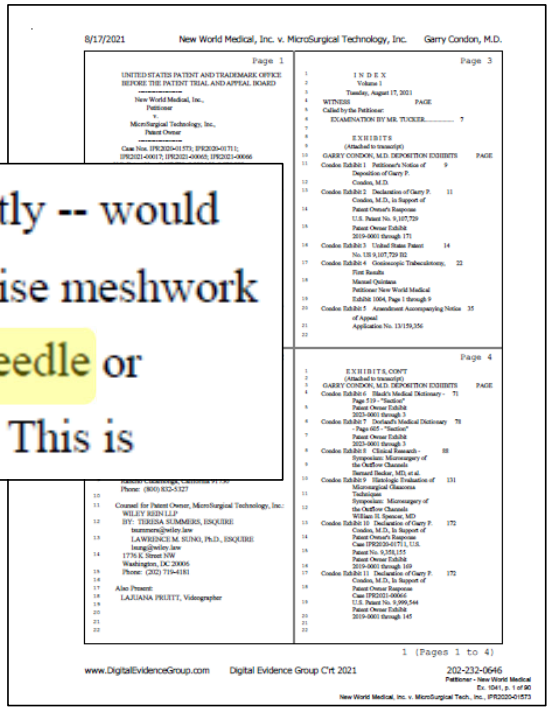
- Dr. Condon admits Quintana's procedure could leave TM on needle tip thereby admitting removal of TM
- Patent Owner wrongly equates Quintana's use of terms "section" and "stripping" with "incising" or "opening"
- Quintana's "key concern" was improving on prior techniques that failed due to reclosure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

IPR2020-01573, Paper 35, 13.

Dr. Condon Admits Quintana's Procedure Could Leave TM on Needle Tip Thereby Admitting Removal of TM

12 trabecular meshwork. If you inadvertently -- would
13 there be, you know, a perfect way to incise meshwork
14 without leaving some on the tip of the needle or
15 whatever accidentally. I mean, but, no. This is

Ex.1041, 82:7-15; *see* IPR2020-01573, Paper 35, 9; IPR2020-01711, Paper 27, 8; IPR2021-00017, Paper 26, 8; IPR2021-00065, Paper 24, 9.


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

Page 1

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 Nos. IPR2020-01573; IPR2020-01711;
IPR2021-00017; IPR2021-00065; IPR2021-00066

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LAJUANA PRUITT, Videographer

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Volume 1
Tuesday, August 17, 2021
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Petitioner - New World Medical
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New World Medical, Inc. v. MicroSurgical Tech., Inc., IPR2020-01573

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

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

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.

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

Paper 29

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEW WORLD MEDICAL, INC.,
Petitioner,

v.

MICROSURGICAL TECHNOLOGY, INC.,
Patent Owner.

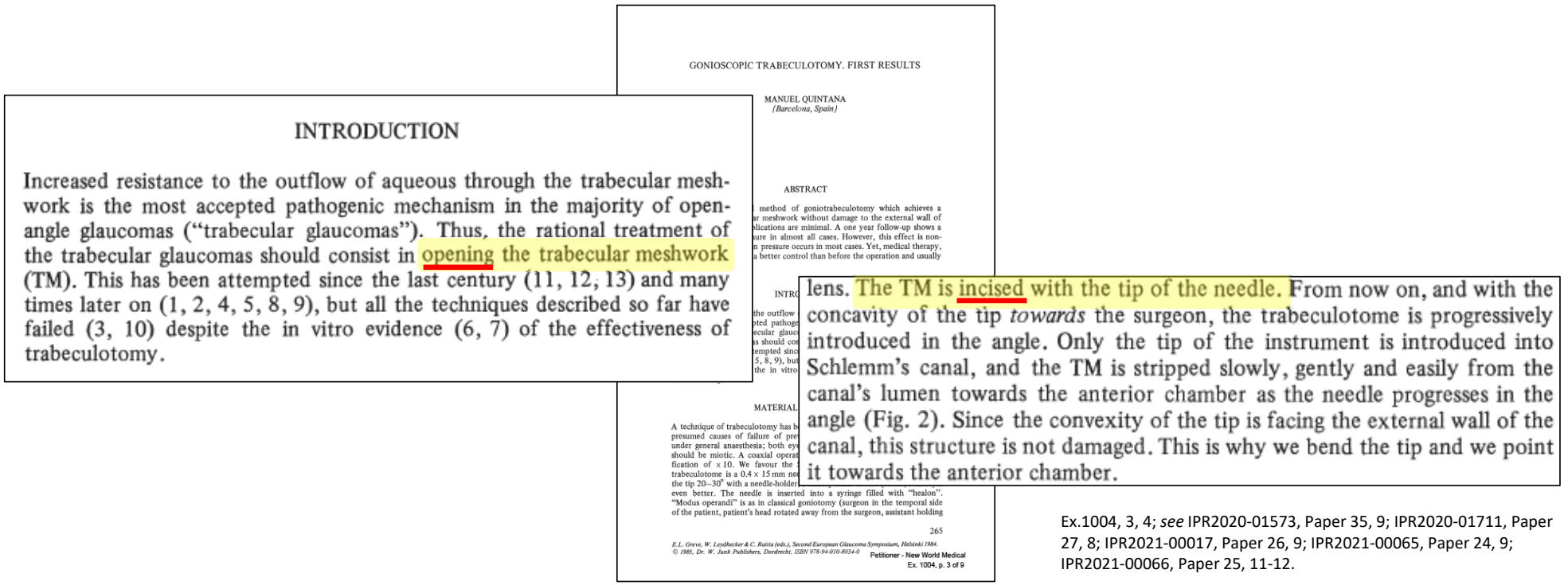
Case IPR2020-01573
U.S. Patent No. 9,107,729

Filed: June 8, 2021

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

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



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.

GONIOSCOPIC TRABECULOTOMY. FIRST RESULTS

MANUEL QUINTANA
(Barcelona, Spain)

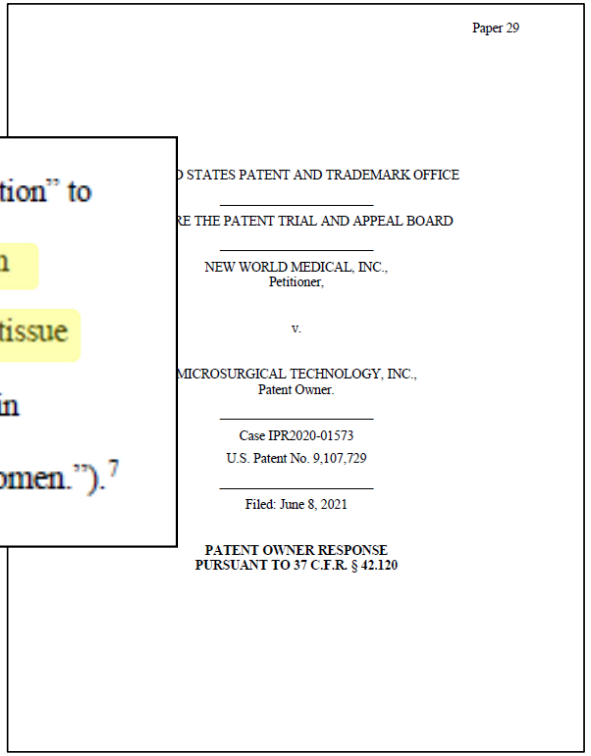
ABSTRACT

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.

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.

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.").[7]



Paper 29

STATES PATENT AND TRADEMARK OFFICE

RE 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

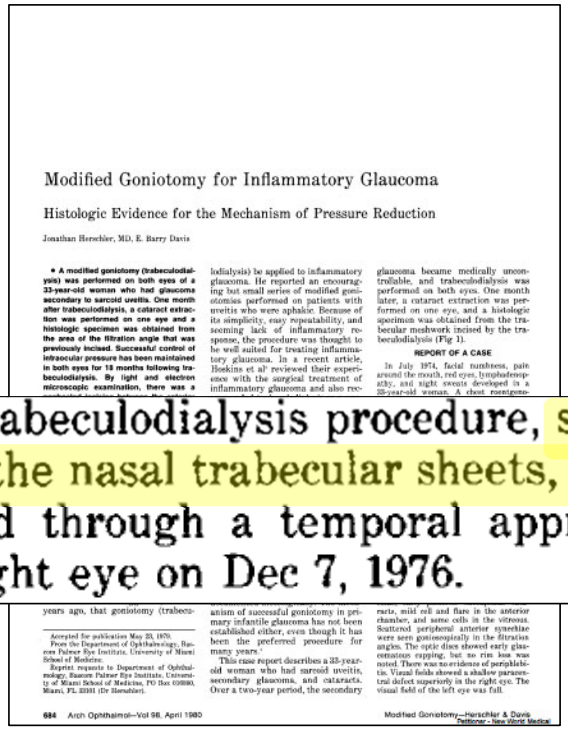
PATENT OWNER RESPONSE PURSUANT TO 37 C.F.R. § 42.120

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"

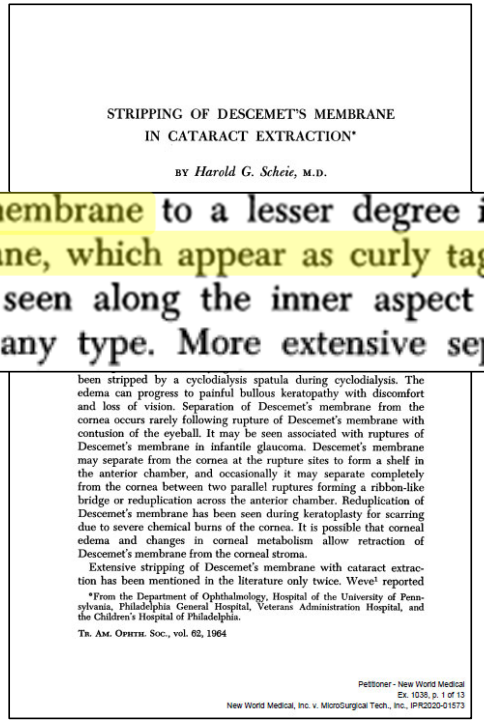


Modified Goniotomy for Inflammatory Glaucoma

Histologic Evidence for the Mechanism of Pressure Reduction

Jonathan Herschler, MD, E. Barry Davis

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



STRIPPING OF DESCEMET'S MEMBRANE IN CATARACT EXTRACTION*

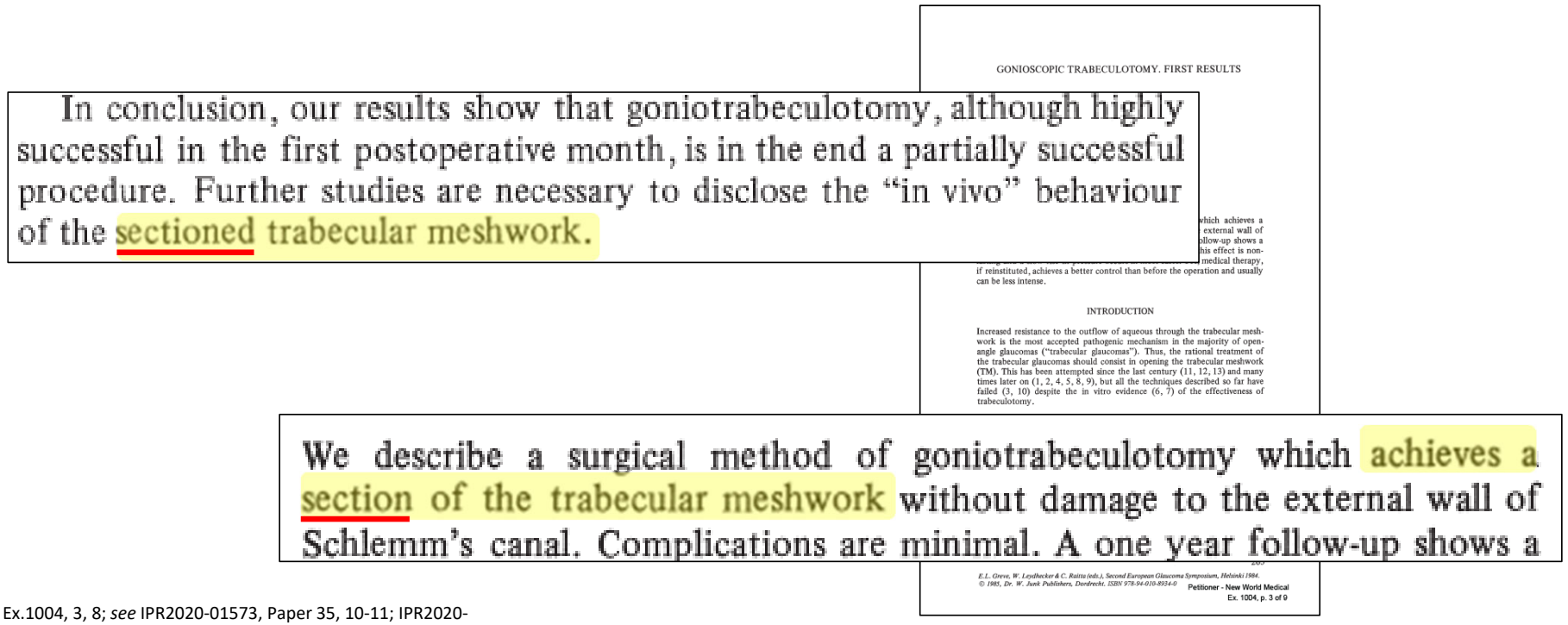
BY *Harold G. Scheie*, M.D.

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

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.

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



In conclusion, our results show that goniotrabeculotomy, 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 sectioned trabecular meshwork.

GONIOSCOPIC TRABECULOTOMY. FIRST RESULTS

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.

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

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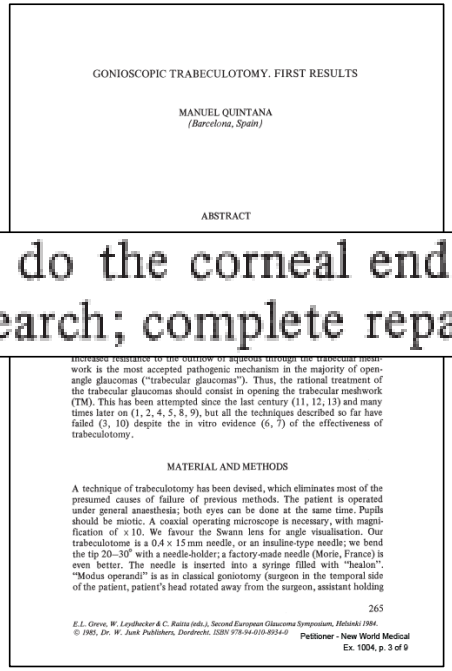
Petitioner - New World Medical
Ex. 1004, p. 3 of 9

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.

“Remaining Cells” Means Tissue Was Excised

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



GONIOSCOPIC TRABECULOTOMY. FIRST RESULTS

MANUEL QUINTANA
(Barcelona, Spain)

ABSTRACT

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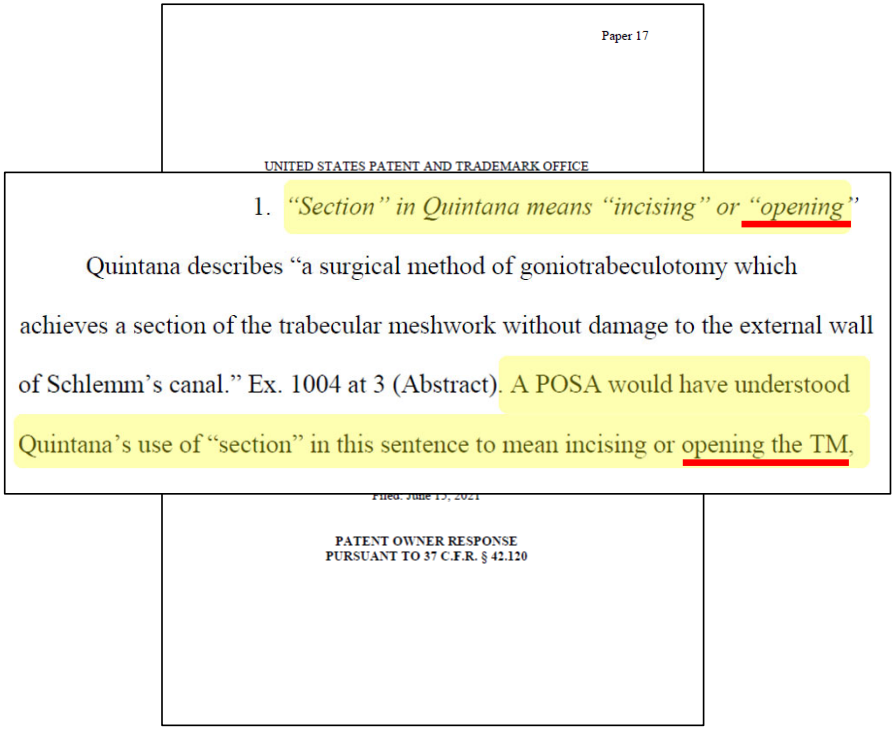
Petitioner - New World Medical
Ex. 1004, p. 3 of 9

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

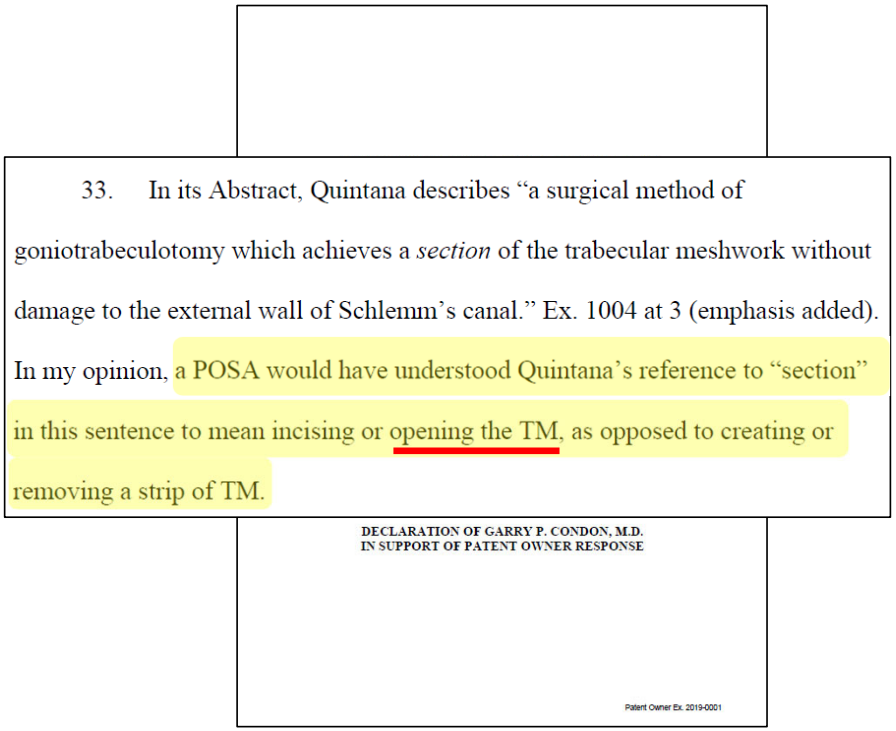
1. *"Section" in Quintana means "incising" or "opening"*

Quintana describes "a surgical method of 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,

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.



33. In its Abstract, 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 (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

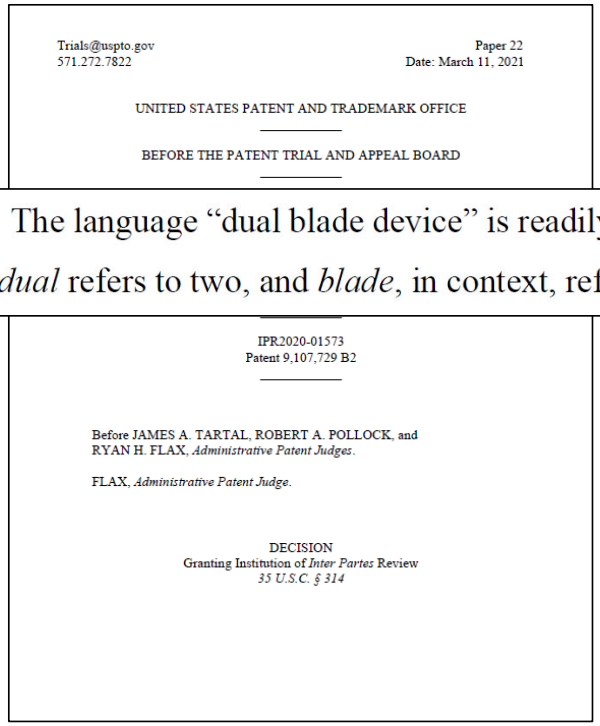
Patent Owner Ex. 2019-0001

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) .

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

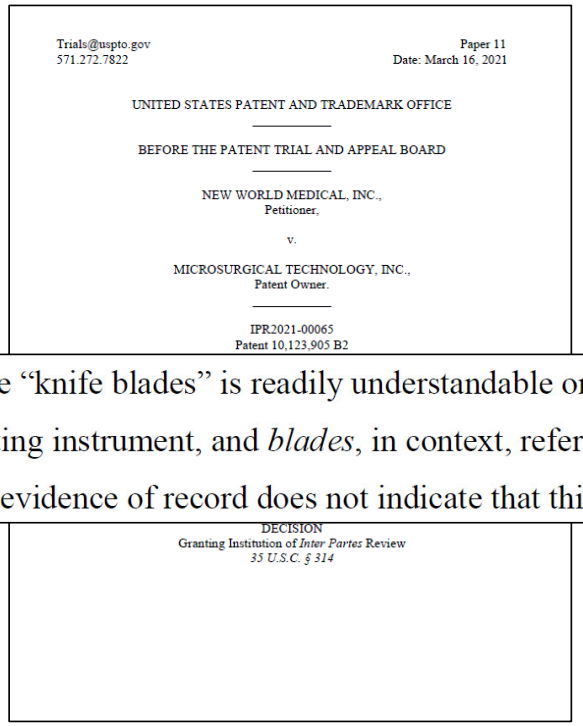
IPR2020-01573
Patent 9,107,729 B2

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

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



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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

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

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

IPR2020-01573, Paper 22, 17; *see also* IPR2020-01711, Paper 11, 13; IPR2021-00017, Paper 11, 13.

IPR2021-00065, Paper 11, 16.

Patented Device Is a Bent Needle

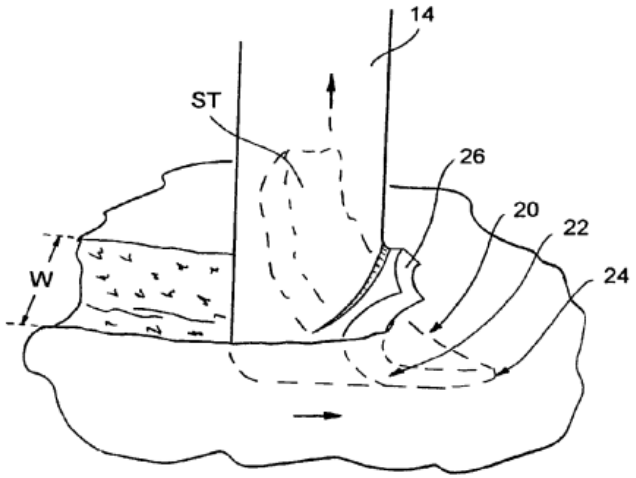
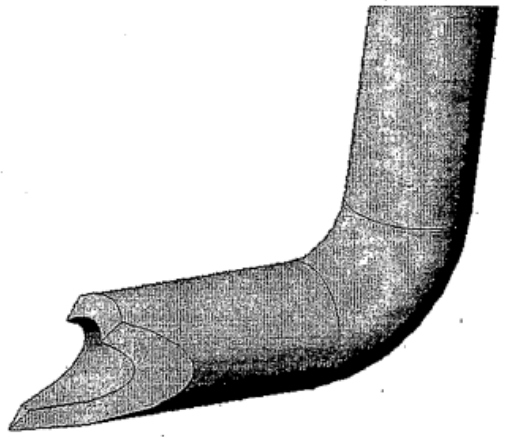


Fig. 4



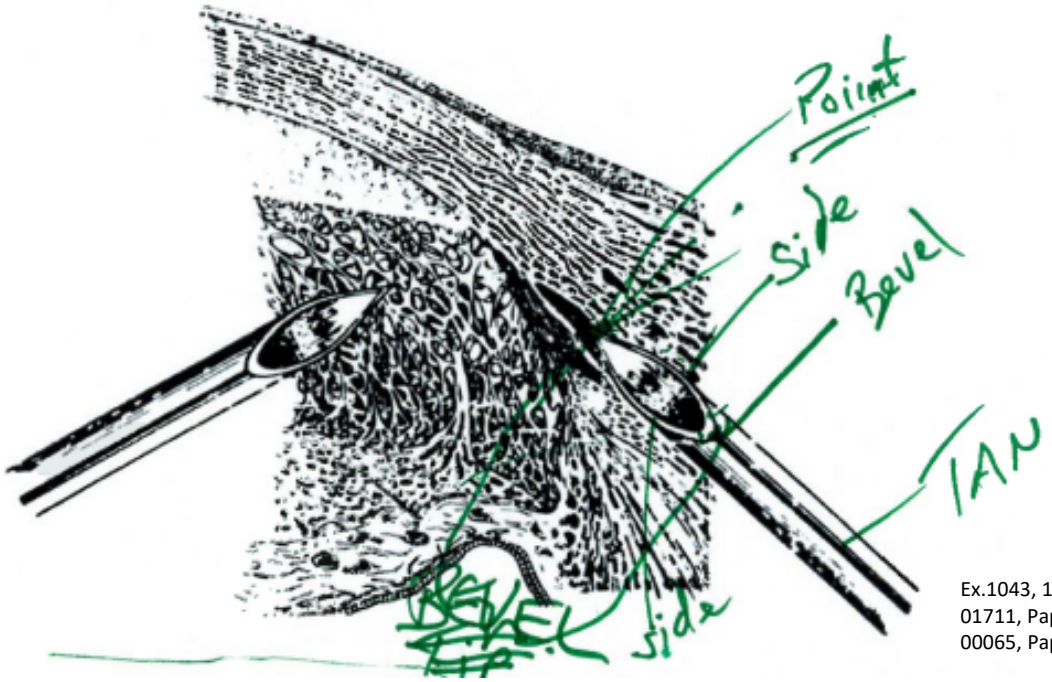
‘729/’155/’885 Patent Fig. 4

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.

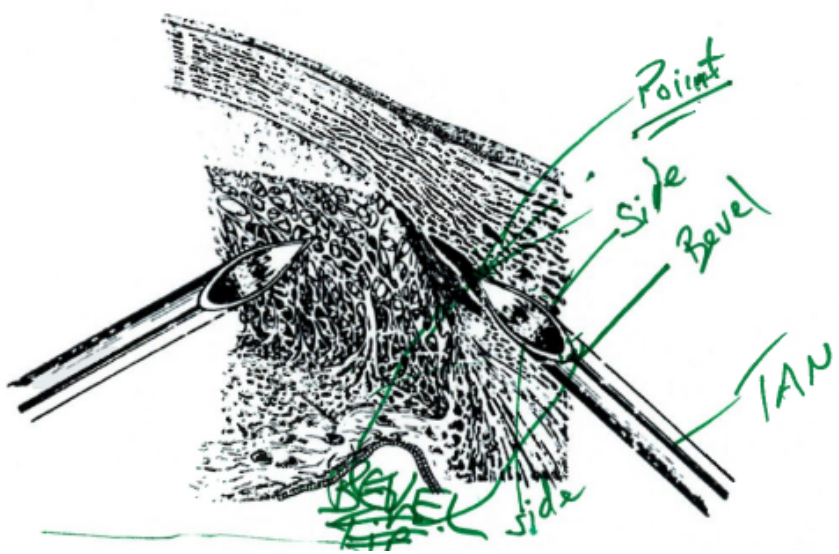
Dr. Condon's Testimony and Annotated Figure Demonstrate Quintana's Needle Has Two Cutting Parts and Thus Meets the Board's Constructions



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

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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.

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).

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).

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).

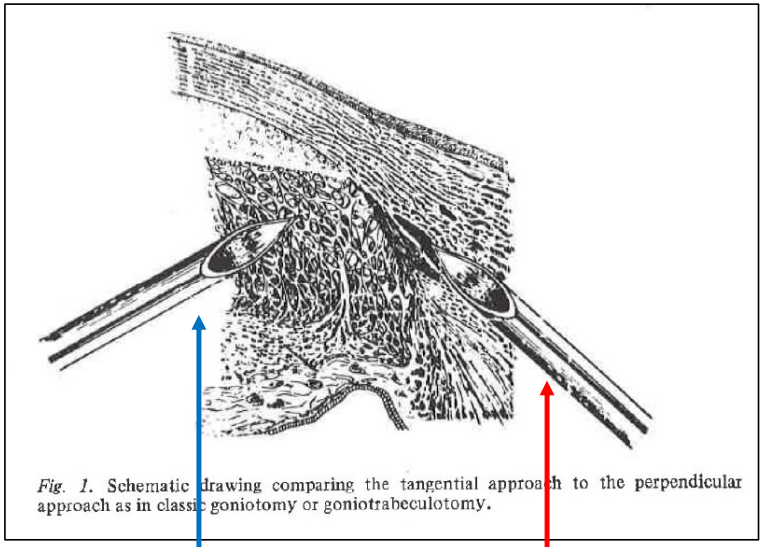
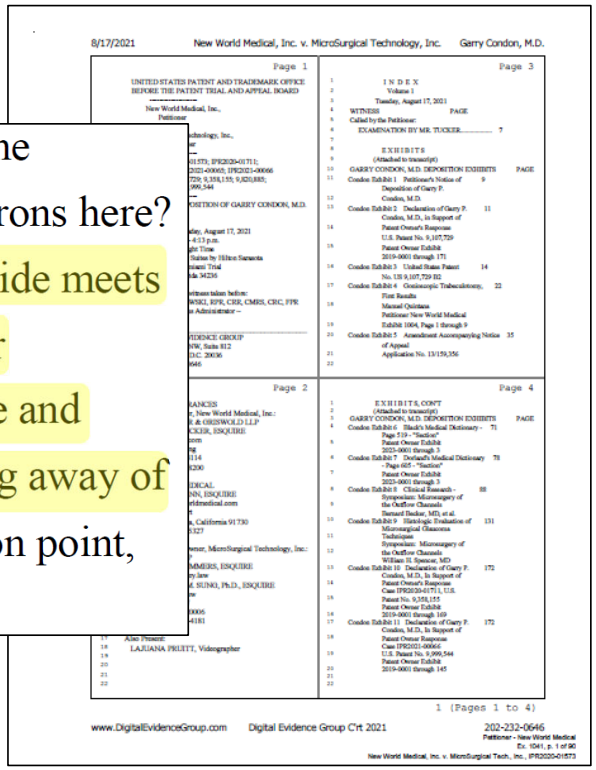


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

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.

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

So where the sides end, I mean, at the point, we're talking -- are we talking microns here? Is it possible that, you know, where the side meets the point, that that contacts the trabecular meshwork? I'll give you that it's possible and could -- may assist in creating that tearing away of the trabecular meshwork from its insertion point, 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.

Quintana Explicitly States the Tip Contacts the TM

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.

GONIOSCOPIC TRABECULOTOMY. FIRST RESULTS

MANUEL QUINTANA
(Barcelona, Spain)

MATERIAL AND METHODS

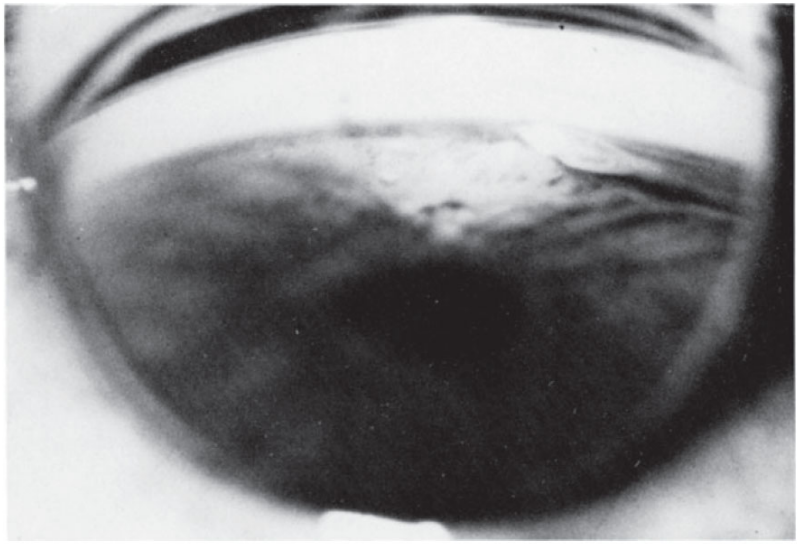
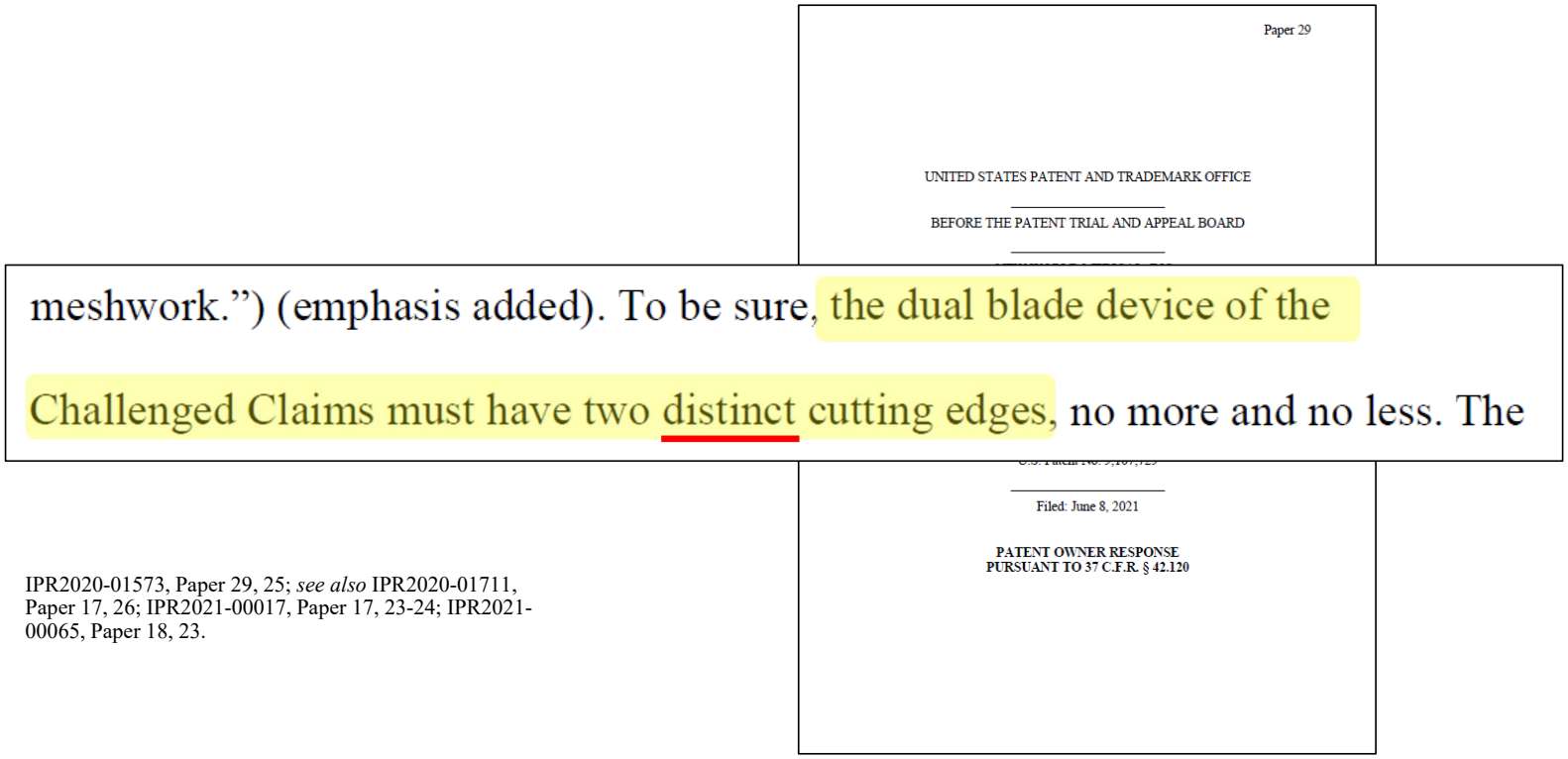


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

Ex. 1004, p. 3 of 9

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



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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

Filed: June 8, 2021

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

Reading “Distinct” Into Claim Is Inconsistent with Intrinsic Record

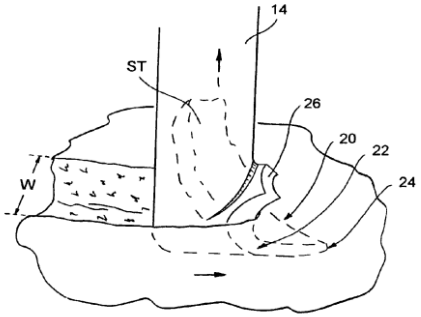


Fig. 4

‘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).

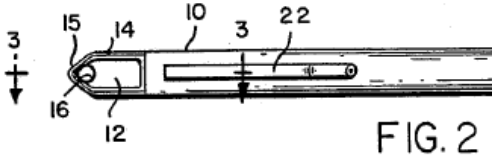
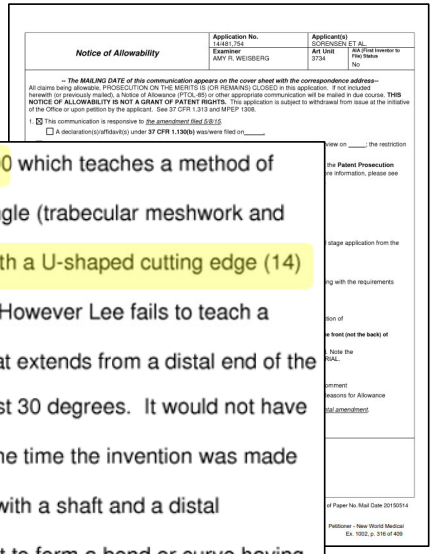


FIG. 2

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.



Notice of Allowability

Application No. 14/481,754 | Applicant(s) SORENSEN ET AL.
Examiner AMY R. WEISBERG | Art Unit 3734 | AIA (First Inventor to File) Status No

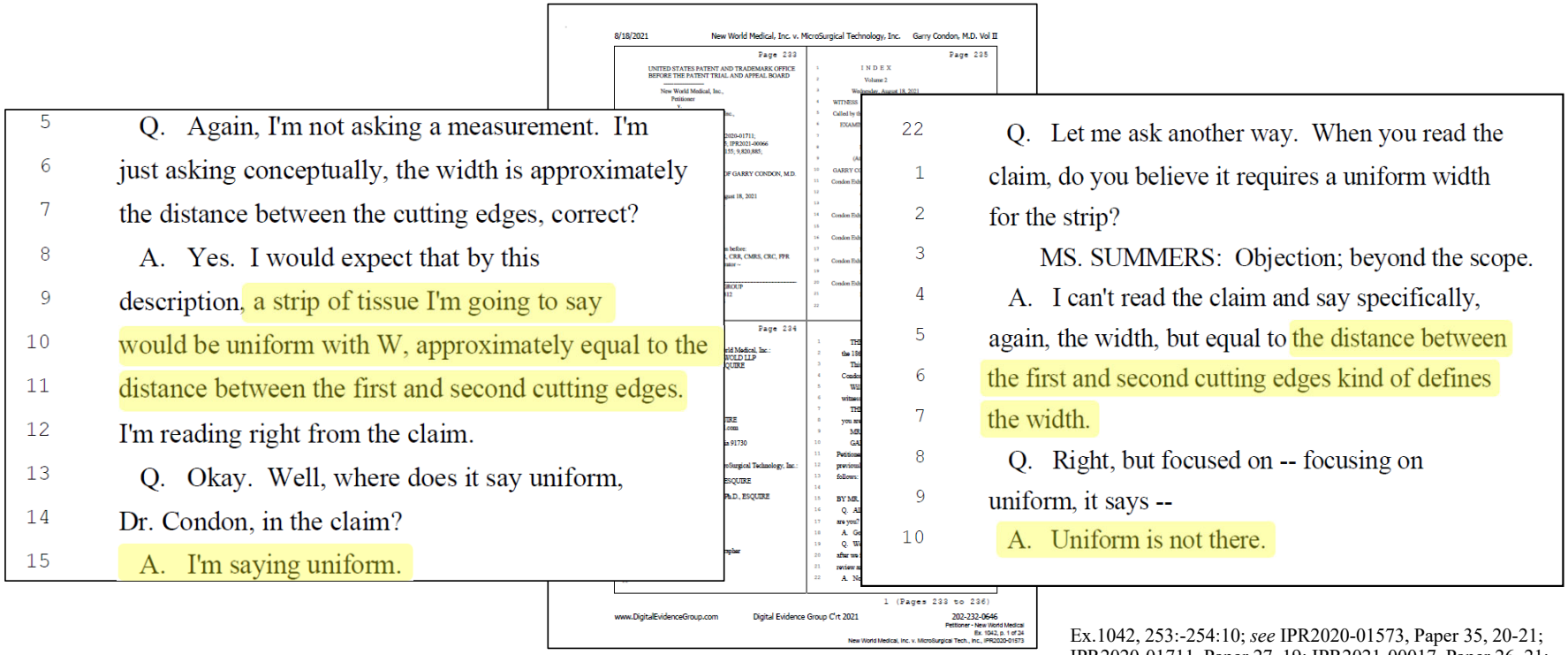
-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--
All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate 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 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 6/8/15.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____

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



Q. Again, I'm not asking a measurement. I'm just asking conceptually, the width is approximately the distance between the cutting edges, correct?

A. Yes. I would expect that by this description, a strip of tissue I'm going to say would be uniform with W, approximately equal to the distance between the first and second cutting edges. I'm reading right from the claim.

Q. Okay. Well, where does it say uniform, Dr. Condon, in the claim?

A. I'm saying uniform.

Q. Let me ask another way. When you read the claim, do you believe it requires a uniform width for the strip?

MS. SUMMERS: Objection; beyond the scope.

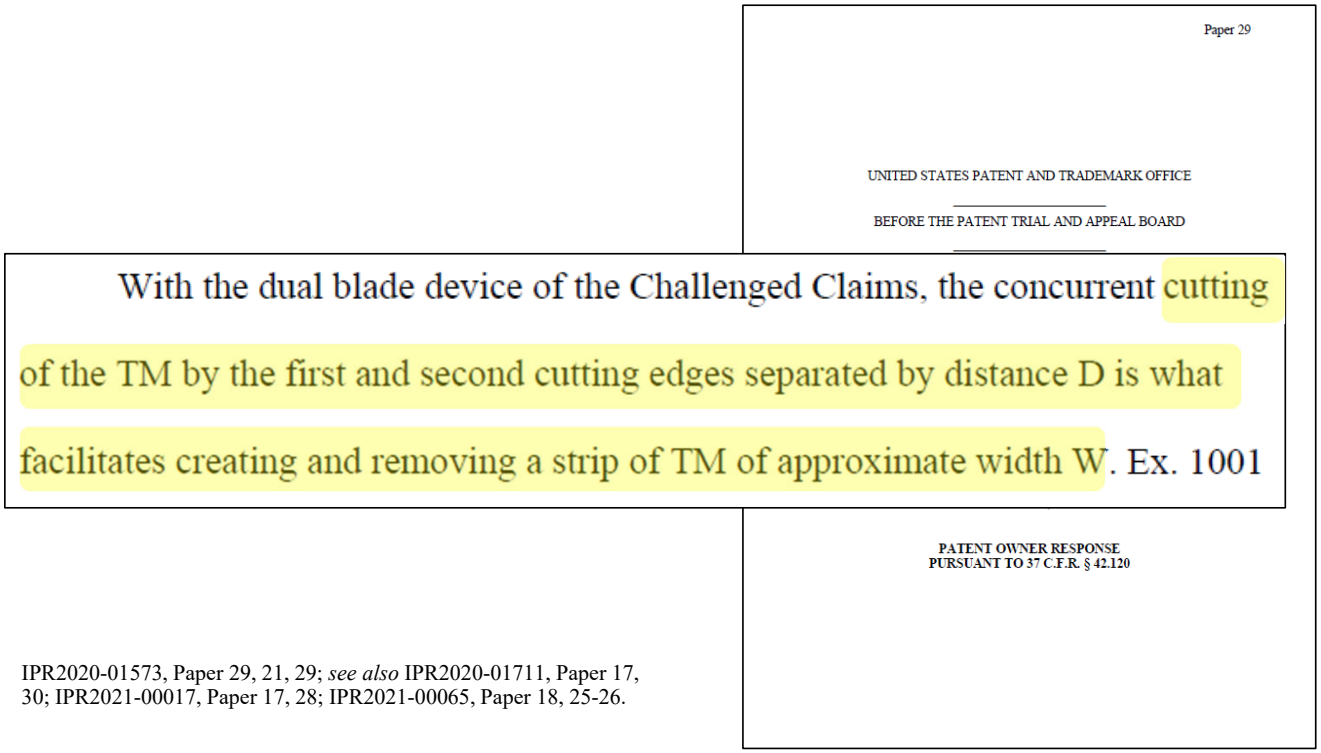
A. I can't read the claim and say specifically, again, the width, but equal to the distance between the first and second cutting edges kind of defines the width.

Q. Right, but focused on -- focusing on uniform, it says --

A. Uniform is not there.

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



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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

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

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)

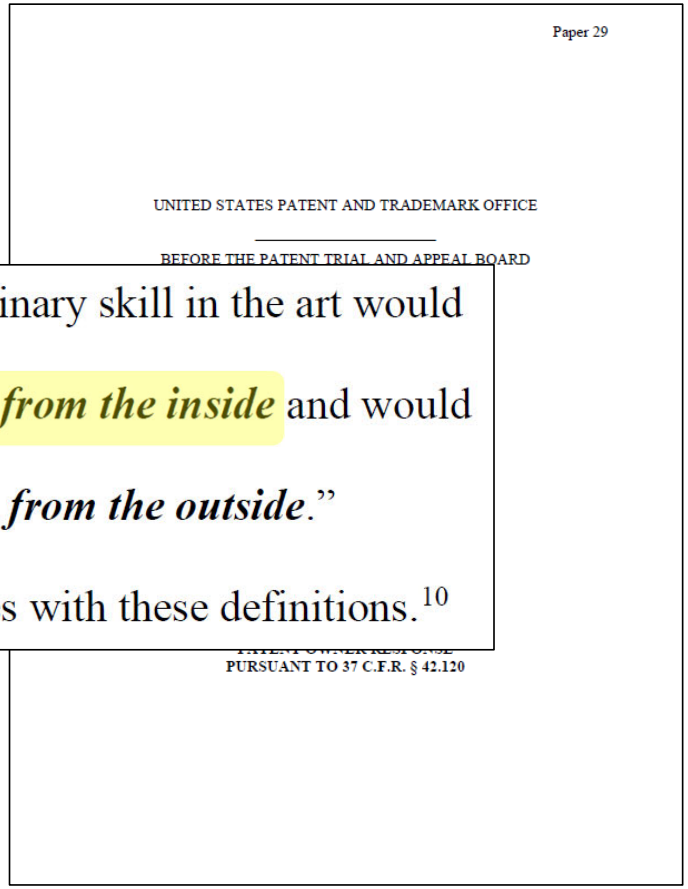
- Board construed "ab interno" according to plain and ordinary meaning
  - IPR2020-01573, Paper 22, 17; IPR2020-01711, Paper 11, 13; IPR2021-00066, Paper 10, 20-21.
- Plain and ordinary meaning of "ab interno" is "from the inside"
  - IPR2020-01573, Paper 29, 31; IPR2020-01711, Paper 17, 35; IPR2021-00066, 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"

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.[10]

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


Paper 29

UNITED STATES PATENT AND TRADEMARK OFFICE

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PURSUANT TO 37 C.F.R. § 42.120

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 goniolens. Once the needle is in the anterior chamber, the goniolens is inserted, held with the surgeon's left hand. A drop of "healon" is a good wetting agent between cornea and goniolens. 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.

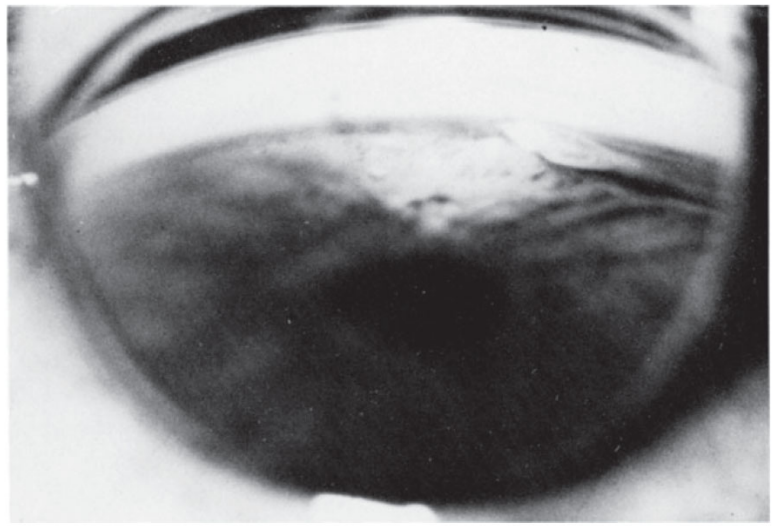


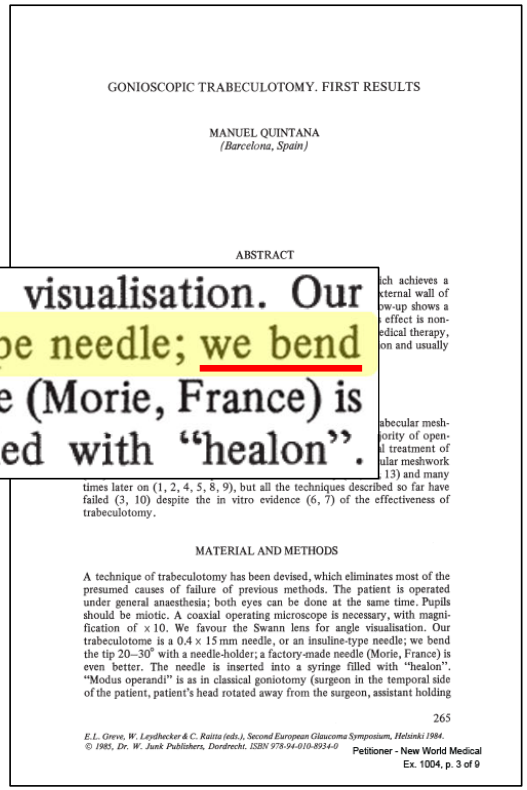
Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

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

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

fication of × 10. We favour the Swann lens for angle visualisation. Our trabeculotome is a 0.4 × 15 mm needle, or an insuline-type needle; we bend the tip 20–30° with a needle-holder; a factory-made needle (Morie, France) is even better. The needle is inserted into a syringe filled with “healon”.

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



GONIOSCOPIC TRABECULOTOMY. FIRST RESULTS

MANUEL QUINTANA
(Barcelona, Spain)

ABSTRACT

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 × 10. We favour the Swann lens for angle visualisation. Our trabeculotome is a 0.4 × 15 mm needle, or an insuline-type needle; we bend the tip 20–30° with a needle-holder; a factory-made needle (Morie, 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.

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

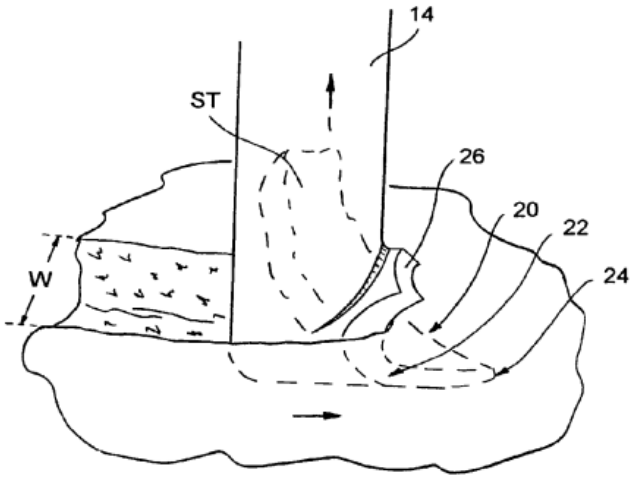
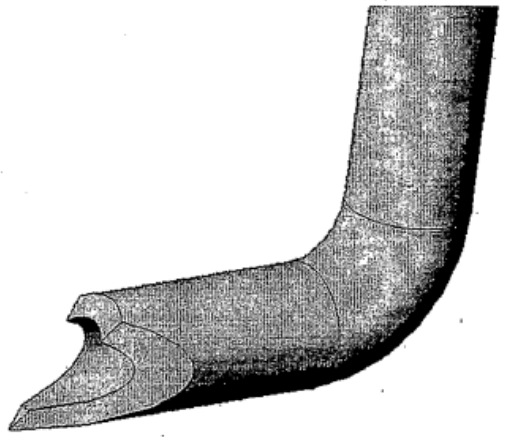


Fig. 4



‘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

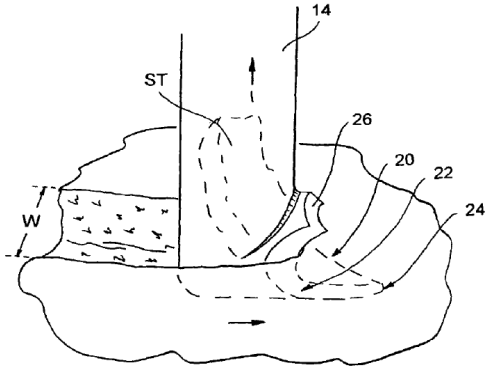
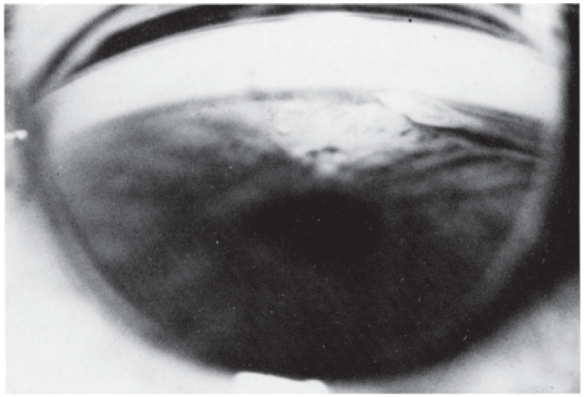


Fig. 4



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).

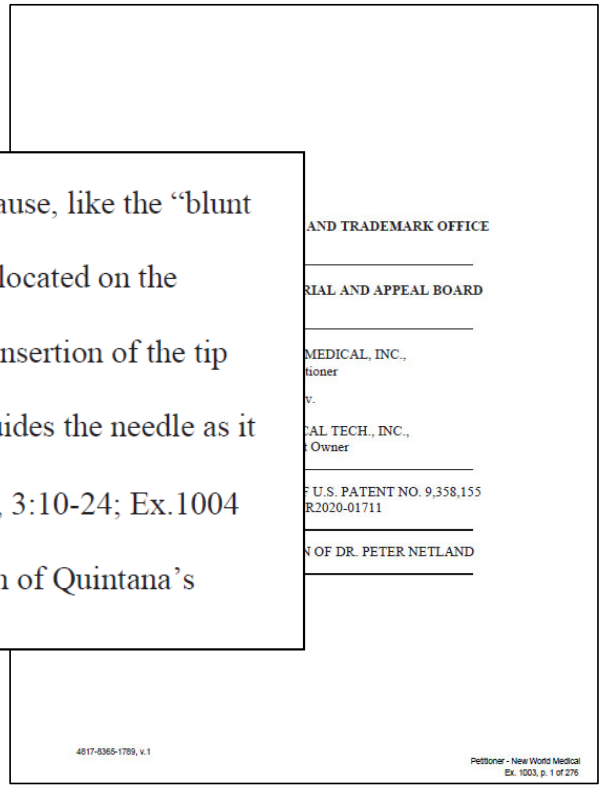
lens. The TM is incised with the tip of the needle. From now on, and with the concavity of the tip *towards* the surgeon, the trabeculotome is progressively introduced in the angle. Only the tip of the instrument is introduced into Schlemm's canal, and the TM is stripped slowly, gently and easily from 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

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



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

Q. Does the '155 patent give any indication how to determine or measure bluntness?

MS. SUMMERS: Objection; form, outside the scope.

A. You know, in the interest of time, I'm not going to read this while we're sitting here, but to my recollection and -- I don't remember anything in the '155 specifying how to measure bluntness. I don't know what bluntness refers to in any of these documents, the "ness." Blunt is just not sharp.

Q. Okay.

A. So bluntless -- bluntness would be not sharpness. I'm not sure I can put it any better.

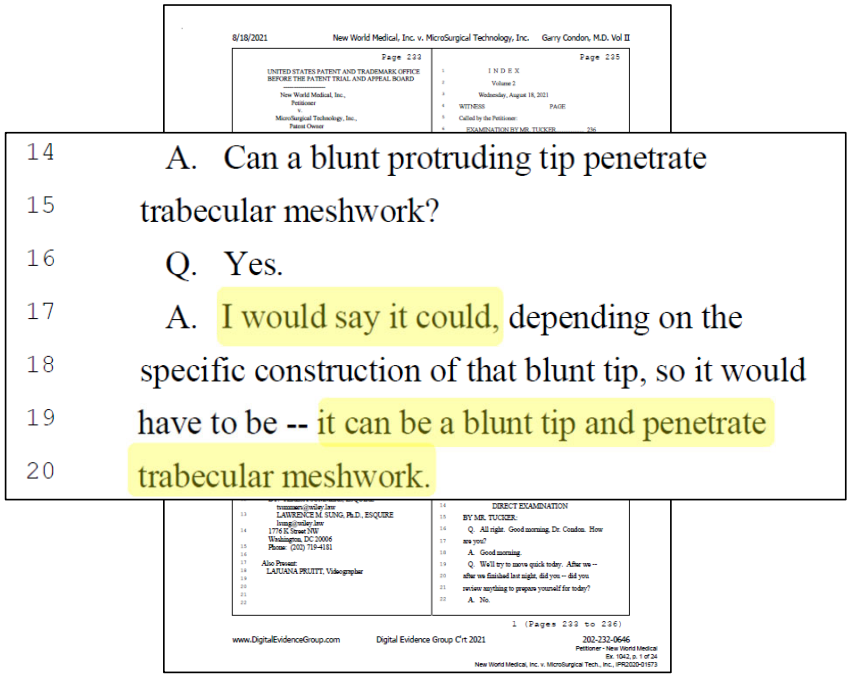
Q. So, just so I understand, you -- your testimony is that you know Quintana's edges are not sharp but you don't know what sharp means?

MS. SUMMERS: Objection; form, misstates the testimony.

A. Sharp means that they're not blunt. I mean, anything that's sharp is not blunt. That's my testimony.

IPR2020-01711, Ex.1042, 281:5-282:9 (*see* Paper 27, 20 n.9).

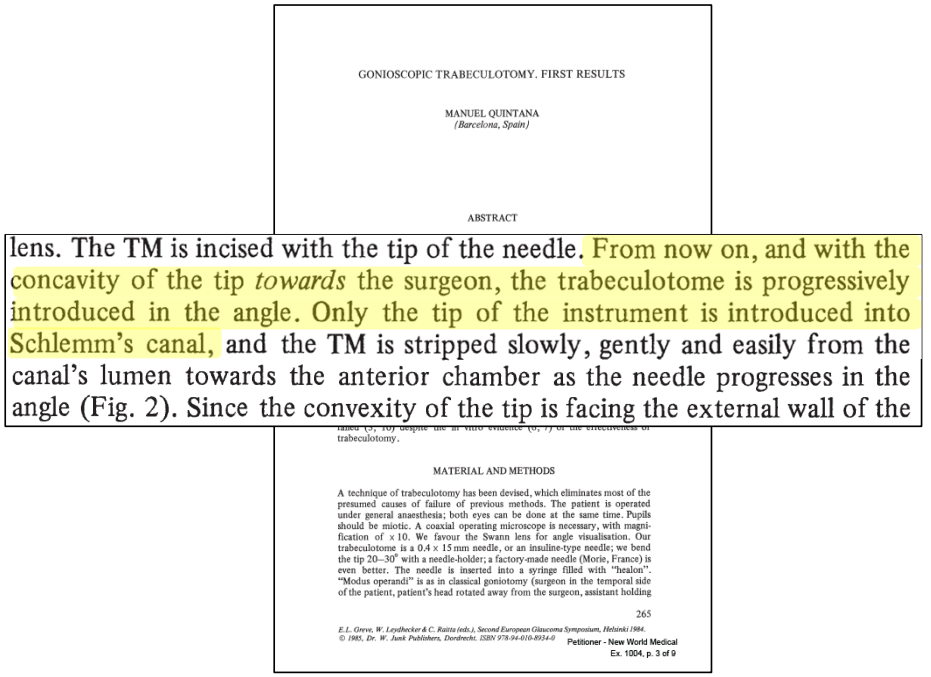
Dr. Condon Concedes a “Blunt” Tip Can Penetrate TM



8/18/2021 New World Medical, Inc. v. MicroSurgical Technology, Inc. Gerry Condon, M.D. Vol II

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).



GONIOSCOPIC TRABECULOTOMY. FIRST RESULTS

MANUEL QUINTANA
(Barcelona, Spain)

ABSTRACT

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

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 necesary, 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 insuline-type needle; we bend the tip 20–30° with a needle-holder; a factory-made needle (Morie, 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.
© 1985, Dr. W. Junk Publishers, Dordrecht. ISBN 978-94-010-8954-0

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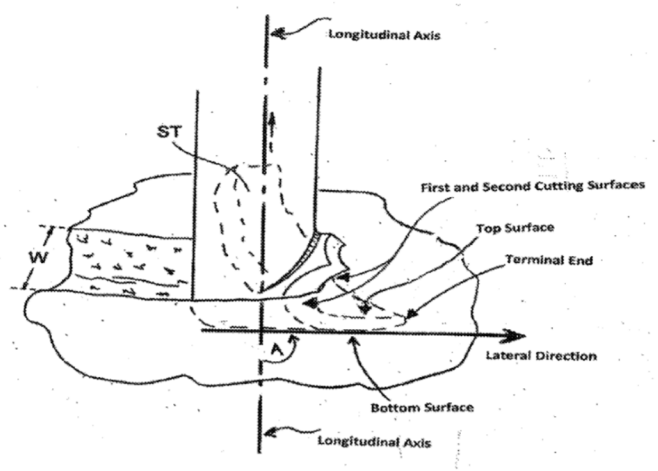
Ex. 1004, p. 3 of 9

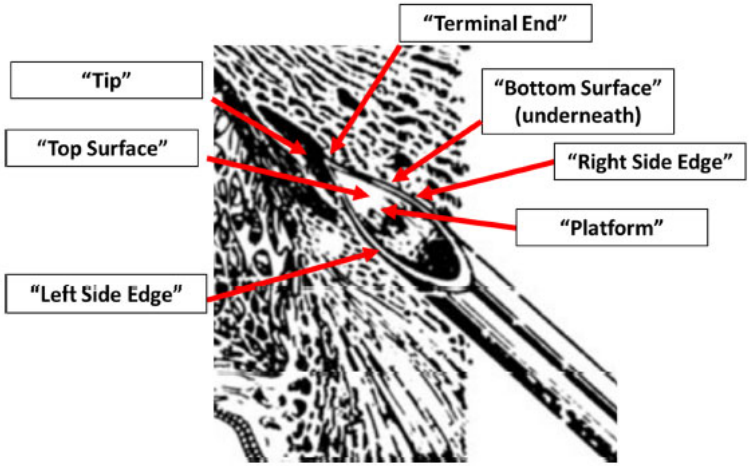
IPR2020-01711, Ex.1004, 4 (*see* Paper 1, 44-56).

Quintana Discloses a "Platform" ('855, cl.1)



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

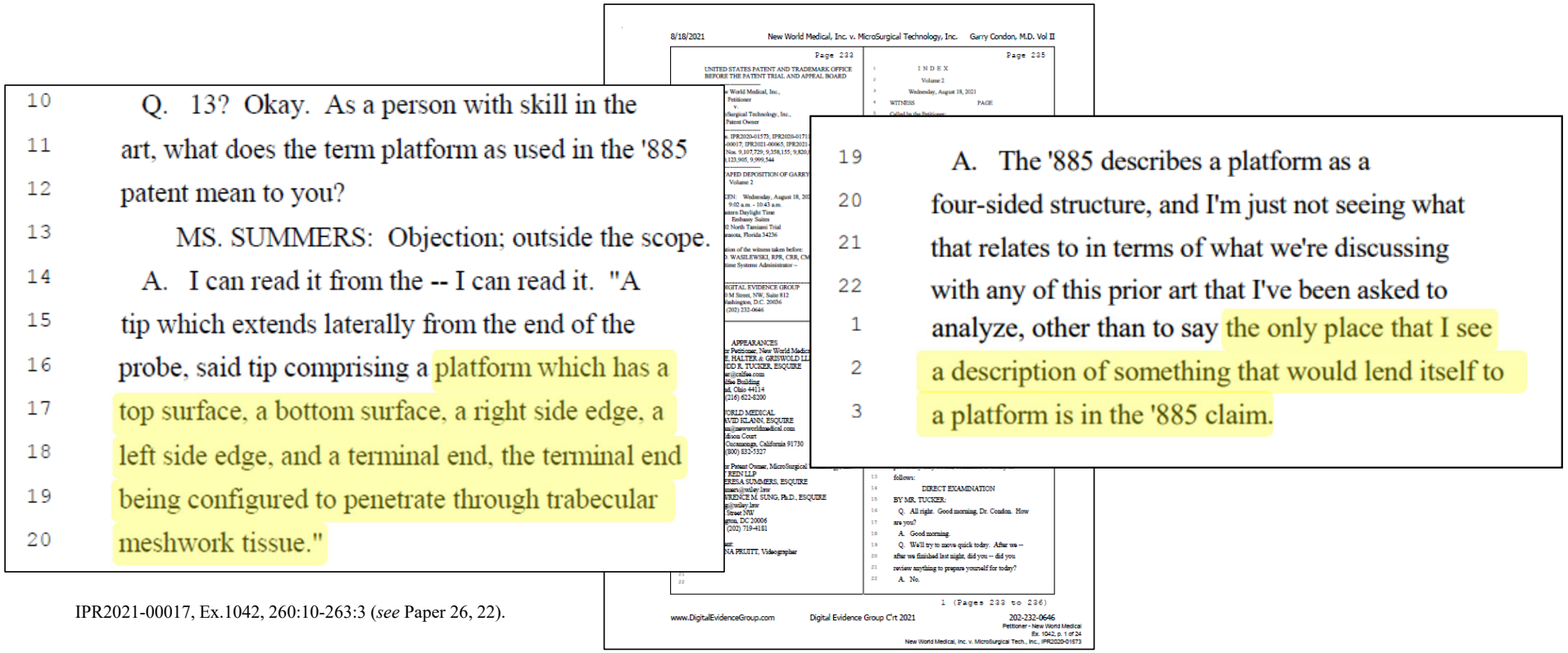
IPR2020-01711, Ex.1002, 199 (see Paper 1, 23-24); IPR2021-00017, Ex.1023, 199 (see Paper 1, 23-24).



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

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

Dr. Condon Defined "Platform" Consistent with NWM's Interpretation



Q. 13? Okay. As a person with skill in the art, what does the term platform as used in the '885 patent mean to you?

MS. SUMMERS: Objection; outside the scope.

A. I can read it from the -- I can read it. "A tip which extends laterally from the 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."

A. The '885 describes a platform as a four-sided structure, and I'm just not seeing what that relates to in terms of what we're discussing with any of this prior art that I've been asked to analyze, other than to say the only place that I see a description of something that would lend itself to a platform is in the '885 claim.

IPR2021-00017, Ex.1042, 260:10-263:3 (*see* Paper 26, 22).

Quintana Discloses a "Protector Member" ('905, cl.1)

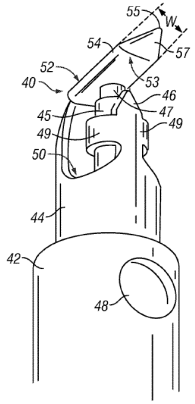
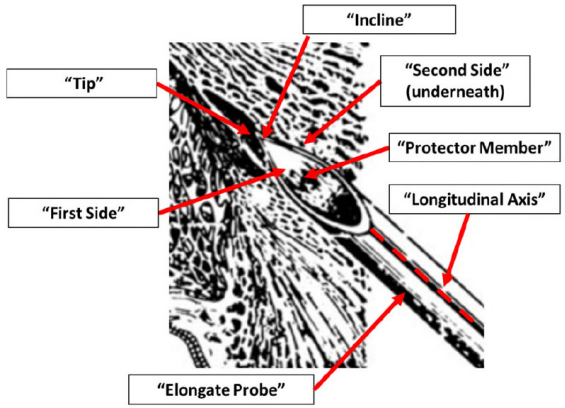


FIG. 5A

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 goniectomy procedure.

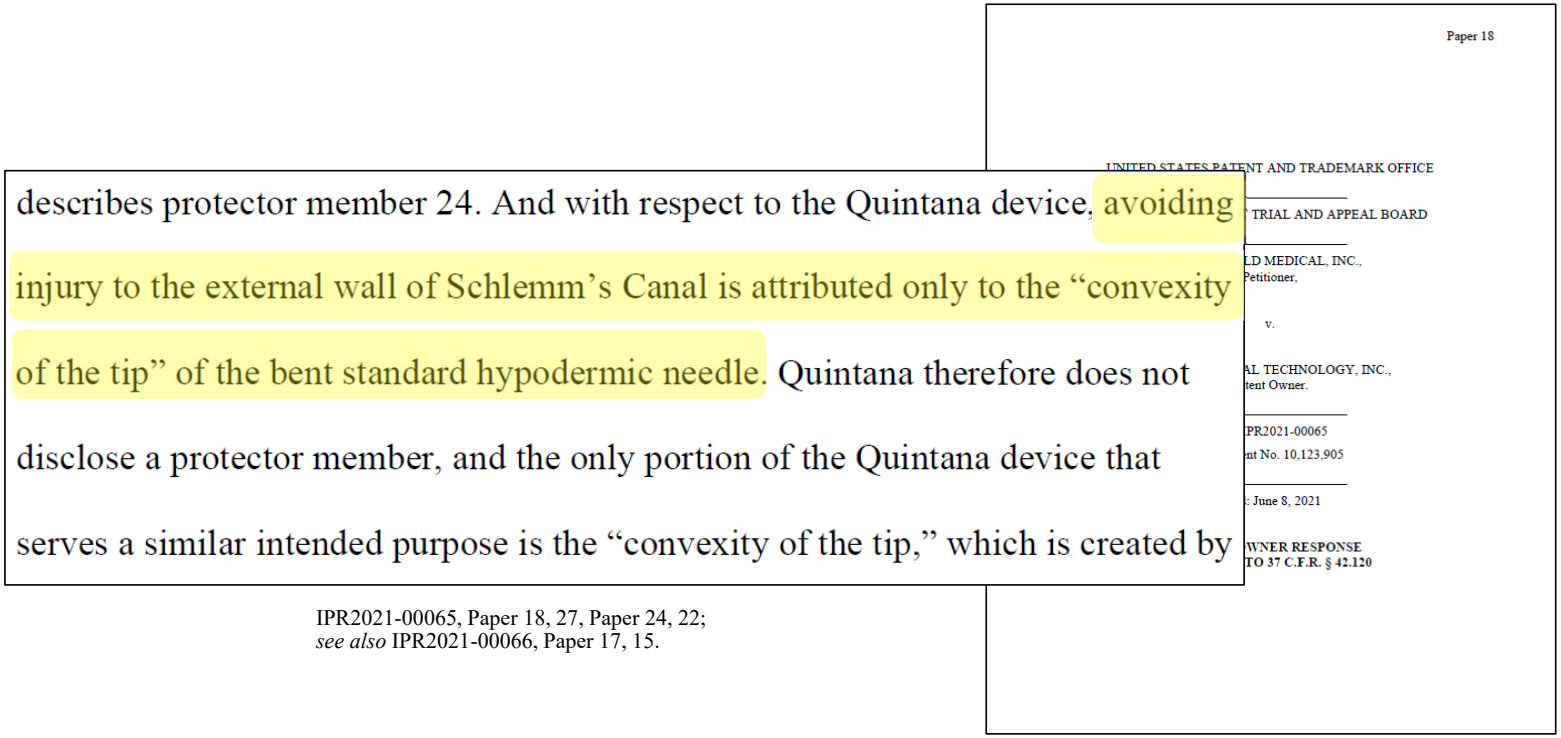
IPR2021-00065, Ex.1001, 9:9-17, Fig.5A (*see* Paper 1, 19-20).



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"



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

Paper 18

UNITED STATES PATENT AND TRIAL AND APPEAL BOARD

LD MEDICAL, INC.,
Petitioner,

v.

AL TECHNOLOGY, INC.,
tent Owner.

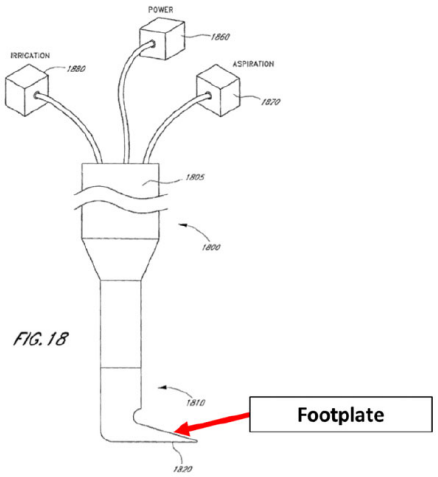
PR2021-00065
nt No. 10,123,905

June 8, 2021

WNER RESPONSE
TO 37 C.F.R. § 42.120

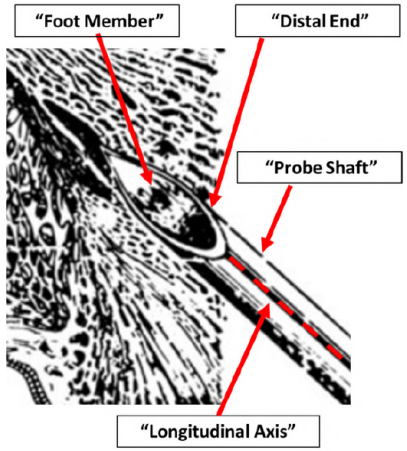
IPR2021-00065, Paper 18, 27, Paper 24, 22;
see also IPR2021-00066, Paper 17, 15.

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)

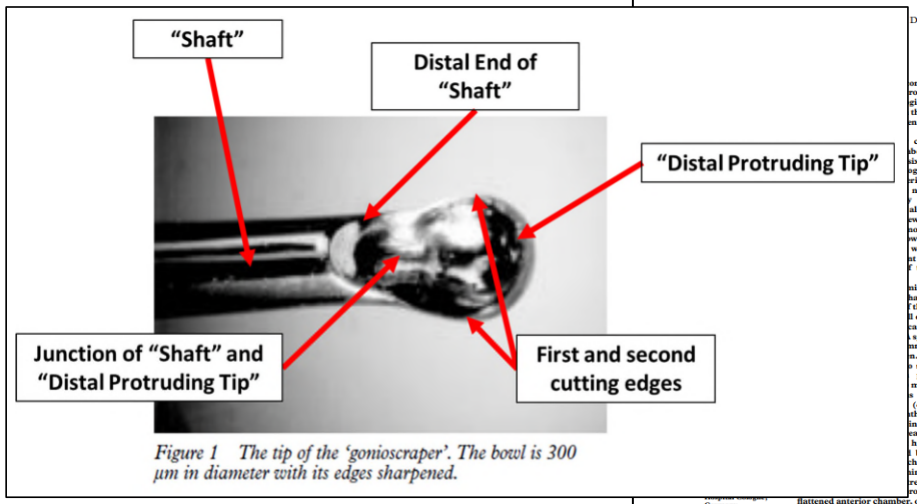


Figure 1 The tip of the 'gonioscraper'. The bowl is 300 µm in diameter with its edges sharpened.

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

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

Dietlein, Günter K Krieglstein

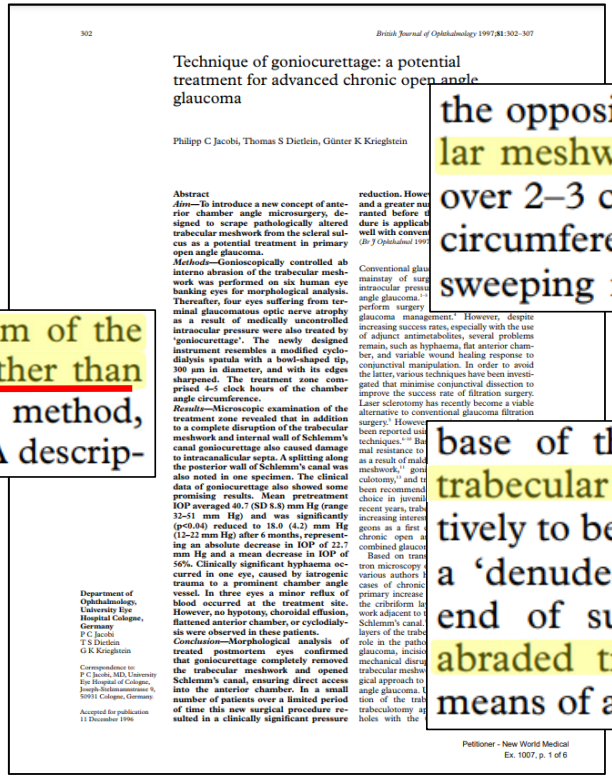
was designed. The 'gonioscraper' consists of a small handle and a slightly convex-shaped arm for intraocular use and very much resembles a cyclodialysis spatula. However, the tip of the instrument is shaped as a tiny bowl with 300 µm diameter and with its edges sharpened (Fig 1). In order to abrade clockwise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

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

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



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

Technique of goniocurettage: 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 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 'goniocurettage'. 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 4–5 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 goniocurettage 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 goniocurettage also showed some promising results. Mean pretreatment IOP averaged 40.7 (SD 8.8) mm Hg (range 32–51 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 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 goniocurettage 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. Howe and a greater nu ranted before t dure is applicab well with convent**

(Br J Ophthalmol 1997

Conventional glau mainstay of surg intraocular pressu angle glaucoma.[1–3] perform surgery glaucoma management.[4] However, despite increasing success rates, especially with the use of adjunct antimetabolites, several problems remain, such as hyphaema, 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 sclerotomy has recently become a viable alternative to conventional glaucoma filtration surgery.[5] Howeve been reported usi techniques.[6–10] Ba mal resistance to as a result of male meshwork,[11] goni culotomy,[12] and t been recommend choice in juvenil recent years, trab increasing interest geons as a first chronic open a combined glauco Based on trans tron microscopy various authors h cases of chronic primary increase the cribriform la work adjacent to Schlemm's canal layers of the trabe role in the patho glaucoma, incisio mechanical disru trabecular meshw gical approach to angle glaucoma. tion of the trab trabeculotomy a holes with the

Department of Ophthalmology, University Eye Hospital Cologne, Germany
P C Jacobi
T S Dietlein
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Correspondence to:
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Accepted for publication 11 December 1996

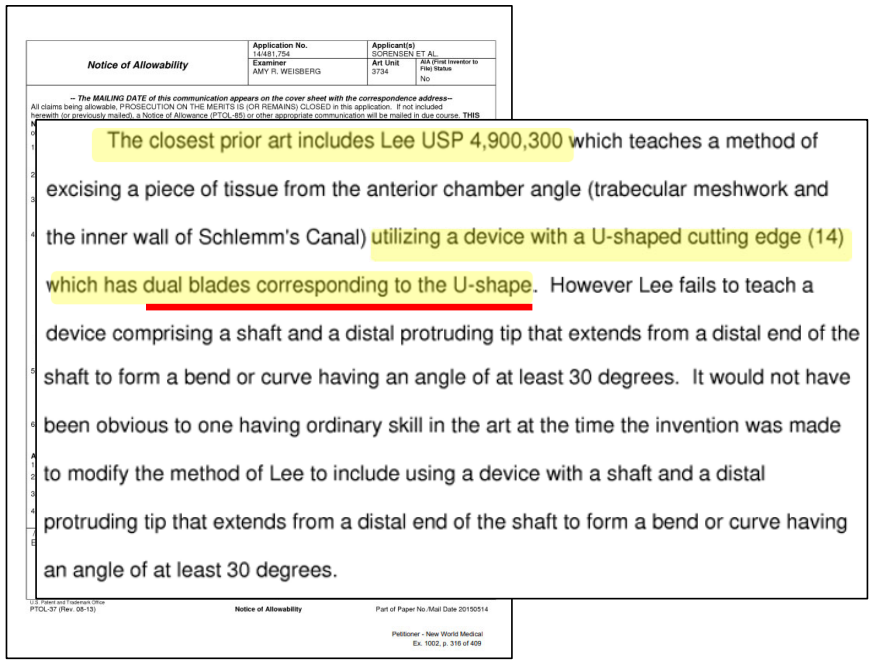
Petitioner - New World Medical
Ex. 1007, p. 1 of 6

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

base of the iris. Gonioscopically, strings of trabecular tissue could be observed intraoperatively to be removed by goniocurettage, 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.

The ‘729’s Notice of Allowance Confirms that a U-Shaped Cutting Edge is “Dual Blade”



Notice of Allowability

Application No. 14/481,754	Applicant(s) SORENSEN ET AL.
Examiner AMY R. WEISBERG	Art Unit 3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

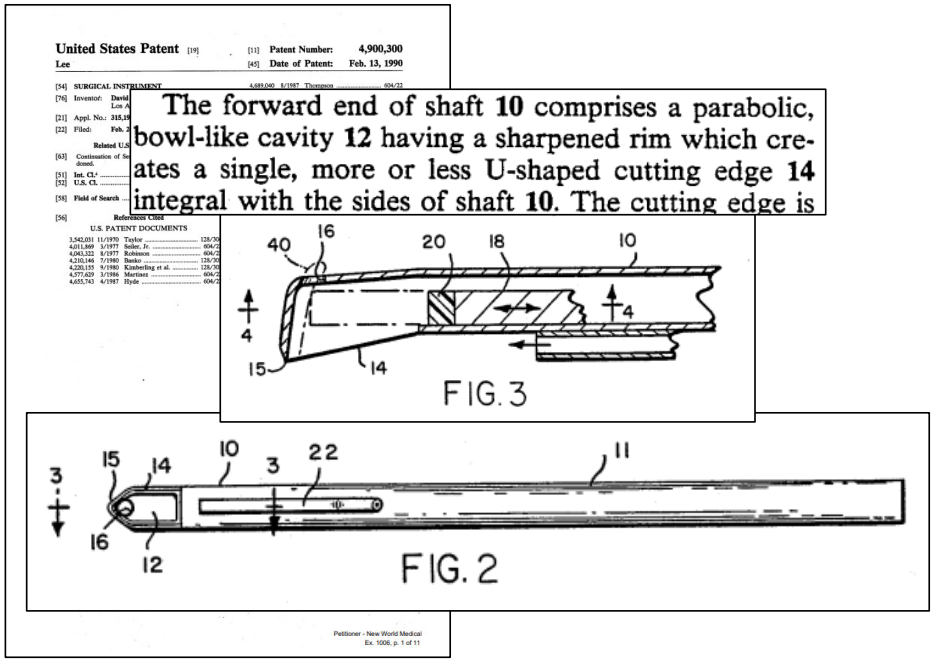
The closest prior art includes Lee USP 4,900,300 which teaches a method of excising a piece of tissue from the anterior chamber angle (trabecular meshwork and the inner wall of Schlemm's Canal) utilizing a device with a U-shaped cutting edge (14) which has dual blades corresponding to the U-shape. However 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.

Notice of Allowability

Part of Paper No./Mail Date 20150514

Petitioner - New World Medical Ex. 1002, p. 316 of 409

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).



United States Patent [19]

Lee

[11] Patent Number: 4,900,300

[45] Date of Patent: Feb. 13, 1990

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

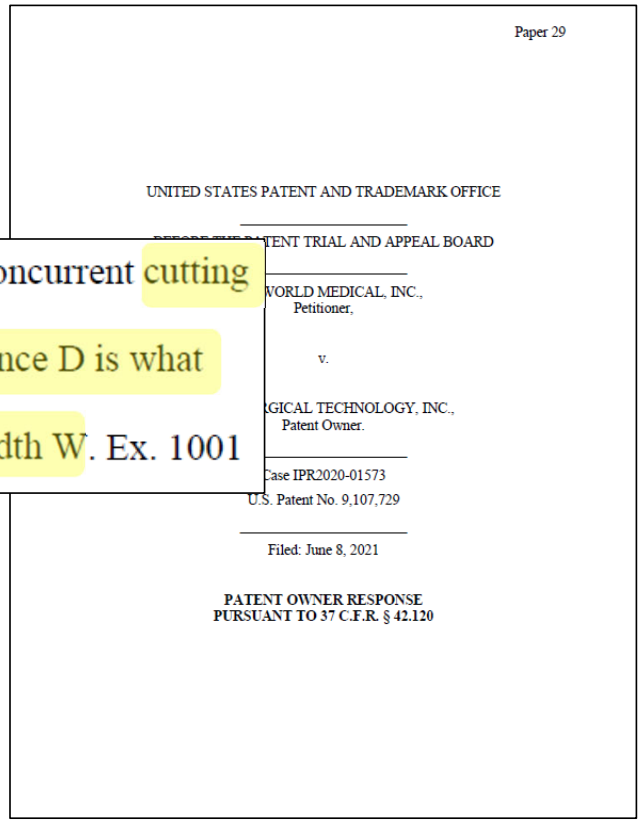
Petitioner - New World Medical Ex. 1006, p. 1 of 11

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

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



Paper 29

UNITED STATES PATENT AND TRADEMARK OFFICE

TENT TRIAL AND APPEAL BOARD

WORLD MEDICAL, INC.,
Petitioner,

v.

GICAL 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

Obvious to Modify Jacobi So TM Passes Over "Protector Member" Before Contacting the "Knife Blades" ('905, cl.1)

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

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

Philipp C Jacobi, Thomas S Dietlein, Günter K Krieglstein

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P C Jacobi
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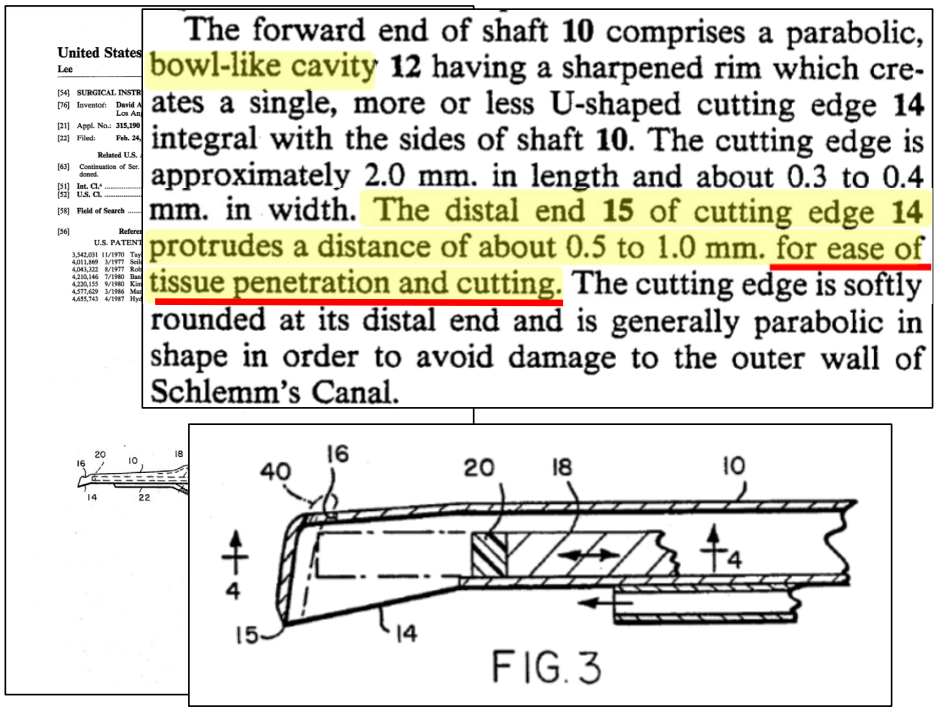
Accepted for publication 11 December 1996

treated postmortem eyes confirmed that goniocurettage 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

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

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

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.



United States
Lee

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 approximately 2.0 mm. in length and about 0.3 to 0.4 mm. in width. The distal end **15** of cutting edge **14** protrudes a distance of about 0.5 to 1.0 mm. for ease of tissue penetration and cutting. The cutting edge is softly rounded at its distal end and is generally parabolic in shape in order to avoid damage to the outer wall of Schlemm's Canal.

FIG. 3

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

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

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.

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

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

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Abstract

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.

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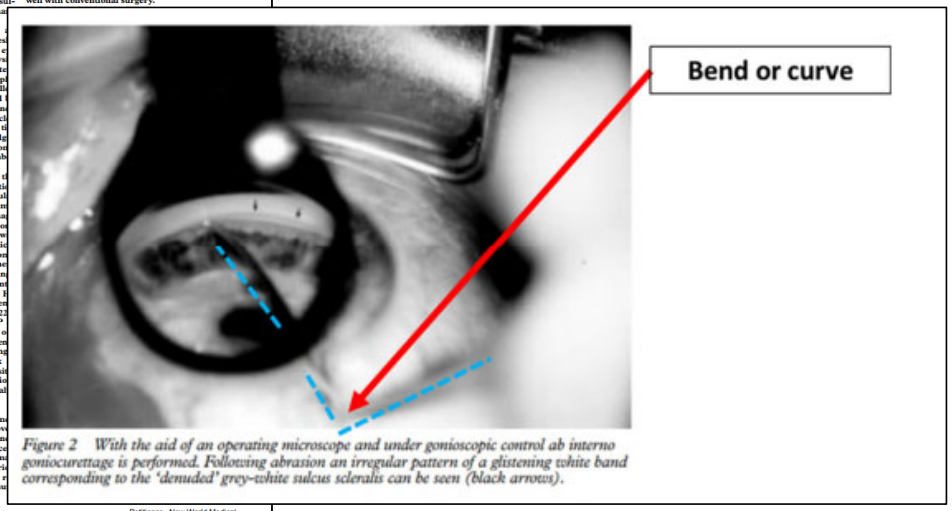
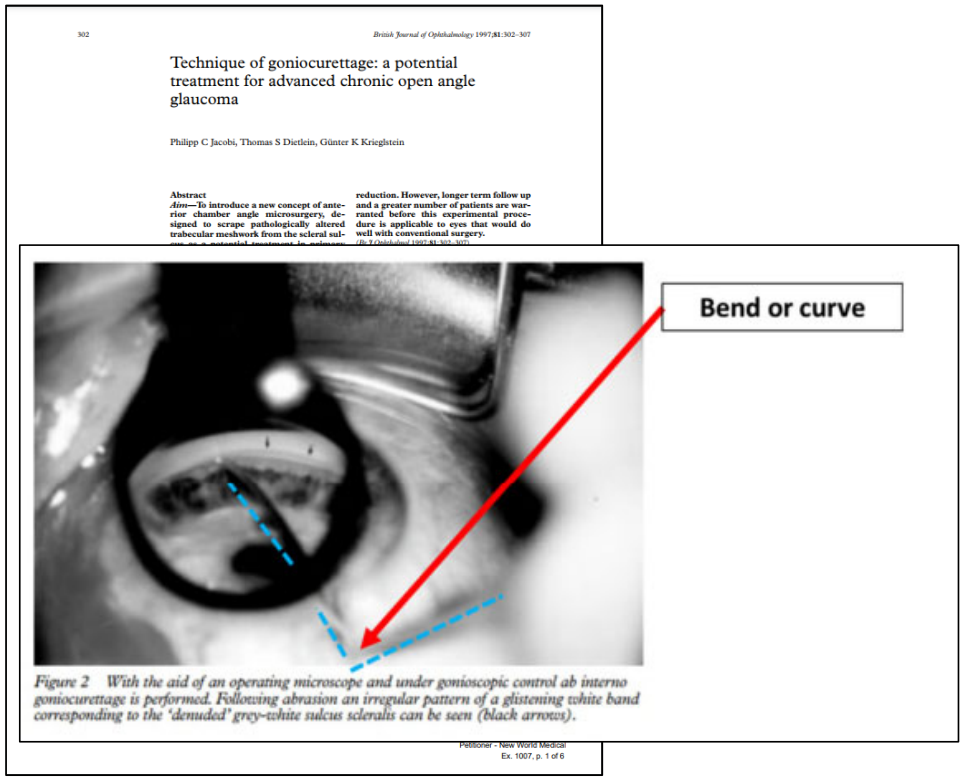


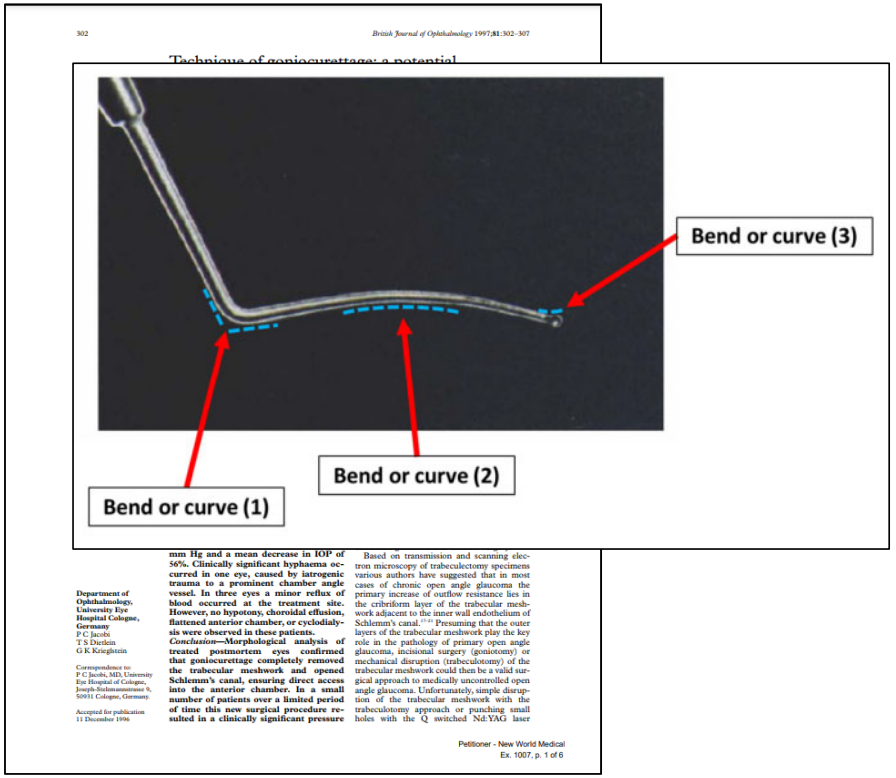
Figure 2 With the aid of an operating microscope and under gonioscopic control ab interno goniocurettage is performed. Following abrasion an irregular pattern of a glistening white band corresponding to the ‘denuded’ grey-white sulcus scleralis can be seen (black arrows).

Ex.1007, 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



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.



Ex.1013, Fig.1(b); *see* IPR2020-01573, Paper 1, 82; IPR2020-01711, Paper 1, 84-85; IPR2021-00017, Paper 1, 85, 80-84; IPR2021-00066, Paper 1, 75-76.

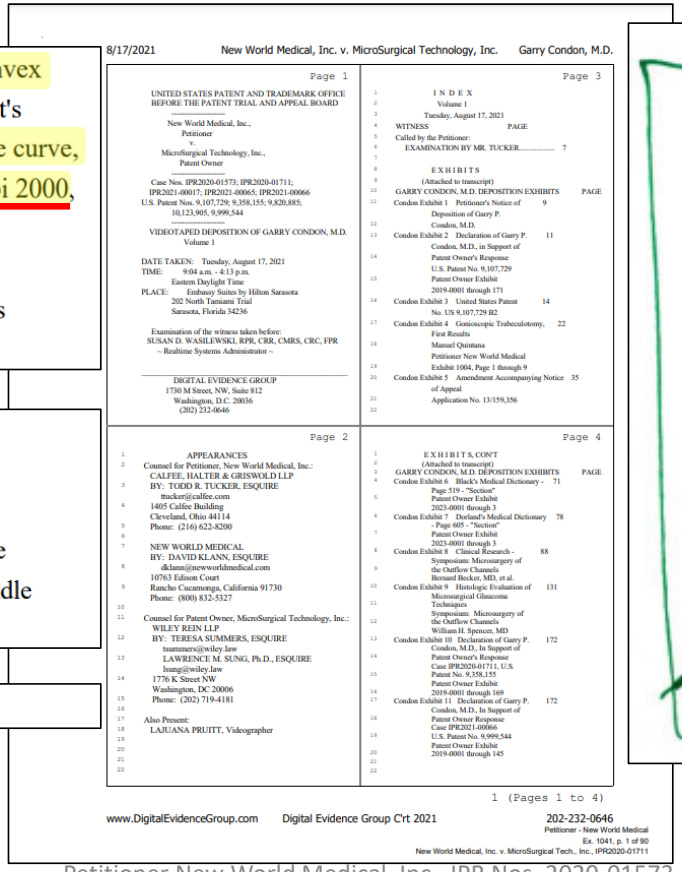
Dr. Condon Admitted Jacobi Has A Bend

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

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

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.

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

VIDEOTAPED DEPOSITION OF GARRY CONDON, M.D.
Volume 1

DATE TAKEN: Tuesday, August 17, 2021
TIME: 9:04 a.m. - 4:13 p.m.
Eastern Daylight Time
PLACE: Embassy Suites by Hilton Sarasota
202 North Tamiami Trial
Sarasota, Florida 34236

Examination of the witness taken before:
SUSAN D. WASILEWSKI, RPR, CRR, CMRS, CRC, FPR
~ Realtime Systems Administrator ~

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Tuesday, August 17, 2021

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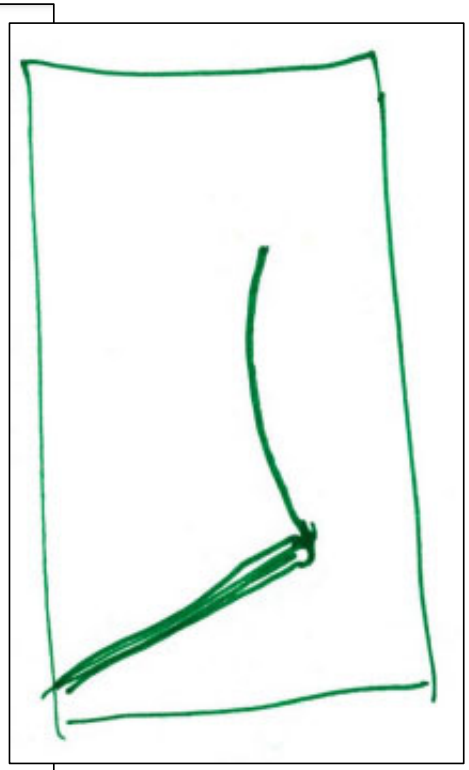
New World Medical, Inc. v. MicroSurgical Tech., Inc., IPR2020-01711



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)

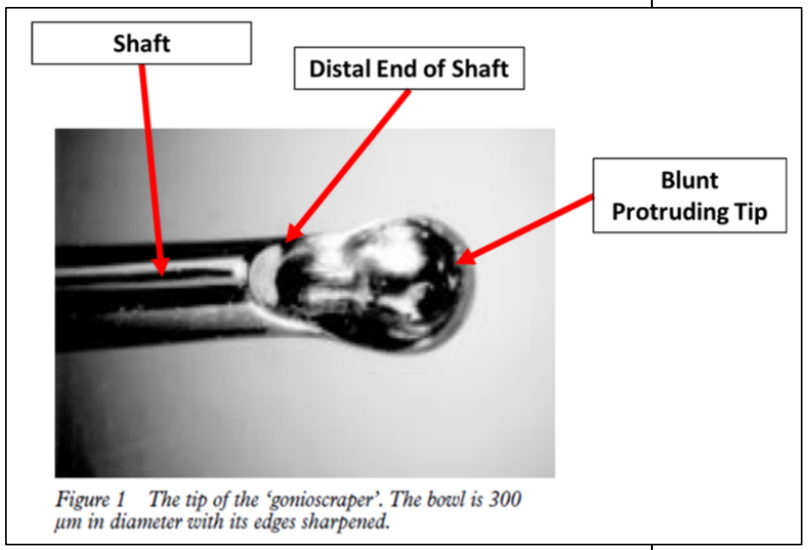
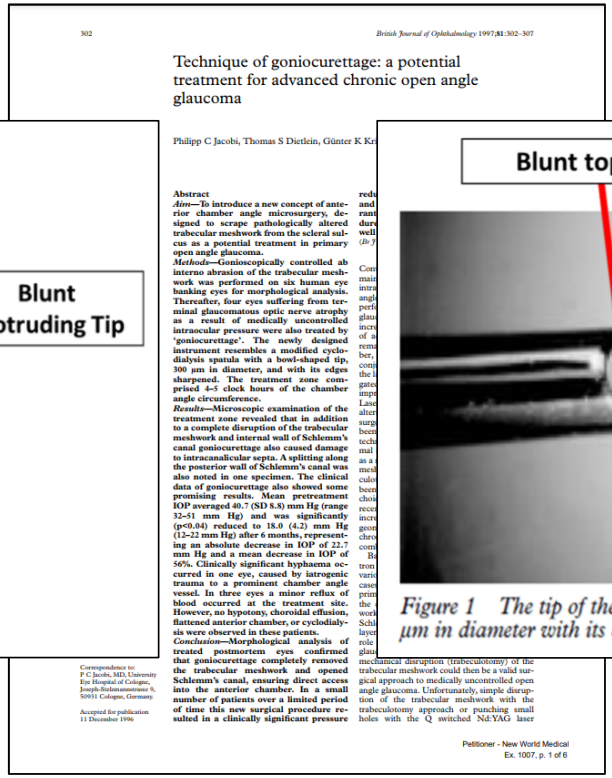


Figure 1 The tip of the ‘gonioscraper’. The bowl is 300 μm in diameter with its edges sharpened.

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



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

Technique of goniocurettage: 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 ‘goniocurettage’. 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 4–5 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 goniocurettage 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 goniocurettage also showed some promising results. Mean pretreatment IOP averaged 40.7 (SD 8.8) mm Hg (range 32–51 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 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 goniocurettage 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

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Accepted for publication 11 December 1996

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

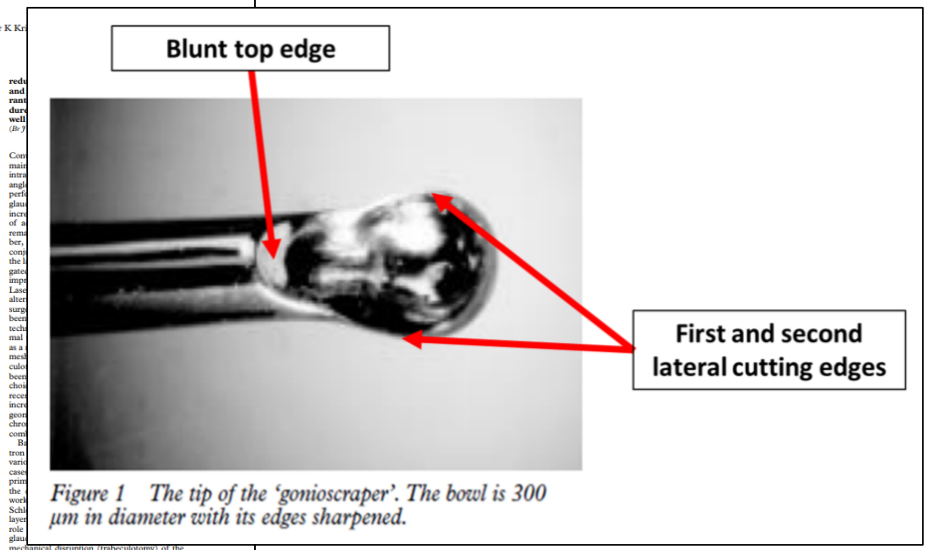
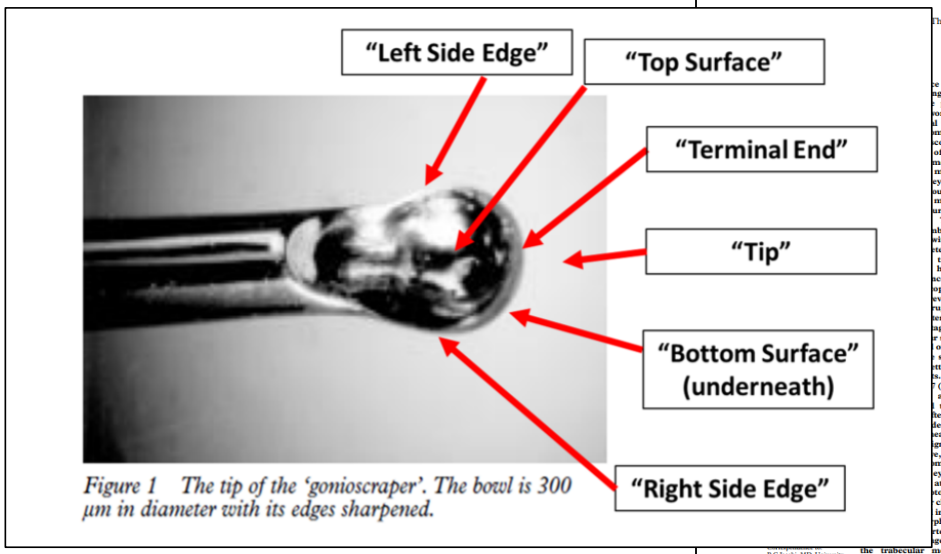


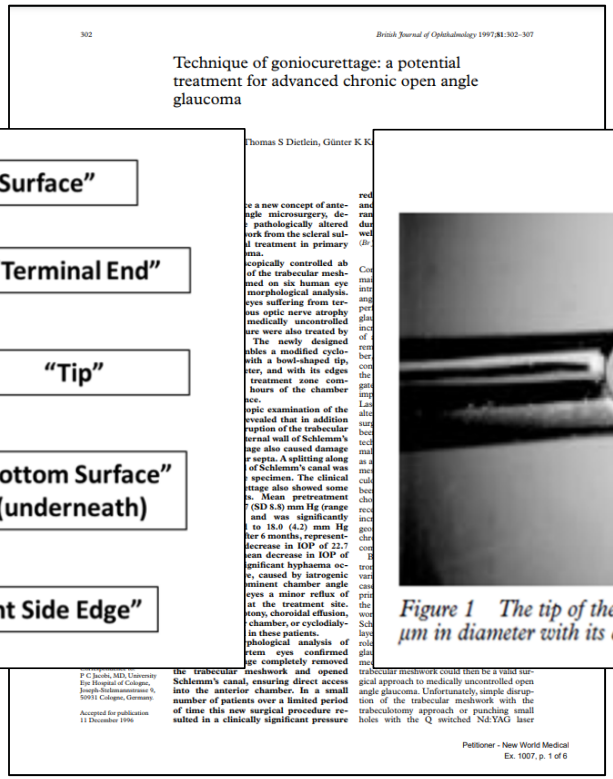
Figure 1 The tip of the ‘gonioscraper’. The bowl is 300 μm in diameter with its edges sharpened.

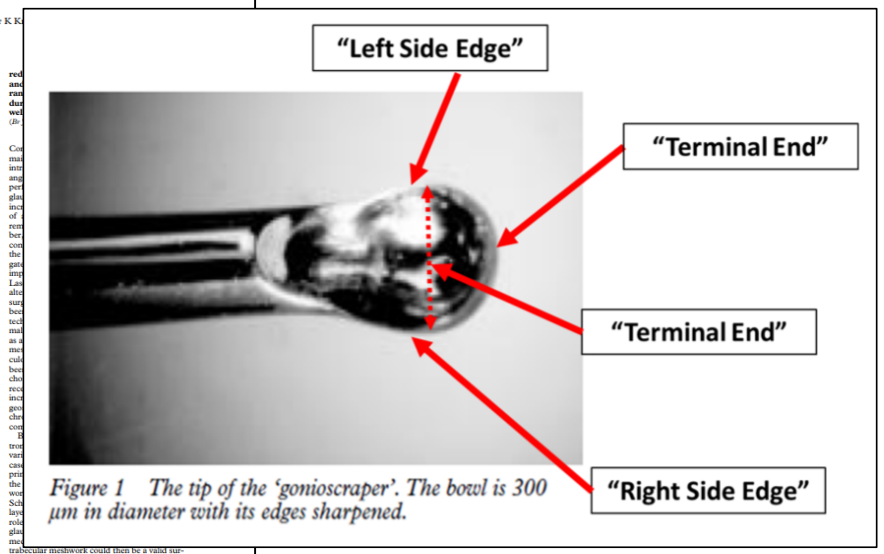
IPR2020-01711, Ex.1007, (*see* Paper 1, 91).

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



IPR2021-00017, Ex.1007, Fig.1 (*see* Paper 1, 64).



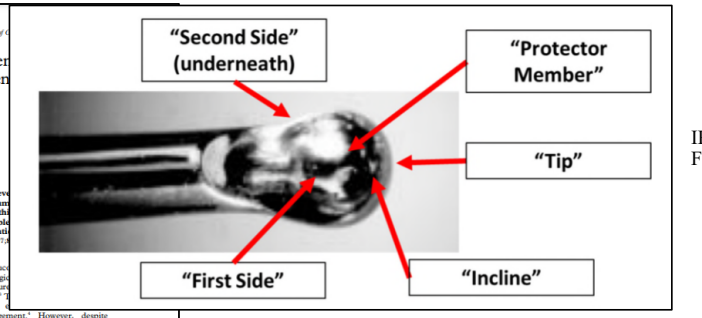


IPR2021-00017, Ex.1007, Fig.1 (*see* Paper 1, 65).

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.



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

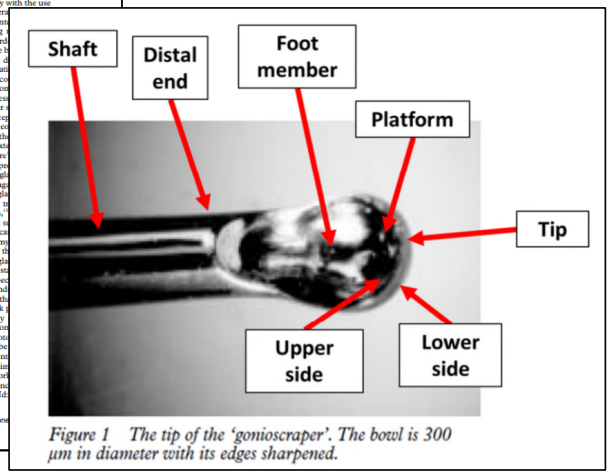


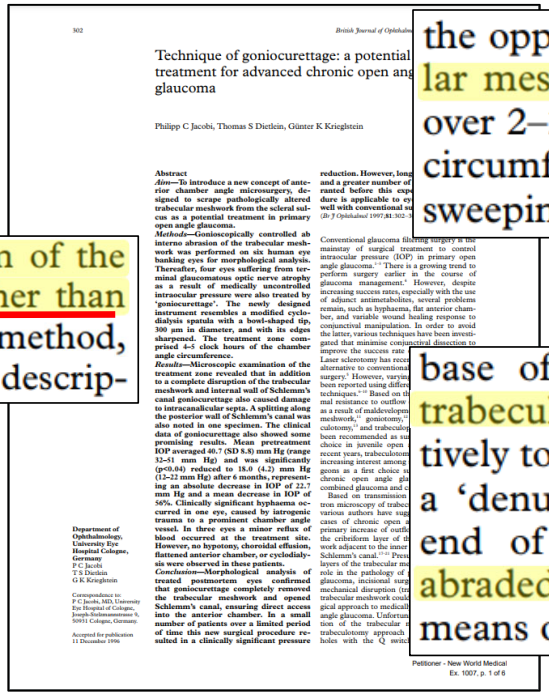
Figure 1 The tip of the 'gonioscraper'. The bowl is 300 μm in diameter with its edges sharpened.

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)

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



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Philipp C Jacobi, Thomas S Dietlein, Günter K Krieglstein

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(*Br J Ophthalmol* 1997;**81**:302–3

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Accepted for publication 11 December 1996

Conventional glaucoma filtering surgery is the mainstay of surgical treatment to control intraocular pressure (IOP) in primary open angle glaucoma.[1–3] There is a growing trend to perform surgery earlier in the course of glaucoma management.[4] However, despite increasing success rates, especially with the use of adjunct antimetabolites, several problems remain, such as hyphaema, 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 sclerotomy has recei alternative to conventiona surgery.[5] However, varyin been reported using differe techniques.[6–9] Based on th mal resistance to outflow as a result of maldevelopm meshwork,[11] goniotomy,[culotomy,[4] and trabeculo been recommended as sur choice in juvenile open recent years, trabeculotom increasing interest among geons as a first choice su chronic open angle gla combined glaucoma and c

Based on transmission tron microscopy of trabec various authors have sug cases of chronic open a primary increase of outflo the cribriform layer of th work adjacent to the inner Schlemm's canal.[12–15] Press layers of the trabecular me role in the pathology of glaucoma, incisional surg mechanical disruption (tra trabecular meshwork could gical approach to medicall angle glaucoma. Unfortun tion of the trabecular trabeculotomy approach holes with the Q switc

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

base of the iris. Gonioscopically, strings of trabecular tissue could be observed intraoperatively to be removed by goniocurettage, 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.

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	
• Quintana	✓	✗	• ~~Quintana's Affidavit~~
• Jacobi	✓		
• Dr. Netland	✓	?	• Dr. Condon
• Testing	✓		

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.