UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IVANTIS, INC., ALCON RESEARCH, LLC, ALCON VISION, LLC, AND ALCON INC.,
Petitioners

v.

SIGHT SCIENCES, INC.,
Patent Owner.

IPR2022-01540
U.S. Patent No. 9,486,361

PETITION FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. § 42.101

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1007	RESERVED
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1011	U.S. Pub. No. 2006/0195187 ("Stegmann")
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1023	LexMachina Statistics
1024	WO 2002036052 ("Tu '052")
1025	U.S. Pub. No. 2004/0254520 ("Porteous")
1026	"Glaucoma drainage implants: a critical comparison of types," Schwartz et al. (2006)
1027	"Glaucoma drainage implants," Sidoti & Baerveldt (1994)
1028	U.S. Pub. No. 2005/0266047 ("Tu")
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1037	U.S. Publ. No. 2004/0102719 ("Shadduck")
1038	Excerpts of Sight Sciences Inc.'s Corrected Initial Infringement Contentions, Ex. C (Aug. 26, 2022)
1039	The "Gauge" System for the Medical Use, Table 1, Letters to the Editor, American Society of Anesthesiologists (2002)
1040	Aragona, Pasquale et al., Long Term Treatment with Sodium Hyaluronate-Containing Artificial Tears Reduces Ocular Surface Damage in Patients with Dry Eye, 86 The British Journal of Ophthalmology 2 (2002)
1041	Myers, T D, and R J Olson, Comparison of the Effects of Viscoelastic Agents on Clinical Properties of the Unfolder Lens Injection System, 25 Journal of Cataract and Refractive Surgery 7, at 953–58 (1999)
1042	E. A. Balazs, et al., Hyaluronic Acid and Replacement of Vitreous and Aqueous Humor, 10 Modern Problems in Ophthalmology 3-21 (1972)
1043	J. S. Jacob, Corneal thickness changes following cataract surgery: effect of lens implantation and sodium hyaluronate, 69 British Journal of Ophthalmology 567-571 (1985)
1044	Summary of Safety and Effectiveness Data, STAARVISCTM (sodium hyaluronate) Premarket Approval (Apr. 18, 2001)
1045	G. J. Wild et al., Dilation of Schlemm's Canal in Viscocanalostomy: Comparison of 2 Viscoelastic Substances, 27 Journal of Cataract and Refractive Surgery 8 at 1294-97 (2001)

1046	A.P. Nesterov, Role of Blockage of Schlemm's Canal in Pathogenesis of Primary Open Angle Glaucoma, 70 Am. J. Ophthalmology 691, 691 (1970)
1047	Robert Stegmann, Anc Pienaar, David Miller, Viscocanalostomy for Open-Angle Glaucoma in Black African Patients, 25 Journal of Cataract & Refractive Surgery 3, at 316-322 (1999)
1048	U.S. Patent No. 5,360,399 ("Stegmann 1994")
1049	U.S. Patent No. 5,486,165 ("Steggman 1996")
1050	Matthias U.H. Drusedau,et al, Viscocanalostomy for primary open-angle glaucoma: The Gross Pankow experience, J CATARACT REFRACT SURG – Vol. 26, (September 2000)
1051	Robert Stegmann, MD: taking on the challenges of ocular trauma and disease, Ocular Surgery News (Sept. 15, 2002)
1052	U.S. Pub. No. 2005/0277864 ("Haffner II")
1053	U.S. Patent No. 6,375,642 ("Grieshaber 642")

I. INTRODUCTION

U.S. Patent No. 9,486,361 ("'361 patent") is one of several patents in a family directed to a concept that has been widely known and understood for decades before the priority date: treating an eye condition by implanting a stent-like support made of known components and configurations to help drain fluid from the anterior chamber of the eye. The claims of the '361 patent track the inherent or result-effective characteristics of prior art stent configurations and stent implantation methodologies and reflect nothing more than mere design choices and configurations that would have been obvious to a person of ordinary skill in the art ("POSITA").

Patent Owner's assertion of the '361 patent against Petitioners in *Sight Sciences, Inc. v. Ivantis, Inc.*, C.A. No. 21-1317-GBW (D. Del.), filed September 16, 2021 ("Delaware Litigation"), does not justify denial of this petition. Delaware's median time to trial is over two and a half years, and that case was only recently assigned to Judge Williams. Thus, trial in the Delaware action will not likely occur until after the Board's final written decision deadline. The PTAB therefore presents the more efficient avenue for hearing Petitioners' invalidity arguments.

Petitioners Ivantis, Inc., Alcon Research, LLC, Alcon Vision, LLC, and Alcon Inc., respectfully request *Inter Partes* Review ("IPR") of '361 claims 1-3 and 5-9.

II. MANDATORY NOTICES

A. 37 C.F.R. § 42.8(b)(1): Real Parties-in-Interest

The real parties-in-interest are Ivantis, Inc., Alcon Research, LLC, Alcon Vision, LLC, and Alcon Inc.

B. 37 C.F.R. § 42.8(b)(2): Related Matters

Patent Owner asserted the '361 patent against Petitioners in the Delaware Litigation. Petitioners are concurrently filing IPR petitions for three other patents in the same family as the '361 patent, all of which are asserted in the Delaware Litigation: U.S. Patent Nos. 8,287,482; 9,370,443; and 10,314,742. This case may affect, or be affected by, the Delaware Litigation.

C. 37 C.F.R. § 42.8(b)(3)&(4): Lead and Back-up Counsel and Service Information

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A Power of Attorney accompanies this Petition pursuant to 37 C.F.R. § 42.10(b). Petitioners consent to electronic service by email at Ivantis_IPR@kirkland.com.

III. PAYMENT OF FEES PURSUANT TO 37 C.F.R. § 42.103

Petitioners authorize the Office to charge the filing fee and any other necessary fee to Deposit Account No. 506092.

IV. CERTIFICATION OF STANDING UNDER 37 C.F.R. § 42.104

Petitioners certify the '361 patent is available for IPR and that Petitioners are not barred or estopped from requesting IPR on the grounds identified herein.

V. OVERVIEW OF CHALLENGE AND RELIEF REQUESTED

A. 37 C.F.R. § 42.104(b)(1): Claims for Which IPR is Requested

Petitioners challenge claims 1-3 and 5-9 of the '361 patent.

B. 37 C.F.R. § 42.104(b)(2): Grounds for Challenge

Petitioners challenge the claims based on the following references, none of which were applied or discussed by the examiner during prosecution:

1. U.S. Pub. No. 2005/0266047 to Tu et al. ("Tu"), filed March 18, 2005, published December 1, 2005, is prior art under § 102(a),(e) (pre-AIA).

2. U.S. Pub. No. 2002/0165478 to Gharib et al. ("Gharib"), filed May 2, 2001, published November 7, 2002, is prior art under § 102(b) (pre-AIA).

3. U.S. Patent No. 7,186,232 to Smedley et al. ("Smedley"), filed on Mar. 7, 2003, issued on Mar. 6, 2007, is prior art under § 102(e) (pre-AIA).

4. U.S. Pub. No. 2004/0102729 to Haffner et al. ("Haffner"), filed on Aug. 5, 2003, published on May 27, 2004, is prior art under § 102(b) (pre-AIA).

Petitioners request IPR on the following grounds:

Ground	Basis	Claims	Reference(s)
1	§ 103	1-3, 5-9	Tu
2	§ 103	1-3, 5-9	Gharib in combination with Smedley
3	§ 103	1-3, 5-9	Gharib in combination with Haffner

C. 37 C.F.R. § 42.104(b)(3): Claim Construction

Claims are construed under the claim-construction principles set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*). 37 C.F.R. § 42.100(b). Petitioners reserve the right to respond to any constructions that Patent Owner submits.

The '361 patent is rife with vague language in the claims and written description that fails to provide clear guidance regarding the scope of the claims at issue. For the purposes of applying prior art in this *Inter Partes* Review, Petitioners

have adopted Patent Owner's interpretations of the claim language for the terms listed below: [1]

"***wherein at least a portion of the arcuate member has a radius of curvature smaller than a radius of curvature of Schlemm's canal***" **(Claim 1):** The '361 patent states that "[t]he support may comprise a stiff arcuate member having a radius of curvature smaller or larger than that of Schlemm's canal" (Ex.1003 (4:18-20)), but is silent on how or where to measure the radius of curvature. For the purposes of this Petition, Petitioners have adopted Patent Owner's interpretation that a support meets the limitation if, once implanted, it has an overall radius smaller than Schlemm's canal such that a portion of the support protrudes from Schlemm's canal. *See* Ex.1020 (Ex.N at 10).

"***delivering a high viscosity fluid into Schlemm's canal***" **(Claim 1):** The '361 patent states that the claimed method includes "delivering a high viscosity fluid into Schlemm's canal" (Ex.1003 (cl. 3)), but is silent as to a method or criteria to determine what constitutes a "high viscosity fluid," instead only disclosing sodium hyaluronate as an example. Ex.1003 (17:51-53). For the purposes of this Petition, Petitioners have adopted Patent Owner's interpretation that all viscoelastics are high

[1] Petitioners reserve the right to challenge (in district court or otherwise) the claim terms discussed below for failing to satisfy 35 U.S.C. §112.

viscosity fluids. *See* Ex.1020 (Ex.N at 4 ("[T]he Hydrus Microstent implantation procedure involves '**delivering a high viscosity fluid**,' such as viscoelastic, **'into Schlemm's canal**.'")).

Additionally, the claimed method does not recite when or how a high viscosity fluid is delivered into Schlemm's canal. Patent Owner has alleged that high viscosity fluid may be delivered using a separate cannula in advance of implanting a stent into Schlemm's canal. *See* Ex.1020 (Ex.N at 4 (alleging performing viscoelastic delivery in advance of delivering a stent infringes)).

D. 37 C.F.R. § 42.104(b)(4): How the Claims are Unpatentable

Section XI details how the Challenged Claims are unpatentable.

E. 37 C.F.R. § 42.104(b)(5): Evidence Supporting Challenge

A list of exhibits is provided at the beginning of the Petition. The relevance of this evidence and the specific portions supporting the challenge are provided, *e.g.*, in §XI. Petitioners submit a declaration of Dr. Michael Reynard (Ex.1001) in support of this Petition under 37 C.F.R. § 1.68.

VI. BACKGROUND OF THE TECHNOLOGY

A. Glaucoma

Glaucoma is an ophthalmic condition characterized by elevated intraocular pressure, which in turn places increased pressure on the optic nerve and can lead to loss of vision if left untreated. Ex.1001 (¶23) (citing Ex.1008 (¶6)). Elevated eye pressure results from an internal imbalance of the fluid inside the eye—called

aqueous humor. *Id*. Aqueous humor is constantly produced in the ciliary body, and flows through the pupillary opening in the iris and into the anterior chamber of the eye. *Id*. (¶23) (citing Ex.1008 (¶7)). It then flows through the trabecular meshwork, which is a wedge-shaped structure that runs around the circumference of the angle of the iris and cornea and acts like a sieve to filter the aqueous humor. *Id.* ¶23 (citing Ex.1008 (¶8)). After passing through the trabecular meshwork, aqueous humor flows into Schlemm's canal, which abuts the trabecular meshwork and encircles the posterior junction of the cornea and sclera. *Id.* In general, Schlemm's canal is a flexible, continuous passage (or vessel) that goes 360-degrees around the eye. *Id.* The cross-section of Schlemm's canal, therefore, varies as well. After aqueous humor flows into Schlemm's canal, it exits through collector channel openings in the wall of Schlemm's canal and is cleared by the venous system. *Id.* (citing Ex.1008 (¶9)). Figure 2 of the '361 patent itself shows the general flow of aqueous humor from ciliary body 12 between lens 16 and iris 18, through pupil 22 into the anterior chamber 20, across the trabecular meshwork 28, and into Schlemm's canal 30. Ex.1003 (6:39-48).

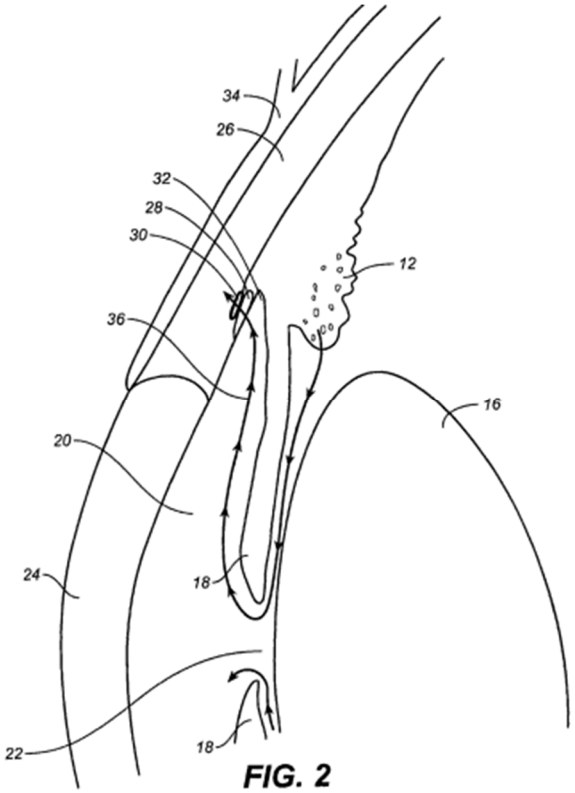


FIG. 2

Ex.1003 Figure 2.

In healthy eyes, aqueous humor production approximately equals aqueous humor outflow, keeping intraocular pressure fairly constant. Ex.1001 (¶24) (citing Ex.1008 (¶7)). In primary open angle glaucoma—the most common form of glaucoma—ocular pressure can increase due to decreased aqueous humor outflow across the trabecular meshwork and through Schlemm's canal. Ex.1001 (¶24) (citing Ex.1008 (¶8-9)). Schlemm's canal can also collapse, which prevents aqueous humor outflow into the collector channels and out through the body's normal outflow pathways. Ex.1001 (¶24) (citing Ex.1012 (5:11-17)); *see also* Ex.1003 (1:59-61). Thus, many glaucoma treatments seek to improve aqueous humor outflow across these structures. Ex.1001 (¶24) (citing Ex.1008 (¶¶13-19)).

B. Surgical Glaucoma Treatments were Well-Known

Physicians have long studied the mechanisms of aqueous generation and outflow in glaucoma patients and there is, accordingly, a rich history of surgical treatment options. "***Not surprisingly*** there have been two basic approaches to lowering eye pressure surgically: (1) increase outflow and (2) decrease inflow of aqueous humor." Ex.1001 (¶25) (citing Ex.1013 (E39)). It was recognized as early as 1925 that "[t]he ideal operation, therefore, would be one which creates a permanent outlet for the pent up intraocular fluids and causes least trauma[]." Ex.1001 (¶25) (citing Ex.1014 (681)). This tenet is so self-evident that "[a]lthough there have been numerous refinements on the original procedures, little conceptually new has happened in the past 100 years." Ex.1001 (¶25) (citing Ex.1013 (E45)).

The trabecular meshwork and inner wall of Schlemm's canal are understood to be the sites of increased resistance in glaucoma patients, and therefore, glaucoma treatments are generally directed at bypassing the diseased tissue. Ex.1001 (¶26) (citing Ex.1015 (Abstract)). In 1925, Stefansson invented gold wire implants designed to channel aqueous out of the anterior chamber (figures below). Ex.1001 (¶26) (citing Ex.1015 (681, 683)). The perpendicular ends of the supports below (the twisted ends of 1, 2, and 4 and the vertical tube in 3), when inserted into the anterior chamber, provided an outlet for excess aqueous humor to exit the chamber through the resulting opening. Ex.1001 (¶26) (citing *Id*. (683-684)).

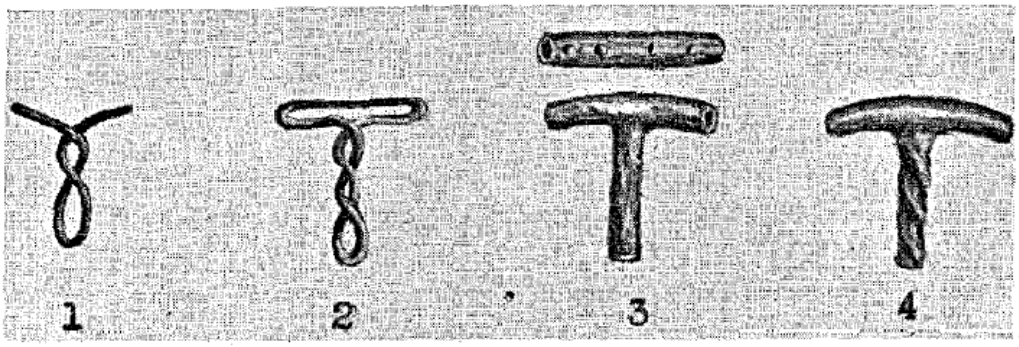
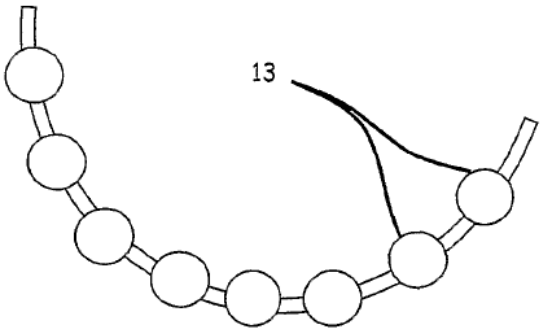


Fig. 3. Different types of inserts used in order of design. Base of No. 3 perforated to facilitate drainage.

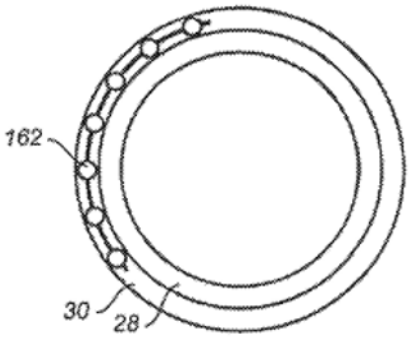
Many known devices, such as shunts and stents, channel aqueous humor out of the anterior chamber to reduce pressure similarly to Dr. Stefansson's devices. Device designs vary, but generally fall within two categories: (1) treatments that create a new outflow pathway, and (2) treatments that encourage and improve physiologic drainage channels. Ex.1001 (¶27) (citing Ex.1013 (E39)). Both types of treatments were well-known as of the date of the alleged invention. *Id*.

a. **Schlemm's Canal Implants Extending Into or Through the Trabecular Meshwork were Well-Known**

In some patients, the increased pressure in the anterior chamber can collapse Schlemm's canal. Ex.1016 (19:48-67); Ex.1001 (¶24, 30). As of the priority date, it was well-known to insert a device into Schlemm's canal to prop it open. For example, prior art WO 2006/066103 ("Stegmann") (Ex.1017) discloses "[a]n implant placed within Schlemm's canal and provides tension to the trabecular meshwork" that "increases the aqueous outflow," a technique and device that bear striking resemblance to the alleged invention. *Id.* (Abstract).

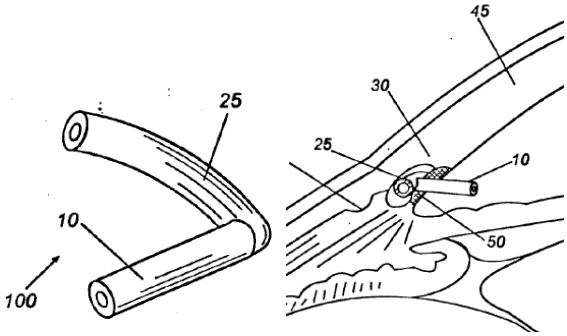


Ex.1017 Figure 4a.

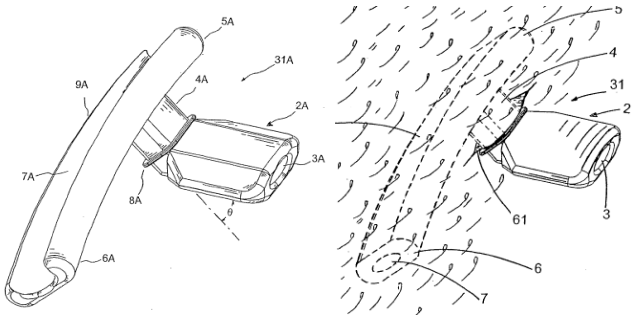


Ex.1003 Figure 10B

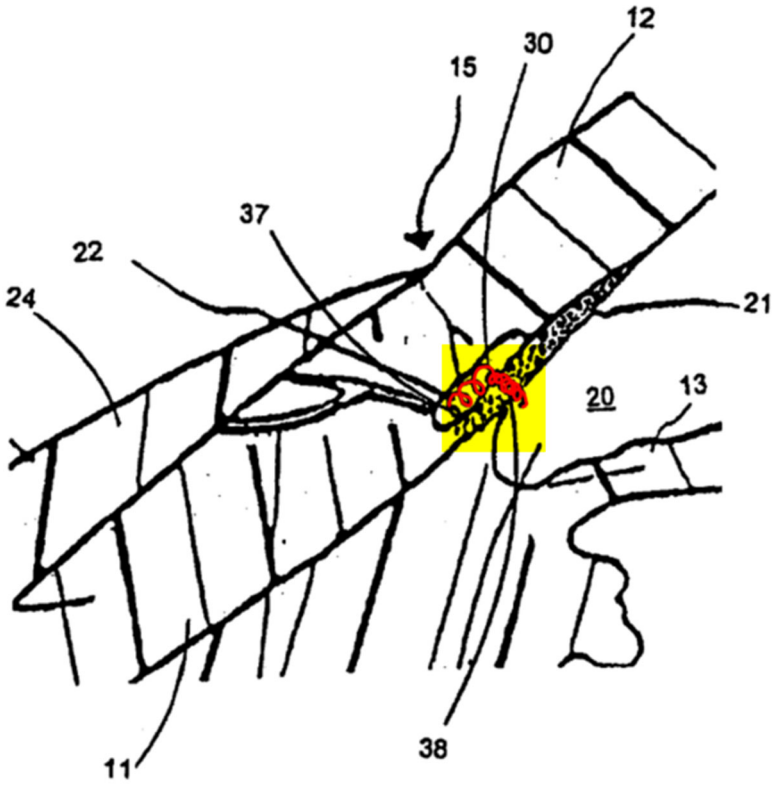
While some implants rest entirely within Schlemm's canal, others also include a channel for direct connection from the anterior chamber, through the trabecular meshwork, to the propped open Schlemm's canal, and the portion protruding from the canal can anchor it in place. Ex.1001 (¶¶31-32). Some examples are shown here:



Ex.1008 Figures 5A, 6B



Ex.1024 Figures 4, 6



Ex.1025 Fig. 3 (annotated)

VII. THE '361 PATENT

The '361 patent issued from Application No. 13/445,816, filed June 12, 2012, and claims to be a continuation of application No. 12/695,053, filed January 27, 2010, which claims to be a continuation of application No. 11/475,523, filed June 26, 2006. Ex.1003. Because the application claims priority to an application filed before March 16, 2013, its patentability is not governed by the America Invents Act.

A. Alleged Problem

The '361 patent admits that using bypass stents "to bridge a blocked trabecular meshwork" and to connect the anterior chamber to Schlemm's canal with a stent were both known. Ex.1003 (2:25-28). Allegedly, "it is difficult to consistently and

reliably implant a bypass stent." Ex.1003 (2:28-29). The '361 patent also suggests that "stents can become clogged and lose functionality over time," a problem that allegedly happens even to so-called "tubular elongated cylindrical hollow stents" "as a result of occlusion or scarring." *Id*. (2:31-37). According to the '361 patent, the walls of tubular stents "can have significant surface area contact with the trabecular meshwork and/or the collector channels, which can result in blockage of the meshwork or collector channels, substantially interfering with transmural flow across Schlemm's canal and into the eye's collector channel." *Id*. (2:46-52). Finally, the '361 patent states that "Schlemm's canal is small" and "[t]herefore, it can be difficult or expensive to design and manufacture hollow tubular stents of appropriate dimensions for use in opening Schlemm's canal." *Id*. (2:38-42).

B. Alleged Invention

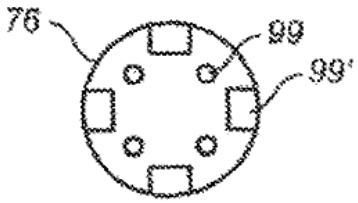
The '361 patent allegedly overcomes these issues by using "devices for reducing pressure within the eye [that] comprise a support implantable circumferentially within Schlemm's canal that is configured to maintain the patency of at least a portion of the canal." Ex.1003 (2:61-64).

The '361 patent describes traditional Schlemm's canal stent elements: a solid or hollow, biocompatible support that is inserted into Schlemm's canal to improve aqueous humor flow from the anterior chamber and eventually into the collector channels. Ex.1003 (2:1-5, 51-52). The support may take a variety of configurations,

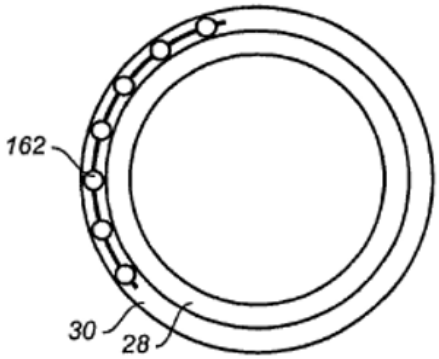
e.g., having "smooth, rough, spiked, or fluted" surfaces, "made from mesh," or including fenestrations. *Id*. (3:53-55). The support may comprise an "arcuate member having a radius of curvature smaller or larger than that of Schlemm's canal." *Id*. (4:18-19).

The '361 patent provides the following exemplary embodiments of the devices:

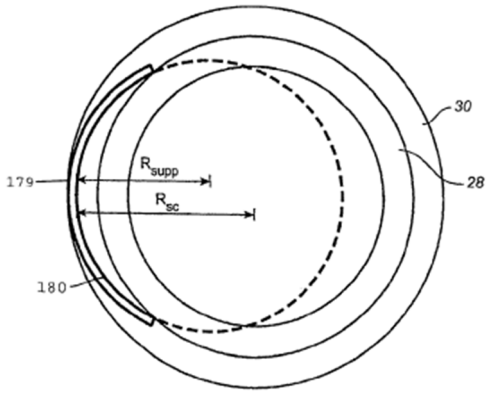
Ex.1003 Figure 7B



Ex.1003 Figure 6C



Ex.1003 Figure 10B



Ex.1003 Figure 11B

Figure 7B shows an exemplary support comprising beads, 76, which partially prop open Schlemm's canal. Ex.1003 (9:51-56). Figure 6C, showing a cross-section of a bead, includes fenestrations 99 and 99' which can "have any suitable cross-

sectional shape," and make the support "more porous." *Id.* Figure 10B shows the support positioned inside Schlemm's canal. *Id.* (12:2-3).

The '361 patent also discusses a "syringe that can be used to insert a support into Schlemm's canal," Ex.1003 (6:10-11), which is depicted in Figure 14A:

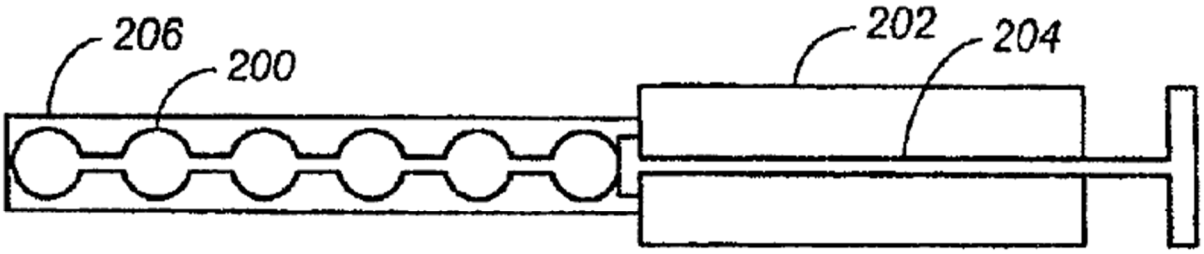


FIG. 14A

C. Prosecution History

During prosecution, the claims of the application that led to the '361 patent originally recited "a method for delivering high viscosity fluid into Schlemm's canal," and were rejected as anticipated by US 2005/0277864 ("Haffner II") (Ex.1052)[2] and US 6,375,642 ("Grieshaber '642") (Ex.1053). Patent Owner amended the independent claim and argued that Haffner II and Grieshaber '642 did

[2] Haffner II is a different reference than Haffner U.S. Pub. No. 2004/0102729 (Ex.1035), cited in Ground 3 below, and includes a different disclosure.

not disclose inserting a support into Schlemm's canal by passing it through a tubular cannula, as the amended claims required. Ex.1004 (Aug. 3, 2015, Remarks at 5).

The '361 patent was then rejected over Grieshaber '642 in view of US 2004/0193262 ("Shadduck") (Ex.1037). In response, Patent Owner filed a request for continued examination and argued that Grieshaber '642 does not disclose "passing the support through a tubular cannula" as claimed, and that it would not be obvious to modify Grieshaber in view of Shadduck because Shadduck disclosed trabecular meshwork devices. Ex.1004 (Nov. 19, 2015, Remarks at 5-7). Patent Owner then amended the claims to recite a "method for reducing intraocular pressure" and to claim "an arcuate member, wherein at least a portion of the arcuate member has a radius of curvature smaller than the radius of curvature of Schlemm's canal." Ex.1004 (June 14, 2016, Claims). The examiner allowed the claims without explanation. Ex.1004 (July 13, 2016, Notice of Allowance).

VIII. DISCRETIONARY DENIAL IS NOT APPROPRIATE HERE

A. The Presented Grounds and Argument are Dissimilar to the Art and Arguments Previously Presented to the Office

1. *Becton Dickinson* Factors

All factors considered by the Board under 35 U.S.C. § 325(d) weigh in favor of institution. *Becton, Dickinson, & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017); *see also Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13,

2020). The Board has consistently "held that a reference that 'was neither applied against the claims nor discussed by the Examiner' does not weigh in favor of exercising [] discretion under §325(d)." *Fasteners for Retail, Inc. v. RTC Indus., Inc.*, IPR2019-00994, Paper 9 at 7-11 (PTAB Nov. 5, 2019). The grounds presented in the petition include obviousness challenges applying Tu, Gharib, Smedley, and Haffner as base references. Tu, Gharib, Smedley, and Haffner were not applied against the Challenged Claims or discussed by the Examiner during prosecution of the '361 or its parent applications. In addition, none of the references applied by the examiner in either the '361 or its parent applications is cumulative of the references cited here.

No grounds in this Petition were evaluated during prosecution. *Bowtech Inc. v. MCP IP, LLC*, IPR2019-00383, Paper 14 at 5 (PTAB Aug. 6, 2019).

B. Efficiency, Fairness, and the Merits Support the Exercise of the Board's Authority to Grant the Petition

1. *Fintiv* Factors

Taking into consideration Director Vidal's recent memorandum, the Board should not exercise its discretion under § 314(a) in light of the Delaware Litigation. This petition presents evidence that the '361 patent claims are met by the prior art such that, if unrebutted at trial, would plainly lead to a conclusion that one or more claims are unpatentable by a preponderance of the evidence. *See* §XI. Accordingly, the Board should not discretionarily deny institution of this compelling, meritorious

challenge to the '361 patent claims. *Apple v. Fintiv*, IPR2020-00019, Paper 11 at 6 (PTAB Mar. 20, 2020) (precedential); Vidal Memo (4-5) ("Where the PTAB determines that the information presented at the institutions stage presents a compelling unpatentability challenge, that determination alone demonstrates that the PTAB should not discretionarily deny institution under Fintiv.").

Further, recent statistics show the median time to trial in Delaware is 971 days. Ex.1023 (LexMachina Statistics). Here, the Delaware Litigation was filed in September 2021, placing the median trial time near May 2024. The Final Written Decision in this IPR, if instituted, would fall in March 2024. Therefore, the Board's final written decision is likely to be due well before the Delaware Litigation goes to trial, especially in light of the fact that the case was only recently assigned to Judge Williams. Ex.1021; Ex.1022; Ex.1032. Accordingly, this factor weighs in favor of institution. *See* Vidal Memo at 9 ("The PTAB will weigh this factor against exercising discretion to deny institution under *Fintiv* if the median time-to-trial is around the same time or after the projected statutory deadline for the PTAB's final written decision.").

Finally, institution will enable the Board to resolve the issue of patentability, and a finding of unpatentability will relieve the District Court of the need to continue with the majority of the Delaware Litigation. Petitioners will move the District Court for a stay, providing the Board the sole opportunity to adjudicate §102/103 issues.

The opportunity for such simplification increases the likelihood the court will grant a stay in view of IPR institution. *Bio-Rad Lab'ys. Inc. v. 10X Genomics, Inc.*, No. 18-1679-RGA, 2020 WL 2849989, at *1 (D. Del. June 2, 2020) (staying case in view of IPR because of infancy of case and likelihood of simplifying issues for trial set more than a year away); *Ethicon LLC v. Intuitive Surgical, Inc.,* No. 17-871-LPS, 2019 WL 1276029, at *3 (D. Del. Mar. 20, 2019) (same, less than seven months before trial); *see also SEVEN Networks, LLC v. Apple Inc.*, C.A. No. 2:19-cv-00115-JRG, Dkt. 313 (E.D. Tex. Sept. 22, 2020) (same, less than six weeks before trial).

"Considering the *Fintiv* factors as part of a holistic analysis," it would run counter to "the interests of efficiency and integrity of the system" if this Board were "to deny institution of a potentially meritorious Petition." *Sand Revolution*, Paper 24 at 14. Thus, the Board should decline to exercise its discretion under §314(a).

IX. LEVEL OF ORDINARY SKILL IN THE ART

A POSITA as of June 2006 would have had an M.D. and residency training in ophthalmology, or a four-year degree in engineering and at least five years of experience in research, manufacturing, or designing ophthalmic implants. Additional education or experience in related fields could compensate for deficits in the above qualifications. Ex.1001 (¶¶52-53).

X. OVERVIEW OF THE PRIMARY PRIOR ART

A. Tu

Tu is directed to treatments for glaucoma by implanting stent devices such that they bypass the trabecular meshwork and decrease intraocular pressure by restoring outflow of aqueous humor from the anterior chamber of the eye. Ex.1028 (Title, Abstract, ¶3). Tu discloses using a delivery applicator to implant a stent within Schlemm's canal that extends into the anterior chamber to allow aqueous to flow from the anterior chamber into Schlemm's canal. *Id.* (¶¶25-34). The delivery applicator comprises a hollow body that houses the trabecular stent (which can take many configurations) and a button for deploying the trabecular stent at the desired location. *Id.* (¶363); *see also id.* Figs. 3-28, 33-42, 46, 49, 51D, 55-64. The injector can also inject a fluid, such as viscoelastic, into Schlemm's canal to inflate it before, during, or after stent insertion. *Id.* (¶361).

B. Gharib

Gharib teaches treating glaucoma, often characterized by buildup of aqueous humor in the anterior chamber that leads to an increase in intraocular pressure. Ex.1005 (¶¶1, 50). Gharib discloses implanting a support device through the trabecular meshwork and stabilizing it inside Schlemm's canal by using a delivery device. *Id.* (¶¶25-27). Gharib's support can maintain an opening in the trabecular meshwork and Schlemm's canal to allow aqueous humor to flow from the anterior chamber, into Schlemm's canal and out of the eye's natural outflow pathways. *Id.*

(¶¶1, 67). The support's outlet section that is disposed in Schlemm's canal can be curved or angled, and can take a variety of shapes, such as elliptical, round, circular, D-shape, semi-circular, or asymmetrical shape. *Id.* (¶¶29, 56, 66).

XI. EACH OF THE CHALLENGED CLAIMS IS UNPATENTABLE

A. Ground 1: Tu Renders Obvious Claims 1-3 and 5-9.

1. Independent Claim 1

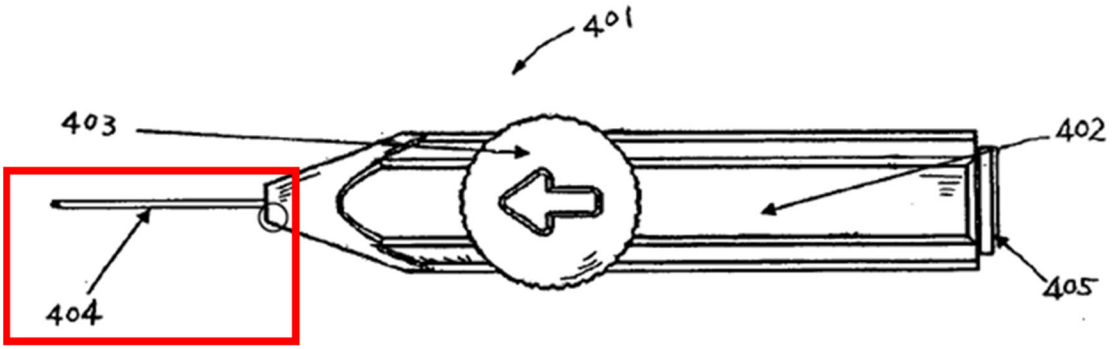
a. **"A method for reducing intraocular pressure, comprising:"**

Generally, "preamble language is not treated as limiting." *See Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1347 (Fed. Cir. 2012). Nonetheless, Tu discloses "medical devices and methods for reducing the intraocular pressure...." *See* Ex.1028 (¶¶3, 6-10, 18, 25-26); *see also id.* (Abstract (similar)); *id.* (¶151) (similar).

b. **"introducing a tubular cannula having a lumen at least partially within Schlemm's canal;"**

Tu teaches multiple delivery applicators that include a tubular cannula having a lumen that can be at least partially introduced within Schlemm's canal to inject viscoelastic and stents. *E.g.* Ex.1028 (Figs. 31, 45, 51A, 66; ¶¶284, 361-62). Tu's delivery applicator is used to implant a stent into Schlemm's canal via a tubular cannula to reduce intraocular pressure by creating a pathway for aqueous to flow from the anterior chamber. Ex.1028 (¶¶3, 25-34). In practice, Schlemm's canal may also be dilated with a viscoelastic to facilitate insertion of a stent. *See* Ex.1001 (¶57).

One of Tu's delivery applicators, as seen in Figure 66, has "a trabecular stent…held with a lumen of the stem 404" that is inserted into Schlemm's canal. Ex.1028 (¶363). Stem 404 is a tubular cannula because it is a hollow tube. *See* Ex.1001 (¶58).

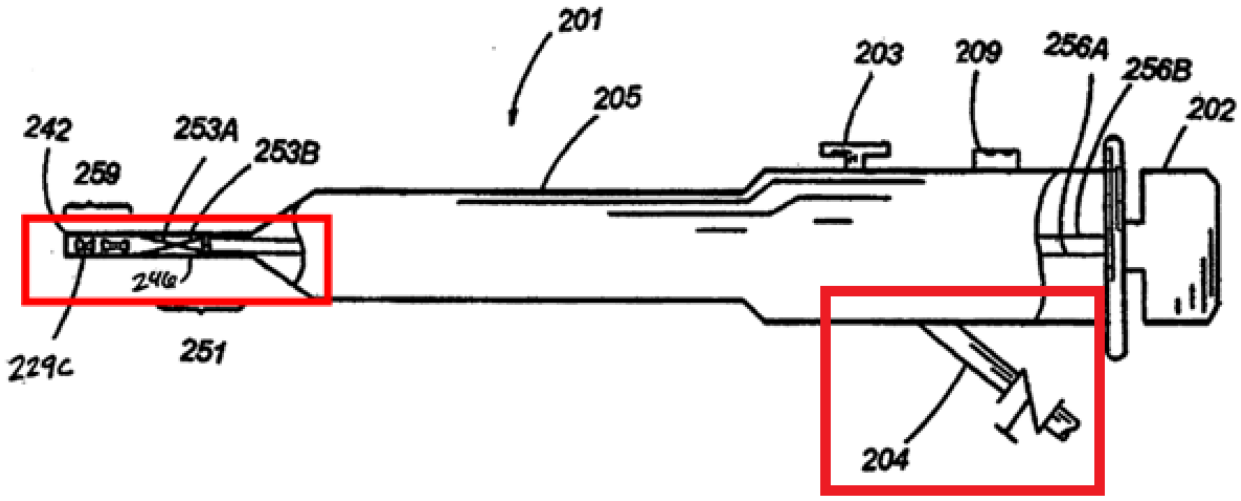


Ex.1028 Figure 66 (tubular cannula annotated)

The delivery applicator may also "supply irrigating fluid, e.g., saline, viscoelastic, to inflate the canal…before, after, or during stent insertion." Ex.1028 (¶¶361-364). The inflation of the canal involves "pressurizing or fluid irrigation at one or more than one places along the circumference of Schlemm's canal." *Id.* (¶362). As Tu states, viscodilation procedures (*e.g.*, viscocanalostomy) involve cannulating Schlemm's canal (*i.e.*, inserting a tubular cannula into Schlemm's canal) to deliver viscoelastic into the canal. Ex.1028 (¶18); *see* Ex.1001 (¶59). Thus, the tubular cannula of the delivery apparatus is placed at least partially within Schlemm's canal when dilating Schlemm's canal with viscoelastic. As "[c]anal inflation may occur before, after, or during stent insertion," Ex.1028 (¶357), and Tu teaches "utilizing [an] instrument to deliver [an] implant through a wall of

Schlemm's canal," *Id.* (¶51), a POSITA would have understood that the lumen of the tubular cannula is at least partially within Schlemm's canal during stent insertion in addition to during viscoelastic delivery. Ex.1001 (¶59).

Another delivery applicator, seen in Figure 51A, has similar capabilities. Ex.1028 (¶¶282-308, Figs. 51A-D); Ex.1001 (¶60). The applicator contains "an injection sheath 246," which is a hollow tube (*i.e.*, a tubular cannula) that "store[s] and discharge[s] a plurality of any combination of the stents." Ex.1028 (¶¶282-284). Ex.1001 (¶60). It includes "a fluid infusing port 204 for fluid infusion or viscocanalostomy," a procedure that involves cannulating and injecting viscoelastic into Schlemm's canal. Ex.1028 (¶¶18, 282-284); Ex.1001 (¶60).



Ex.1028 Figure 51A (tubular cannula and fluid infusion port annotated)

Thus, it would have been obvious in light of Tu's delivery applicators, which can deliver both stents and viscoelastic by introducing a tubular cannula having a lumen at least partially within Schlemm's canal, to perform viscodilation "before,

after, or during" insertion of a stent into Schlemm's canal. Ex.1001 (¶61); Ex.1028 (¶¶362-363). Injecting viscoelastic would facilitate stent insertion because it is a lubricant, and would dilate Schlemm's canal to increase the amount of operating space while reducing the amount of tissue that would resist or interfere with insertion. Ex.1001 (¶61). A POSITA would also have had a reasonable expectation of success in both viscoelastic and stent delivery via a tubular cannula having a lumen at least partially within Schlemm's canal because Tu discloses the combined application, and the combination would simplify stent insertion. *Id.*

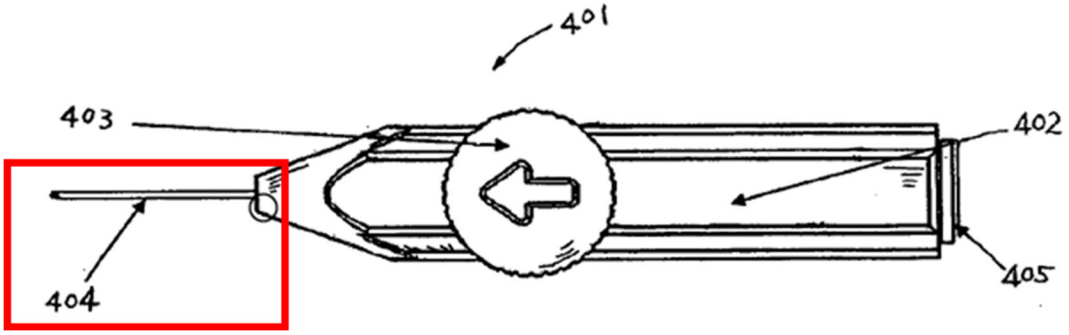
c. **"delivering a high viscosity fluid into Schlemm's canal; and"**

As discussed in §V.C, for the purpose of this IPR, Petitioners have adopted Patent Owner's interpretation that viscoelastics are high viscosity fluids. Under this interpretation, Tu discloses and/or renders obvious delivering a high viscosity fluid, such as a viscoelastic, into Schlemm's canal. *See* §XI.A.1.b; *see also* Ex.1001 (¶63).

d. **"inserting a support into Schlemm's canal by passing the support through the tubular cannula,"**

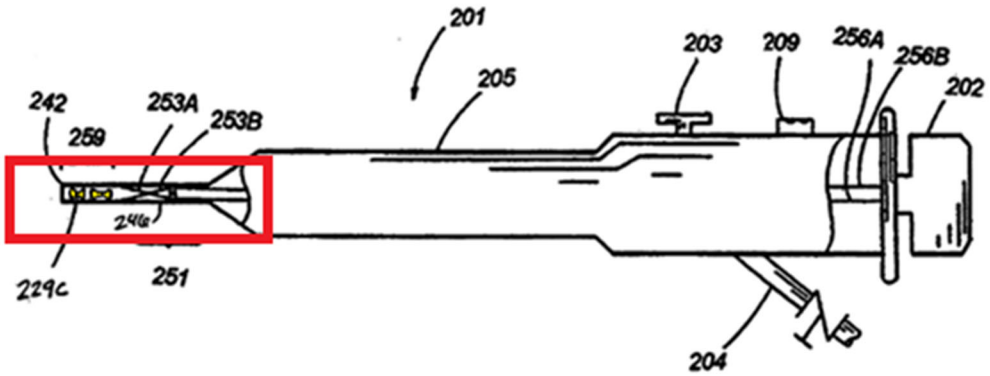
As described above, Tu discloses delivery applicators comprising a tubular cannula for delivering viscoelastic into Schlemm's canal before, after, or during implanting a stent support. §XI.A.1.b. Tu also discloses that the support is inserted into Schlemm's canal by passing it through the tubular cannula. For example, the applicator shown in Figure 66 drives a "trabecular stent into Schlemm's canal" by

deploying it from the "lumen of the stem 404" when button 403 is pushed. Ex.1028 (¶361, 363).



Ex.1028 Figure 66 (annotated)

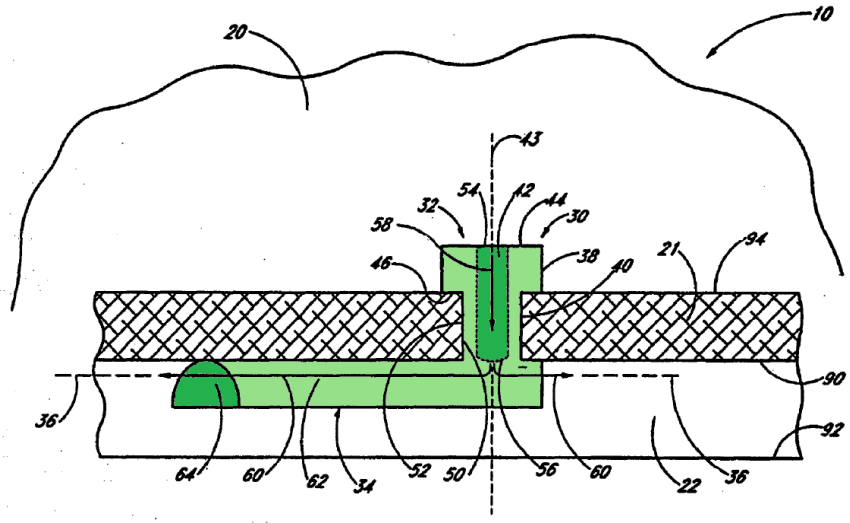
Similarly, the cannula portion of the applicator shown in Figure 51A can be configured to "store and discharge…any combination of the stents" into Schlemm's canal "from the applicator sheath 246, one stent at a time." Ex.1028 (¶283). Figure 51A illustrates two stents 229C held within the tubular cannula that are allowed to "pass when the stent 229C is pushed by the plunger 244." *Id.* (¶290).



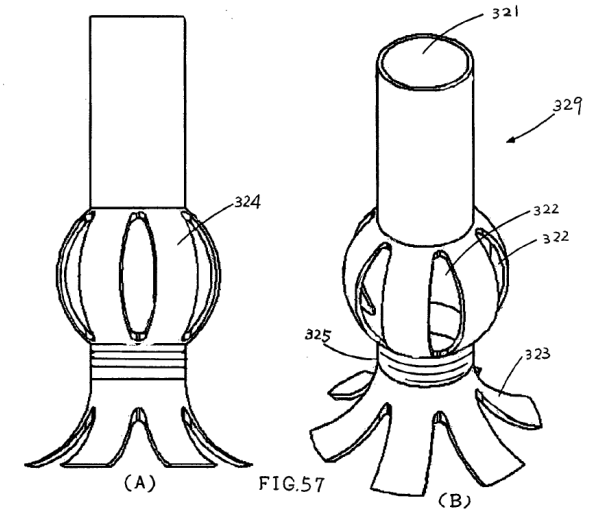
Ex.1028 Figure 51A (annotated)

Tu discloses stent supports "configured to extend between the anterior chamber of the eye and Schlemm's canal for enhancing outflow of aqueous from the anterior chamber so as to reduce intraocular pressure." Ex.1028 (Abstract). Tu

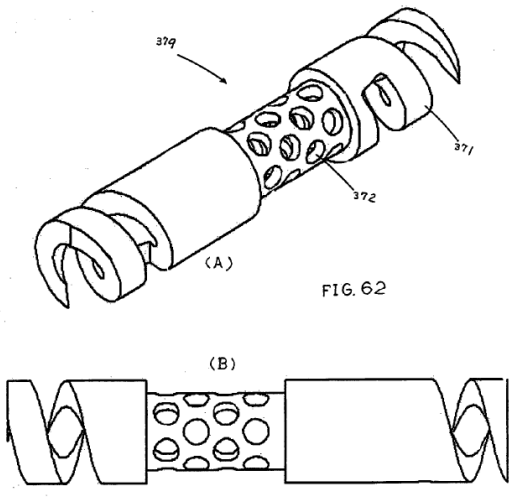
teaches that the disclosed supports "can have features for anchoring the stent into Schlemm's canal as well as preventing the walls of Schlemm's canal from closing the outlet of the stents." *Id.* For example, Tu discloses different stents, delivered via a delivery applicator comprising a cannula, including a stent with a snorkel and curved blade (Figure 3), one with a center bulb and anchors (Figure 57), and another with screws (Figure 62), each of which a POSITA would recognize as supports. *Id.* (¶¶159-169, 345-347, 355); Ex.1001 (¶¶66-68); *see also* Demonstratives 1 and 2 below (showing Figure 57 and 62A's stent implanted in Schlemm's canal, as in Figure 3)



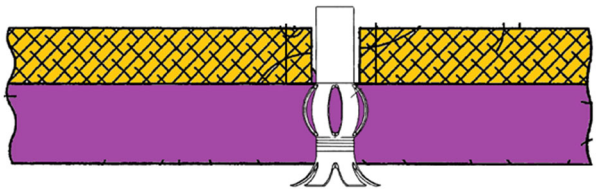
Ex.1028 Figure 3 (blade stent in green)



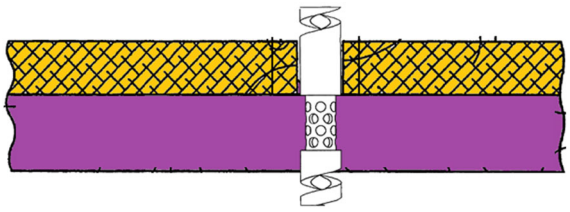
Ex.1028 Figure 57 (bulb-like stent)



Ex.1028 Figure 62A (screw-like stent)



Demonstrative 1: Modified Figure 3 demonstrating Figure 57 extending out of Schlemm's canal (purple) into the trabecular meshwork (yellow)



Demonstrative 2: Same with respect to Figure 62

These stents are all supports. The blade stent shown above in Figure 3 is disposed within Schlemm's canal and "abuts or rests against the trabecular meshwork 21 to stabilize the glaucoma stent 30 within the eye 10," which maintains the patency of Schlemm's canal. Ex.1028 (¶¶161, 163, 167). Thus, the blade stent is a support inside of Schlemm's canal with an "inlet port" and an "outlet port." *Id.* (¶166). The stent's lumen can be "efficaciously shaped…giving due consideration to the goals of providing sufficient aqueous outflow…." *Id.* Further, the stent

supports of Tu are designed to "prevent[] the walls of Schlemm's canal from closing the outlet of the stents." *See id.* (Abstract); *see also id.* (¶¶346, 355).

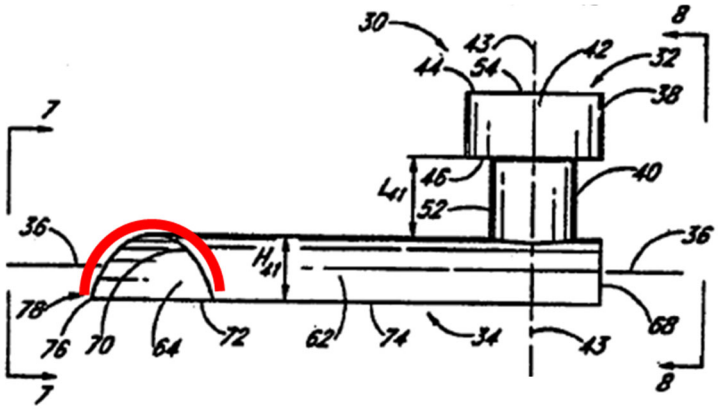
Similarly, the bulb stent shown above in Figure 57 has an "outwardly expandable scleral anchor arrangement 323…provided at the distal end of the stent 329" with "sharp tip and grooves" to "assist with retention strength." Ex.1028 (¶346). Once the stent is placed in Schlemm's canal, Tu teaches that "the outflow ducts 322 bulge open" to "buttress Schlemm's canal." *Id.* (¶¶346-347). Thus, the bulb stent is a support that both anchors to provide stability and retention strength, and buttresses to maintain the patency of Schlemm's canal. *See also* Ex.1001 ¶67.

Another example is the screw stent shown above in Figure 62 that can "be screwed into the scleral wall of Schlemm's canal, thus creating a scleral anchor." Ex.1028 (¶355); *see also* Ex.1001 (¶68). The stent contains screws at both ends, which allow it to act as a column propping open Schlemm's canal and be a support inside of Schlemm's canal. Ex.1001 (¶68).

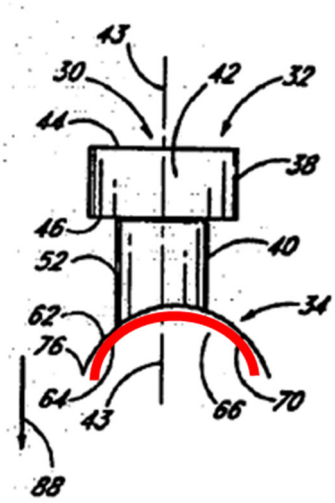
Thus, Tu discloses and/or renders obvious inserting a support into Schlemm's canal by passing the support through the tubular cannula. *See also* §XI.A.1.b.

e. **"wherein the support comprises an arcuate member,"**

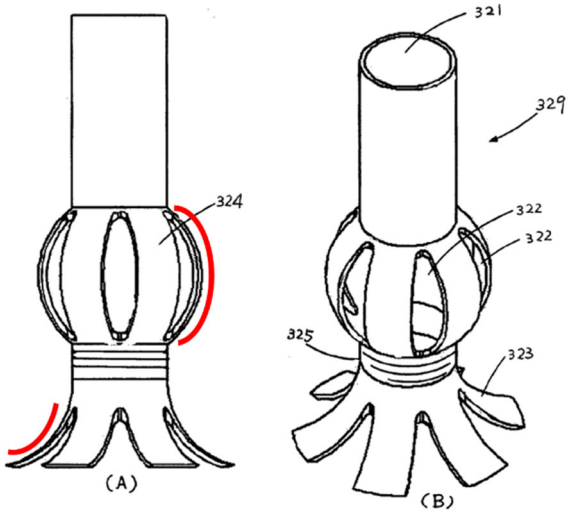
Tu's supports have one or more arcuate members, such as "a curved blade" (Figures 4 and 7), a "center bulb" with curved "anchors" (Figure 57), or "a screw" (Figure 62). Ex.1028 (¶¶35, 169, 345-346, 355); *see* Ex.1001 (¶72).



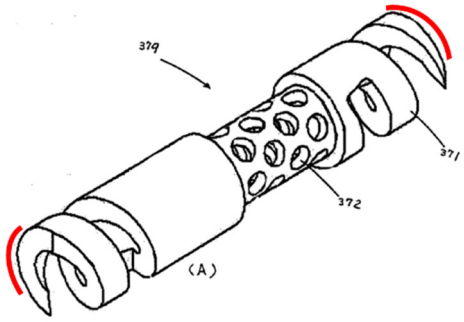
Ex.1028 Figure 4 (arcuate member annotated)



Ex.1028 Figure 7 (same)



Ex.1028 Figure 57 (same)



Ex.1028 Figure 62A (same)

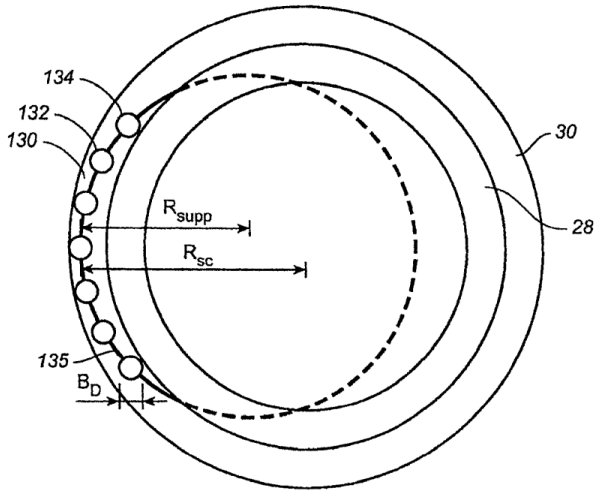
For example, Figures 4 and 7 contain a blade stent that is "a generally curved elongated sheet- or plate-like structure with an upper curved surface 62 and a lower curved surface 64...." Ex.1028 (¶194). Similarly, Figure 57 is a bulb stent with an arcuate center bulb 324 and arcuate "outwardly expandable scleral anchor arrangement 323." *Id*. (¶346). In addition, Figure 62 is a screw stent that is not only

arcuate because of its cylindrical nature, but also because it contains arcuate threads to "screw[] into the scleral wall of Schlemm's canal, thus creating a scleral anchor." *Id.* (¶355).

Thus, Tu discloses a support that comprises an arcuate member.

f. **"wherein at least a portion of the arcuate member has a radius of curvature smaller than a radius of curvature of Schlemm's canal, and"**

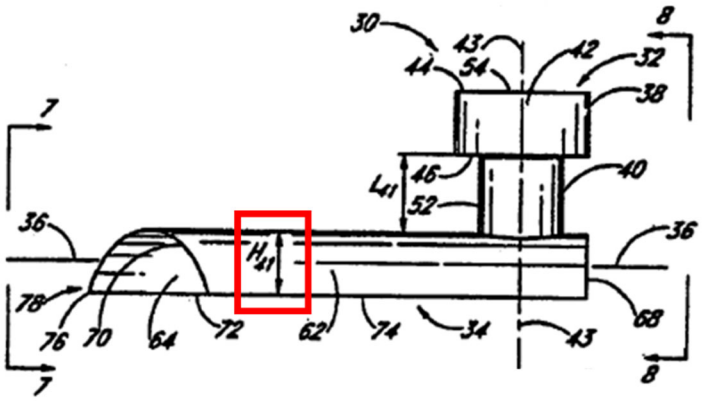
The '361 patent lacks clear guidance regarding where one measures a radius of curvature for comparison or what constitutes a radius of curvature of Schlemm's canal. The '361 patent describes Schlemm's canal as "a narrow ***circumferential*** passageway generally surrounding the exterior border of," or extending "***360° circumferentially around***[,] the trabecular meshwork." Ex.1003 (1:44-49, 6:40-41). Thus, one possible radius of curvature disclosed by the '361 patent is the circumferential radius of curvature of Schlemm's canal, which is denoted as R_{SC} in Figure 11A below. U.S. Patent No. 10,299,958 (which also names Paul and David Badawi as inventors) states that 6 mm is "the approximate radius of curvature of Schlemm's canal in an adult human." Ex.1031 (22:61-67); *see* Ex.1001 (¶75).



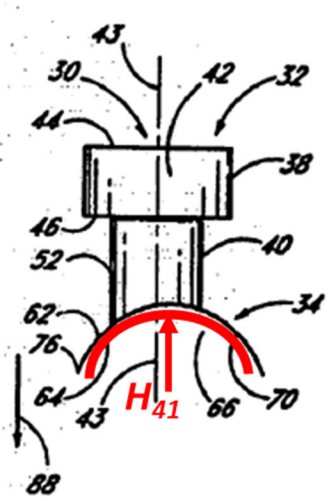
Ex.1003 Figure 11A

The ’361 patent also states that the cross-sectional diameter of Schlemm’s canal “is about 190 to about 370 microns.” Ex.1003 (9:13-16). Thus, another possible radius of curvature disclosed by the ’361 patent is based on a cross-section of Schlemm’s canal. *See id.* The circumferential radius of curvature of Schlemm’s canal described above is on the millimeter scale (*e.g.*, 6 mm), which is a thousand times larger than the cross-sectional radius described here on the micron scale (*e.g.*, 190 to 370 microns). *See* Ex.1003 (2:38-39, 12:29-33).

Given that the arcuate members disclosed in Tu fit *within* Schlemm’s canal, their radii of curvature must be smaller than the radius of curvature of Schlemm’s canal whether measured based on the circumferential radius or the cross-sectional radius. Ex.1001 (¶76). For example, the curved blade of the stent support shown in Figures 4 and 7 below has a radius of curvature measured in microns.



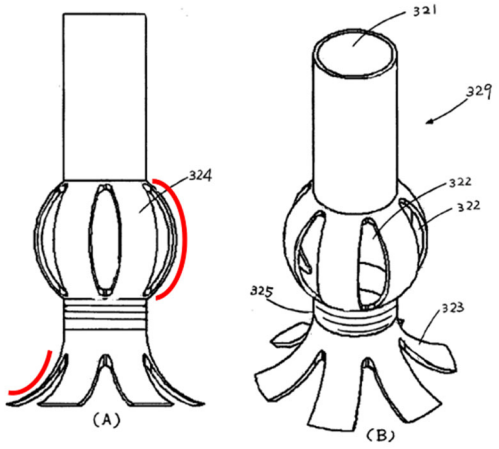
Ex.1028 Figure 4 (height, H41, of the blade annotated)



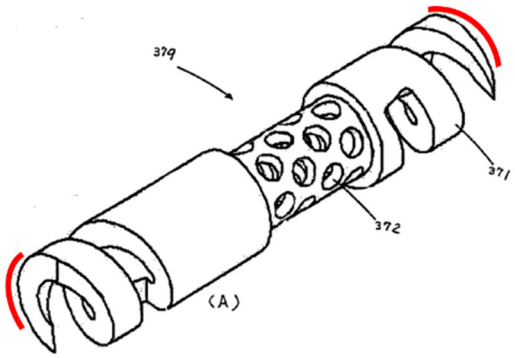
Ex.1028 Figure 7 (same)

Tu states that the height of the curved blade, H_{41}, is 400 microns, which a POSITA would have understood can be used to estimate its radius of curvature. *See* Ex.1001 (¶77). This height, or radius, of the blade stent support that fits inside of Schlemm's canal is 400 microns (0.4mm), which is less than the circumferential radius of curvature of Schlemm's canal (6mm). *See* Ex.1001 (¶77). Thus, Tu discloses that at least a portion of an arcuate member has a radius of curvature smaller than a radius of curvature of Schlemm's canal.

Tu also teaches that other stent supports, such as those shown in Figures 57 and 62 below, have arcuate members that fit within Schlemm's canal.



Ex.1028 Figure 57 (arcuate members annotated)



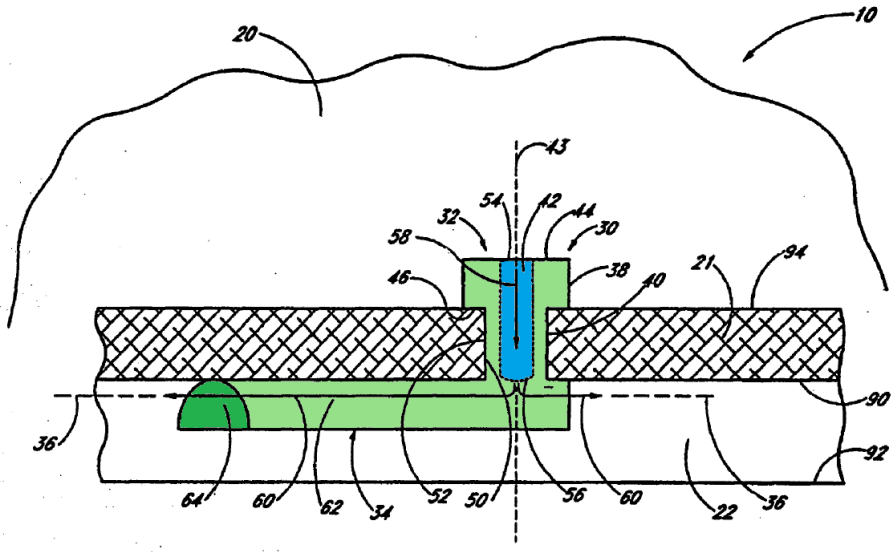
Ex.1028 Figure 62A (same)

The stents, including their arcuate members, are "shaped and sized to be introduced into Schlemm's canal," the "depth [of which] is typically about less than 400 microns." Ex.1028 (¶¶42, 46, 176). The stents, designed to be anchored in Schlemm's canal, "prevent[] the walls of Schlemm's canal from closing the outlet of the stents." *See id.* (Abstract). A POSITA would have understood that the micron-sized radii of curvature for each of the arcuate members in §XI.A.1.e aboveare smaller than the radius of curvature of the cross-section of Schlemm's canal, which means that it also must be smaller than the millimeter-sized radius of curvature of the circumference of Schlemm's canal. *See* Ex.1001 (¶80).

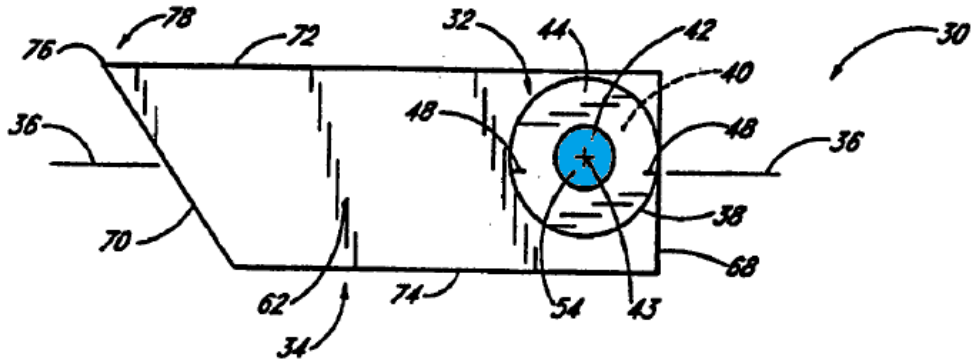
Thus, Tu discloses that at least a portion of an arcuate member has a radius of curvature smaller than a radius of curvature of Schlemm's canal.

g. **"wherein the support comprises at least one fenestration."**

The stent supports disclosed in Tu have at least one fenestration. For example, the blade stent in Figures 3 and 5 below has inlet 54 and outlet 56 openings, which are colored in blue, in lumen 42. Ex.1028 (¶166).



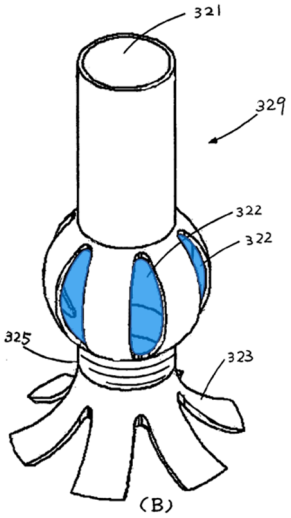
Ex.1028 Figure 3 (side view opening in blue)



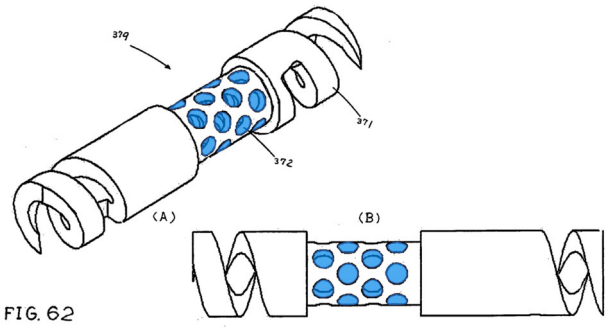
Ex.1028 Figure 5 (top view opening in blue)

Additionally, the bulb stent in Figure 57B below has "outflow ducts [*i.e.*, fenestrations] 322 [that] bulge open" to "create multiple pathways for the outflow of aqueous via a stent lumen 321." Ex.1028 (¶346). Additionally, the screw stent in

Figure 62 below is a trabecular support containing "[p]ores **372** [*i.e.* fenestrations] arrayed circularly around the domed outflow surface" that "provide many outflow paths for aqueous flow." *Id.* (¶355).



Ex.1028 Figure 57B (fenestrations colored blue)



Ex.1028 Figure 62 (same)

Tu also discloses that including pores in the stent devices prevents clogging and improves aqueous flow. Ex.1028 ¶¶341, 347-49, 352-57. A POSITA would have been motivated to include additional fenestrations to "help prevent aqueous clogging," which would facilitate aqueous flow from the anterior chamber, through Schlemm's canal, to the collector channels. *See* Ex.1028 (¶¶341, 347-49, 352-57); Ex.1001 (¶82). A POSITA would also have had a reasonable expectation of success in including fenestrations because Tu discloses pores in stents for the purpose of regulating intraocular pressure. Ex.1001 (¶82).

Thus, Tu discloses and/or renders obvious a support comprising at least one fenestration. Ex.1001 (¶82).

2. Dependent Claim 2

The method of claim 1, wherein the delivered fluid dilates the canal.

Tu discloses that the viscoelastic substance delivered into Schlemm's canal dilates the canal. Ex.1028 (¶¶18, 282-84, 361-364); *see* §§XI.A.1.b-XI.A.1.c; *see also* Ex.1001 (¶¶83-84).

3. Dependent Claim 3

The method of claim 1, wherein the high viscosity fluid is sodium hyaluronate

As discussed in §§XI.A.1.b-XI.A.1.c, Tu discloses and/or renders obvious delivering a high viscosity fluid, such as viscoelastic, into Schlemm's canal. Using sodium hyaluronate as the viscoelastic would have been an obvious choice.

Tu discloses that "HEALON® viscoelastic (VE) can be injected to maintain the anterior chamber." Ex.1028 (¶322). HEALON® is a "brand name" of sodium hyaluronate. Ex.1001 (¶¶37, 85); Ex.1038 (Ex.C at 39-41) ("Sodium hyaluronate…e.g., Healon®[.]"). A POSITA would have been motivated to use sodium hyaluronate to dilate the canal because sodium hyaluronate is the viscoelastic that Tu discloses for maintaining the anterior chamber and would have been a readily available and obvious choice to a POSITA reading Tu. Ex.1001 (¶85). Additionally, sodium hyaluronate is a well-established viscoelastic used in

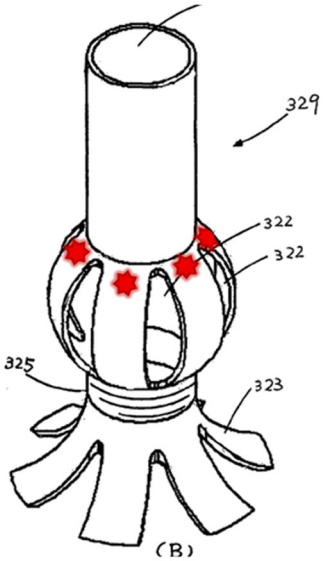
glaucoma surgeries, and a POSITA would have expected it to be safe to use. Ex.1001 (¶¶37, 85). A POSITA would have had a reasonable expectation of success using sodium hyaluronate as the viscoelastic to inflate Schlemm's canal given its prevalence in ophthalmic treatments. Ex.1001 (¶85).

Thus, Tu renders obvious using sodium hyaluronate as the high viscosity fluid.

4. Dependent Claim 5

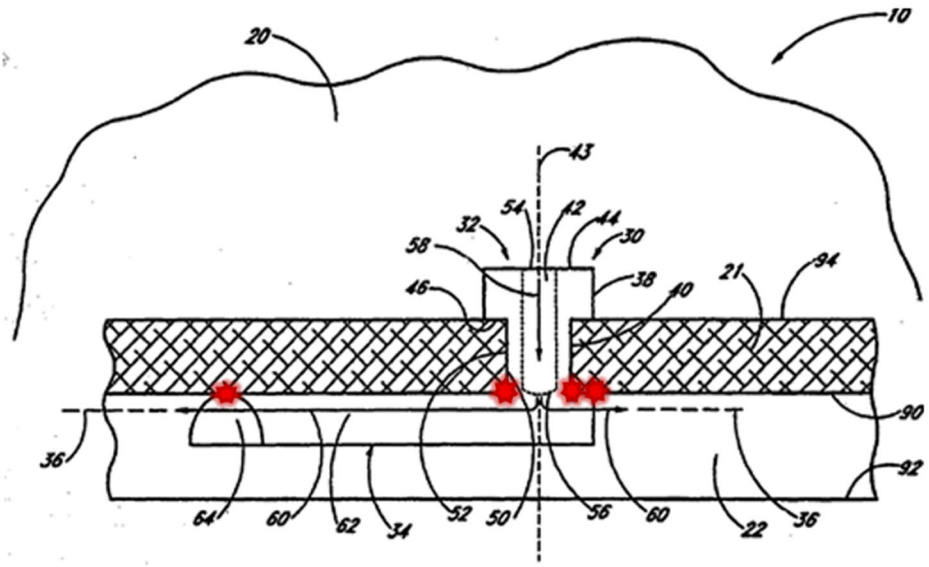
The method of claim 1, wherein the support contacts the interior wall of the canal at least at three points.

Tu discloses that the support contacts the canal's interior wall at least at three points. For example, the bulb stent of Tu is a fenestrated structure as shown in Figure 57B that contacts Schlemm's canal so that it can "buttress" the canal. Thus, the stent support would contact the interior wall of Schlemm's canal at least at three points between its multiple fenestrations. Ex.1001 (¶87).



Ex.1028 Figure 57B (annotated showing multiple contact points)

As another example, the blade stent shown in Figure 3 below makes at least three points of contact when "adjacent to a front wall 90 of Schlemm's canal 22." Ex.1028 (¶177). The stent support contacts the interior wall of Schlemm's canal at multiple points, including blade 34's leftmost edge, both sides of shank 40 as it enters Schlemm's canal, and blade 34's rightmost edge. Ex.1001 (¶86).



Ex.1028 Figure 3 (annotated showing multiple contact points)

Thus, Tu discloses supports that contact the interior wall of Schlemm's canal at least at three points.

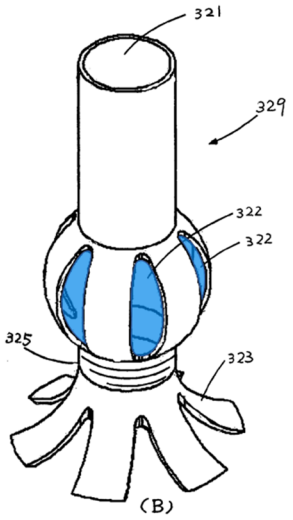
5. Dependent Claim 6

> **The method of claim 1, wherein the support does not substantially interfere with longitudinal flow along the canal.**

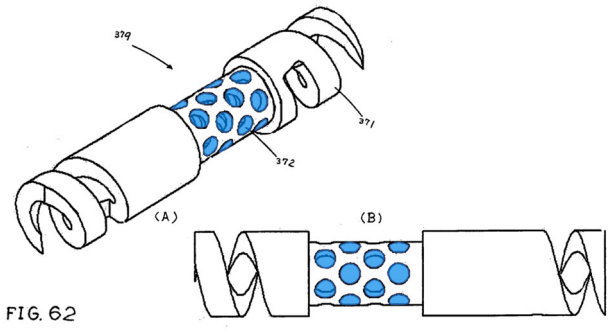
The stent supports disclosed in Tu do not substantially interfere with longitudinal flow (*i.e.*, circumferential) along Schlemm's canal. Tu discloses that "Schlemm's canal is a narrow channel…and it provides measurable resistance to the flow of aqueous." Ex.1028 (¶339). To overcome this resistance, the stents that are in Schlemm's canal include pores that "help prevent aqueous clogging." *E.g.*, *Id.* (¶¶341, 347, 356).

For example, the bulb stent shown in Figure 57B includes "outflow ducts" that "create multiple pathways for the outflow of aqueous via a stent lumen **321**" and

"prevent aqueous clogging." *Id.* (¶¶346, 347). Similarly, the screw stent shown in Figure 62 includes "pores **372** arrayed circularly around the domed outflow surface [to] provide many outflow paths for aqueous flow," which "help prevent aqueous clogging." *Id.* (¶354); *see also* Ex.1001 (¶88). Thus, Tu provides explicit motivation to include many fenestrations in the stent to facilitate longitudinal flow along Schlemm's canal. Ex.1001 (¶88). Further, a POSITA would have had a reasonable expectation of success in including additional fenestrations to facilitate longitudinal flow along Schlemm's canal because Tu discloses that fenestrations "create multiple pathways for the outflow of aqueous" and "prevent aqueous clogging." Ex.1001 (¶88); Ex.1028 (¶¶346, 347).



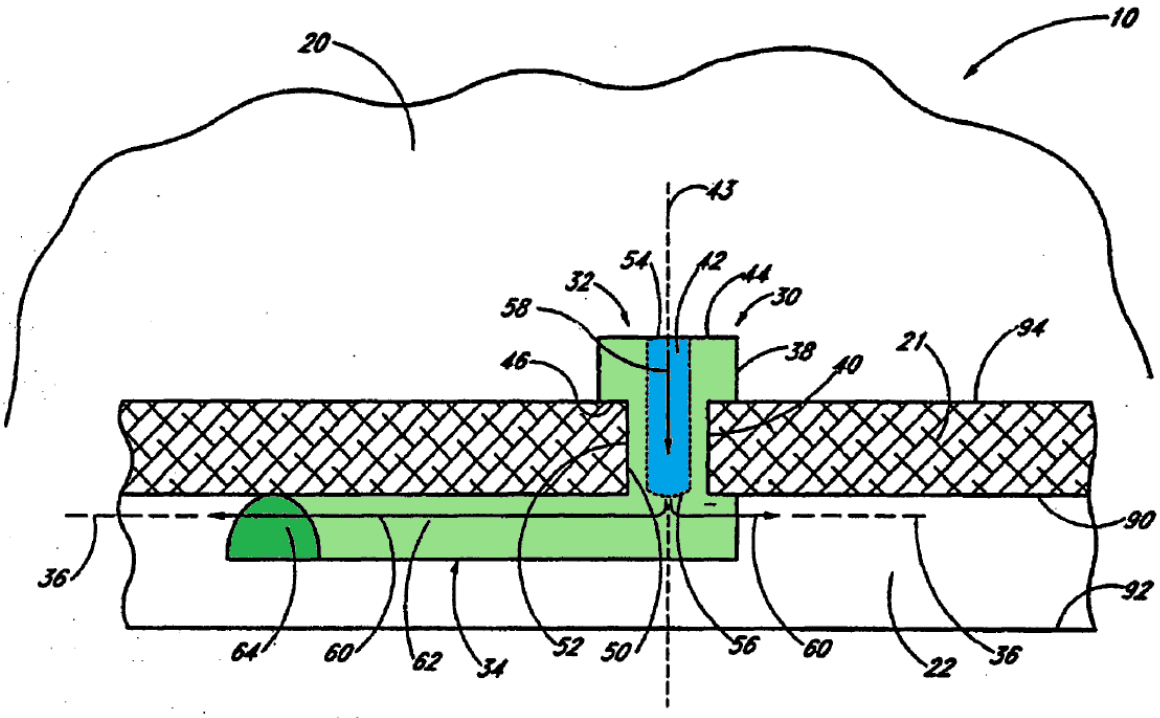
Ex.1028 Figure 57B (fenestrations colored blue)



Ex.1028 Figure 62 (same)

The blade stent in Figure 3 below includes a lumen that connects to outlet ports that permit aqueous flow into Schlemm's canal longitudinally along line **60**,

demonstrating that the blade stent would not substantially interfere with longitudinal flow along Schlemm's canal. Ex.1001 (¶89); Ex.1028 (¶¶161, 163, 167).



Ex.1028 Figure 3 (annotated)

Thus, Tu discloses and/or renders obvious a support that does not substantially interfere with longitudinal flow along Schlemm's canal. Ex.1001 (¶90).

6. Dependent Claim 7

> **The method of claim 1, wherein the support does not substantially interfere with transmural flow across the inner wall of the canal.**

The '361 patent states that "'does not substantially interfere' with transmural flow" means "that the support does not significantly block either fluid outflow from the trabecular meshwork or fluid outflow to the collection channels." Ex.1003 (7:43-47). The stent supports disclosed in Tu do not substantially interfere or significantly

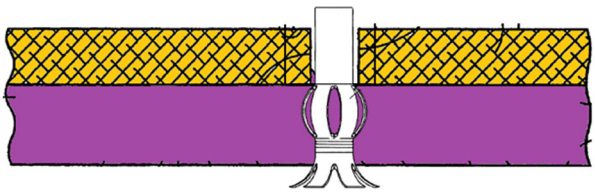
block transmural flow across the inner wall of the canal (*i.e.*, the interface between trabecular meshwork and Schlemm's canal). Ex.1001 (¶91); Ex.1003 (7:64-8:4).

The goal in Tu is "reducing intraocular pressure by providing outflow of aqueous from an anterior chamber of an eye." Ex.1028 (¶34). This reduction can be achieved by implanting a stent with "an inlet portion configured to be positioned in the anterior chamber of an eye and an outlet portion…positioned at least partially in Schlemm's canal of the eye." *Id.* (¶59). The stent allows aqueous to flow "from the anterior chamber into the inlet portion, then into the outlet portion, and then into Schlemm's canal." *Id.* Aqueous flowing from the anterior chamber into Schlemm's canal must pass across the inner wall of Schlemm's canal. Ex.1001 (¶92). The stent supports assist in transporting aqueous humor across the inner wall of Schlemm's canal by creating a pathway from the anterior chamber, through the trabecular meshwork, and into Schlemm's canal. Ex.1001 (¶92).

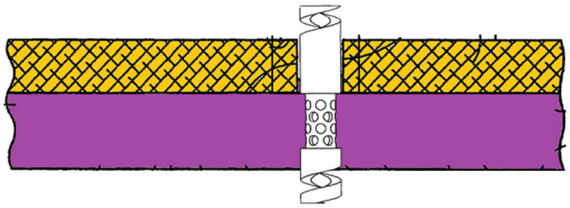
Demonstratives 1 and 2 below show that when the bulb stent (Figure 57) and the screw stent (Figure 62) are implanted, a pathway from the anterior chamber, through the trabecular meshwork (yellow), and into Schlemm's canal (purple) is created. These pathways facilitate transmural flow across the inner wall of Schlemm's canal. There is also no suggestion in Tu that these flow-assisting devices would occlude the interface between the trabecular meshwork and Schlemm's canal

such that they would substantially interfere with transmural flow across Schlemm's canal's inner wall.

Thus, Tu discloses supports that do not substantially interfere with transmural flow across the inner wall of Schlemm's canal.



Demonstrative 1: Modified Figure 3 demonstrating Figure 57 extending out of Schlemm's canal (purple) into the trabecular meshwork (yellow)



Demonstrative 2: Modified Figure 3 demonstrating Figure 62 in the same manner

7. Dependent Claim 8

The method of claim 1, wherein the support does not substantially interfere with transmural flow across the outer wall of the canal.

The '361 patent states that "'does not substantially interfere' with transmural flow" means "that the support does not significantly block either fluid outflow from the trabecular meshwork or fluid outflow to the collection channels." Ex.1003 (7:43-47). The stent supports disclosed in Tu do not substantially interfere or significantly block transmural flow across the outer wall of the canal, which a POSITA would understand to mean the interface between Schlemm's canal and the collector channels. Ex.1001 (¶93); *see also* Ex.1003 (7:64-8:4).

Tu discloses "targeted placement" of stents "for the purpose of providing a maximum benefit in the form of maximum outflow facility," Ex.1028 (¶339), which

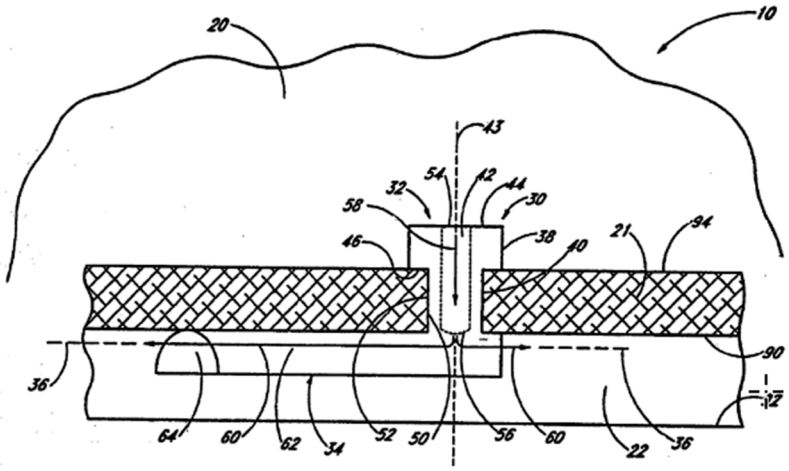
is transmural flow across the outer wall of Schlemm's canal, Ex.1001 (¶94); *see also* Ex.1003 (7:43-47). Tu further discloses that "targeted placement" of stents at or near "a large collector channel" or "a group of smaller ones" provides "the best improvement in outflow." Ex.1028 (¶339). Additionally, Tu discloses "locat[ing]/detect[ing] the most appropriate collector channel(s) to implant a trabecular shunting stent adjacent to the collector channel(s)" to provide "maximum outflow" of aqueous from Schlemm's canal into the collector channels. *Id.*; *see also id.* (¶¶52-53, 246-48); Ex.1001 (¶95). Aqueous flowing from Schlemm's canal into the collector channels necessarily traverses the canal's outer wall. Ex.1001 (¶95). As shown in Demonstratives 1 and 2 above, the bulb and screw stents create pathways through the trabecular meshwork and into Schlemm's canal allowing aqueous to flow to the collector channels. Ex.1001 (¶95). Similarly, the blade stent maintains the patency of the canal and can be shaped to provide "sufficient aqueous outflow," which "prevent[s] the walls of Schlemm's canal from closing the outlet of the stents." Ex.1028 (Abstract, ¶¶161, 163, 166-167, 346, 355). The goal of Tu is to "permit[] and/or enhance[e] aqueous outflow…toward existing outflow pathways." *Id.* (¶3).

Thus, Tu discloses supports that do not substantially interfere with transmural flow across the outer wall of Schlemm's canal.

8. Dependent Claim 9

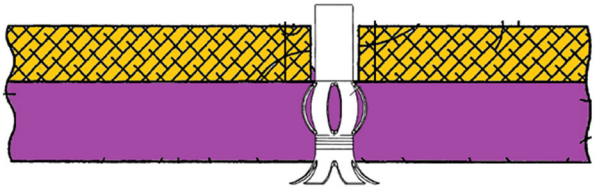
The method of claim 1, wherein at least a portion of the support extends out of Schlemm's canal and into the trabecular meshwork.

Tu discloses that at least a portion of the support extends out of Schlemm's canal and into the trabecular meshwork. Ex.1028 (¶32). The blade stent contains a snorkel, which extends "through the trabecular meshwork." *Id.* (¶34). As shown in Figure 3, shank 40 extends out of Schlemm's canal and into the trabecular meshwork providing a pathway for aqueous to flow from the anterior chamber into Schlemm's canal. *Id.* (¶¶160, 165).

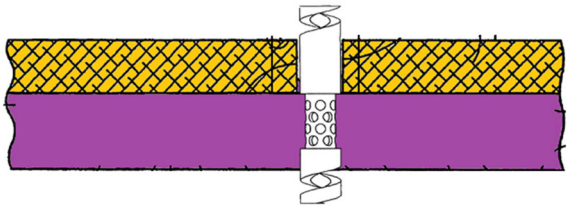


Ex.1028 Figure 3

Additionally, the bulb and screw stents disclosed in Figures 57 and 62, respectively, similarly contain portions that would extend out of Schlemm's canal and into the trabecular meshwork when implanted into Schlemm's canal, which allows aqueous to flow from the anterior chamber.



Demonstrative 1: Modified Figure 3 demonstrating Figure 57 extending out of Schlemm's canal (purple) into the trabecular meshwork (yellow)



Demonstrative 2: Modified Figure 3 demonstrating Figure 62 in the same manner

Thus, Tu discloses that at least a portion of the support extends out of Schlemm's canal and into the trabecular meshwork.

B. Ground 2: Gharib in view of Smedley Renders Obvious Claims 1-3 and 5-9.

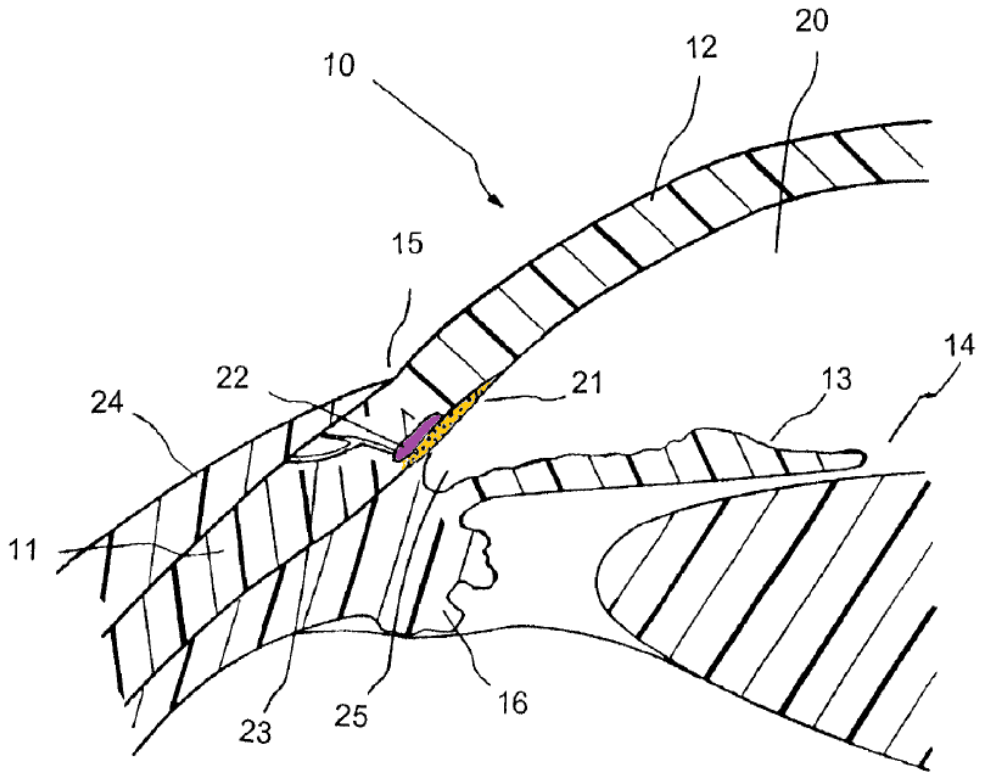
1. Independent Claim 1

a. "A method for reducing intraocular pressure, comprising:"

Generally, "preamble language is not treated as limiting." *See Aspex*, 672 F.3d at 1347. Nonetheless, Gharib discloses "devices and methods for reducing intraocular pressure," more specifically "to the treatment of glaucoma by permitting aqueous humor to flow out of the anterior chamber through a surgically implanted pathway." Ex.1005 (¶¶1, 3, 4, 54).

b. "introducing a tubular cannula having a lumen at least partially within Schlemm's canal;"

Gharib Figure 2 below provides a close-up, cross-sectional view of the relevant space—showing the trabecular meshwork 21 (yellow), the anterior chamber 20, and Schlemm's canal 22 (purple). Ex.1005 (¶50).

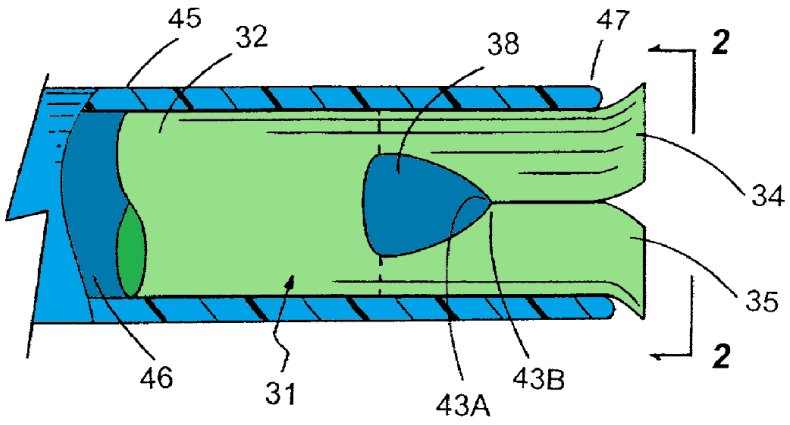


Ex.1005 Figure 2 (annotated)

With respect to the claimed "tubular cannula having a lumen," Gharib discloses a tubular cannula—a "hollow delivery apparatus 45" in Figure 4A below—that houses a device 31 to be implanted into Schlemm's canal. Ex.1005 (¶¶55, 58). Gharib's delivery apparatus has a "size range of 20 to 40 gauge," *id.* ¶69, *i.e.*, it is a tubular cannula having a lumen, similar to a hollow hypodermic needle. Ex.1001 (¶¶103-106).

With respect to "introducing" the cannula "at least partially within Schlemm's canal," Gharib teaches using its tubular cannula delivery apparatus (blue) to insert a device (green) into Schlemm's canal. For reasons discussed below, this insertion

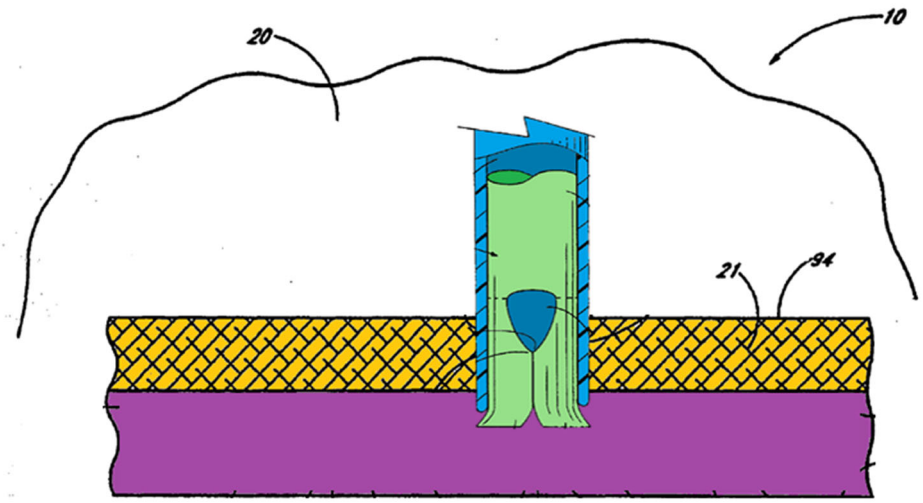
would necessarily involve introducing the tubular cannula holding the device at least partially within Schlemm's canal. *See, e.g.*, Ex.1005 (¶¶69-71); Ex.1001 (¶106).



Ex.1005 Figure 4A (annotated support (green) within hollow delivery apparatus (blue))

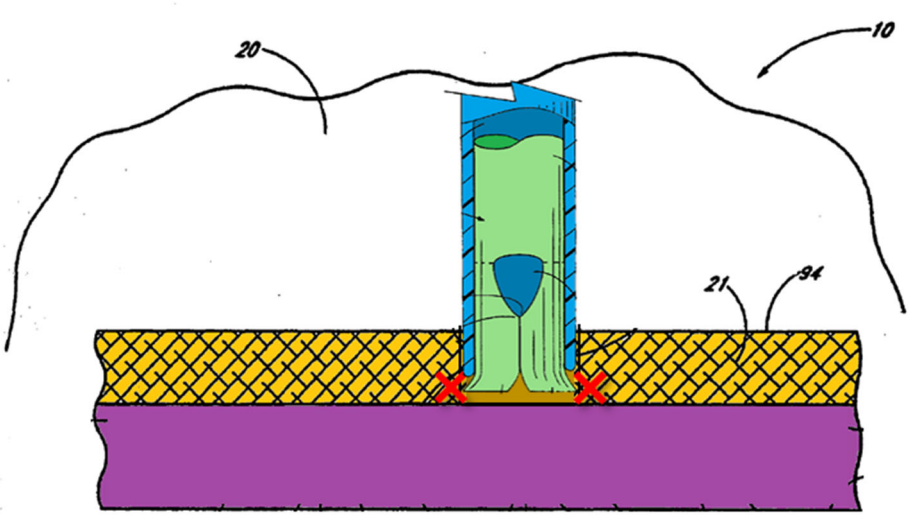
For example, Gharib describes a method of implanting device by creating an opening in the trabecular meshwork, introducing the delivery apparatus into the space, and inserting a device that is "adapted to be bifurcated, positioned, and stabilized *inside Schlemm's canal*." Ex.1005 (¶55, 69-70). Gharib describes the delivery device as comprising a plunger, and delivering the device involves pushing the plunger so that "the distal end 47 of the delivery apparatus 45 retreats, [and] the two bifurcatable elements 34, 35 continue to deploy in two substantially opposite directions." Ex.1005 (¶59). A POSITA would have understood that when Gharib teaches inserting the device into Schlemm's canal, it would have required introducing the cannula that holds the device at least partially within Schlemm's canal. Ex.1001 (¶109); *see also* Ex.1005 (¶59, cl. 37 (claiming a "method

comprising…positioning the first and second bifurcatable elements inside a Schlemm's canal")). Insertion would allow for the "bifurcatable elements" to be positioned and stabilized inside Schlemm's canal. Ex.1005 (¶¶55, 70, cl. 37).



Demonstrative 3: Gharib Figure 4A modified to show delivery of support into Schlemm's canal

If Gharib's tubular cannula were *not* introduced at least partially into Schlemm's canal, the device could not be positioned and stabilized inside Schlemm's canal. The device would instead be improperly deployed outside the canal, as illustrated below. Ex.1001 (¶109).

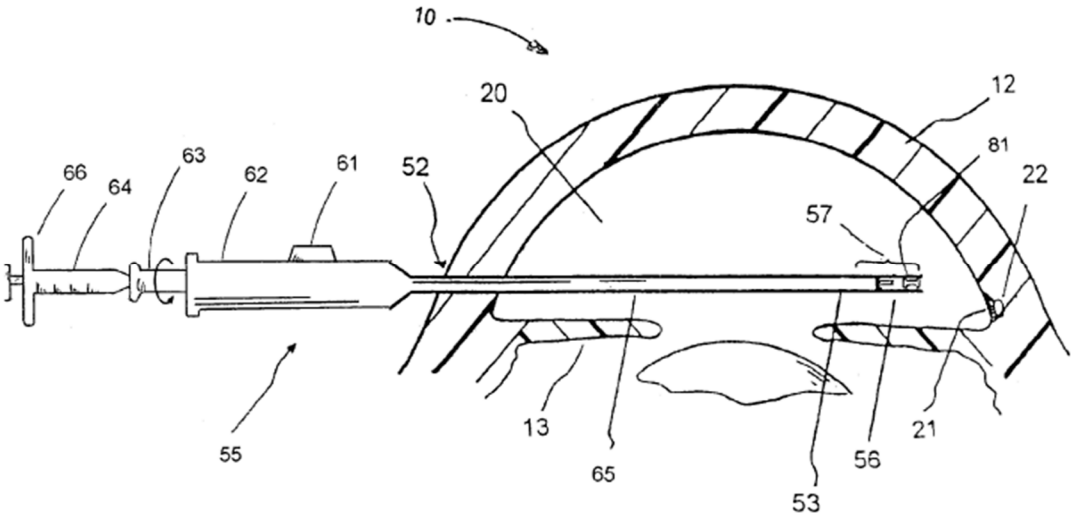


Demonstrative 4: Gharib Figure 4A modified to show failed deployment

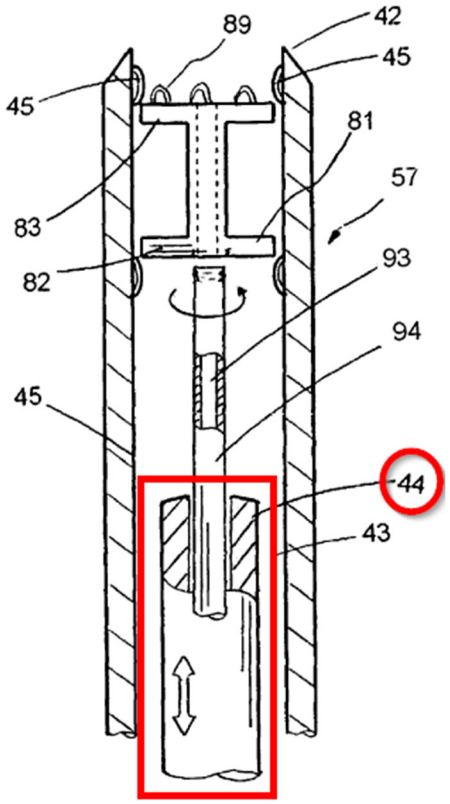
To the extent Gharib does not explicitly disclose introducing the cannula at least partially within Schlemm's canal, doing so when deploying Gharib's bifurcatable device would have been obvious. Indeed, a POSITA would have been motivated to introduce the cannula holding Gharib's device at least partially within Schlemm's canal to ensure that the bifurcatable members 34, 35 successfully deploy in the canal instead of in the trabecular meshwork. Ex.1001 (¶111). Otherwise, the bifurcatable members could not be stabilized inside Schlemm's canal to provide the stenting capability Gharib seeks to lower intraocular pressure. *Id*.; *see also* Ex.1005 (¶¶22, 55, 60). A POSITA would have had a reasonable expectation of success of introducing a cannula at least partially within Schlemm's canal because the canal is Gharib's target treatment area given that Gharib teaches inserting a support into the canal, and introducing a cannula into the canal was known to be successful for other procedures, like viscocanalostomy. *See* Ex.1005 (¶14).

Thus, Gharib discloses and/or renders obvious introducing a tubular cannula having a lumen at least partially within Schlemm's canal.

Additionally, it would have been obvious to a POSITA to look to the prior art for a delivery apparatus that may simplify delivering Gharib's device into Schlemm's canal. Ex.1001 (¶112). Smedley, like Gharib, teaches a delivery apparatus that delivers supports into Schlemm's canal via a tubular cannula with a "plunger [44]." Ex.1036 (4:65-5:5; 5:58-67; 6:11-16, 10:14-17, Figs. 5, 6); Ex.1005 (¶¶26, 58-59).



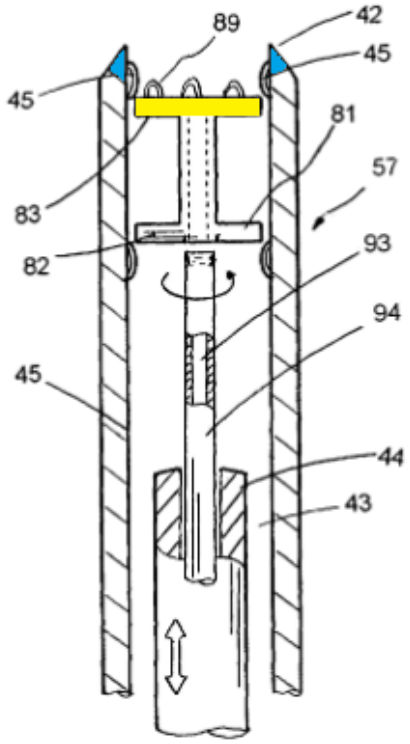
Ex.1036 Figure 6



Ex.1036 Figure 5 (annotated showing close-up view of distal portion 57 in Figure 6 and plunger 44)

To deliver the support, Smedley teaches a similar surgical technique to that of Gharib, which involves inserting the delivery applicator at least partially within Schlemm's canal to implant a device. Ex.1001 (¶115). Specifically, Smedley's delivery includes making an incision in the trabecular meshwork, introducing the delivery apparatus into the space, and then deploying the device "from the applicator 55 once the distal section 83 [of the stent] passes beyond the edge of the trabecular meshwork." Ex.1036 (5:45-47; 10:11-13). The distal section 83 of the stent is *within* the delivery applicator as show in Figure 5 below, meaning that the delivery

applicator must also pass beyond the edge of the trabecular meshwork and must be introduced at least partially within Schlemm's canal to deploy the device.



Ex.1036 Figure 5 (annotated cutting means 42 (blue) and distal section (yellow))

Smedley discloses various benefits and attributes of its delivery device. For example, it may comprise a distal cutting means 42 for creating an opening in the trabecular meshwork for stent placement. Ex.1036 (10:6-9). Thus, unlike Gharib's two-step procedure that uses another device to create a hole in the trabecular meshwork before using the delivery apparatus to deliver the device, Ex.1005 (¶¶68-70), Smedley's apparatus combines the cutting means and the delivery mechanism into one apparatus. Ex.1036 (10:6-9); Ex.1001 (¶113). Smedley simplifies the

procedure and reduces the number of foreign objects inserted into a patient's eye. Ex.1001 (¶113). Thus, a POSITA would have been motivated to deliver Gharib's support with Smedley's delivery apparatus that provides a simpler, safer procedure. Ex.1001 (¶¶113-114).

A POSITA would have had a reasonable expectation of success of using Smedley's apparatus to deliver Gharib's support. Ex.1001 (¶114). Like Gharib, Smedley discloses a tubular cannula having a "lumen for holding the trabecular microstent." Ex.1036 (5:21-28, 10:4-5, 10:63-65, 11:3-5 ("[The] delivery applicator…comprises 'a cannula portion 65.'")). And both Gharib and Smedley disclose similar proportions, preferably a 30-guage cannula. Ex.1005 (¶69); Ex.1036 (10:65-11:3). A POSITA would have, therefore, reasonably expected success of using Smedley's delivery apparatus to deliver Gharib's support devices. Ex.1001 (¶114).

Thus, Gharib alone discloses and/or renders obvious, or, alternatively, Gharib in combination with Smedley renders obvious "introducing a tubular cannula having a lumen at least partially within Schlemm's canal." Ex.1001 (¶116).

c. **"delivering a high viscosity fluid into Schlemm's canal; and"**

As discussed in §V.C, for the purpose of this IPR, Petitioners have adopted Patent Owner's interpretation that viscoelastics are high viscosity fluids.

Delivering a high viscosity fluid into Schlemm's canal would have been obvious over Gharib in view of Smedley. Ex.1001 (¶117-21). Generally, delivering viscoelastic into Schlemm's canal was well-known in the prior art to facilitate ophthalmic surgeries, and as an aid for implanting a support. *See* Ex.1001 (¶¶34-42, 118). Smedley explains that Schlemm's canal can "become constricted or blocked," and teaches injecting viscoelastic fluid into Schlemm's canal to expand it and "clear[]…any blockages." Ex.1036 (11:27-49; 11:64-12:2). The viscoelastic can (1) provide "fluid therapy" that provides "therapeutic effects" on nearby tissue; (2) dilate the canal and provide permanent deformation; and (3) "therapeutically dilate the aqueous cavity [*i.e.* Schlemm's canal]" "at any convenient time." Ex.1036 (4:65-5:15, 6:22-23, 10:18-20; 11:54-59).

Smedley also teaches viscoelastic delivery in combination with a stent support. As explained above in §XI.B.1.b, Smedley teaches delivering a support via a delivery applicator. Smedley's device can be implanted such that its outflow portion "is positioned in Schlemm's canal." Ex.1036 (6:11-15; 6:63-67; Fig.2). After the support is implanted, Smedley teaches injecting viscoelastic through the lumen of the implanted support to therapeutically dilate Schlemm's canal. *Id.* (4:65-5:8; 11;40-59; 12:14-29); Ex.1001 (¶118).

A POSITA would have been motivated by Smedley to deliver a high viscosity fluid, such as viscoelastic, into Schlemm's canal before, during, or after implanting

a support, like Gharib's, to clear blockages, dilate the canal, and obtain therapeutic effects. Ex.1001 (¶¶118-19); *see also* Ex.1036 (10:18-20) ("any convenient time"). This is particularly true for patients who have a collapsed Schlemm's canal due to angle-closure glaucoma because injecting a viscoelastic would assist in dilating to provide space for implanting a support. Ex.1001 (¶¶39, 119).

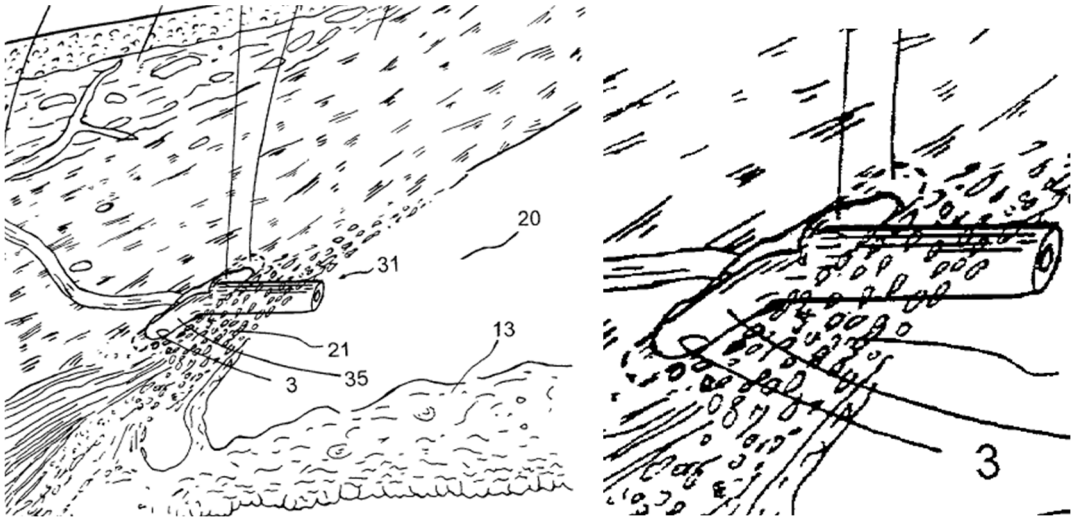
A POSITA would have had a reasonable expectation of success of delivering a high viscosity fluid into Schlemm's canal before, during, or after implanting a support because Smedley teaches viscodilation at any convenient time in conjunction with implanting a support. Moreover, a POSITA would have had a reasonable expectation of success infusing viscoelastic post-implantation of Gharib's support because Smedley teaches injecting viscoelastic through the support's lumen, and Gharib's support has lumen that would accommodate that infusion. Ex.1036 (11:40-50; 12:14-29); Ex.1005 (¶¶55, 60, 66); Ex.1001 (¶120).

Thus, Gharib in view of Smedley renders obvious "introducing a tubular cannula having a lumen at least partially within Schlemm's canal." Ex.1001 (¶116).

d. **"inserting a support into Schlemm's canal by passing the support through the tubular cannula,"**

First, Gharib discloses inserting a support into Schlemm's canal. For example, Gharib's device can comprise "two distal bifurcatable elements" that are deployed from a delivery apparatus and "adapted to be positioned and stabilized inside Schlemm's canal." Ex.1005 (¶¶25, 52, 55, 57, 70). The bifurcatable elements may

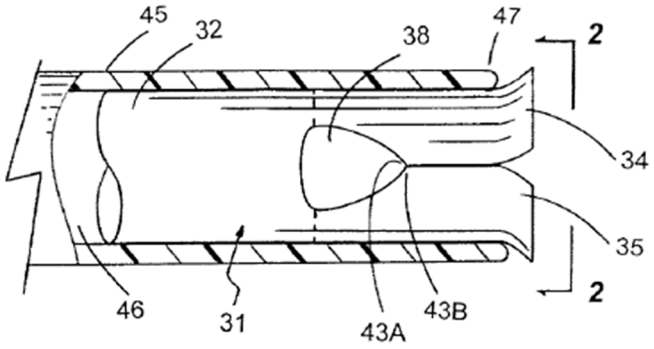
be curved or angled to conform to the contour of Schlemm's canal. Ex.1005 (¶¶63, 66). Figure 8 shows the support implanted "circumferentially within Schlemm's canal" and propping open at least a portion of Schlemm's canal to allow outflow of the aqueous humor. Ex.1005 (Fig. 8, ¶¶60, 67, 70); Ex.1001 (¶123). Gharib explains that "[t]he shape of the end cross-section 35 is to provide a stenting capability when the elements are placed inside Schlemm's canal." Ex.1005 (¶60). A POSITA would have understood that Gharib's "stenting capability" means it is a structural support inside Schlemm's canal. Ex.1005 (¶56-57); Ex.1001 (¶122).



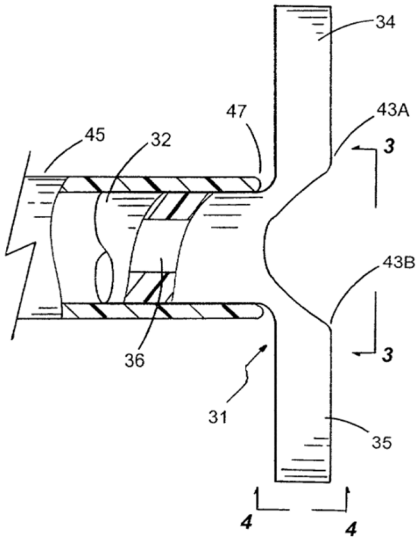
Ex.1005 Figure 8 (right zoomed in)

Second, Gharib's support is inserted into Schlemm's canal by passing the support through a tubular cannula. Gharib's hollow delivery apparatus is a tubular cannula, *see* §XI.B.1.b, inside which a support may be placed and subsequently "deployed from the delivery apparatus into the eye." Ex.1005 (¶26). The support is deployed from the delivery apparatus by continuously pushing a plunger to pass the

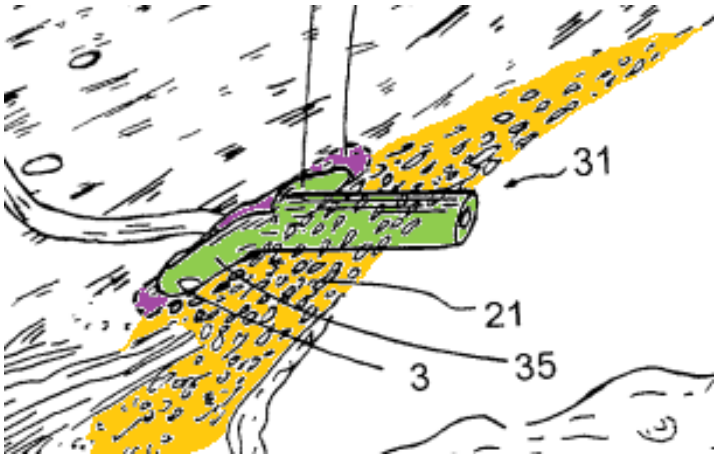
support through the tubular cannula and insert it into Schlemm's canal. *See* Figs. 4A and 5A; *see also* Ex.1005 (¶59). Thus, Gharib teaches inserting a support into Schlemm's canal by passing the support through the tubular cannula.



Ex.1005 Figure 4A (support inside delivery apparatus)



Ex.1005 Figure 5A (support in deployed state)

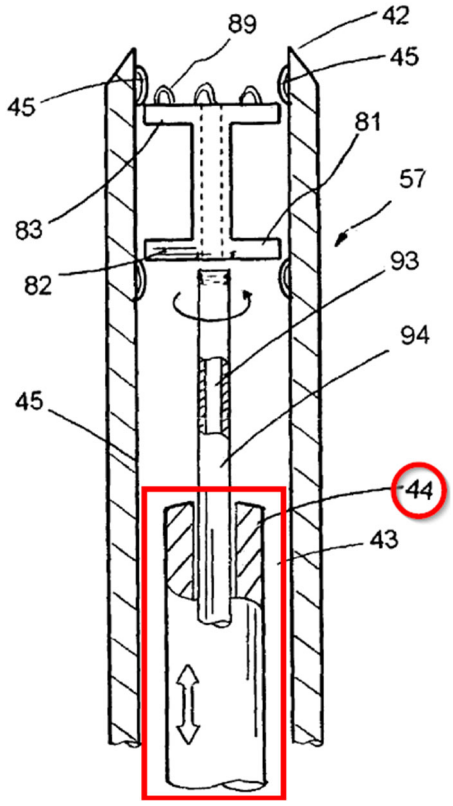


Ex.1005 Figure 8
(annotated support within Schlemm's canal)

Furthermore, as discussed in §XI.B.1.b above, a POSITA would have been motivated to implant Gharib's support with Smedley's delivery apparatus because

Smedley's device provides for a combined, simplified procedure of cutting and delivery. Also as discussed in §XI.B.1.b, a POSITA would have had a reasonable expectation of success of using Smedley's delivery apparatus with Gharib's support because both disclose similarly-sized cannulas for housing a support.

Smedley's delivery apparatus delivers a stent into Schlemm's canal using a "plunger-type deployment mechanism 44," which moves longitudinally along the tubular cannula and pushes the stent out of the distal tip of the cannula so that it is "positioned in Schlemm's canal." Ex.1036 (5:58-67; 6:11-67; 8:3-7, 10:14-54, 12:14-29; Figs. 5, 6); *see also* Ex.1001 (¶125).

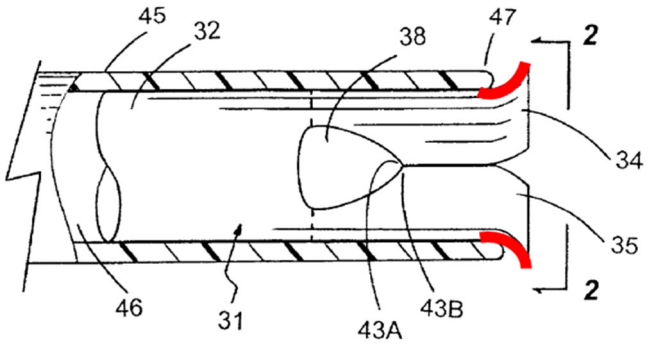


Ex.1036 Figure 6 (annotated)

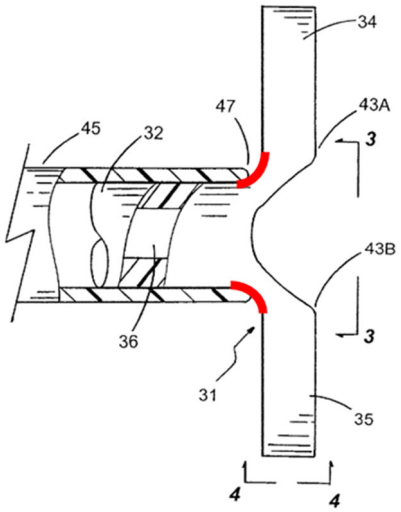
Thus, Gharib discloses inserting a support into Schlemm's canal by passing the support through a tubular cannula, or, in the alternative, doing so would have been obvious in view of Smedley. Ex.1001 (¶¶122, 125).

e. **"wherein the support comprises an arcuate member,"**

Gharib discloses that the bifurcatable elements are "adapted to be positioned and stabilized inside Schlemm's canal," Ex.1005 (¶¶25, 55, 70), which the '361 patent describes a "slightly arcuate cylinder," Ex.1003 (11:28-33). Figure 4A shows a partially deployed version of the Gharib device, and Figure 5A shows a fully deployed version. The bifurcatable elements are "arcuate members." Ex.1005 (¶¶58-60). In Figure 5A, the bifurcatable elements 34 and 35 arc leftwards towards the delivery apparatus 45.



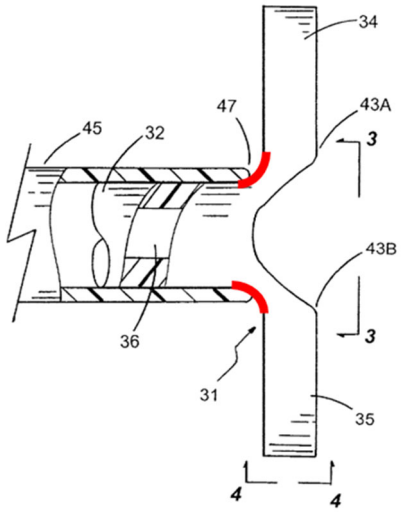
Ex.1005 Figure 4A (annotated)



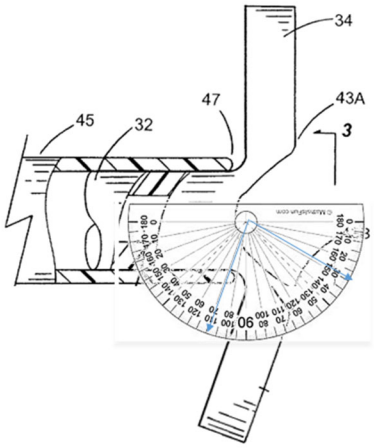
Ex.1005 Figure 5A (annotated)

The bifurcatable elements may be curved or angled at an angle between about 30 degrees to about 150 degrees, preferably between about 70 degrees and about 110

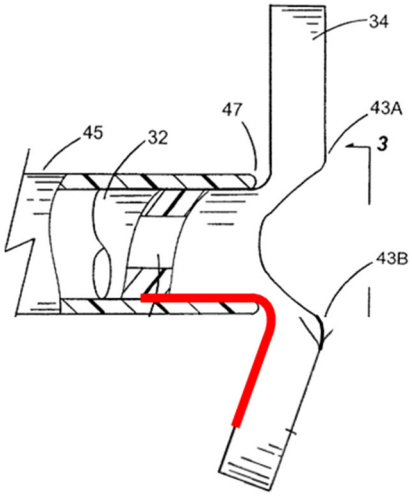
degrees to conform to the contour of Schlemm's canal. Ex.1005 (¶¶63, 66). Gharib's Figure 5A (modified below to illuminate the arcuate member) represents Gharib's teachings regarding the angle of the bifurcatable element:



Ex.1005 Figure 5A (annotated)

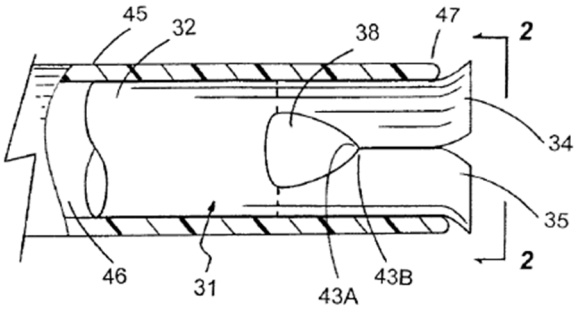


Ex.1005 Figure 5A (modified and protractor imposed)

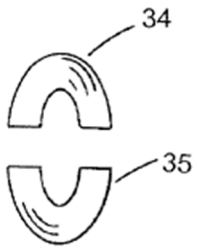


Ex.1005 Figure 5A (modified showing 110º and annotated)

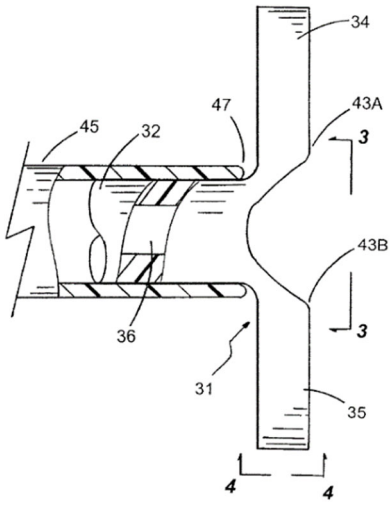
The bifurcatable elements can take a variety of shapes, including the semicircular shape shown in Figure 4B (depicting the cross-section 2-2 of Figure 4A) and Figure 5C (depicting the cross-section 4-4 of Figure 5A). Ex.1005 (¶¶29, 56-60). These are also "arcuate members" disposed in Schlemm's canal that assist in propping it open. Ex.1005 (¶¶29, 56-60); Ex.1001 (¶130).



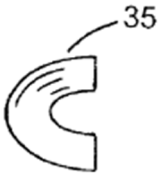
Ex.1005 Figure 4A



Ex.1005 Figure 4B

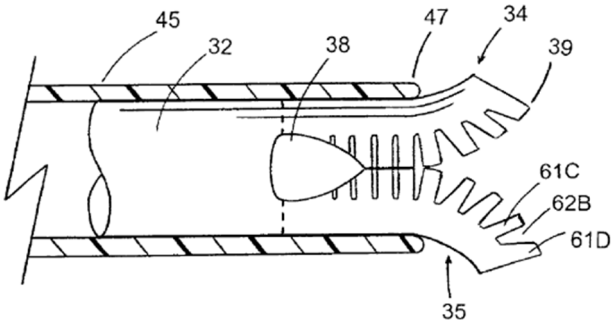


Ex.1005 Figure 5A



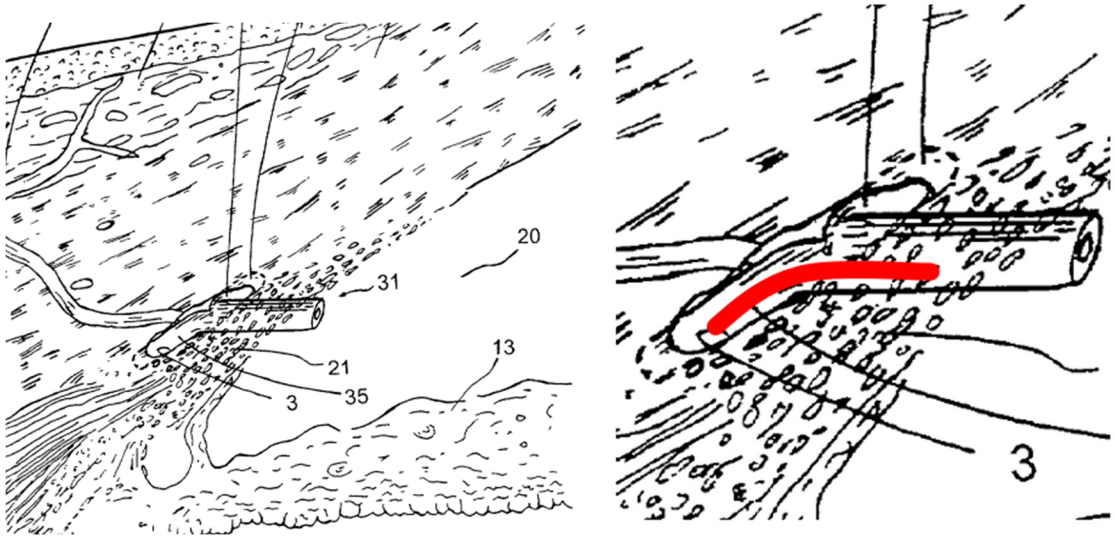
Ex.1005 Figure 5C

Figure 7B further demonstrates that the bifurcatable element is an "arcuate member," depicted in a semi-deployed state. Ex.1005 (¶65).



Ex.1005 Figure 7B

Finally, Figure 8 shows the bifurcated elements stenting open Schlemm's canal and bending outwards in an arcuate manner into the meshwork:

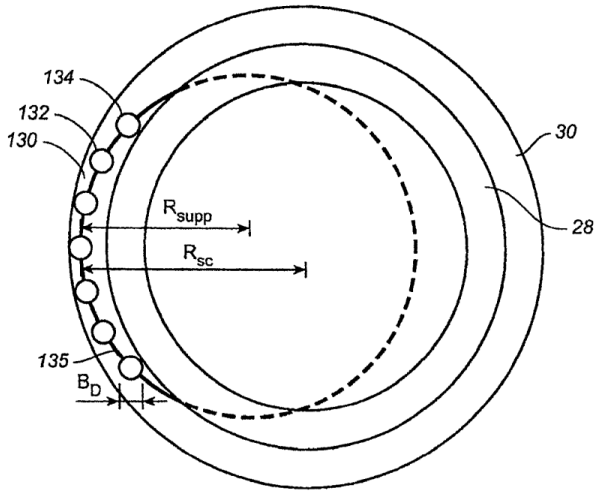


Ex.1005 Figure 8 (right zoomed in and annotated)

A POSITA would have recognized Gharib's disclosed supports comprise "arcuate members." Ex.1001 (¶130).

f. **"wherein at least a portion of the arcuate member has a radius of curvature smaller than a radius of curvature of Schlemm's canal, and"**

The '361 patent lacks clear guidance regarding where one measures a radius of curvature for comparison or what constitutes a radius of curvature of Schlemm's canal. As explained in §XI.A.1.f, one possible radius of curvature is the Schlemm's canal's circumferential radius (measured from the center of the eye as in Figure 11A below), which is approximately 6mm. Another possible radius of curvature can be based on the cross-section of Schlemm's canal, which the '361 patent states "is about 190 to about 370 microns." *See* §XI.A.1.f; *see also* Ex.1001 (¶131).



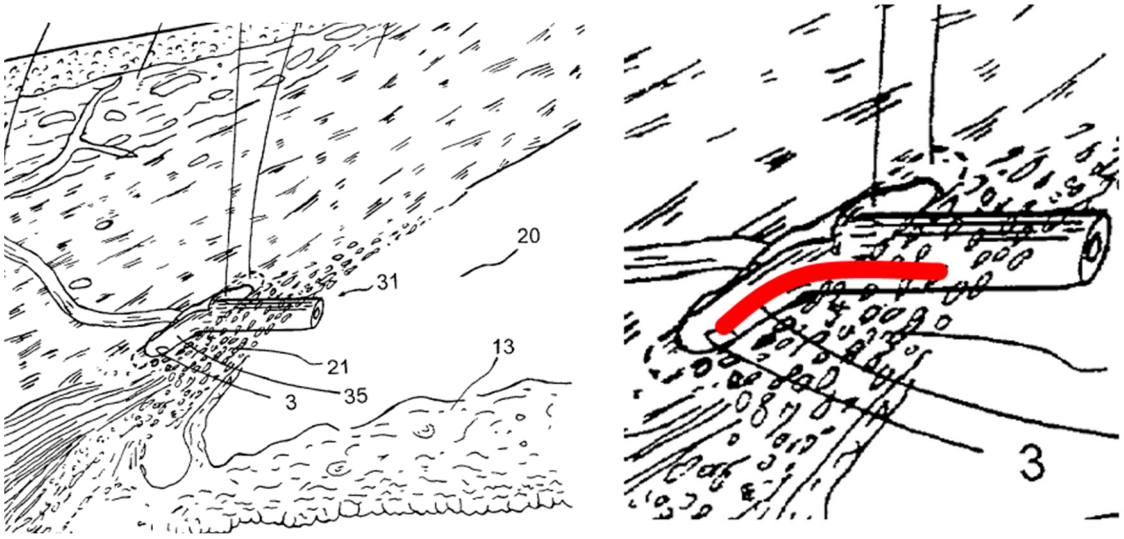
'361 Patent Figure 11A

A POSITA would understand that the radius of curvature of an arcuate member fitting *within* the cross-section of Schlemm's canal has a radius of curvature less than both the cross-sectional and circumferential radius of curvature of Schlemm's canal. Ex.1001 (¶¶131-132). Given that Gharib's support fits *within* Schlemm's canal, its radius of curvature must be smaller than a radius of curvature of Schlemm's canal, whether based on the circumferential radius or cross-sectional radius. Ex.1005 (¶¶25, 55, 60, 62); Ex.1001 (¶¶132-134).

Additionally, Patent Owner has interpreted that a support meets this limitation if, once implanted, it protrudes at one end out of Schlemm's canal. *See* Ex.1020, (Ex.N at 10). Gharib's support also meets Patent Owner's interpretation.[3] Figure 8 shows Gharib's bifurcated element disposed within Schlemm's canal forms an

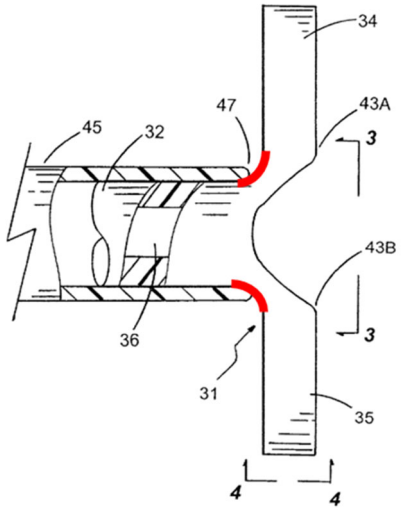
[3] Gharib would also meet this limitation under any plain and ordinary meaning.

arcuate shape with the remainder of the body of the device protruding out of Schlemm's canal. Ex.1005 (¶¶52, 54, 67-70); Ex.1001 (¶136).

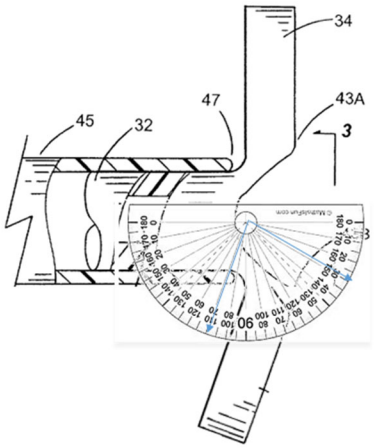


Ex.1005 Figure 8 (right zoomed in and annotated)

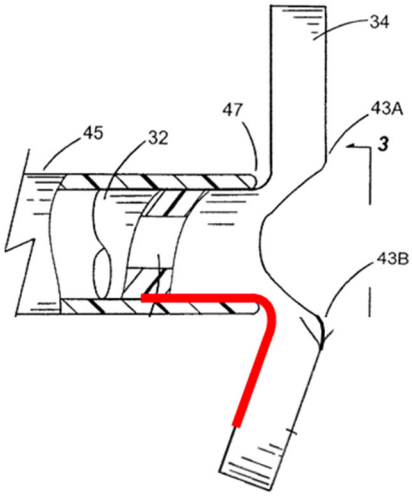
The bifurcatable elements may be curved or angled between about 30 degrees to about 150 degrees, preferably between about 70 degrees and about 110 degrees to conform to the contour of Schlemm's canal. Ex.1005 (¶¶63, 66). Gharib's Figure 5A (modified below) represents Gharib's teachings regarding the angle of the bifurcatable elements Ex.1001 (¶137):



Ex.1005 Figure 5A (annotated)



Ex.1005 Figure 5A (modified and protractor imposed)



Ex.1005 Figure 5A (modified showing 110º and annotated)

Thus, Gharib teaches a support comprising an arcuate member that, once implanted, protrudes at one end out of Schlemm's canal, which meets Patent Owner's interpretation of the limitation. Ex.1001 (¶137).

g. **"wherein the support comprises at least one fenestration."**

Gharib teaches that the support has at least one fenestration because the outlet section, *i.e.*, bifurcatable elements, may comprise fenestrations and may take various configurations that would comprise fenestrations. Ex.1005 (¶29 (describing mesh, porous, fenestrated, coil, spiral, and permeable supports)). Ex.1001 (¶138).

2. Dependent Claim 2

The method of claim 1, wherein the delivered fluid dilates the canal.

For the reasons discussed in §XI.B.1.c, Gharib in view of Smedley renders obvious that the delivered fluid dilates the canal. Smedley teaches that a fluid such as "saline, viscoelastic, or the like" can be injected into Schlemm's canal for "fluid therapy" and to "therapeutically dilate the aqueous cavity [*i.e.* Schlemm's canal]" "at any time convenient." Ex.1036 (4:65-5:8, 6:22-23 ("In some embodiments the aqueous cavity is Schlemm's canal."); 10:18-20). Further, a POSITA would have been motivated to dilate Schlemm's canal to make it easier to insert a support and because of the therapeutic benefits associated with dilating Schlemm's canal. *See* §XI.B.1.c; Ex.1001 (¶139). And a POSITA would have also had a reasonable expectation of success dilating Schlemm's canal with a high viscosity fluid. *See* §XI.B.1.c. Ex.1001 (¶139).

Thus, Gharib in view of Smedley renders obvious that the delivered fluid dilates the canal. Ex.1001 (¶140).

3. Dependent Claim 3

The method of claim 1, wherein the high viscosity fluid is sodium hyaluronate.

Gharib in view of Smedley renders obvious that the high viscosity fluid is sodium hyaluronate. Smedley discloses that one viscoelastic that can be used to dilate Schlemm's canal is Healon®, Ex.1036 (11:60-64), which is sodium

hyaluronate and was a well-known viscoelastic that could be safely injected into Schlemm's canal. *See* Ex.1001 (¶¶141-142); *see also* §XI.A.3.

Thus, Gharib in view of Smedley renders obvious that the high viscosity fluid is sodium hyaluronate. Ex.1001 (¶143).

4. Dependent Claim 5

The method of claim 1, wherein the support contacts the interior wall of the canal at least at three points.

Gharib's support contacts the interior wall of Schlemm's canal at least at three points when implanted. Patent Owner contends that if a support's outer surface breaks contact with the wall of Schlemm's canal at more than two spots, it meets this limitation. *See, e.g.*, Ex.1038 (Ex.C at 39-41).

Gharib's configurations, shapes, and surfaces would satisfy this limitation. Ex.1001 (¶145); *see, e.g.*, Ex.1005 (¶¶29, 56, 66 (describing various shapes and forms including coil, mesh, porous, and fenestrated and explaining that "the outer surface of the outlet section 33," which is the section that is disposed within Schlemm's canal, "may comprise a stubbed surface, ribbed surface, surface with pillars, textured surface, or the like")). A POSITA would have recognized that Gharib's support comprising stubs, ribs, pillars, or textured surface would contact a wall of Schlemm's canal "at least at three points," as would the various forms Gharib discloses such as coil, mesh, porous, or fenestrated forms. Ex.1001 (¶¶144-45). For example, even including two stubs or pillars on each of Gharib's bifurcatable

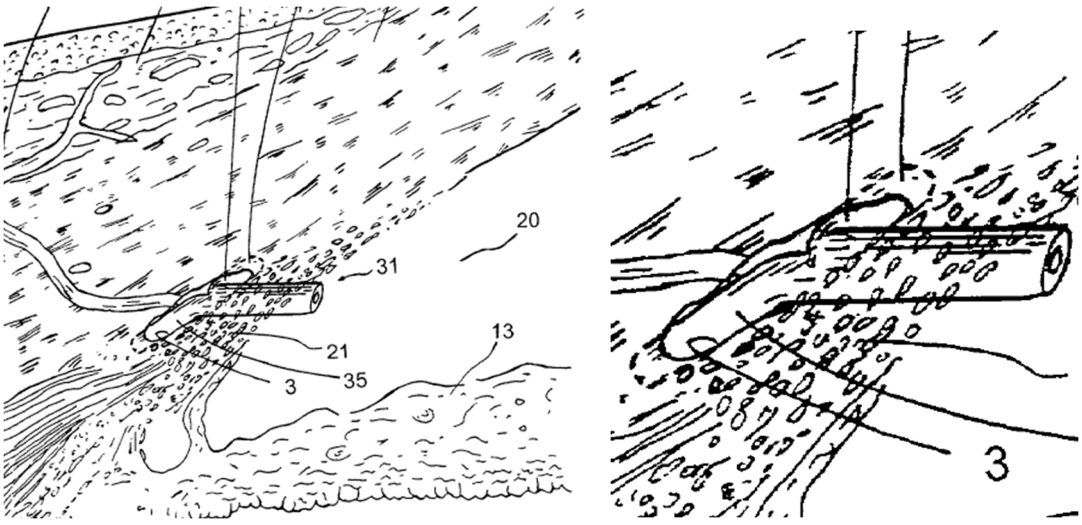
elements on the outlet section would mean the support contacts the interior wall of the canal at least at four points. Ex.1001 (¶144). The cutaways, openings, and pathways taught by Gharib provide additional independent contact points with a wall of Schlemm's canal that would exceed "at least three" contact points. Ex.1001 (¶145).

Thus, Gharib discloses that its support contacts the interior wall of Schlemm's canal at least at three points.

5. Dependent Claim 6

The method of claim 1, wherein the support does not substantially interfere with longitudinal flow along the canal.

Gharib's support does not substantially interfere with longitudinal flow along Schlemm's canal. For example, Gharib's support is implanted to establish an outflow pathway through the body's existing outflow pathway, as shown in Figure 8. Ex.1005 (¶¶51-52). The shape of the bifurcatable elements disposed within Schlemm's canal "allows aqueous to freely flow into aqueous collector channels in the external wall of Schlemm's canal." Ex.1005 (¶60); *see also Id.* (¶67). The "aqueous humor is transported into Schlemm's canal and subsequently into the aqueous collectors and the aqueous veins so that the intraocular pressure is properly maintained within a therapeutic range." Ex.1005 (¶54). Thus, Gharib's support promotes longitudinal flow. Ex.1001 (¶¶146-147).



Ex.1005 Figure 8 (right zoomed in)

Moreover, as with the "rough, spiked, or fluted perimeters" that may allow "circumferential fluid flow through or around [the support]" according to the '361 patent (Ex.1003 (9:32-35)), Gharib's bifurcatable elements can have a "stubbed surface, ribbed surface, surface with pillars, textured surface, or the like." Ex.1005 (¶56). Thus, Gharib's support surface modifications would facilitate, not substantially interfere with, longitudinal flow along Schlemm's canal. Ex.1001 (¶147).

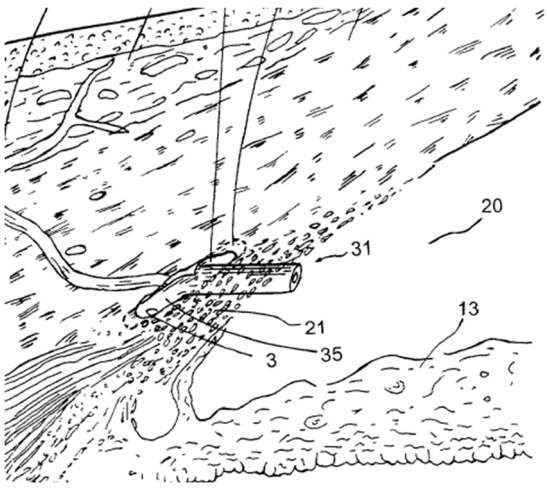
6. Dependent Claim 7

> **The method of claim 1, wherein the support does not substantially interfere with transmural flow across the inner wall of the canal.**

The '361 patent states that "'does not substantially interfere' with transmural flow" means "that the support does not significantly block either fluid outflow from the trabecular meshwork or fluid outflow to the collector channels." Ex.1003 (7:43-

47). A POSITA would understand the inner wall of Schlemm's canal to mean the interface between the trabecular meshwork and Schlemm's canal. Ex.1001 (¶148).

Gharib's support does not substantially interfere with transmural flow across the inner wall. The main purpose of Gharib's device "is for transporting aqueous humor at the level of the trabecular meshwork and partially using the existing outflow pathway for aqueous humor, i.e., utilizing the entire outflow pathway except for the trabecular meshwork, which is bypassed by the trabecular shunt 31. ***In this manner, aqueous humor is transported into Schlemm's canal***…." Ex.1005 (¶54). Once disposed within Schlemm's canal as in Figure 8, the device expands the canal to enhance aqueous flow in the now-stented areas, through the trabecular meshwork, and into Schlemm's canal. *Id*. (¶60); Ex.1001 (¶¶149-50). Thus, Gharib facilitates, rather than substantially interferes with, transmural flow across the inner wall of Schlemm's canal.



Ex.1005 Fig. 8

Further, Gharib's device, directed to using existing outflow pathways to allow aqueous humor to drain, Ex.1005 (¶52), can be various shapes with various surfaces. For example, "the outer surface of the outlet section 33," which is the section that is disposed within Schlemm's canal, "may comprise a stubbed surface, ribbed surface, surface with pillars, textured surface, or the like. The outer surface of the trabecular shunt 31 is biocompatible and tissue-compatible so that the interaction between the outer surface of the shunt and the surrounding tissue of Schlemm's canal is minimal, and inflammation is reduced." *Id*. (¶56). Furthermore, Gharib teaches that the outlet section "may be configured as a coil, mesh, spiral, or other appropriate configuration as will [be] apparent to those of skill in the art." *Id.* (¶29). The outlet section "may be made of a material form selected from a group comprising coil form, mesh form, spiral form, porous form, semi-permeable form, fishbone form…." *Id.* (¶59). These configurations and materials all reduce the overall contact between the support and the wall of Schlemm's canal and thus improve outflow from the trabecular meshwork, or at a minimum do not "substantially interfere with transmural flow" or

"significantly block…fluid outflow from the trabecular meshwork." Ex.1005 (¶¶70-71); Ex.1001 (¶152).[4]

Thus, a POSITA would have recognized that Gharib's various support forms and configurations were designed to facilitate, not substantially interfere with, transmural flow across the inner wall of Schlemm's canal. Ex.1001 (¶¶152-153).

7. Dependent Claim 8

The method of claim 1, wherein the support does not substantially interfere with transmural flow across the outer wall of the canal.

The '361 patent states that "'does not substantially interfere' with transmural flow" means "that the support does not significantly block either fluid outflow from the trabecular meshwork or fluid outflow to the collector channels." Ex.1003 (7:43-47). A POSITA would understand the outer wall of the canal to mean the interface between Schlemm's canal and the collector channels. Ex.1001 (¶155).

Gharib's support does not substantially interfere with the transmural flow across the outer wall of Schlemm's canal. The main purpose of Gharib's device "is for transporting aqueous humor at the level of the trabecular meshwork and partially

[4] Indeed, the '361 patent also discloses making the support of mesh material, as Gharib taught. *Compare, e.g.,* Ex.1003 (10:53-56 ("support…can be at least partially made from a mesh")) *with* Ex.1005 (¶29 ("mesh form")).

using existing the outflow pathway for aqueous humor, i.e., utilizing the entire outflow pathway except for the trabecular meshwork, which is bypassed by the trabecular shunt 31. In this manner, ***aqueous humor is transported into Schlemm's canal and subsequently into the aqueous collectors and the aqueous veins*** so that the intraocular pressure is properly maintained within a therapeutic range." Ex.1005 (¶54) (emphasis added). Gharib's invention, therefore, facilitates aqueous outflow from Schlemm's canal into the collector channels, *i.e.*, the purpose of Gharib's invention is to facilitate aqueous flow across the outer wall of Schlemm's canal. Ex.1001 (¶156). Furthermore, the cross-section of the bifurcatable elements deployed within Schlemm's canal "allows aqueous to freely flow into aqueous collector channels in the external wall of Schlemm's canal." Ex.1005 (¶60). Thus, Gharib's support assists with transporting aqueous humor across the outer wall of Schlemm's canal, and therefore does not substantially interfere with transmural flow across the outer wall of Schlemm's canal.

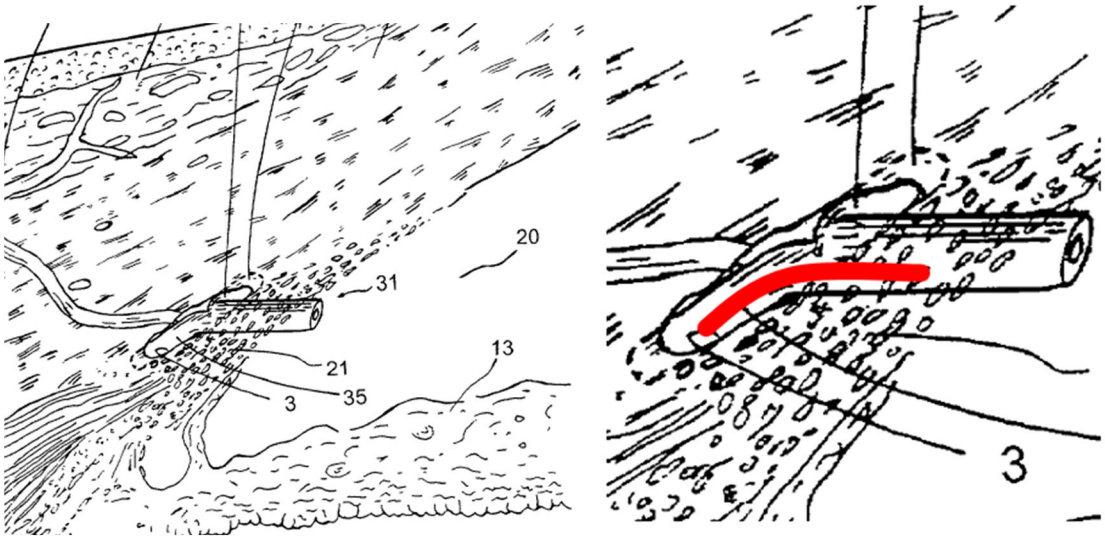
Further, nothing in Gharib suggests that implanting the taught support would substantially interfere with transmural flow across the outer wall of Schlemm's canal. Instead, the purpose of Gharib is to *improve* flow, Ex.1005 (¶52), including by transporting aqueous into Schlemm's canal and into the collector channels, *id.* (¶54). Thus, by further opening up the natural outflow pathways, Gharib's support

would facilitate, not substantially interfere with, transmural flow across the outer wall of Schlemm's canal. Ex.1001 (¶157).

8. Dependent Claim 9

The method of claim 1, wherein at least a portion of the support extends out of Schlemm's canal and into the trabecular meshwork.

As discussed in §XI.B.1.f, at least a portion of Gharib's bifurcated element, when implanted, extends out of Schlemm's canal and into the trabecular meshwork. *See also* Ex.1005 (Fig. 8). Thus, Gharib teaches at least a portion of the support extends out of Schlemm's canal and into the trabecular meshwork.



Ex.1005 Figure 8 (right zoomed in and annotated with red line showing the bifurcated support in Schlemm's canal and extending into the trabecular meshwork and into the anterior chamber)

C. Ground 3: Gharib in view of Haffner Renders Obvious Claims 1-3 and 5-9.

1. Independent Claim 1

a. "A method for reducing intraocular pressure, comprising:"

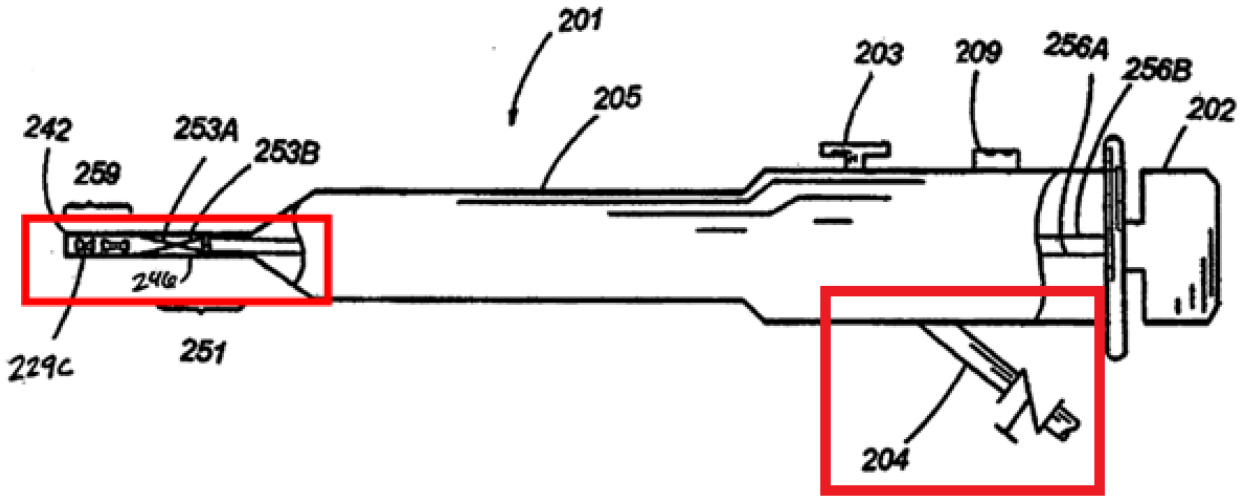
Generally, "preamble language is not treated as limiting." *See Aspex*, 672 F.3d at 1347. Nonetheless, Gharib discloses a method for reducing intraocular pressure. *See* §XI.B.1.a

b. "introducing a tubular cannula having a lumen at least partially within Schlemm's canal;"

As discussed in §XI.B.1.b, Gharib discloses and/or renders obvious introducing a tubular cannula having a lumen at least partially within Schlemm's canal.

Additionally, Gharib in view of Haffner renders obvious introducing a tubular cannula having a lumen at least partially within Schlemm's canal. Haffner's delivery applicators, such as the one in Figure 51A below, can be at least partially introduced within Schlemm's canal, either to inject viscoelastic and/or implant a trabecular stent into Schlemm's canal. *See e.g.*, Ex.1035 (¶¶3, 35-66, 282-284); Ex.1001 (¶¶164-65). The applicator contains "an injection sheath 246," which is a hollow tube (*i.e.*, a tubular cannula) that "store[s] and discharge[s] a plurality of any combination of the stents." *Id.* (¶¶258, 282-284); Ex.1001 (¶164). It also includes "a fluid infusing port 204 for fluid infusion or viscocanalostomy," which involves cannulating Schlemm's

canal (*i.e.*, inserting a tubular cannula within Schlemm's canal) to inject viscoelastic into Schlemm's canal to dilate it. *Id.* (¶¶18, 260, 282-284); Ex.1001 (¶¶165-67).



Ex.1035 Figure 51A (annotated showing tubular cannula and fluid infusion port)

A POSITA would have been motivated to dilate Schlemm's canal with viscoelastic prior to inserting a support because it would lubricate the canal for easier insertion and provide additional operating space. Ex.1001 (¶168). Dilation can be especially important when portions of Schlemm's canal have collapsed, such as in patients suffering from angle-closure glaucoma. Ex.1001 (¶¶39, 168). Haffner's delivery apparatus would have allowed a POSITA to perform both viscodilation and stent insertion with the same device.

Further, a POSITA would have been motivated to use Haffner's delivery apparatus to deliver a support and perform viscodilation because it would further Gharib's and Haffner's stated goals of providing a surgery that is "simple, effective, disease site-specific, and can potentially be performed on an outpatient basis."

Ex.1005 (¶23); Ex.1035 (¶28); Ex.1001 (¶169). Haffner's device allows a surgeon to perform viscodilation prior to implanting the support without needing a separate delivery apparatus, which simplifies the procedure. Ex.1001 (¶169).

Haffner's delivery apparatus also provides surgeons with the flexibility to perform viscodilation techniques *ab interno*, which involve smaller incisions and minimize eye trauma and shorten recovery time, rather than potentially riskier *ab externo* procedures. Ex.1001 (¶¶171-172). Haffner discloses imaging techniques that assist surgeons in *ab interno* viscodilation. For example, Haffner's delivery apparatus includes guidewires, which "deflect" the tip of the cannula in Figure 51A above, allowing the surgeon to more precisely position the cannula in Schlemm's canal. Ex.1035 (¶¶282-283). Haffner further discloses other features, such as "illumination" and "optical and ultrasonic imaging," which "enhance viewing and positioning of the distal end **242** of the apparatus" and allow surgeons to see the injection site better. *Id.* (¶278, 282, 295). These imaging techniques would make it easier for a POSITA to precisely position the apparatus to deliver viscoelastic. Ex.1001 (¶172). Thus, a POSITA would have been motivated to use Haffner's delivery apparatus, which at least partially enters Schlemm's canal, to more easily perform viscodilation, which in turn simplifies stent insertion. Ex.1001 (¶¶173-174).

Additionally, a POSITA would have had a reasonable expectation of success using Haffner's device to predilate Schlemm's canal because Haffner discloses such

techniques and dilating Schlemm's canal with viscoelastic had known benefits. *See e.g.*, Ex.1005 (¶14); Ex.1035 (¶1); *see also* Ex.1001 (¶173).

Thus, Gharib, in view of Haffner, renders obvious introducing a tubular cannula with a lumen at least partially within Schlemm's canal. Ex.1001 (¶174).

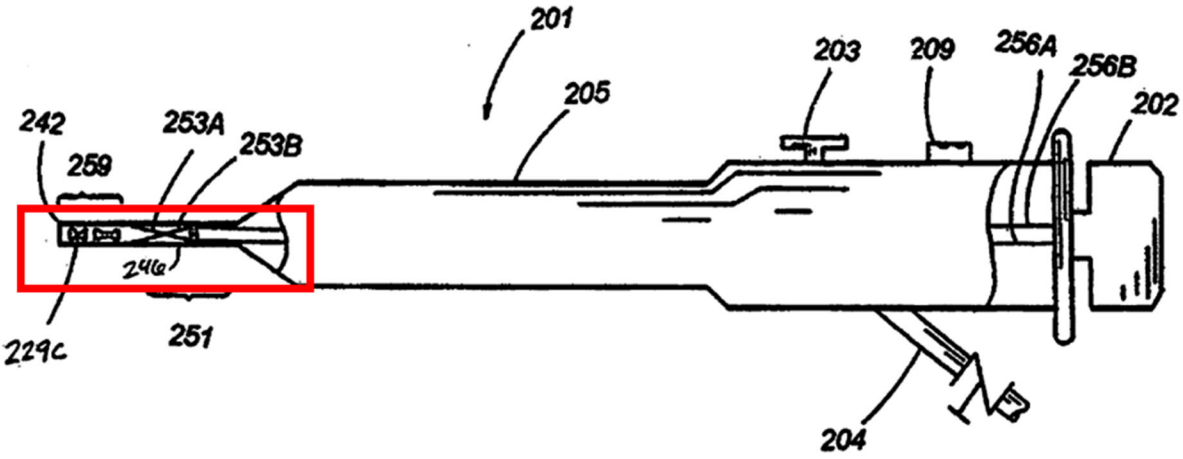
c. "delivering a high viscosity fluid into Schlemm's canal; and"

As discussed in §V.C, for the purpose of this IPR, Petitioners have adopted Patent Owner's interpretation that viscoelastics are high viscosity fluids.

Delivering a high viscosity fluid into Schlemm's canal would have been obvious over Gharib in view of Haffner, at least because it would have facilitated implantation of Gharib's support. *See* §XI.C.1.b. Haffner's delivery apparatus (which includes a tubular cannula) would have been capable of delivering viscoelastic into Schlemm's canal *and* inserting a support like Gharib's. *See id.*; Ex.1001 (¶177). Further, a POSITA would have been motivated to deliver viscoelastic into Schlemm's canal to facilitate inserting Gharib's support and would have had a reasonable expectation of success. *See* §XI.C.1.b.

For example, a POSITA would have been motivated to combine viscodilation and stent implantation because it may have cumulative benefits such as improved IOP balance, especially in patients with acute cases of glaucoma who showed less responsiveness to filtering techniques alone (*e.g.*, viscocanalostomy). Ex.1001 (¶179). Moreover, the combination of viscoelastic and support delivery into

Schlemm's canal would simplify procedures, improve safety by reducing the number of times a foreign object enters the eye, reduce recovery time, and increase speed to allow surgeon to treat more patients. Ex.1001 (¶¶169-174, 181). Haffner's device would have allowed a POSITA to achieve these benefits with a single device because it can deliver viscoelastic and a support into Schlemm's canal via the fluid infusing port and tubular cannula. *See* §XI.C.1.b; Ex.1035 (¶¶258-260); Ex.1001 (¶180). Thus, Haffner's delivery apparatus would have enabled a surgeon to more simply inject viscoelastic and insert trabecular microstents, and a POSITA would have been motivated to use Haffner's device for delivering supports, like Gharib's, in conjunction with viscoelastic. *See* §XI.C.1.b.



Ex.1035 Figure 51A (annotated showing tubular cannula)

A POSITA would have also had a reasonable expectation of success of using Haffner's device for delivering a stent (such as Gharib's) and viscodilation because

Haffner discloses that process and viscoelastic is commonly used in the eye. Ex.1001 (¶¶34-42, 181); *see* §XI.C.1.b.

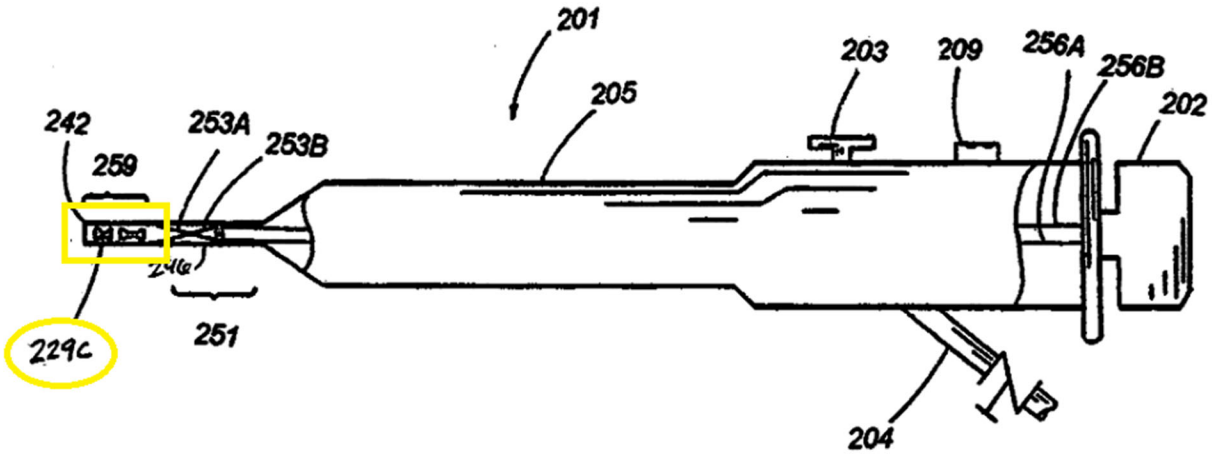
Thus, it would have been obvious to a POSITA in view of Gharib and Haffner to deliver a high viscosity fluid into Schlemm's canal. Ex.1001 (¶182).

d. **"inserting a support into Schlemm's canal by passing the support through the tubular cannula,"**

Gharib's bifurcatable device is a support, and Gharib teaches inserting a support into Schlemm's canal by passing it through the tubular cannula. *See* §XI.B.1.d.

Additionally, it would have been obvious to a POSITA to insert a support into Schlemm's canal by passing the support through the same tubular cannula used to deliver viscoelastic, which would simplify delivering viscoelastics and supports while simultaneously reducing surgery time. Ex.1001 (¶184); *see also* §§XI.C.1.b.

Haffner discloses inserting stent supports (such as Gharib's bifurcatable support) into Schlemm's canal by passing the support through a tubular cannula (*e.g.*, applicator sheath of Figure 246). *See* Ex.1035 (¶¶33, 188, 265-266, 269, 272-273). Each of the stents may be discharged from the applicator sheath "one stent at a time" at the push of a button. *Id.* (¶259). Figure 51A below illustrates two stents in the distal end of a tubular cannula that then "pass [through the tubular cannula]…when the stent 229C is pushed by the plunger 244." *Id.* (¶266).

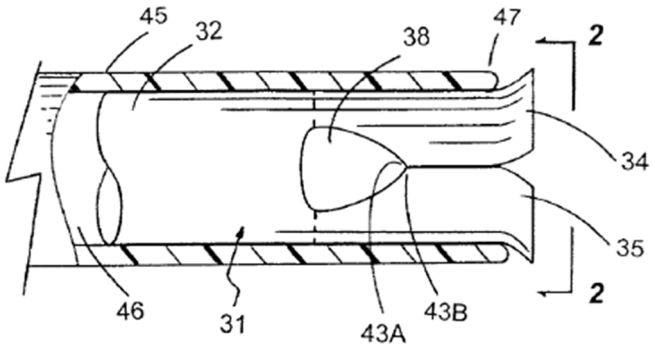


Ex.1035 Figure 51A (showing delivery apparatus and annotated to show stents 229c (yellow))

Using the same tubular cannula to deliver both a high viscosity fluid and a support into Schlemm's canal would have allowed for a faster and safer insertion procedure. *See* Ex.1001 (¶187). As Gharib explains, there is "a great clinical need for the treatment of glaucoma by a method that is faster, safer, and less expensive than currently available modalities." Ex.1005 (¶21). Haffner's single delivery applicator meets this need. For example, Haffner's delivery apparatus allows for faster procedures because it allows for a "one-step procedure to make an incision in the trabecular mesh 21 and place the stent or implant." Ex.1035 (¶132). Additionally, performing a one-step procedure reduces the number of times a foreign object enters the eye, thus minimizing any chance of inadvertent trauma or bleeding in the eye. *See* Ex.1035 (¶¶160, 258-259); Ex.1001 (¶187). Thus, a POSITA would have been motivated to insert a support into Schlemm's canal through a tubular cannula using

a single delivery applicator such as the one disclosed in Haffner. Ex.1001 (¶187); *see also* §§XI.C.1.b-XI.C.1.b.

Furthermore, a POSITA would have had a reasonable expectation of success of using Haffner's delivery apparatus to deliver Gharib's support because Haffner also discloses delivering supports. Ex.1001 (¶188). In addition, Haffner's delivery apparatus, although more advanced, is similar to Gharib's delivery apparatus. *Id.* Gharib teaches placing the support "inside a hollow delivery apparatus" and deploying it "from the delivery apparatus into the eye" via a "plunger." Ex.1005 (¶26). Haffner similarly teaches hollow delivery apparatuses with plunger mechanisms for trabecular stent delivery. *See* Ex.1035 (¶¶91, 114-117, 179, 258-260).



Gharib Figure 4A (showing support inside delivery apparatus)

Thus, Gharib in view of Haffner renders obvious inserting a support into Schlemm's canal by passing the support through the tubular cannula. Ex.1001 (¶190).

e. **"wherein the support comprises an arcuate member,"**

As discussed in §XI.B.1.e, Gharib teaches this limitation.

f. **"wherein at least a portion of the arcuate member has a radius of curvature smaller than a radius of curvature of Schlemm's canal, and"**

As discussed in §XI.B.1.f, Gharib teaches this limitation.

2. Dependent Claim 2

The method of claim 1, wherein the delivered fluid dilates the canal.

Haffner discloses that the viscoelastic substance delivered into Schlemm's canal dilates the canal. *E.g.*, Ex.1035 (¶¶18, 260); *see also* §§XI.C.1.b-XI.C.1.c; Ex.1001 (¶¶194-195).

3. Dependent Claim 3

The method of claim 1, wherein the high viscosity fluid is sodium hyaluronate.

As discussed in §§XI.C.1.b-XI.C.1.c, Gharib in view of Haffner renders obvious delivering a high viscosity fluid, such as viscoelastic, into Schlemm's canal. Using sodium hyaluronate would have been an obvious choice.

Haffner teaches injection Healon® (*i.e.*, sodium hyaluronate) into the eye to maintain the anterior chamber. Ex.1035 (¶298); *see also* §XI.A.3. A POSITA would have been motivated to use sodium hyaluronate to dilate the canal because sodium hyaluronate is the viscoelastic that Haffner discloses for maintaining the anterior chamber and would have been a readily available and obvious choice to a POSITA

reading Haffner. Ex.1001 (¶196). Additionally, sodium hyaluronate is a well-established viscoelastic used in glaucoma surgeries, and a POSITA would have expected it to be safe to use. Ex.1001 (¶¶37, 196). A POSITA would have had a reasonable expectation of success using sodium hyaluronate as the viscoelastic to inflate Schlemm's canal given its prevalence in ophthalmic treatments. Ex.1001 (¶196); *see also* §XI.A.3.

Thus, Gharib in view of Haffner renders obvious that the high viscosity fluid is sodium hyaluronate. *See* Ex.1001 (¶196).

4. Dependent Claim 5

> **The method of claim 1, wherein the support contacts the interior wall of the canal at least at three points.**

As discussed in §XI.B.4, Gharib teaches this limitation.

5. Dependent Claim 6

> **The method of claim 1, wherein the support does not substantially interfere with longitudinal flow along the canal.**

As discussed in §XI.B.5 Gharib teaches this limitation.

6. Dependent Claim 7

> **The method of claim 1, wherein the support does not substantially interfere with transmural flow across the inner wall of the canal.**

As discussed in §XI.B.6, Gharib teaches this limitation.

7. Dependent Claim 8

> **The method of claim 1, wherein the support does not substantially interfere with transmural flow across the outer wall of the canal.**

As discussed in §XI.B.7, Gharib teaches this limitation.

8. Dependent Claim 9

> **The method of claim 1, wherein at least a portion of the support extends out of Schlemm's canal and into the trabecular meshwork.**

As discussed in §XI.B.8, Gharib teaches this limitation.

XII. SECONDARY CONSIDERATIONS OF NONOBVIOUSNESS

Patent Owner asserts "many factors are relevant to considerations of non-obviousness." Ex.1034 (11-12). Patent Owner baldly alleges that (1) "products" and Ivantis have enjoyed commercial success, (2) Ivantis attempted to purchase a pending parent application with no issued claims, (3) Ivantis' product (Hydrus) has received praise; (4) Ivantis copied the alleged invention, and (5) failure of others may exist "[t]o the extent" Hydrus has superior efficacy to other stents/implants. *Id.* Petitioners dispute that Hydrus embodies the alleged invention. Additionally, Patent Owner's vague attorney arguments are unsupported by any evidence and insufficient to overcome Petitioners' strong obviousness case, and Patent Owner has not addressed any nexus to the Challenged Claims. *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1068 (Fed. Cir. 2016) (patentee bears the burden of showing requisite nexus of objective indicia to the claims). Moreover,

Patent Owner assertions that Ivantis "copied" the alleged invention are legally irrelevant (in addition to being disputed) as Patent Owner already admitted it does not sell any products that practice the '361 patent. Ex.1033 at 2; *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004) (*evidence* of copying, including of a specific product, is required; not merely allegations of infringement). Petitioners reserve the right to respond to any additional allegations or evidence.

XIII. CONCLUSION

For the foregoing reasons, Petitioners respectfully request that the Board institute *Inter Partes* Review and cancel the Challenged Claims.

Date: September 16, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This Petition complies with the type-volume limitations as mandated in 37 C.F.R. § 42.24. According to the word processing system used to prepare this document, the brief contains 13,984 words.

/s/ *Kat Li*
Kat Li

CERTIFICATE OF SERVICE

In compliance with 37 C.F.R. §§ 42.105, 42.6(e), the undersigned hereby certifies that a copy of the foregoing Petition and supporting exhibits were sent on the 16th day of September, 2022, via Federal Express® directed to PO at the correspondence address of record:

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