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.

IPR2022-01530
U.S. Patent No. 10,314,742

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

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I. INTRODUCTION

U.S. Patent No. 10,314,742 ("'742 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 '742 patent track the inherent or result-effective characteristics of prior art stent configurations, 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 '742 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 '742 claims 1-3, 6-9, 12-13, 15, and 17-20 ("Challenged Claims").

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 '742 against Petitioners in the Delaware Litigation. Petitioners are concurrently filing IPR petitions for three other patents in the same family as the '742 patent, all of which are asserted in the Delaware Litigation: U.S. Patent Nos. 8,287,482; 9,370,443; and 9,486,361.[1] 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

Lead Counsel	Backup Counsel
Gregg F. LoCascio, P.C. Reg. No. 55,396 gregg.locascio@kirkland.com Postal and Hand-Delivery Address: KIRKLAND & ELLIS LLP 1301 Pennsylvania Ave., N.W. Washington, D.C. 20004 Telephone: (202) 389-5000 Facsimile: (202) 389-5200	Kat Li Reg. No. 64,857 kat.li@kirkland.com Postal and Hand-Delivery Address: KIRKLAND & ELLIS LLP 401 Congress Avenue Austin, TX 78701 Telephone: (512) 678-9100 Facsimile: (512) 678-9101 W. Todd Baker Reg. No. 45,265 todd.baker@kirkland.com

[1] Each patent in the family will be referenced by its last three digits.

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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 '742 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, 6-9, 12-13, 15, and 17-20 of the '742.

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

Petitioners challenge the claims based on the following references:

1. 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).

2. Canadian Patent Application 2,244,646 to Grieshaber et al. ("Grieshaber"), filed August 11, 1998, published February 15, 1999, is prior art under § 102(b) (pre-AIA).

3. U.S. Pub. No. 2005/0038334 to Lynch et al. ("Lynch"), filed July 27, 2004, published February 17, 2005, is prior art under § 102(b) (pre-AIA).

4. U.S. Pub. No. 2003/0060752 to Bergheim et al. ("Bergheim"), filed May 1, 2002, published March 27, 2003, is prior art under § 102(b) (pre-AIA).

5. U.S. Pub. No. 2004/0147870 to Burns et al. ("Burns"), filed October 28, 2003, published July 29, 2004, is prior art under § 102(b) (pre-AIA).

Petitioners request IPR on the following grounds:

Ground	Basis	Claims	Reference(s)
1	§102	1–3, 6-9, 12, 15, 17-20	Gharib
2	§103	13	Gharib alone, or in view of Bergheim
3	§102	1-3, 9, 12, 15, 17-20	Grieshaber
4	§103	6-8	Grieshaber
5	§103	13	Grieshaber alone, or in view of Bergheim
6	§102	1-3, 9, 12, 15, 17-18	Lynch
7	§103	13	Lynch alone, or in view of Bergheim
8	§103	6-8	Lynch in view of Gharib

Ground	Basis	Claims	Reference(s)
9	§103	19-20	Lynch in view of Burns

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 '742 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:[2]

"***Internal wall surface area C, the support contacts less than 30% of C***": the '742 patent states that "[t]he fraction of canal wall surface area in contact with a support can be ***estimated*** by viewing the inside of Schlemm's canal as a ***slightly arcuate cylinder*** C having length L, extending circumferentially from a first end X_1, to a second end X_2 of support 152, and inside radius R_i." *Id*. (11:30-34). There is

[2] 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.

nothing in the '742 patent to indicate any criticality or anything special about the claimed 30% number. Apparently recognizing the difficulty of estimating the fraction of the canal wall surface area in contact with the support as mentioned in the '742 Patent (estimated as a slightly arcuate cylinder), Sight Sciences' Delaware Complaint ignores the specification and assumes instead that Schlemm's canal is a regular cylinder.[3] *See* Ex.1020 (Ex.M at 18 (calculating the surface area for a cylinder, "which is less than 30% of a 7.1 mm cylinder with a radius of 146 μm," but not accounting for any curvature)). Accordingly, for the purposes of this IPR, Petitioners adopt Patent Owner's construction of this term, which assumes that that the scope of "internal wall surface area C" at least includes the surface area of a regular cylinder.

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

Section XI provides a detailed explanation of 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 Section XI. Petitioners submit a declaration of Dr. Michael Reynard (Ex.1001) in support of this Petition under 37 C.F.R. § 1.68.

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[3] Petitioners note that Schlemm's Canal is not in fact cylindrical.

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)). The fluid 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*. (¶23). In general, Schlemm's canal is a flexible, continuous passage (or vessel) that goes 360-degrees around the eye. *Id*. (¶23). 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*. (¶23) (citing Ex.1008 (¶9)). Figure 2 of '742 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 (6:53-55).

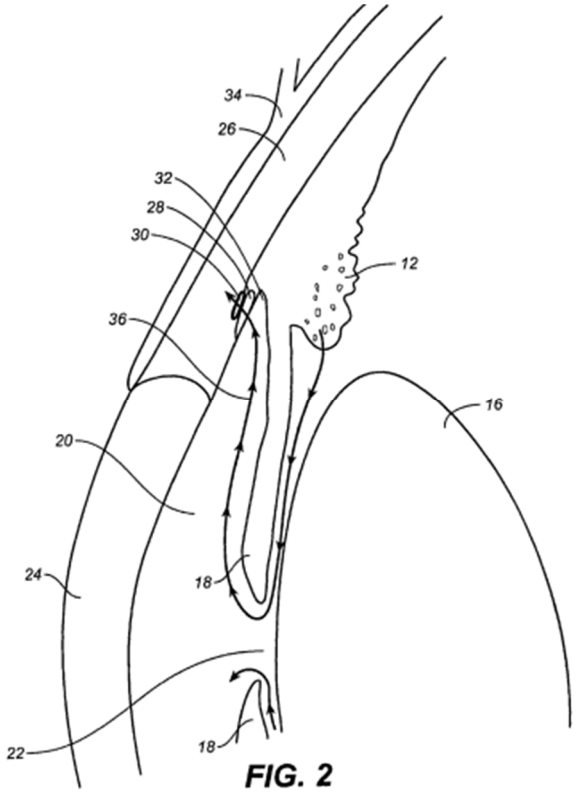


FIG. 2

Ex.1003 Fig.2

In healthy eyes, aqueous humor production approximately equals aqueous humor outflow, and intraocular pressure remains 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)). In some glaucoma cases, Schlemm's canal is collapsed, 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 (1:37-59). 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)). As early as 1925, skilled artisans have recognized that "[t]he ideal operation, 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, Dr. Stefansson invented several gold wire implants designed to channel aqueous out of the anterior chamber as shown in the Figures below. Ex.1001 (¶26) (citing Ex.1014 (681, 683)). The perpendicular ends of the supports below (the twisted ends of 1, 2, and 4 and the vertical tube in 3) were

inserted into the anterior chamber to provide an outlet for excess aqueous humor to exit the chamber through the resulting opening. Ex.1001 (¶26) (citing Ex.1014 (683-684)).

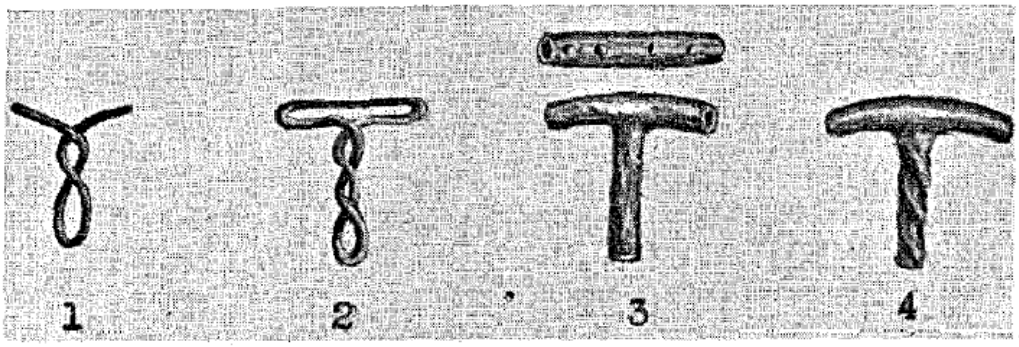


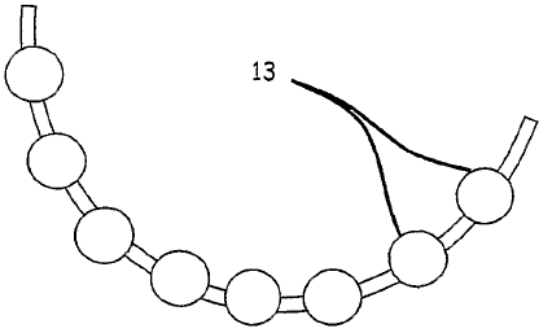
Fig. 3. Different types of inserts used in order of design. Base of No. 3 perforated to facilitate drainage.

Many known devices, such as shunts and stents, channel aqueous out of the anterior chamber to reduce pressure very 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.*

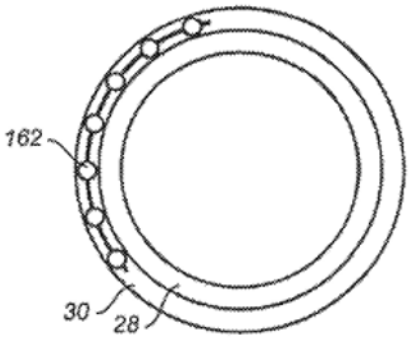
C. Schlemm's Canal Implants Extending Out of Schlemm's Canal Were Well Known

In some patients, the increased pressure in the anterior chamber can collapse Schlemm's canal. Ex.1016 (19:48-67); Ex.1001 (¶24). 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. Abstract.

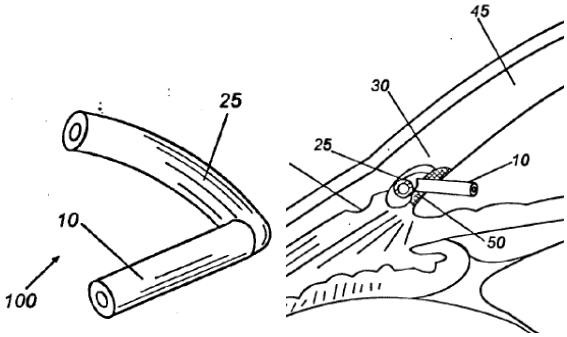


Ex.1017 Fig.4a.

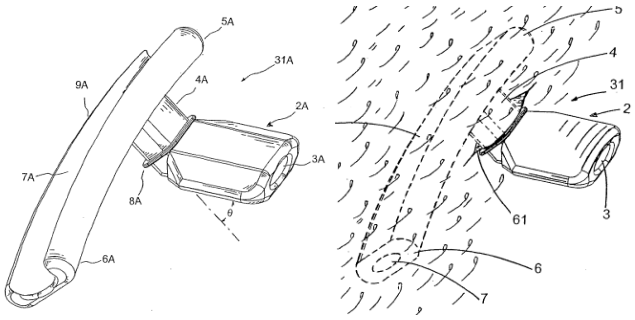


Ex.1003 Fig.10B

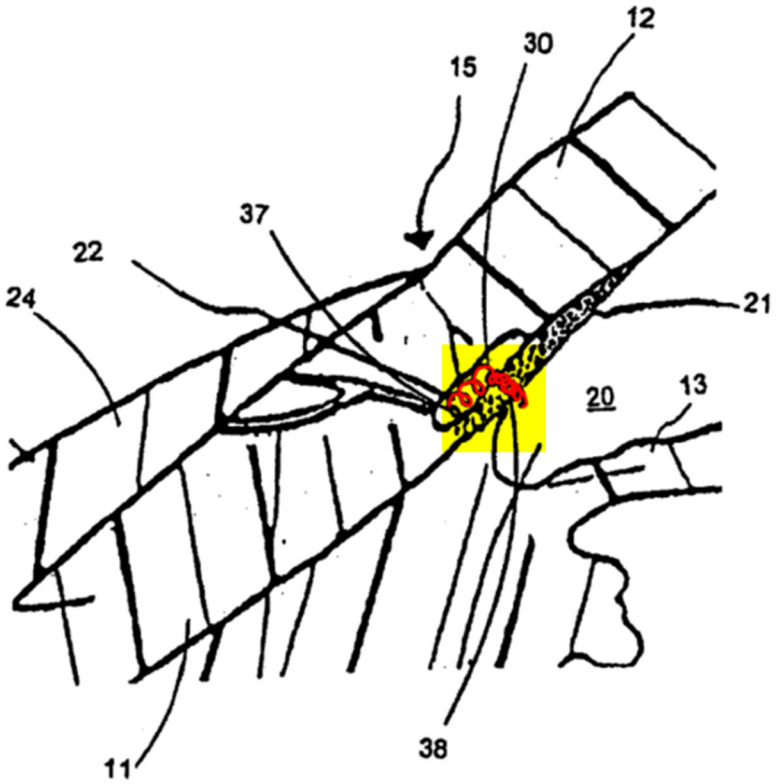
While some implants rest entirely within Schlemm's canal, others also include a channel that provides a direct connection from the anterior chamber, through the trabecular meshwork, to the propped open Schlemm's canal, and the portion protruding from the canal can anchor it in place. Ex.1001 (¶31-32).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



Ex.1008 (Lynch '334) Figs.5A, 6B



Ex.1024 (Tu WO2002036052) Figs.4, 6



Ex.1025 (Porteous U.S. 2004/0254520) Fig.3 (annotated)

VII. THE '742 PATENT

The '742 patent issued from Application No. 15/182,165, filed June 14, 2016, and claims to be a continuation of application No. 13/025,112, filed February 10, 2011, which claims to be a division 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 '742 patent admits that using bypass stents "to bridge a blocked trabecular meshwork" and to connect the anterior chamber to Schlemm's canal 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 '742 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 '742 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 '742 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).

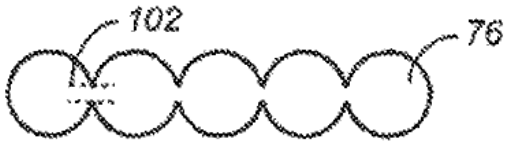
B. Alleged Invention

The '742 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 (2:61-67).

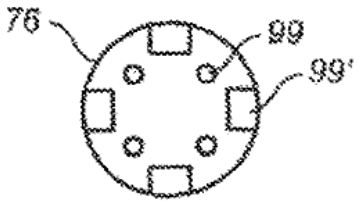
The '742 patent describes traditional elements of a Schlemm's canal stent: a solid or hollow, biocompatible support that is inserted into Schlemm's canal to improve aqueous humor flow from the anterior chamber and eventually into the collector channels. Ex.1003 (2:1-5, 51-52; 2:66-3:1). The support may take a

variety of configurations, *e.g.*, having "smooth, rough, spiked, or fluted" surfaces, "made from mesh," or including fenestrations. *Id*. (3:53-56, 4:15-17). The support may comprise an "arcuate member having a radius of curvature smaller or larger than that of Schlemm's canal." *Id*. (4:18-20).

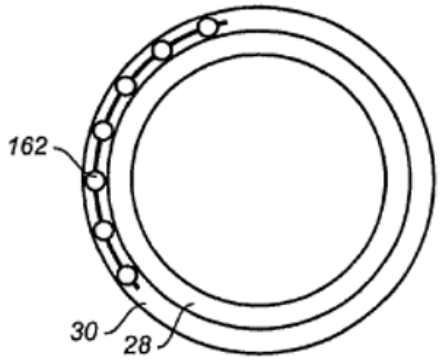
The '742 patent provides the following exemplary embodiments of the devices:



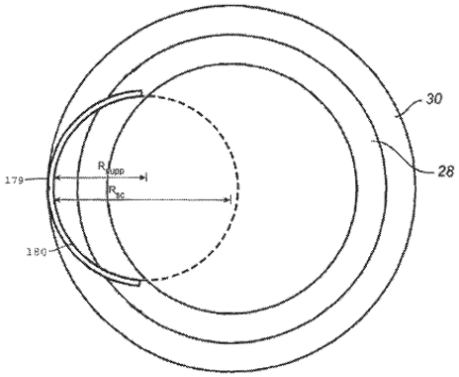
Ex.1003 Fig.7B



Ex.1003 Fig.6C



Ex.1003 Fig.10B



Ex.1003 Fig.11D

Figure 7B shows an exemplary support comprising beads 76, which partially prop open Schlemm's canal. Ex.1003 (9:40-48). 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*. (9:35-36; 9:36-38; 14:28-29). Figure 10B shows the support positioned inside Schlemm's canal. *Id.* (11:53-54). Figure 11D, added during prosecution, shows a support extending out of Schlemm's canal and into the trabecular meshwork.

C. Prosecution History

The '742 patent was not subject to any rejections over prior art during prosecution. Instead, the claims faced only §112, paragraph 1 and statutory double patenting rejections.

During prosecution, the '742 patent's parent application, No. 13/025,112, was rejected over various references, including Lynch U.S. Pub. No. 2004/0260228 ("Lynch '228") (Ex.1010),[4] Stegmann U.S. Pub. No. 2006/0195187 ("Stegmann") (Ex.1011), and U.S. Patent No. 6,494,857 ("Neuhann") (Ex.1009). Patent Owner made various arguments, including that Lynch, Stegmann, or Neuhann did not meet the limitation "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 so that at least a portion of the arcuate member is configured to extend out of

[4] Lynch '228 is a different reference than Lynch U.S. 2005/0038334, cited in Grounds 7-9 below, and includes different disclosure.

Schlemm's canal and into the trabecular meshwork" or the "30% of C" surface area limitation. Ex.1004 (920-937); Ex.1001 (¶40-50).

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 anticipation and obviousness challenges applying Gharib, Grieshaber, and Lynch as base references, none of which was applied against the Challenged Claims or discussed by the Examiner during prosecution of the '742 patent or its parent applications. In addition, none of the references applied by the examiner in either the '742 patent or its parent applications is cumulative of the references cited here.

During prosecution the ’742 patent’s parent application was rejected over Neuhann. Patent Owner argued Neuhann’s support resides entirely within Schlemm’s canal and therefore does not meet the limitation “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 so that at least a portion of the arcuate member is configured to extend out of Schlemm’s canal and into the trabecular meshwork.” This distinction is not applicable here because the ’742 does not have an identical limitation, and Gharib, Grieshaber, and Lynch all meet the arcuate member limitation as claimed in the ’742 patent.

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. The present petition presents evidence that the ’742 patent’s 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* Section XI. Accordingly, the Board should not discretionarily deny institution of this compelling, meritorious challenge to the ’742 patent claims. *Apple Inc. v. Fintiv,*

Inc. IPR2020-00019, Paper 11 at 6 (PTAB Mar. 20, 2020) (precedential); Vidal Memo at 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. CV 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. CV 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 (¶51-52).

X. OVERVIEW OF THE PRIMARY PRIOR ART

A. Gharib

Gharib is directed to treating glaucoma, often characterized by buildup of aqueous humor in the anterior chamber leading to increased 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. Ex.1005 (¶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. Ex.1005 (¶¶1, 67). The support's outlet section, 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. Ex.1005 (¶¶29, 56, 66). The support may also be made of a variety of materials, but preferably shape memory material like Nitinol. Ex.1005 (¶¶29, 53, 62).

B. Grieshaber

Grieshaber is directed to treatments for reducing intraocular pressure in glaucoma by inserting a support into Schlemm's canal to prop it open and allow aqueous to flow longitudinally and across the the canal. Ex.1012 (Abstract, 1:1–6; 2:6–21; 5:11-19, 14:6-15, Figs. 4-12). Grieshaber's support can take a variety of shapes, can be made of a variety of materials, and can include outflow openings to improve drainage to the body's natural collector channels. Ex.1012 (8:6-10; 8:11-

13; 9:1-10; 9:11-18; 10:1-4; 10:10-12; 11:9-11; 14:6-15; cls 16, 18). The support can be "designed longitudinally somewhat arcuate" or "axially somewhat arcuate" or "can be automatically deformed into an arcuate shape." Ex.1012 (11:20-22; 19:6-9). The support can also be "designed conically tapering longitudinally from one end to the other," Ex.1012 (12:1-2), can have a torus-shaped transition portion, Ex.1012 (8:15-17), and can have a portion that extends out of Schlemm's canal and fits closely against the face of a scleral incision to prevent the device from moving after implantation, Ex.1012 (8:1-4). Ex.1012 (Figs. 4–6).

C. Lynch

Lynch is directed to glaucoma treatments using shunt devices that improve aqueous humor outflow through natural pathways. Ex.1008 (Title, Abstract, ¶¶3, 24). Lynch's devices are implanted within Schlemm's canal and can include a portion that extends from Schlemm's canal into the anterior chamber to help divert aqueous humor, to provide an anchor to ensure proper placement of the device, and to permit flow longitudinally and across Schlemm's canal to the collector channels. Ex.1008 (¶¶51, 59-60, 79). Lynch contemplates "many different configurations…provided that each assists in channeling aqueous humor from the anterior chamber to Schlemm's canal." Ex.1008 (¶53, 64).

XI. EACH OF THE CHALLENGED CLAIMS IS UNPATENTABLE

A. Ground 1: Gharib anticipates Claims 1-3, 6-9, 12, 15, and 17-20.

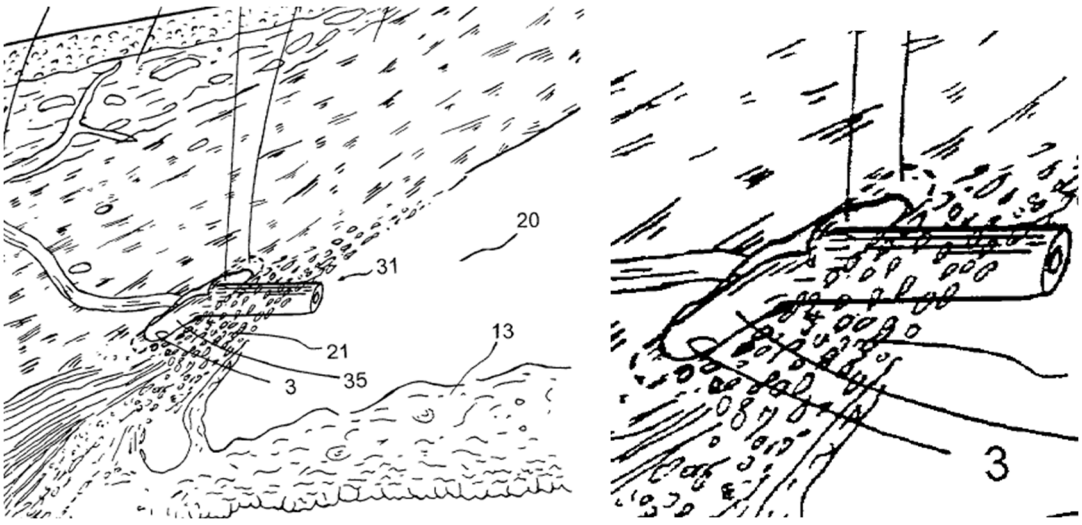
1. Independent Claim 1

a. **"A method for treating an eye condition, 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, Gharib discloses "devices and methods for reducing intraocular pressure," more particularly "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. **"implanting a support within Schlemm's canal,"**

Gharib's device can comprise "two distal bifurcatable elements" that are deployed out of a delivery apparatus and are "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 (¶57-58).

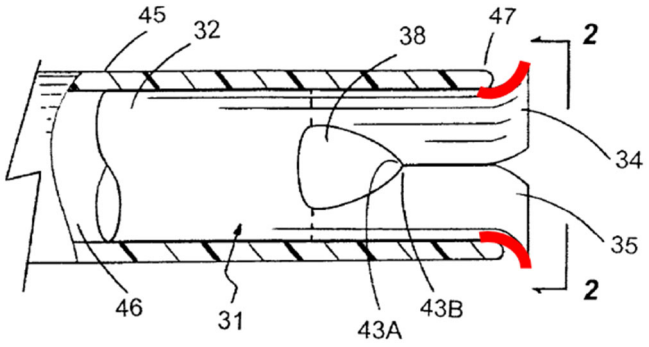


Ex.1005 Fig. 8

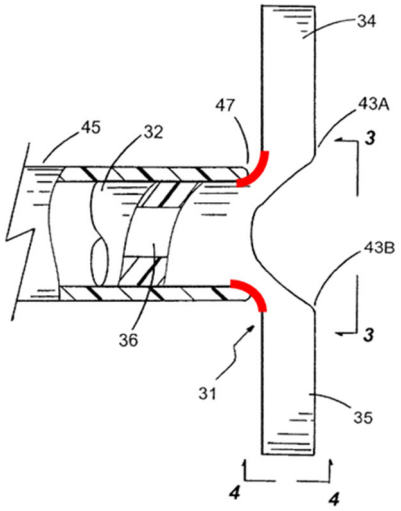
Gharib explains that "[t]he shape of the end cross-section 35 is to provide a stenting capability when the elements are placed inside Schlemm's canal." Ex.1005 (¶60). A POSITA would have understood that Gharib's disclosure of "stenting capability" would mean it is a structural support. Ex.1001 (¶¶57-58).

c. **"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 '742 patent describes as a "slightly arcuate cylinder," Ex.1003 (11:30-34). Figure 4A shows a partially deployed version, and Figure 5A shows a fully deployed version of the Gharib device. Ex.1005 (¶¶58-60). The bifurcatable elements are "arcuate members." Ex.1001 (¶59-60). As shown in Figure 5A, the bifurcatable elements 34 and 35 arc leftwards towards the delivery apparatus 45. Ex.1001 (¶59-60)

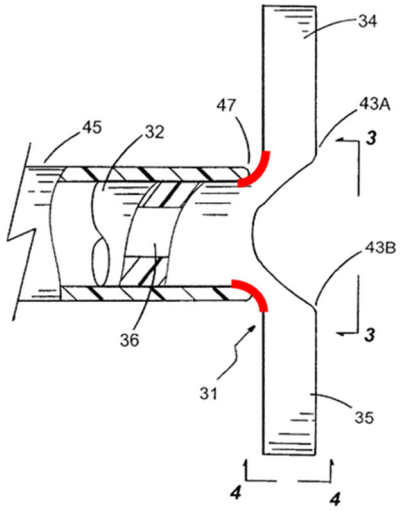


Ex.1005 Fig.4A (annotated)

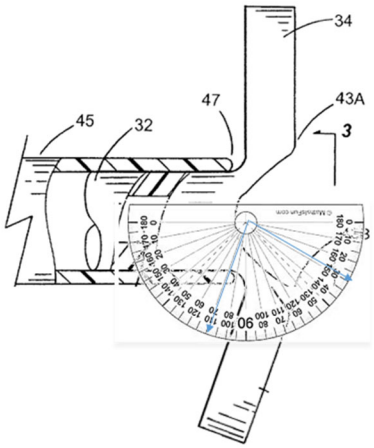


Ex.1005 Fig.5A (annotated)

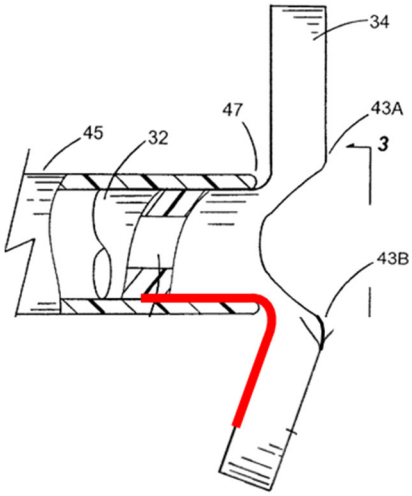
Gharib explains that the bifurcatable elements may be curved or angled at an angle between about 30 degrees to about 150 degrees, preferably between about 70 degrees and about 110 degrees so as to conform to the contour of Schlemm's canal. Ex.1005 (¶¶63, 66). Gharib's Figure 5A below has been modified to represent Gharib's teachings regarding the angle of the bifurcatable elements, and to illuminate the arcuate member, (Ex.1001 (¶60)):



Ex.1005 Fig.5A (annotated)

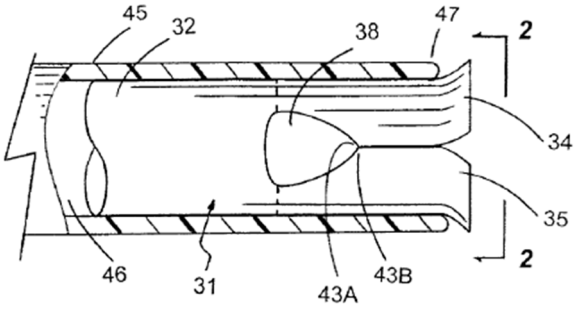


Ex.1005 Fig.5A (modified and protractor imposed)



Ex.1005 Fig.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 and assist in propping it open. Ex.1005 (¶¶29, 56-60); Ex.1001 (¶63).



Ex.1005 Fig.4A

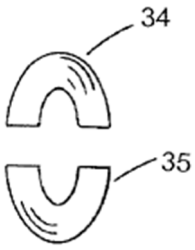
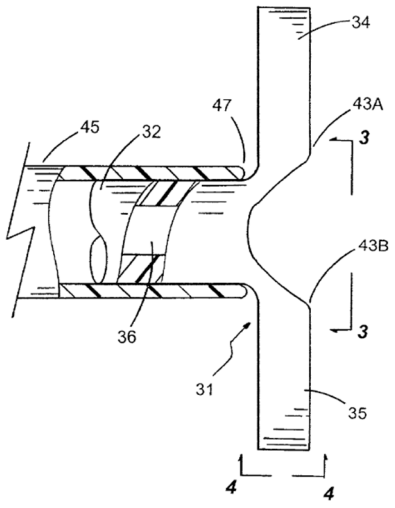


FIG. 4B

Ex.1005 Fig.4B



Ex.1005 Fig.5A

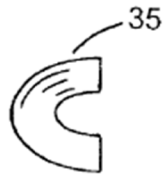


FIG. 5C

Ex.1005 Fig.5C

Figure 7B further demonstrates that the bifurcatable element is an "arcuate member," depicted in a semi-deployed state. Ex.1005 (¶65); Ex.1001 (¶61).

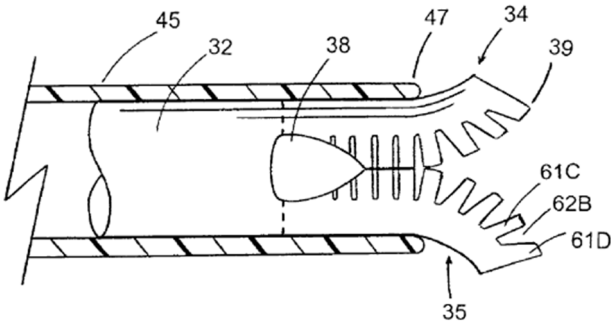
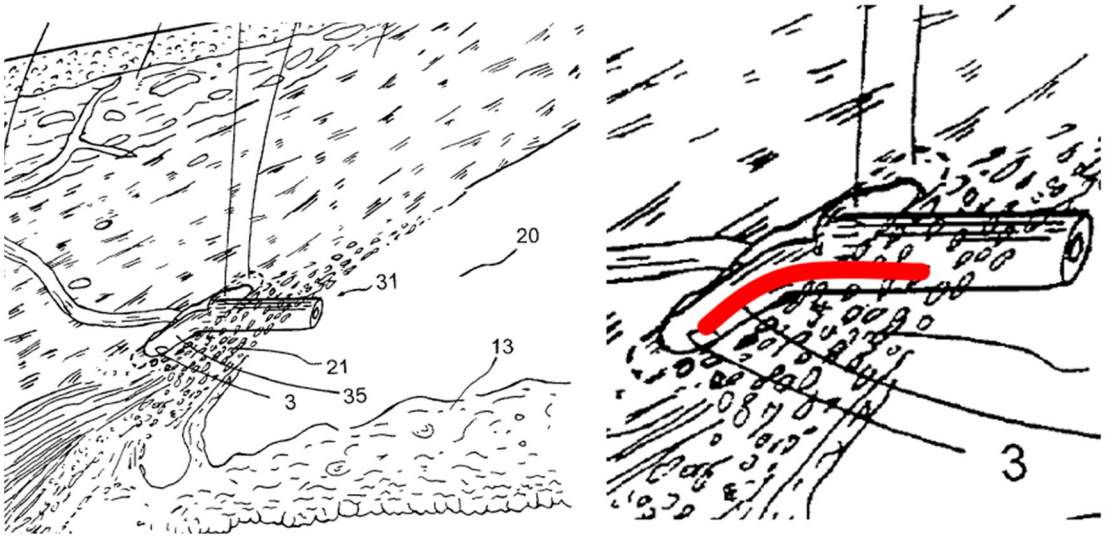


FIG. 7B

Ex.1005 Fig. 7B

Finally, Figure 8 shows the bifurcated elements stenting open Schlemm's canal and bending outwards in an arcuate manner into the meshwork (Ex.1001 (¶62)):



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

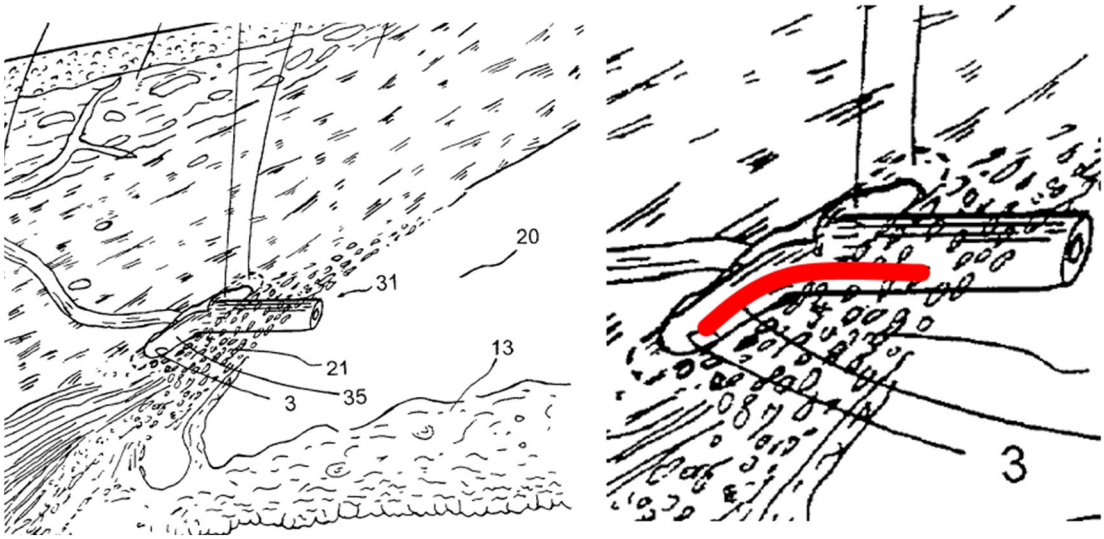
A POSITA would have recognized Gharib's disclosed shapes as "arcuate members." Ex.1001 (¶59-63).

d. **"wherein at least a portion of the arcuate member has a radius of curvature smaller than the radius of curvature of Schlemm's canal such that at least a portion of the arcuate member extends out of Schlemm's canal."**

The '742 patent lacks clear guidance regarding where one measures the radius of curvature for comparison or what constitutes the radius of curvature of Schlemm's canal. For the purposes of this IPR, Petitioners have adopted Patent Owner's

interpretation that a support meets the limitation if, once implanted, it protrudes at one end out of Schlemm's canal. *See* Ex.1020 (Ex.N at 7-8).[5]

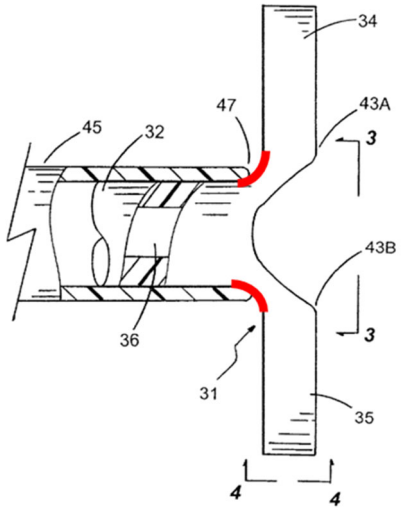
Gharib's support meets Patent Owner's interpretation. As shown in Figure 8, Gharib's bifurcated element disposed within Schlemm's canal forms an arcuate shape with the remainder of the device body implanted within the trabecular meshwork. Ex.1005 (¶¶52, 54, 67-70). Ex.1001 (¶64-65).



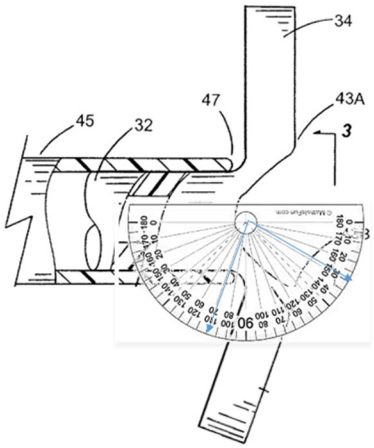
Ex.1005 Fig. 8 (right Figure zoomed in and annotated)

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 below has been modified to represent Gharib's teachings regarding the angle of the bifurcatable elements (Ex.1001 (¶66)):

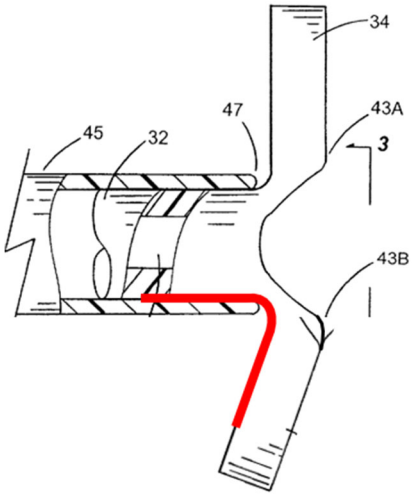
[5] Gharib would also meet this limitation under any plain and ordinary meaning.



Ex.1005 Fig. 5A (annotated)



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



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

Gharib therefore teaches that at least a portion of the arcuate member has a radius of curvature smaller than the radius of curvature of Schlemm's canal such that at least a portion of the arcuate member extends out of Schlemm's canal. Ex.1001 (¶66).

2. Dependent Claim 2

The method of claim 1, wherein the support has 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 (¶67).

3. Dependent Claim 3

The method of claim 1, wherein the support has a length equal to about a quarter or less than a quarter of the circumference of Schlemm's canal.

The '742 patent provides no guidance regarding how to measure the circumference of Schlemm's canal or how long a support must be to be "equal to about a quarter or less than a quarter of the circumference." U.S. Patent No. 10,299,958 (which also names Paul and David Badawi as inventors), however, states 6 mm is "the approximate radius of curvature of Schlemm's canal in an adult human." Ex.1003 22:61-67. Thus, the '742 patent's inventors estimate the circumference of Schlemm's canal as approximately 38 mm, a quarter of which is 9.5 mm. For purposes of this IPR, a support with a circumference of less than 9.5 mm would meet this limitation.

Gharib's support "may have a length between about 0.5 mm to over a few millimeters. Thus, Gharib teaches this limitation. Ex.1001 (¶68-69).

4. Dependent Claim 6

The method of claim 1, wherein at least a portion of the support is made from a shape memory material.

Gharib teaches that "at least one of the two bifurcatable elements is made of a shape-memory material, such as Nitinol." Ex.1005 (¶28); *see also Id.* (¶¶29, 53, 55, 62-63). Thus, Gharib teaches this limitation. Ex.1001 (¶70).

Moreover, selecting this known material for an ophthalmic support is merely an obvious design choice well within the skill of an ordinarily skilled artisan. *Sinclair & Carroll Co. v. Interchemical Corp.,* 325 U.S. 327, 335 (1945) ("Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle."); *Hicks v. Kelsey*, 85 U.S. 670, 673 (1873) (using "one material instead of another in constructing a known machine is, in most cases, so obviously a matter of mere mechanical judgment…that it cannot be called an invention" absent some showing of improvement); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007) (simple substitution of one known element for another known element in the field to obtain predictable results is obvious); Ex.1001 (¶71,72).

5. Dependent Claim 7

The method of claim 6, wherein the shape memory material comprises a shape memory alloy.

As explained above in §XI.A.4, Gharib discloses supports can be made of Nitinol, which the '742 patent recognizes as a shape memory, biocompatible, nickel titanium alloy. Ex.1003 (3:10-12, 12:27-29, 13:9-12, 13:51-53, claim 8).

6. Dependent Claim 8

The method of claim 7, wherein the shape memory alloy comprises a nickel titanium alloy.

As explained above in §XI.A.4 and XI.A.5, Gharib teaches this limitation. Ex.1001 (¶73).

7. Dependent Claim 9

The method of claim 1, wherein at least a portion of the support is made from a biocompatible metal.

Gharib and the '742 patent characterize Nitinol as "biocompatible." Ex.1005 (¶53); Ex.1003 (13:9-12). Thus, as explained above in §XI.A.4 and XI.A.5, Gharib teaches this limitation. Ex.1001 (¶74).

8. Dependent Claim 12

The method of claim 1, wherein at least a portion of the support is porous.

Gharib teaches that the bifurcatable elements "may be made of…porous form" and various configurations that would be considered porous. Ex.1005 (¶29); Ex.1001 (¶75).

9. Dependent Claim 15

The method of claim 1, wherein the support is flexible.

Gharib's support can be made of flexible materials. Ex.1005 (¶¶29, 53, cl. 9 (*e.g.*, "flexible fused silica")). Gharib teaches that, "[i]n general, the bifurcatable elements are relatively flexible…" Ex.1005 (¶¶63, 64). Ex.1001 (¶76).

10. Dependent Claim 17

The method of claim 1, wherein the support does not substantially interfere with longitudinal flow along Schlemm's 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 illustrated 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 (¶77-78).

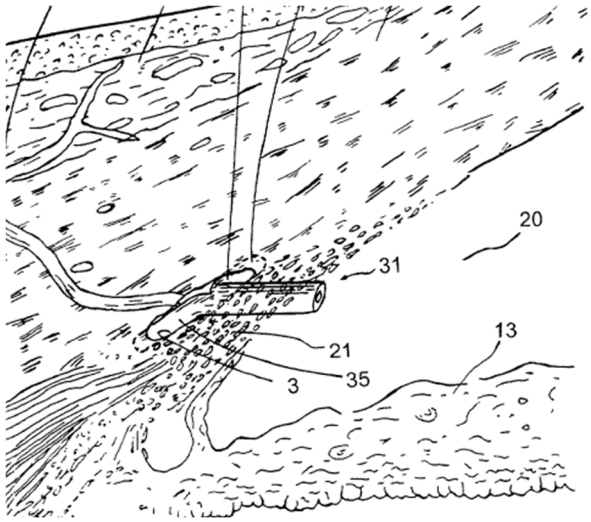
11. Dependent Claim 18

The method of claim 1, wherein the support does not substantially interfere with transmural flow into and out of Schlemm's canal.

The '742 patent indicates 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). Gharib's support does not substantially interfere with either outflow.

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 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). Once disposed within Schlemm's canal, as depicted below, the device expands the canal to enhance aqueous flow in the now-stented areas and into the aqueous collector channels. Ex.1005 (¶60); Ex.1001 (¶79-81). Thus, Gharib facilitates, rather than substantially interferes with, transmural flow across Schlemm's canal.



Ex.1005 Fig. 8

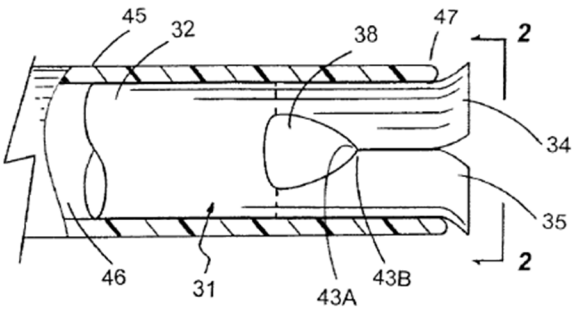
Gharib's device, directed to using existing outflow pathways to allow aqueous humor to drain, Ex.1005 (¶52), can be various shapes and have various surfaces. For example, "the outer surface of the outlet section 33," which is the section that is disposed within Schlemm's canal, "may comprise a stubbed 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." Ex.1005 (¶56). Furthermore, Gharib teaches that 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.* These configurations and materials all reduce the overall contact that the support makes with the wall of Schlemm's canal and thus improve flow, or at a minimum, not "substantially interfere with transmural flow" or "significantly block…fluid outflow from the trabecular meshwork." Ex.1001 (¶82-85). Indeed, the '742 patent also discloses making the support of mesh material, as Gharib taught. *Compare, e.g.,* Ex.1003 (10:53-55 ("a support having an open network structure can be at least partially made from a mesh")) *with* Ex.1005 (¶29 ("mesh form")); *see also* Ex.1001 (¶84).

12. Dependent Claim 19

The method of claim 1, further comprising preloading the support into an introducer and delivering the support from the introducer into Schlemm's canal.

Gharib teaches preloading an introducer for delivering the support. Gharib's support may be placed inside a delivery apparatus or applicator and deployed using, *e.g.*, a plunger. Ex.1005 (¶¶26, 27, 58); *see also Id.* (¶¶59, 61, 64-65 (discussing delivery apparatus/applicator)); Ex.1001 (¶86-87).



Ex.1005 Fig. 4A

A POSITA would have recognized Gharib's delivery applicator as an introducer for delivering a preloaded support. Ex.1001 (¶86-87)

13. Dependent Claim 20

> **The method of claim 19, wherein the support is delivered from the introducer using a pusher.**

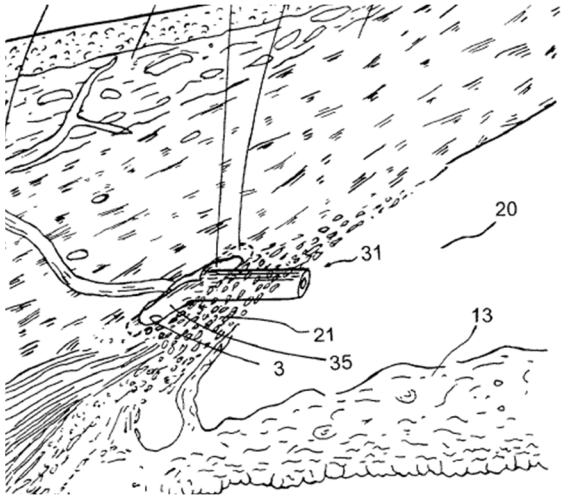
As discussed above in §XI.A.12, Gharib's supports can be deployed/delivered out of the delivery device, which can include a push-pull type plunger. Ex.1005 (¶¶26, 58, 59, cls. 6, 39). Ex.1001 (¶88).

B. Ground 2: Gharib alone or in view of Bergheim renders obvious Claim 13

1. Dependent Claim 13

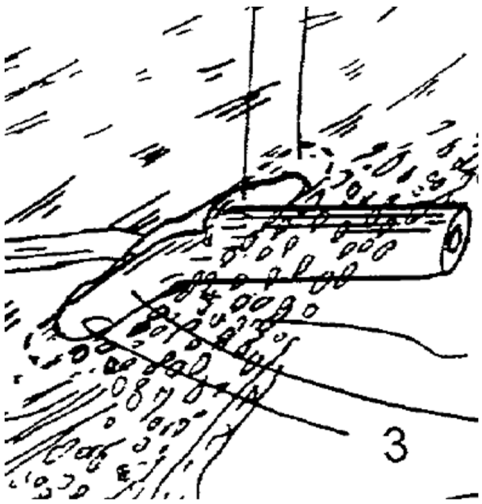
> **The method of claim 1, wherein when the support is disposed within a cylindrical section of the lumen of Schlemm's canal having an internal wall surface area C, the support contacts less than 30% of C.**

As discussed above in Section V.C, for this IPR, Petitioners have adopted Patent Owner's interpretation that Schlemm's canal is cylindrical.[6] Gharib's support is disposed within a cylindrical section of the lumen of Schlemm's canal (as Patent Owner has interpreted it). *See* Ex.1005 (Fig.8, ¶¶55-60, 62-63, 67, cl. 1); Ex.1001 (¶89-90).

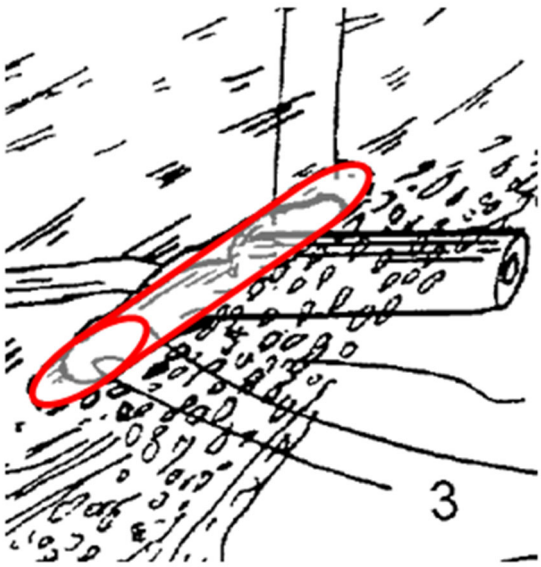


Ex.1005 Fig. 8

[6] Petitioners note that Schlemm's Canal is not in fact cylindrical. Ex.1001 (¶89).



Ex.1005 Fig.8 (zoomed in)

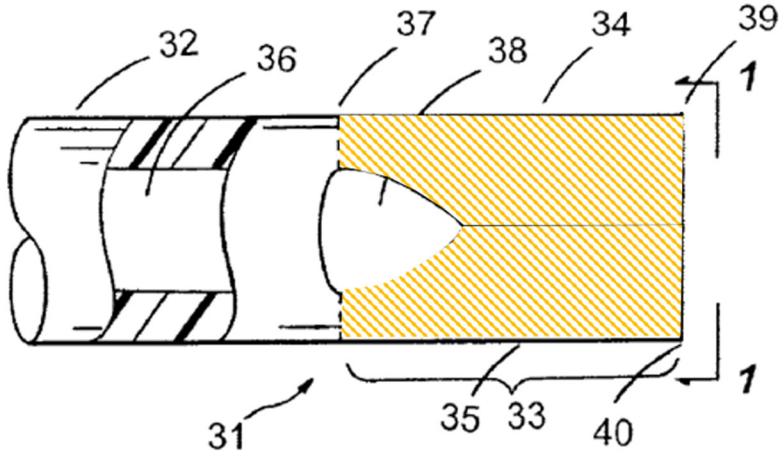


Ex.1005 Fig.8 (zoomed in and annotated)

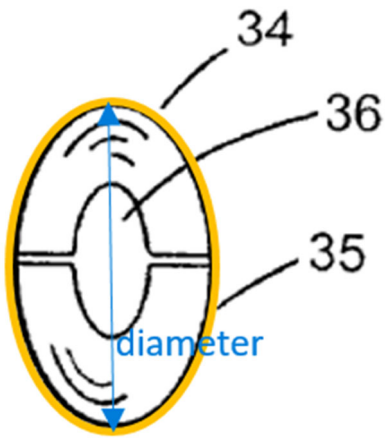
Again, as discussed above in Section V.C, for this IPR, Petitioners have adopted Patent Owner's interpretation that the internal wall surface area C is estimated by viewing the inside of Schlemm's canal as a regular cylinder (despite that this contradicts the '742 patent's description of Schlemm's canal as a "slightly arcuate cylinder"). Adopting Patent Owner's approximation of Schlemm's canal as a regular cylinder, Gharib discloses supports that would contact less than 30% of the surface area of the lumen of the canal in which it is disposed.

Gharib's support, as shown in Figure 3A loaded into a delivery apparatus, comprises an "inlet section 32 and an outlet section 33, wherein the outlet section 33 may comprise two bifurcatable elements 34, 35 that are adapted to be bifurcated, positioned, and stabilized inside Schlemm's canal." Ex.1005 (¶55); *see also Id.* (¶¶25-57).

The outside diameter of the support can range from about 30 to about 500 microns, and the length of the support can range from "about 0.5 mm to over a few millimeters." Ex.1005 (¶66).[7] The outlet section 33 can be curved or angled, and can take a variety of shapes, including a circular or semi-circular shape. Ex.1005 (¶¶29, 56, 66). Gharib's disclosed range of outside diameter values represents the diameter of the outlet section when loaded in the delivery apparatus, as depicted in Figure 3B showing the cross-section of 1-1 from Figure 3A. Ex.1001 (¶91, 95).



Ex.1005 Fig.3A (annotated)



Ex.1005 Fig.3B (annotated)

Utilizing Gharib's outside diameter values and lengths, and assuming a circular cross-section as one of the shapes Gharib discloses, Gharib teaches an outer

[7] Gharib's disclosure of the outside diameter and lumen diameter in units of "(m" is a clear typographical error. A POSITA would have recognized that this was intended to be micron, or micrometer, depicted as "µm." Ex.1001 (¶98).

surface area of the support ranging from 47,124 to 4,712,389 μm^2.[8] Ex.1001 (¶91, 98-100).

The '742 patent's disclosed cross-sectional diameter for Schlemm's canal ("about 190 to about 370 microns"), Ex.1003 (9:13-15), equates to 95-185 micron radius. Accounting for the bifurcated supports by doubling Gharib's lengths (0.5 to 3 mm) equates to a length of about 1 to about 6 mm. The surface area of the canal for those lengths, calculated using the equation (SA=2*π*radius*length), ranges from 596,902-6,974,336 μm^2. Ex.1001 (¶96-97). The ratio of total surface area of Gharib's support to the surface area of Schlemm's canal for the equivalent length is summarized in the following table Ex.1001 (¶101-102):

Radius Value Disclosed in Gharib	Radius Value of Schlemm's Canal Disclosed in '742 Patent	Length's Disclosed in Gharib, doubled to account for bifurcatable elements	Surface Area Ratio (Gharib support to Schlemm's Canal) (Table 2/Table 1)	Surface Area Ratio (%)
(micron)	(micron)	(micron)	(micron^2/ micron^2)	
15	95	1000	47,123.89/ 596,902.60	7.89%
15	95	6000	282,743.34/ 3,581,415.63	7.89%
15	185	1000	47,123.89/ 1,162,389.28	4.05%

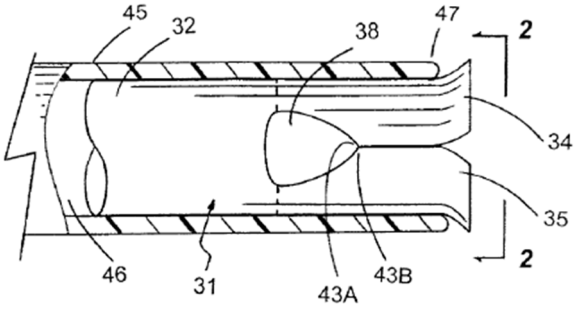
[8] Assuming a cylinder, as the '742 patent inventors do, one can calculate outer surface area by multiplying 2*π*radius*length. Ex.1001 (¶93).

Radius Value Disclosed in Gharib	Radius Value of Schlemm's Canal Disclosed in '742 Patent	Length's Disclosed in Gharib, doubled to account for bifurcatable elements	Surface Area Ratio (Gharib support to Schlemm's Canal) (Table 2/Table 1)	Surface Area Ratio (%)
(micron)	(micron)	(micron)	(micron^2/ micron^2)	
15	185	6000	282,743.34/ 6,974,335.69	4.05%
250	95	1000	785,398.16/ 596,902.60	131.58%
250	95	6000	4,712,388.98/ 3,581,415.63	131.58%
250	185	1000	785,398.16/ 1,162,389.28	67.57%
250	185	6000	4,712,388.98/ 6,974,335.69	67.57%

Thus, Gharib teaches dimensions of supports that would contact less than 30% of the inner wall surface area of Schlemm's canal when disposed therein.[9] *Titanium Metals Corp. v. Banner,* 778 F.2d 775, 782 (Fed. Cir. 1985) (citing *In re Petering*, 301 F.2d 676, 682 (CCPA 1962)) ("[W]hen, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is 'anticipated' if *one* of them is in the prior art.").

[9] Although not mathematically possible, some of the values exceed 100% because the calculations assume an inflexible Schlemm's canal, which is flexible in reality and would stretch to accommodate a larger diameter support (to an extent). Ex.1001 (¶103).

Additionally, Gharib teaches a variety of shapes and designs that have reduced contact with the inner wall surface of Schlemm's canal. For example, Gharib teaches the outlet section of the support 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. Ex.1005 ¶¶29, 56, 66; Ex.1001 (¶104). The cross-sectional shape also provides a stenting capability when placed inside Schlemm's canal. Ex.1005 (¶60); *see, e.g.*, Ex.1005 (¶¶29, 56-60), 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 Fig.4A

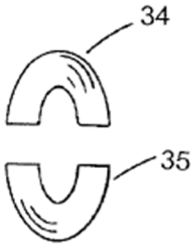
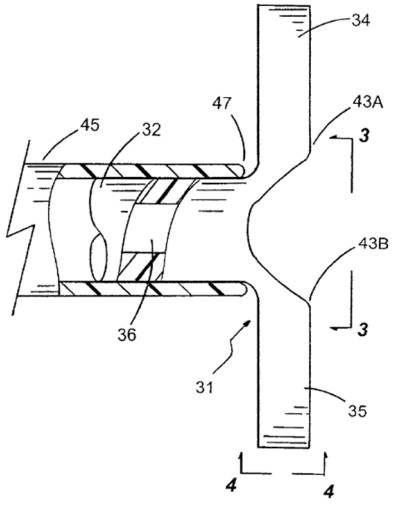


FIG. 4B

Ex.1005 Fig.4B



Ex.1005 Fig.5A

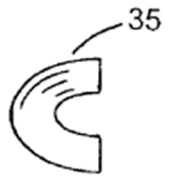


FIG. 5C

Ex.1005 Fig.5C

Gharib further teaches minimizing the interaction between the support and the tissue of Schlemm's canal to reduce inflammation. Ex.1005 (¶56). Thus, a POSITA would have been motivated to minimize the contact between the support and Schlemm's canal while maintaining the stenting capability to improve flow. Ex.1001 (¶105). To that end, Gharib also teaches "the outer surface of the outlet section 33," which is the section disposed within Schlemm's canal, "may comprise a stubbed surface, ribbed surface, surface with pillars, textured surface, or the like." Ex.1005 (¶56). Thus, Gharib teaches reducing the contact between Schlemm's canal and the support that also improves flow. Ex.1001 (¶104-107)

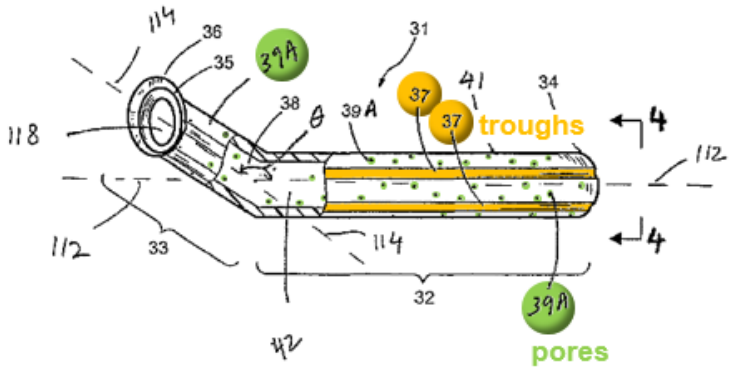
Gharib describes additional shapes and support forms that would further minimize contact with Schlemm's canal. For example, the outlet section "may be made of a material form selected from a group comprising coil form, mesh form, spiral form, porous form, semi-permeable form, fishbone form (*i.e.*, having

interlocking splines and/or fenestrations in a side wall, as illustrated in FIG. 7A)." Ex.1005 (¶29). The '742 patent explains the support can "at least partially be made from a mesh" (Ex.1003 (10:53-55)), akin to Gharib's mesh form disclosure. These additional cutaways, openings, and pathways would further reduce the overall contact between the support and Schlemm's canal. Ex.1001 (¶106-107). Thus, Gharib teaches reducing the contact between Schlemm's canal and the support that also improves flow. Ex.1001 (¶107).

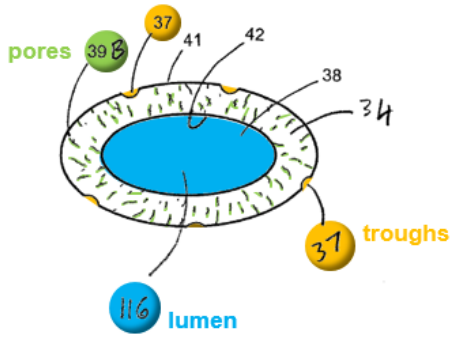
A POSITA reading Gharib would have understood that including the different surfaces on Gharib's support, like stubs or pillars, and shapes/configurations would reduce the overall contact between the support and the canal wall and, as the '742 patent recognizes, improve "circumferential fluid flow." Ex.1003 (9:33-35); Ex.1001 (¶106-107). These designs would necessarily include those contacting less than 30% of the surface area of the inner wall of Schlemm's canal. Ex.1001 (¶107).

Additionally, a POSITA would have been motivated to reduce the surface area contact to improve biocompatibility, reduce inflammation, and improve flow, as taught by Gharib. Ex.1001 (¶106-107). Likewise, a POSITA would have been motivated to increase surface protrusions and/or cutaways/openings/pathways and would have had a reasonable expectation of success in doing so because Gharib teaches such an approach to reduce inflammation while also maintaining the stenting ability of the support. Ex.1001 (¶106-107); *see also* Ex.1005 (¶¶29, 56-60, 66).

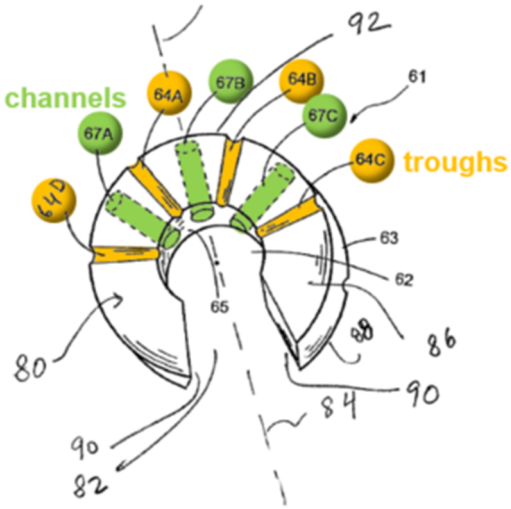
While Gharib alone provides sufficient motivation to reduce surface area contact of its support and a reasonable expectation of success, Bergheim provides additional motivation to reduce the surface area contact between an ocular implant device and the eye to improve aqueous humor outflow. For example, Bergheim discloses devices for reducing intraocular pressure to treat glaucoma by improving aqueous humor outflow and restoring existing outflow pathways, including Schlemm's canal. Ex.1006 (¶¶3, 35). Bergheim teaches the benefits of increased porosity of devices—to "facilitate efficient transport and/or transfusion of aqueous humor." Ex.1006 (¶71). Bergheim also teaches removing material from the exterior surface of the device, such as including twenty troughs or more on the exterior surface, or twenty or more channels to improve aqueous transmission. Ex.1006 (¶¶73-76, 100-111); Figs. 3, 4 and 7 below. Moreover, Bergheim discloses that the length of the device can range from about 0.5mm to about 10mm and discloses that channels can be circular and 250μm (or larger), *i.e.*, 0.25mm. Ex.1006 (¶¶116-19). Thus, Bergheim discloses devices with very large holes relative to the size of the device in addition to the troughs that all would reduce the surface area contact with the wall and improve aqueous flow. *See* Ex.1001 (¶108).



Ex.1006 Fig. 3



Ex.1006 Fig. 4



Ex.1006 Fig. 7

Bergheim would have motivated a POSITA to decrease the amount of material inserted into the eye by increasing the number of channels or troughs in a device such as Gharib's to improve aqueous humor flow into and out of the natural outflow pathways. *See* Ex.1001 (¶108-109). Doing so would also have provided Bergheim's disclosed benefits (increased aqueous flow) and Gharib's disclosed benefits (reduced inflammation). Ex.1001 (¶108-109). Moreover, doing so would have been no more than taking the obvious step of optimizing the contact ratio

between the support and the canal wall to achieve the desired aqueous fluid drainage. *See Merck & Co. Inc. v. Biocraft Lab. Inc.*, 874 F.2d 804, 809 (Fed. Cir. 1989); *In re Kulling*, 897 F.2d 1147, 1149 (Fed. Cir. 1990); *In re Geisler*, 116 F.3d 1465, 1469-70 (Fed. Cir. 1997) ("it is not inventive to discover the optimum or workable ranges by routine experimentation"); *In re Huang*, 100 F.3d 135, 139 (Fed. Cir. 1996) (similar); *Galderma Lab'ys, L.P. v. Tolmar, Inc.*, 737 F.3d 731, 739 (Fed. Cir. 2013) (similar). The surface area contacted is merely an obvious design choice to a POSITA balancing the desire to reduce inflammation plus increase aqueous flow with maintaining the patency of the canal. *Rexnord Indus., LLC v. Kappos*, 705 F.3d 1347, 1356 (Fed. Cir. 2013) (holding claims obvious when "[a]ll of the structural elements of the claims are shown in the references," and a particular dimension "was a design choice"); *Powers-Kennedy Contracting Corp. v. Concrete Mixing & Conveying Co.*, 282 U.S. 175, 185 (1930) ("obviously a mere change in proportion would involve no more than mechanical skill and would not amount to invention"); *see also* Ex.1001 (¶108-109).

A POSITA would also have had a reasonable expectation of success of increasing the number of throughholes in Gharib or decreasing the amount of exterior surface that contacts Schlemm's canal because both Gharib and Bergheim are directed to improving aqueous outflow by including openings or troughs, and with less surface area contact, there is more opportunity for aqueous humor flow.

See Ex.1001 (¶108-109). Thus, it would have been obvious to a POSITA in light of Gharib and Bergheim to use a support that contacts less than 30% of the internal wall of Schlemm's canal.

C. Ground 3: Grieshaber anticipates Claims 1–3, 9, 12, 15, 17-20

1. Independent Claim 1

a. **"A method of treating an eye condition, comprising:"**

Generally, "preamble language is not treated as limiting." *See Aspex*, 672 F.3d at 1347. Nonetheless, Grieshaber discloses that to treat glaucoma, "[t]he object of the invention is to provide a method and device by means of which improved, pressure-regulating circulation of the aqueous humor is achieved and its drainage from the eye is permanently maintained." Ex.1012 (Title, 2:7-9; 5:11-19). Ex.1001 (¶111).

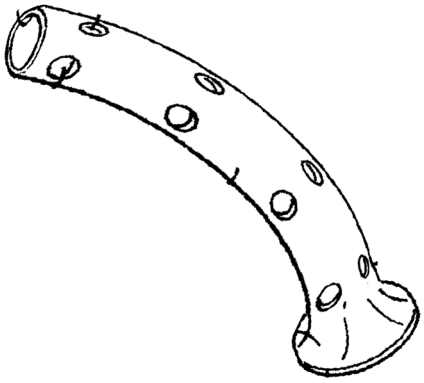
b. **"implanting a support within Schlemm's canal"**

Grieshaber discloses that, after implanting the device, Schlemm's canal is "permanently held in an expanded position" by supporting the inner wall 16' of Schlemm's canal. Ex.1012 (2:11-21); *Id.* (cls 5-6). Ex.1001 (¶112). A POSITA would have understood that Grieshaber's disclosure of expanding the canal would mean it is a structural support. Ex.1001 (¶112).

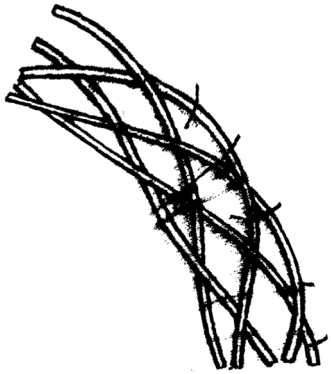
a. **"wherein the support comprises an arcuate member"**

Grieshaber discloses that "the support element 35;40;45;50 or 55 [may be] designed longitudinally somewhat arcuate." Ex.1012 (7:17-8:6; 11:20-12:2; Figures

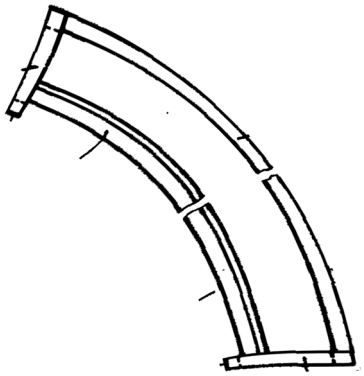
4-7; cl. 14). In addition, Grieshaber discloses that other portions of the support can be arcuate, including the collar shown in Grieshaber Figure 5 below, a helicoidal network of threads (Fig.11 below), a helix-shaped wire (Fig.12 below), or axially-spaced toruses (Fig.9 below). Thus, Grieshaber explicitly teaches that its support can have an arcuate member. The Figures below have been modified to demonstrate what Grieshaber's supports would look like if made "somewhat arcuate" which a POSITA would recognize as taught by Grieshaber. Ex.1001 (¶113-114).



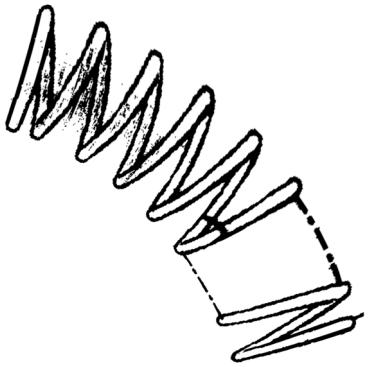
Ex.1012 Fig.5 (modified)



Ex.1012 Fig.11 (modified)



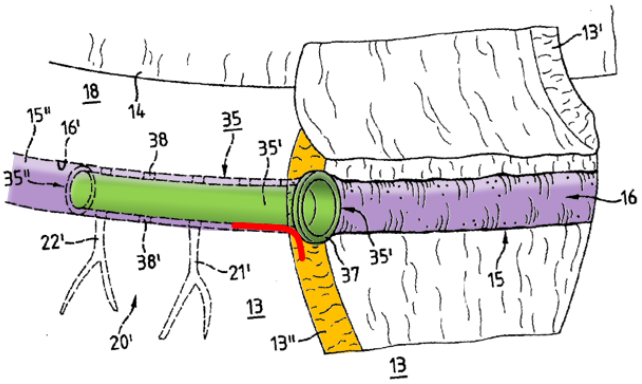
Ex.1012 Fig.9 (modified)



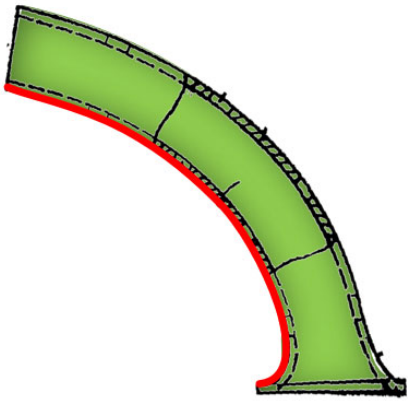
Ex.1012 Fig.12 (modified)

Grieshaber further discloses that one end of the support comprises "a collar which fits closely against the inward face of [the] scleral incision." Ex.1012 (8:1-

4). Figures 4-6 illustrate that the collar 37 also forms an arcuate member. Ex.1001 (¶114).



Ex.1012 Fig.4 (annotated)



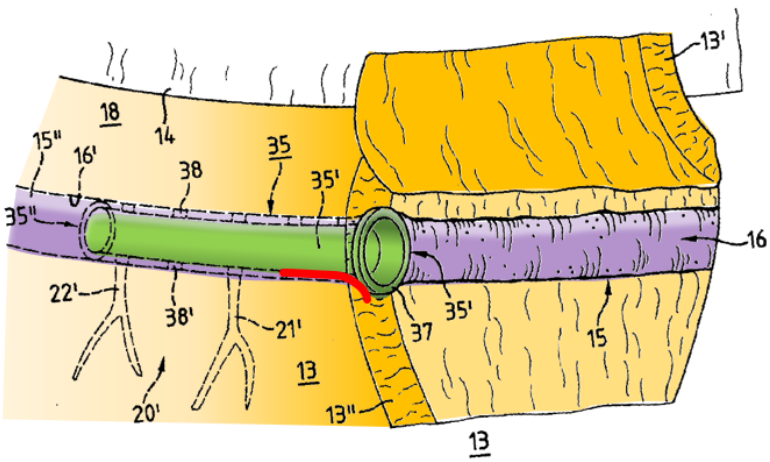
Ex.1012 Fig.6 (modified and annotated)

b. **"wherein at least a portion of the arcuate member has a radius of curvature smaller than the radius of curvature of Schlemm's canal such that at least a portion of the arcuate member extends out of Schlemm's canal"**

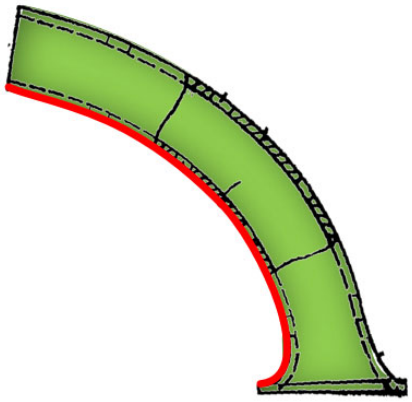
As explained in §XI.A.1.d above, the '742 patent lacks clear guidance regarding the radius of curvature of Schlemm's canal, and a support meets the limitation if, once implanted, it protrudes at one end from Schlemm's canal.[10]

[10] Petitioners contend that Grieshaber would meet this limitation under any plain and ordinary meaning as well.

Grieshaber's support meets Patent Owner's interpretation. Grieshaber expressly discloses that the support 35 can be somewhat arcuate and can include a collar 37 that extends out of Schlemm's canal to "fit[] closely against the inward face of [the] scleral incision, whereby any displacement of the emplaced (implanted) support element in the canal of Schlemm is prevented." Ex.1012 (7:17-8:6; 8:1-4; 11:20-12:2). Because Grishaber's support, once implanted, has a portion (the collar) that extends out of Schlemm's canal as shown in Figure 4 below, it necessarily has an overall radius of curvature smaller than Schlemm's canal. Ex.1001 (¶116-117)



Ex.1012 Fig.4 (annotated)



Ex.1012 Fig.6 (modified and annotated)

2. Dependent Claim 2

The method of claim 1, wherein the support has at least one fenestration.

Grieshaber's support 35 "is further provided with a number of throughholes 38, 38' distributed axially and circumferentially spaced" and configured to connect

to the collector channels of the natural outflow pathway. Ex.1012 (8:4-6); *see also Id.* (7:17-8:6, 8:6-10, 8:11-9:10, 9:11-18, Figures 4-7). Ex.1001 (¶118-119).

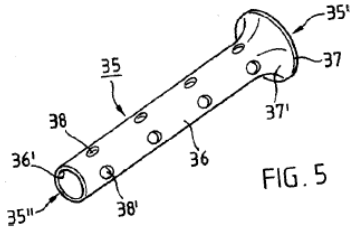


FIG. 5

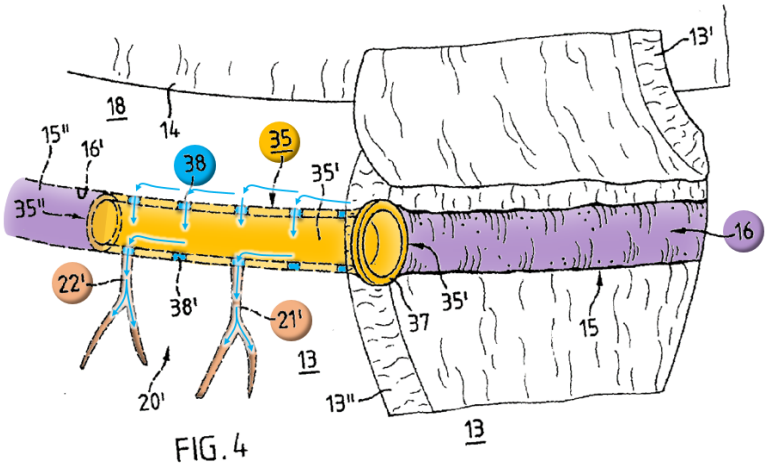


FIG. 4

Ex.1012 Fig.5 **Ex.1012 Fig.4 (annotated)**

3. Dependent Claim 3

The method of claim 1, wherein the support has a length equal to about a quarter or less than a quarter of the circumference of Schlemm's canal.

As explained above in §XI.A.3, a support with a circumference of less than 9.5 mm would meet this limitation. Grieshaber's support, which can be used in one portion of [Schlemm's] canal," can have (but is not limited to) a length of 2 mm. Ex.1012 (7:17-20; 12:7-12). Thus, Grieshaber discloses this limitation. Ex.1001 (¶120-121)

4. Dependent Claim 9

The method of claim 1, wherein at least a portion of the support is made from a biocompatible metal.

Grieshaber discloses that at least a portion of the support can be "made of suitable biocompatible material," such as "stainless steel," "a noble metal," or "a

nickel-titanium alloy." Ex.1012 (11:12-15; 11:6-9; 10:5-9; 10:17-18; 11:13-16; cl. 27). Thus, Grieshaber discloses this limitation. Ex.1001 (¶122).

5. Dependent Claim 12

The method of claim 1, wherein at least a portion of the support is porous.

Grieshaber discloses that at least a portion of the support may be porous, teaching that the support can contain throughholes, which allow aqueous humor to flow across the walls of the support. *See, e.g.*, Ex.1012 (8:4-10; Claim 16). Ex.1001 (¶123).

6. Dependent Claim 15

The method of claim 1, wherein the support is flexible.

Grieshaber's support can be "flexibly designed for automatic adaptation to the lumen of [Schlemm's canal]." Ex.1012 (cl. 29); *see also Id.* (11:12-15; 14:1-5). Ex.1001 (¶124).

7. Dependent Claim 17

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

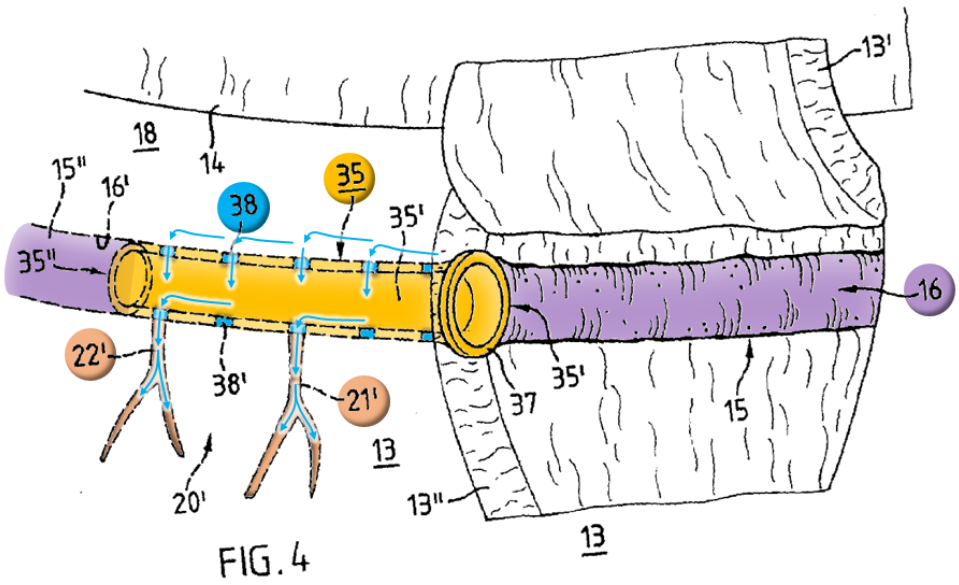
Grieshaber's support does not substantially interfere with longitudinal flow along Schlemm's canal. For example, Grieshaber discloses the support can be hollow or "substantially hollow." Ex.1012 (11:16-17; 13:8-11). Moreover, Grieshaber discloses that "[t]he aqueous humor penetrating through the trabecular

meshwork 18 exits through the canal of Schlemm 15 or *through the interior of the support element* and through the openings and collector channels. *Id*. (9:3-10, Figures 4-7). Thus, Grieshaber's support facilitates, rather than substantially interferes with, the longitudinal flow along Schlemm's canal. Ex.1001 (¶125-126).

8. Dependent Claim 18

The method of claim 1, wherein the support does not substantially interfere with transmural flow into and out of Schlemm's canal.

Grieshaber's support does not substantially interfere with the transmural flow across Schlemm's canal. For example, Grieshaber discloses that "[t]he aqueous humor *penetrating through the trabecular meshwork* exits *through the canal of Schlemm* or through the interior of the support element *and through the openings and collector channels*. Ex.1012 (9:3-10, Figures 4-7). Grieshaber emphasizes the importance of including throughholes or openings in the supports to allow aqueous humor to flow across Schlemm's canal and to the collector channels. *See, e.g., Id.* (8:8-10, 9:3-10, 13-17, 9:21-10:4, 10:9-12, 11:9-11, 14:8-15, 14:21-15:2). Figure 4 depicts outflow openings 38 along the trabecular meshwork 18 and outflow openings 38' connected to collector channels. *Id.* (8:4-10).



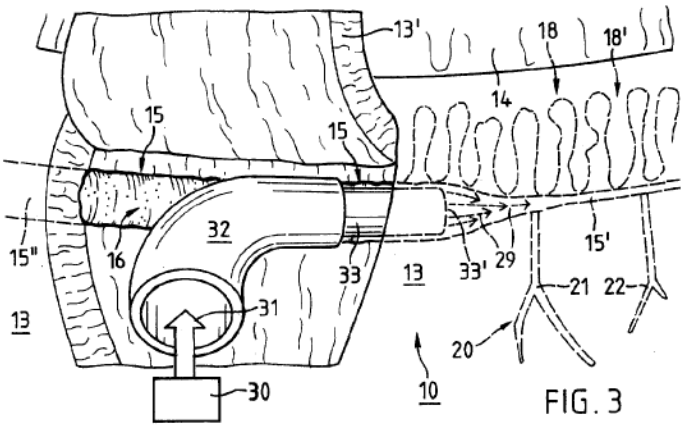
Ex.1012 Fig.4 (annotated showing throughholes connected to collector channels)

Thus, Grieshaber teaches its supports facilitate, rather than interfere with, transmural flow of aqueous humor. Ex.1001 (¶127-130).

9. Dependent Claim 19

The method of claim 1, further comprising preloading the support into an introducer and delivering the support from the introducer into Schlemm's canal.

Grieshaber teaches that its support can be preloaded into and introduced into Schlemm's canal. Grieshaber Figure 3.



Ex.1012 Fig.3

For example, Grieshaber teaches that its support "is placed by means of a separable connection on the distal end of the probe of the injection apparatus." Ex.1012 (12:21-13:4, Figure 3; cl. 30). Grieshaber also discloses that "the distal end of the probe 33 of the injection apparatus 30 is designed as a separable support element 35;40;45;50; or 55." *Id*. (13:6-7; 13:8-12; cls. 31, 32). Ex.1001 (¶131-132).

10. Dependent Claim 20

> **The method of claim 19, wherein the support is delivered from the introducer using a pusher.**

As discussed in §XI.C.9 above, Grieshaber discloses that supports can be positioned by the introducer and pushed from the introducer into Schlemm's canal. Ex.1001 (¶133).

D. Ground 4: Grieshaber renders obvious Claims 6-8

1. Dependent Claim 6

> **The method of claim 1, wherein at least a portion of the support is made from a shape memory material.**

Grieshaber teaches that the support may be made of various biocompatible materials, including, for at least one embodiment, "a nickel-titanium alloy" having a "shape memory effect," which allows the support to be deformed and "automatically returned to its original shape." Ex.1012 (10:17-21); *see also Id.* (11:13-16; cl. 27). Using shape memory materials, Grieshaber explains "has the advantage that it can, for example, be inserted plastically deformed with a relatively small external diameter into [Schlemm's canal]." *Id.* (10:21-11:4). Thus, Grieshaber itself recognizes and extolls the benefit of shape memory materials for its supports. A POSITA would have been motivated to use a shape memory material like nickel-titanium alloys in any of Grieshaber's embodiments because it would allow Grieshaber's support to improve insertion in a plastically deformed shape, while allowing it to automatically return to its original shape as taught by Grieshaber itself. Further, a POSITA would have had a reasonable expectation of success in using nickel-titanium alloys in any of Grieshaber's embodiments because at least some are preferably made with such materials. Ex.1001 (¶134-135).

Moreover, selecting this known material for an ophthalmic support is merely an obvious design choice well within the skill of an ordinarily skilled artisan. *Sinclair*, 325 U.S. at 335; *Sinclair*, 325 U.S. at 335; *Hicks*, 85 U.S. at 673; *KSR*, 550 U.S. at 416; Ex.1001 (¶134-135).

2. Dependent Claim 7

> **The method of claim 6, wherein the shape memory material comprises a shape memory alloy.**

As discussed in §XI.D.1 above, it would have been obvious to make at least a portion of Grieshaber's support of shape-memory material, including nitinol. Ex.1001 (¶136-137).

3. Dependent Claim 8

> **The method of claim 7, wherein the shape memory alloy comprises a nickel titanium alloy.**

As discussed §XI.D.1 above, it would have been obvious to make at least a portion of Grieshaber's support of shape-memory material, including nitinol. Ex.1001 (¶138).

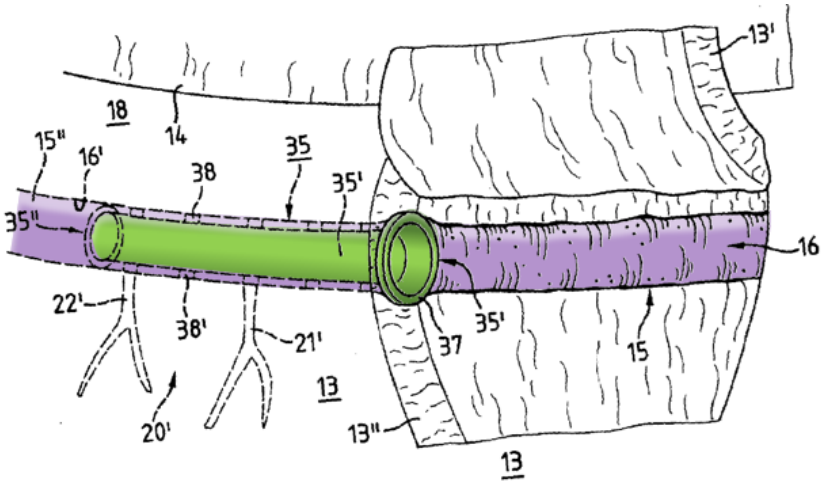
E. Ground 5: Grieshaber alone, or in view of Bergheim, renders obvious Claim 13.

1. Dependent Claim 13

> **The method of claim 1, wherein when the support is disposed within a cylindrical section of the lumen of Schlemm's canal having an internal wall surface area C, the support contacts less than 30% of C.**

Under Patent Owner's interpretation that the canal is cylindrical, Grieshaber's support is disposed within a cylindrical section of the lumen of Schlemm's canal,[11] Ex.1001 (¶139); Ex.1012 (7:17-8:6, 8:11-9:18, Figures 4-7).

[11] Petitioners note that Schlemm's Canal is not in fact cylindrical.

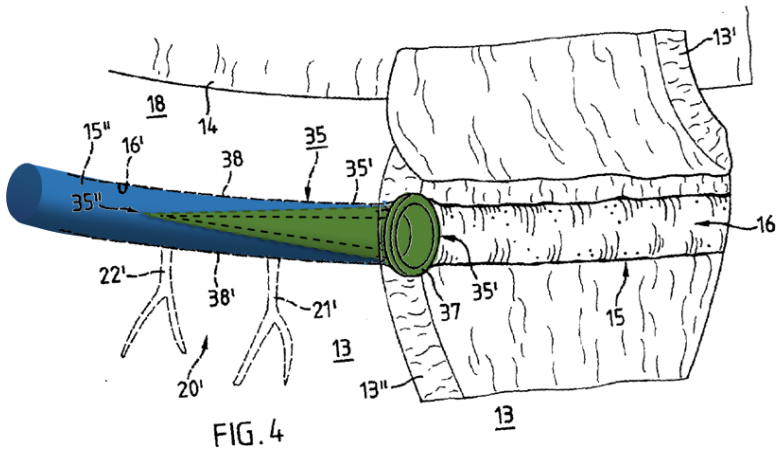


Ex.1012 Fig.4 (annotated)

With respect to the limitation requiring that the support contact less than 30% of the "internal wall surface area," Petitioners have adopted Patent Owner's interpretation that the internal wall surface area C is estimated by viewing the inside of Schlemm's canal as a regular cylinder (despite that this contradicts the '742 Patent's description of Schlemm's canal as a "slightly arcuate cylinder").

Grieshaber teaches a variety of shapes and designs that have reduced contact with the inner wall surface of Schlemm's canal. For example, Grieshaber teaches designing the support such that it is "conically tapered axially" from one end to the other. Ex.1012 (8:18-22). This design would contact the inner surface of Schlemm's canal at one end and taper away from the surface toward the other end, which would

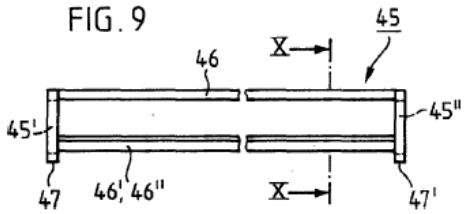
inherently contact less than 30% of the surface area (over the length of the support) as shown by the annotated image below. Ex.1001 (¶141).



Ex.1012 Fig.4 (annotated and modified)

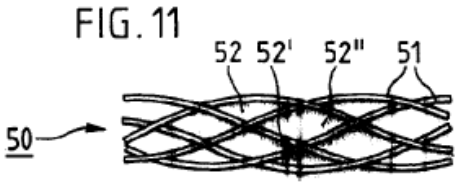
Moreover, Grieshaber's supports are designed to facilitate transmission of aqueous from the anterior chamber into Schlemm's canal, and finally, out through the collector channels in the wall of Schlemm's canal, using "a number of throughholes," "spaced at intervals axially and arbitrarily distributed circumferentially" "such that at least one of the throughholes…connects with the small collector channels" Ex.1012 (7:17-8:6, 8:11-9:18, Figures 4-7; 8:6-10); *see also Id.* (9:1-10 (similar)). A POSITA would have understood from this that increasing the number of throughholes improves the opportunities for better inflow and outflow through the collector channels and therefore a POSITA would have been motivated to further increase the number of holes to achieve that goal. Ex.1001 (¶142-143).

Grieshaber further emphasizes the importance of providing avenues for outflow of aqueous humor through its disclosed supports. One example is "a helicoidal network made of threads," where "the gaps provided between the individual threads serve respectively as outflow openings for the aqueous humor." Ex.1012 (10:5-13, Claim 18, Figure 11). Grieshaber discloses another example in which "axially spaced toruses" are connected by at least two, but preferably three webs 46,46', and 46'' placed circumferentially at intervals linking the end portions 47,47' to each other," where "the recesses 48,48', and 48'', *i.e.,* empty spaces, provided between the webs 46,46', and 46'' serve in each case as outflow openings for the aqueous humor.'' *Id*. at 9:19-10:4, Figs. 9, 10. Ex.1001 (¶142-143).



Ex.1012 Fig.9

Ex.1012 Fig.9 (rendered three-dimensional)

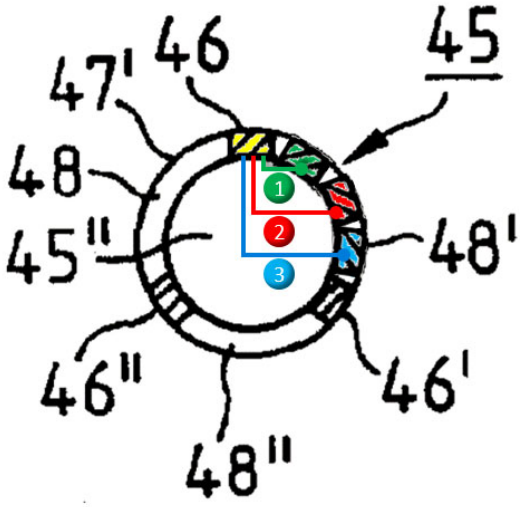


Ex.1012 Fig.11

Ex.1012 Fig.11 ((rendered three-dimensional)

Figure 10 provides a side view of Figure 9 containing three webs (46, 46', 46''). Although there are three webs shown, as noted above, there can be as few as

two webs connecting the round toruses in Grieshaber's Figure 9. Ex.1012 (9:19-10:4). It is readily apparent in Figure 10 that approximately three webs can fit within each of the empty space recesses (48,48', and 48''). *See* Ex.1001 (¶143)



Ex.1012 Fig.10 (annotated and modified)

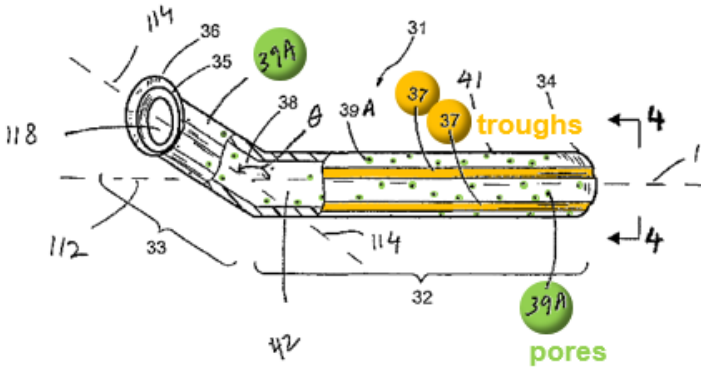
Accordingly, it would take approximately twelve webs to fill out Grieshaber's entire cylindrical-shaped support. *See* Ex.1001 (¶143); Grieshaber's disclosure of three webs, therefore, would contact at most only approximately one fourth (*i.e.,* 3/12 or 25%) of the circumference of the support. *See* Ex.1001 (¶143). Considering Grieshaber's disclosure of "at least two" webs would mean even lower surface area contact of approximately one sixth (*i.e.,* 2/12 or 16.7%). *See* Ex.1001 (¶143). Thus, it would have been immediately apparent to a POSITA that Grieshaber itself discloses supports that contact less than 30% surface area of the wall of Schlemm's canal. *See* Ex.1001 (¶143); *see also Paice LLC v. Ford Motor Co.*, 722 Fed. App'x

1015, 1022 (Fed. Cir. 2018) (explaining that it was reasonable for an expert to rely on visual inspection of patent figure to scale components relative to each other).

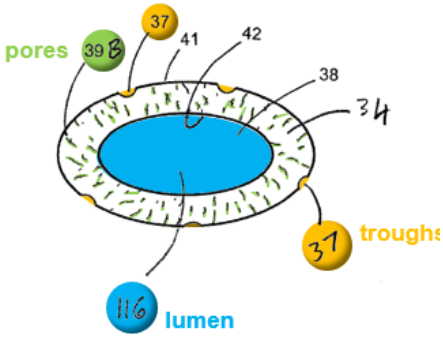
Overall, a POSITA reading Grieshaber would have been motivated to increase the number and size of the outflow openings in each of the depicted support devices (Figs. 4-9), which necessarily reduces the surface area contact with the wall of Schlemm's canal, balancing the goals of permitting better aqueous humor flow and avoiding blocking collector channels with the goal of stenting the canal. *See* Ex.1001 (¶144). A POSITA would also have had a reasonable expectation of success in increasing the amount and size of the outflow pathways because Grieshaber itself teaches multiple embodiments designed to do just that including designs that inherently make less than 30% surface area contact. Ex.1012 (8:18-22; Figures 9-10). *See* Ex.1001 (¶144-145).

While Grieshaber alone provides sufficient motivation to reduce surface area contact of its support and a reasonable expectation of success, Bergheim provides additional motivation to reduce the amount of surface area contact between an ocular implant device and the eye to improve aqueous humor outflow. For similar reasons presented above in §XI.B.1, Bergheim would have motivated a POSITA to increase the number of channels or troughs in a device, such as the throughholes in Grieshaber, to improve aqueous humor flow into and out of the natural outflow pathways. *See* Ex.1001 (¶146-147). Doing so would have also necessarily reduced

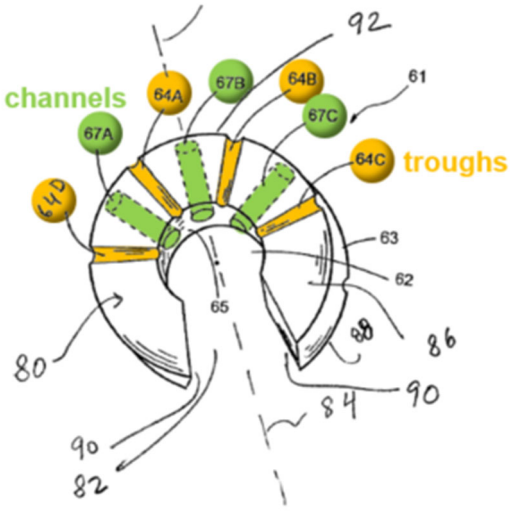
the surface area contact, including below 30%, and would be no more than taking the obvious step of optimizing the contact ratio between the support and the canal wall to achieve the desired aqueous fluid drainage. *See Biocraft,* 874 F.2d at 809; *In re Kulling,* 897 F.2d at 1149; *In re Geisler,* 116 F.3d at 1469-70; *In re Huang*, 100 F.3d at 139; *Galderma*, 737 F.3d at 739. Decreasing the surface area contacted would have been merely an obvious design choice of balancing (1) the desire to reduce contact inflammation and increase aqueous flow with (2) maintaining the patency of the canal. *Rexnord*, 705 F.3d at 1356; *Powers-Kennedy*, 282 U.S. at 185; *See* Ex.1001 (¶146-147).



Ex.1006 Fig.3



Ex.1006 Fig.4



Ex.1006 Fig.7

Likewise, A POSITA would also have had a reasonable expectation of success of increasing the number of throughholes or decreasing the amount of exterior surface that contacts Schlemm's canal because both Grieshaber and Bergheim are directed to improving aqueous outflow by including openings or troughs. *See* Ex.1001 (¶146-147). Thus, it would have been obvious to a POSITA in light of Grieshaber and Bergheim to utilize a support that contacts less than 30% of the internal wall of Schlemm's canal. Ex.1001 (¶144-147).

F. Ground 6: Lynch Anticipates Claims 1–3, 9, 12, 15, 17-18

1. Independent Claim 1

a. "A method of treating an eye condition, comprising:"

Generally, "preamble language is not treated as limiting." *See Aspex*, 672 F.3d at 1347. Nonetheless, Lynch discloses a device that reduces pressure by providing "increased egress of aqueous humor from the anterior chamber to

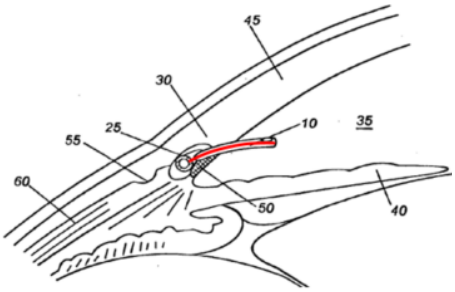
Schlemm's canal for glaucoma management." Ex.1008 (Title, ¶¶3, 7, 24, 51, 72, 76, Figure 6A). Ex.1001 (¶149).

b. **"implanting a support within Schlemm's canal"**

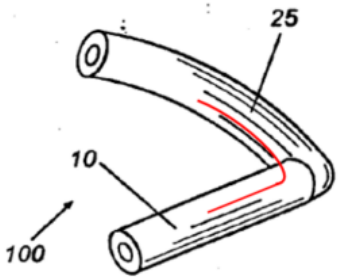
Lynch discloses various devices that are "sized and shaped to be circumferentially received within a portion of Schlemm's canal…" Ex.1008 (¶25, 27-28, 35-36, 38, 43, 51-52, 55, 63, 70, 74-75, 78, 79, 84, 113). Lynch's devices are "supports" at least because they "help to maintain the patency of Schlemm's canal." *Id*. (¶63). Ex.1001 (¶150).

c. **"wherein the support comprises an arcuate member"**

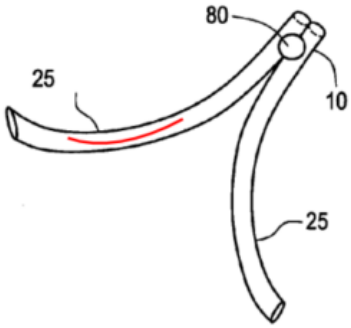
Lynch teaches supports of "many different configurations" that allow for aqueous humor drainage, Ex.1008 (¶53), including those with "arcuate outer surface[s]," *id.* cl. 40. "All or parts of the device may be…precurved," Ex.1008 (¶55), and Lynch discloses various curved supports, *see, e.g.,* Ex.1008 (¶¶62-67, 70). Lynch also discloses that a portion of the support 25 "may have a pre-formed curve to approximate the 6.0 mm radius of Schlemm's canal in a human eye." Ex.1008 (¶74). It is plain from Lynch's Figures that the support can comprise an arcuate member. Ex.1001 (¶151-152).



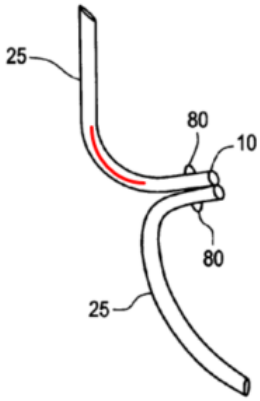
Ex.1008 Fig.6C (annotated)



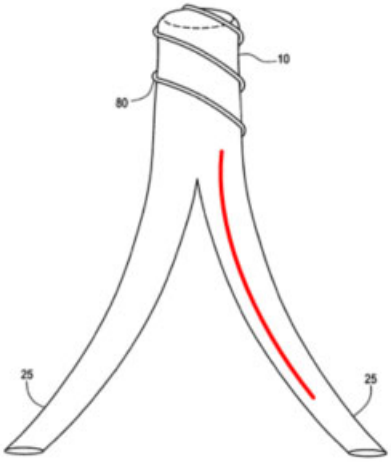
Ex.1008 Fig.5A (annotated)



Ex.1008 Fig.8B (annotated)



Ex.1008 Fig.8C (annotated)



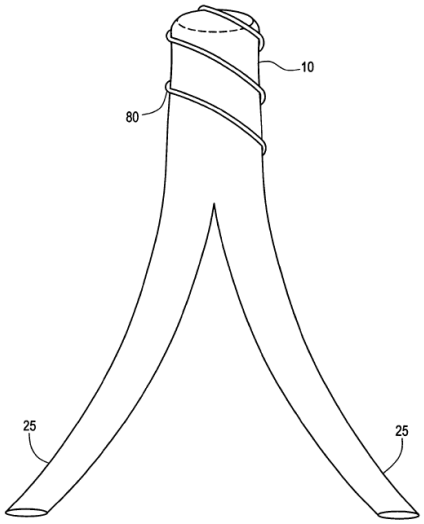
Ex.1008 Fig.10 (annotated)

d. **"wherein at least a portion of the arcuate member has a radius of curvature smaller than the radius of curvature of Schlemm's canal such that at least a portion of the arcuate member extends out of Schlemm's canal"**

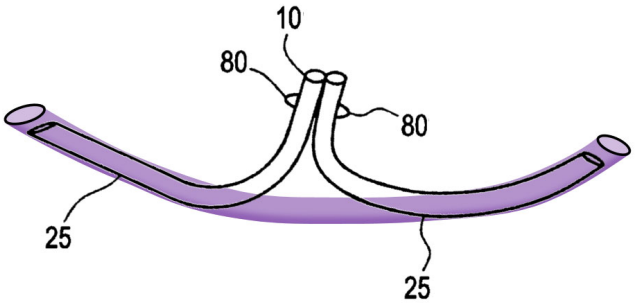
As explained in §XI.A.1.d above, the '742 patent lacks clear guidance regarding radius of curvature measurement comparisons or the radius of curvature

of Schlemm's canal, and a support meets the limitation if, once implanted, it protrudes at one end from Schlemm's canal.[12]

Lynch teaches supports that meet this limitation. Ex.1008 (¶¶64, 66, 70, 77, 78, 81); Ex.1001 (¶153-155). "All or parts of the device[s]" that are disposed within Schlemm's canal and extend into the anterior chamber "may be…precurved." *See, e.g.*, Ex.1008 (¶¶55, 84, Figure 10, 8C).



Ex.1008 Fig.10

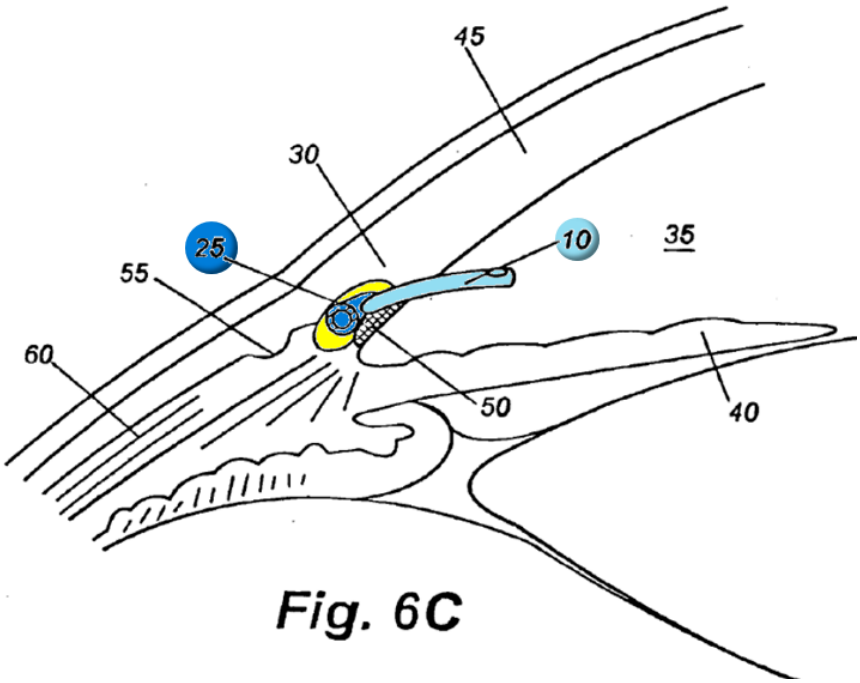


Ex.1008 Fig.8C (annotated)

Lynch discloses that the support comprises "a distal portion…shaped to be circumferentially received within a portion of Schlemm's canal and a proximal portion…shaped to be received within the anterior chamber of the eye," which "permits fluid communication between the proximal portion in the anterior chamber to the distal portion in Schlemm's canal." Ex.1008 (¶51). Because Lynch's support,

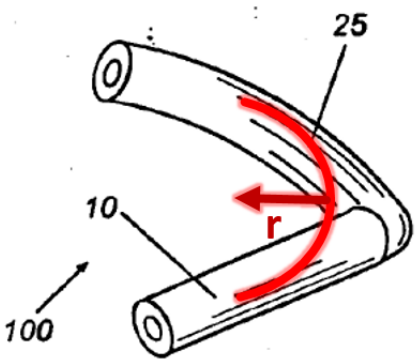
[12] Lynch would also meet this limitation under any plain and ordinary meaning.

once implanted, has a portion (the proximal portion) that extends out of Schlemm's canal and into the anterior chamber of the eye, as shown in Figure 6C below, it necessarily has an overall radius of curvature smaller than Schlemm's canal. *Id*. (¶76); Ex.1001 (¶155). Furthermore, Lynch teaches that the angle between the proximal portion 10 and distal portion 25 may vary from "about + 60 degrees toward the cornea or -30 degrees toward the iris." Ex.1008 (¶76, 85).

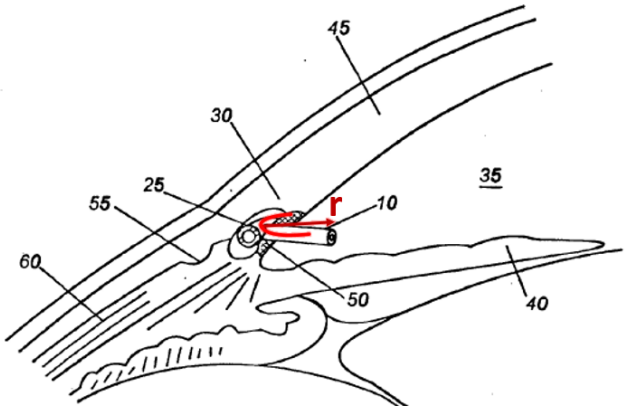


Ex.1008 Fig.6C

As another example, Figure 5A shows a support that would extend out of Schlemm's canal and into the trabecular meshwork once implanted. Ex.1008 (¶64); *see also Id*. (¶¶76-78, Figures 5A, 6B, 6C); Ex.1001 (¶156-157).



Ex.1008 Fig.5A



Ex.1008 Fig.6B

Lynch's various support orientations and the support's extension into Schlemm's canal and then out into the anterior chamber, therefore, discloses that at least a portion of the support can have a radius of curvature smaller than that of Schlemm's canal, such that a portion of the support extends out of Schlemm's canal. Ex.1001 (¶157).

2. Dependent Claim 2

The method of claim 1, wherein the support has at least one fenestration.

Lynch discloses porous, tubular, trough-like, and fenestrated devices, and that each can be fenestrated. Ex.1008 (¶¶53, 55); *see also Id.* (Figs. 2, 4, 5, ¶¶59, 64, 65, 74). The gaps between the intertwined mesh in Lynch's Figure 1C are likewise fenestrations. Ex.1001 (¶158).

3. Dependent Claim 3

The method of claim 1, wherein the support has a length equal to about a quarter or less than a quarter of the circumference of Schlemm's canal.

As explained above in §XI.A.3, a support with a length of less than 9.5 mm would meet this limitation. Lynch's distal portion length "may be between about 1.0 mm to 40 mm, preferably about 4 mm to 6 mm." Ex.1008 (¶56). Thus, Lynch discloses this limitation. Ex.1001 (¶159-160).

4. Dependent Claim 9

The method of claim 1, wherein at least a portion of the support is made from a biocompatible metal.

Lynch discloses that at least a portion of the support can be made of "biocompatible material," Ex.1008 (¶52), such as biocompatible metal, *Id.* (¶69). Thus, Lynch discloses this limitation. Ex.1001 (¶161).

5. Dependent Claim 12

The method of claim 1, wherein at least a portion of the support is porous.

Lynch discloses that at least a portion of the support can be porous, teaching that the support can be comprised of "porous elements" that also assists in fluid communication. Ex.1008 (¶28); *see also Id*. (Fig.1D, ¶¶53, 55, 57, 69, 71, 85). Ex.1001 (¶162)

6. Dependent Claim 15

The method of claim 1, wherein the support is flexible.

Lynch discloses that the support can be flexible. For example, "[t]he portion of the device extending into Schlemm's canal can be fashioned from a flexible material." *Id*. (¶55); *see also Id.* (¶¶55, 69, 74). Ex.1001 (¶163).

7. Dependent Claim 17

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

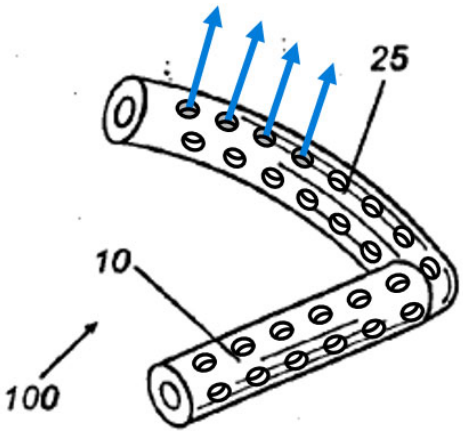
Lynch's support does not substantially interfere with longitudinal flow along Schlemm's canal. For example, Lynch's support "[e]nhanc[es] aqueous flow directly into Schlemm's canal." Ex.1008 (¶23, 64). Lynch further discloses *in vivo* results of implanting a support in animals that demonstrated longitudinal flow along Schlemm's canal. *Id.* (¶¶109–120); Ex.1001 (¶164). Thus, Lynch's support facilitates, rather than substantially interferes with, longitudinal flow along Schlemm's canal. Ex.1001 (¶164); *see also* §XI.F.8 below discussing "transmural flow."

8. Dependent Claim 18

The method of claim 1, wherein the support does not substantially interfere with transmural flow into and out of Schlemm's canal.

Lynch's supports "facilitate[] the normal physiological pathway for drainage of aqueous humor." Ex.1008 (¶24). For example, "[t]he distal portion 25 may contain a plurality of fenestrations to allow fluid egress, arranged to prevent occlusion by the adjacent walls of Schlemm's canal." *Id*. (¶74). These fenestrations "may be round, ovoid, or other shapes as needed for ***optimum aqueous humor channeling function***." *Id.* (¶64). Lynch emphasizes the importance of including fenestrations, which "may be placed along any portion of the device to facilitate the

passage of fluid there-through, but are particularly directed towards the collecting channels of the eye." *Id.* (¶59-60); Ex.1001 (¶165-166). Lynch's device may also be porous, "which may provide wick-lick fluid communication therethrough." Ex.1008 (¶57); *see also Id.* (¶¶68-69, 71 (any portion of the device can be porous to "assist in channeling aqueous humor")); Ex.1001 (¶166-167).



Ex.1008 Fig.5A (modified with fenestrations and arrows)

Lynch's clear goal is to permit aqueous flow across and through the canal. Ex.1001 (¶165-168). A POSITA would have understood that Lynch discloses including many fenestrations arranged in a scattered fashion to avoid occlusion as well as porous structures to assist with flow. Ex.1001 (¶165-168). These configurations and structures are designed to facilitate, rather than interfere, with transmural flow of aqueous humor through the trabecular meshwork, into Schlemm's canal, through the fenestrations, and finally into the collector channels. Ex.1001 (¶165-168). Thus, Lynch's device assists in, rather than substantially interferes with, transmural flow across Schlemm's canal. *Id.* (¶168).

G. Ground 7: Lynch alone, or in view of Bergheim, renders obvious Claim 13

1. Dependent Claim 13

> **The method of claim 1, wherein when the support is disposed within a cylindrical section of the lumen of Schlemm's canal having an internal wall surface area C, the support contacts less than 30% of C.**

Under Patent Owner's interpretation that the canal is cylindrical, Lynch's support is disposed within a cylindrical section of the lumen of Schlemm's canal.[13] Ex.1001 (¶170); Ex.1008 (¶¶51, 55, 56, 57, 58, 59, 60, 65, 78, Figs. 6B-7B). Lynch's support is "sized and shaped to be circumferentially received within a portion of Schlemm's canal." Ex.1008 (¶51). Figure 6B shows the insertion of the distal portion 25 of the support into Schlemm's canal 30.

[13] Petitioners note that Schlemm's Canal is not in fact cylindrical.

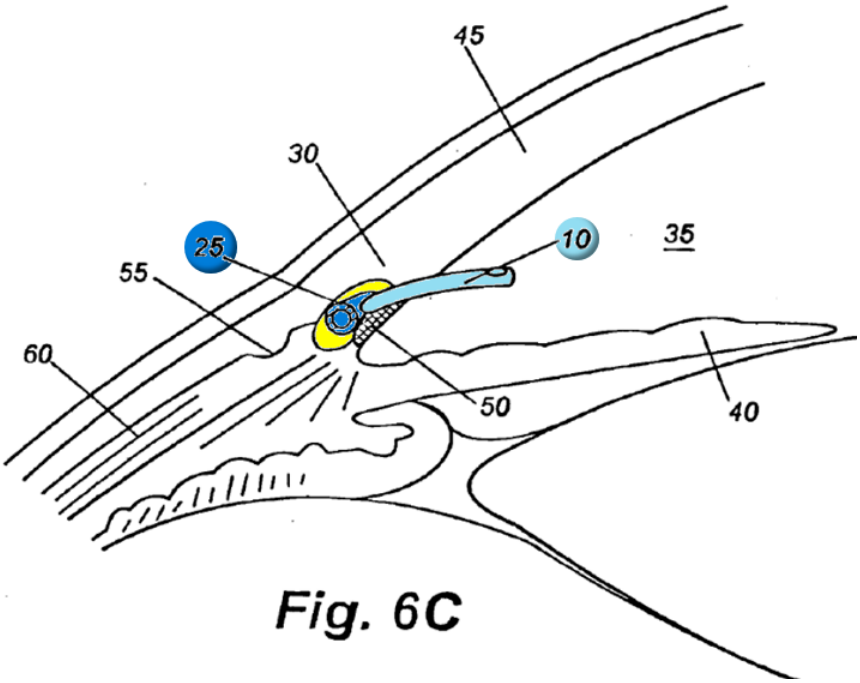


Fig. 6C

Ex.1008 Fig.6B

With respect to the limitation requiring that the support contact less than 30% of the "internal wall surface area," Petitioners have adopted Patent Owner's interpretation that the internal wall surface area C is measured by estimating Schlemm's canal as a cylinder (despite that this contradicts the '742 Patent's description of Schlemm's canal as a "slightly arcuate cylinder").

Lynch's various configurations and disclosed materials are aimed at reducing surface area contact. Ex.1001 (¶172-173). Lynch explains the goal is to "facilitate[] the normal physiologic pathway for drainage of aqueous humor from the anterior chamber," Ex.1008 (¶24), that a need exists to enhance drainage through the collector channels, Ex.1008 (¶23), that fenestrations and other openings can be added "as needed for optimum aqueous humor channeling function within the

anatomic spaces involved," Ex.1008 (¶64), and that additional fenestrations are desirable to allow fluid ingress and to prevent occlusion, Ex.1008 (¶71, 74). Lynch's supports "can be constructed of a solid, matrix, mesh, fenestrated, or porous material." Ex.1008 (¶53). Figure 1C depicts a mesh structure, which would have decreased surface area contact with a wall of Schlemm's canal and would assist in permitting aqueous flow. Ex.1001 (¶173).[14] A POSITA would have understood from this that Lynch teaches reducing surface area contact either using configurations such as mesh or increasing the number of fenestrations to improve fluid flow, and that one should arrange them in a scattered fashion to avoid occlusion, or covering, of the openings that would impede flow. Ex.1001 (¶173). Lynch, therefore, encourages using supports that make less than 30% surface area contact with the internal wall of Schlemm's canal. Ex.1001 (¶173).

[14] The '742 patent itself explains that at least a portion of the support can be made from mesh, Ex.1003 (3:54-55), and that open network structures "will have minimal surface area contact with the walls of Schlemm's canal." Ex.1003 (10:54-55). Ex.1001 (¶173).

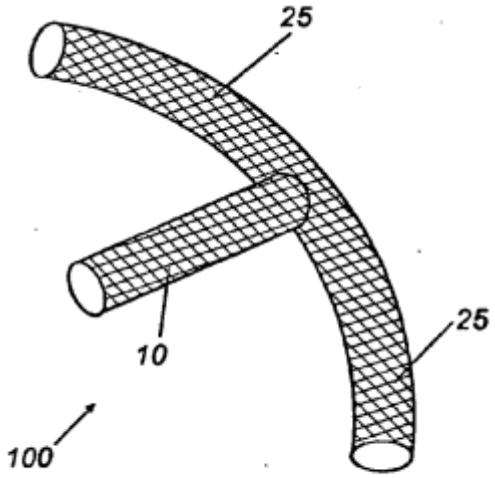


Fig. 1C

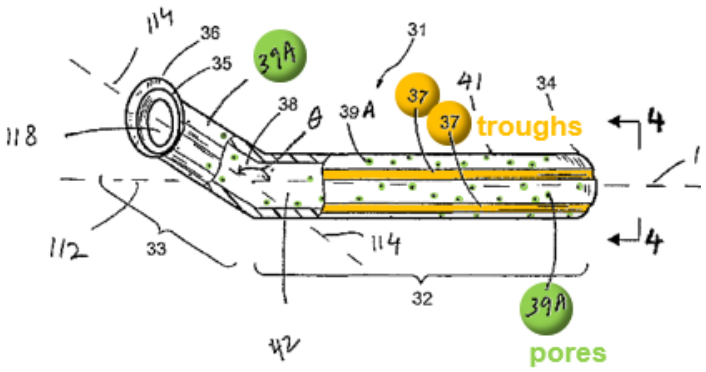
Ex.1008 Fig.1C

Moreover, Lynch encourages using supports designed to "create and maintain the natural physiological egress…to the collecting channels." Ex.1008 (¶54, 59-60). Lynch's trough-like supports, depicted in Lynch Figure 4 as having approximately 50% of its exterior removed, are oriented to open toward the collecting channels to facilitate aqueous humor egress. Ex.1008 (¶67). Therefore, in addition to fenestrations, Lynch teaches another means of reducing the risk of blocking collector channels by decreasing the amount of material in the device to improve fluid ingress and egress while still maintaining the patency of the canal. Ex.1008 (¶¶71, 74); Ex.1001 (¶174-175). As the collector channels are critical to the outflow of aqueous humor from Schlemm's canal, a POSITA would have been motivated by Lynch to increase the number and size of fenestrations and to decrease the amount of material exposed to the wall of Schlemm's canal to ensure access to the collector channels

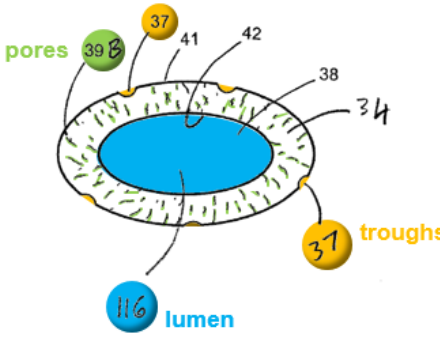
and to ensure one is not impeding flow to those channels, which in turn necessarily results in decreasing surface area in contact with Schlemm's canal. Ex.1001 (¶173); *see* Ex.1008 (¶¶60, 64, 70). Lynch would have also provided a POSITA with a reasonable expectation of successfully increasing fenestrations and reducing material that would contact Schlemm's canal to achieve Lynch's goal of improving aqueous ingress and egress for drainage and maintain Lynch's stenting capability teaching. Ex.1001 (¶173-174). Thus, the 30% surface area contact limitation would have been obvious in view of Lynch. Ex.1001 (¶173-174); *see also In re Aller*, 220 F.2d 454, 456 (C.C.P.A. 1955) ("it is not inventive to discover the optimum or workable ranges by routine experimentation.").

While Lynch alone provides sufficient motivation to reduce surface area contact of its support and a reasonable expectation of success, Bergheim provides additional motivation to reduce the amount of surface area contact between an ocular implant device and the eye to improve aqueous humor outflow. For similar reasons presented above in §XI.B.1, Bergheim would have motivated a POSITA to increase the number of channels or troughs in a device, such as the fenestrations in Lynch, to improve aqueous humor flow into and out of the natural outflow pathways. *See* Ex.1001 (¶175-176). Doing so would have also necessarily reduced the surface area contact, including below 30%, and would be no more than taking the obvious step of optimizing the contact ratio between the support and the canal wall to achieve the

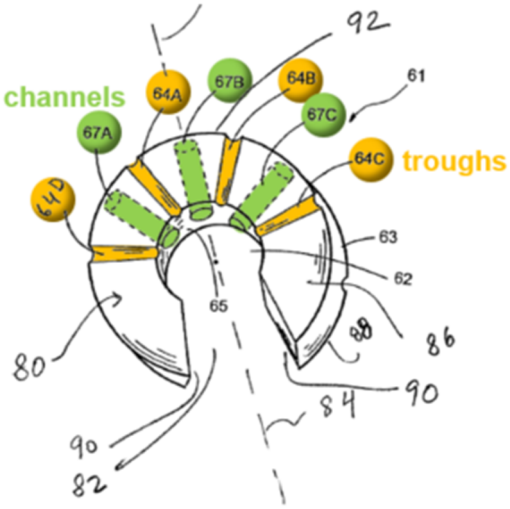
desired aqueous fluid drainage. *See Biocraft,* 874 F.2d at 809; *In re Kulling,* 897 F.2d at 1149; *In re Geisler,* 116 F.3d at 1469-70; *In re Huang*, 100 F.3d at 139; *Galderma*, 737 F.3d at 739. Decreasing the surface area contacted would have been merely an obvious design choice of balancing (1) the desire to reduce contact inflammation and increase aqueous flow with (2) maintaining the patency of the canal. *Rexnord*, 705 F.3d at 1356; *Powers-Kennedy*, 282 U.S. at 185; *See* Ex.1001 (¶175-176).



Ex.1006 Fig.3



Ex.1006 Fig.4



Ex.1006 Fig.7

Likewise, a POSITA would also have had a reasonable expectation of success of increasing the number of throughholes in Lynch or decreasing the amount of exterior surface that contacts Schlemm's canal because both Lynch and Bergheim are directed to improving aqueous outflow by including openings or troughs, and with less surface area contact, there is more opportunity for aqueous humor flow. *See* Ex.1001 (¶174-176). Thus, it would have been obvious to a POSITA in light of Lynch and Bergheim to use a support that contacts less than 30% of the internal wall of Schlemm's canal. Ex.1001 (¶174-176).

H. Ground 8: Lynch In View Of Gharib Renders Obvious Claims 6-8

1. Dependent Claim 6

The method of claim 1, wherein at least a portion of the support is made from a shape memory material.

Lynch's support can be designed using various biocompatible materials, including polymers, plastics, and metals, and is preferably not "structurally compromised during its in situ tenure." Ex.1008 (¶¶52, 69). Although Lynch does not explicitly teach a support that is made from a shape memory material, it would have been obvious for a POSITA to look for a suitable or desirable material to achieve the same goals as Lynch, *i.e.*, facilitating effective aqueous humor drainage through natural outflow pathways and reducing the amount of trauma to the eye during the insertion procedure. *See, e.g.*, Ex.1008 (¶¶24, 15, 17, 19, 23); Ex.1001 (¶179).

Gharib teaches making at least a portion of a Schlemm's canal support from biocompatible Nitinol, Ex.1005 (¶¶53, 63), which the '742 patent recognizes as a shape memory, biocompatible, nickel titanium alloy. Ex.1003 (3:10-12, 12:27-29, 13:9-12, 13:51-53, claim 8). Gharib teaches Nitinol allows for a support that "has a preshape and a shape-transition temperature, such that the shape-memory trabecular shunt bifurcates to its preshape when it is heated to above the shape-transition temperature." Ex.1005 (¶28); *see also Id.* (¶¶29, 53, 55, 62-63). Thus, Gharib teaches Nitinol is a suitable material with which to make at least a portion of a Schlemm's canal support because it is biocompatible and allows for a device to be delivered in a smaller form and then expand into a preshape post-insertion. Ex.1001 (¶180-181).

Thus, as taught by Gharib, a POSITA would have been motivated to use a shape memory material like Nitinol in Lynch because it is biocompatible, suitable for stent devices, and would allow for inserting Lynch's support in a more compact state that can then naturally return to its pre-shape after it is implanted. Ex.1001 (¶179-181). A smaller pre-insertion shape would reduce the trauma to the eye during the insertion procedure while also benefiting from the larger shape post-implantation to allow for effective transmission of aqueous through the natural outflow pathways. Ex.1001 (¶180-181). Further, a POSITA would have had a reasonable expectation of success in using shape memory material, such as Nitinol, for at least a portion of

Lynch's support because Gharib teaches the benefits and implementation of such materials in Schlemm's canal supports, and because Lynch teaches making such supports from a variety of materials, including metals. Ex.1008 (¶69); Ex.1001 (¶179-181).

Moreover, selecting this known material for an ophthalmic support is merely an obvious design choice well within the skill of an ordinarily skilled artisan. *Sinclair*, 325 U.S. at 335; *Hicks*, 85 U.S. at 673; *KSR*, 550 U.S. at 416; Ex.1001 (¶181).

2. Dependent Claim 7

> **The method of claim 6, wherein the shape memory material comprises a shape memory alloy.**

As discussed in §XI.H.1 above, it would have been obvious in light of Lynch and Gharib to make at least a portion of the support of shape-memory material, including nitinol. Ex.1001 (¶182).

3. Dependent Claim 8

> **The method of claim 7, wherein the shape memory alloy comprises a nickel titanium alloy.**

As discussed §XI.H.1-XI.H.2 above, it would have been obvious in light of Lynch and Gharib to make at least a portion of the support of nitinol. Ex.1001 (¶183).

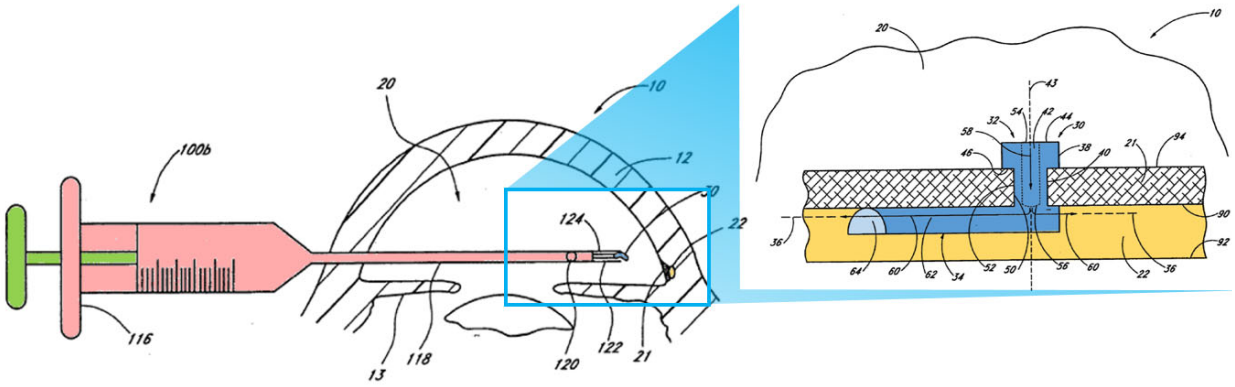
I. Ground 9: Lynch In View of Burns Renders Obvious Claims 19 and 20

1. Dependent Claim 19

The method of claim 1, further comprising preloading the support into an introducer and delivering the support from the introducer into Schlemm's canal.

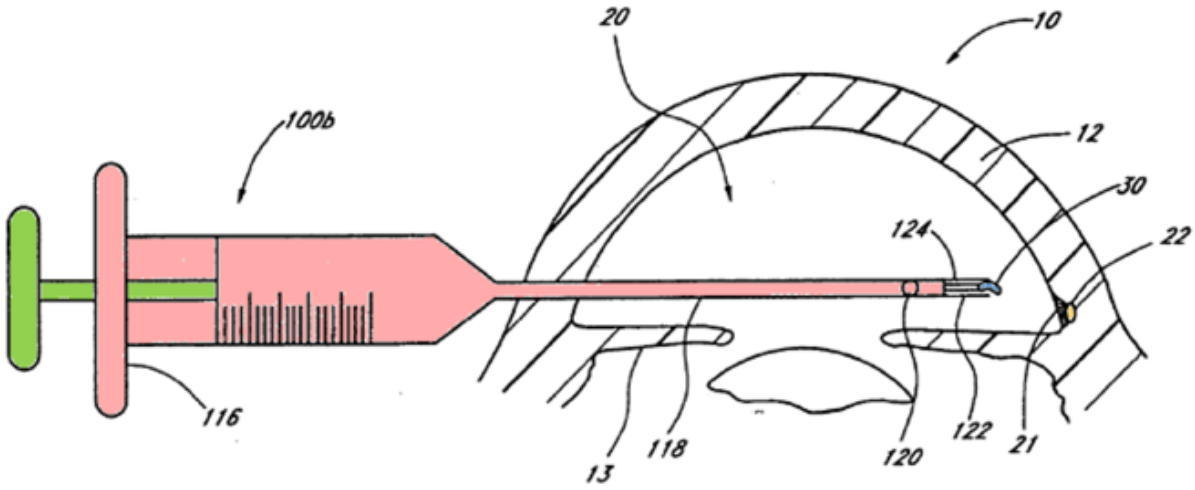
Lynch in combination with Burns renders obvious preloading an introducer for delivering the support. Although Lynch does not explicitly detail an "introducer," it would have been obvious for a POSITA to look to the prior art for a suitable introducer for Lynch's support. Ex.1001 (¶185).

For example, Burns discloses a "glaucoma treatment kit" that includes implants or stents packaged with delivery applicators to conveniently perform implantations into an eye. Ex.1007 (¶¶58, 127-132, 345-351, Figures 55A-E, cls. 1-8). Burns teaches delivering Schlemm's canal supports akin to Lynch's supports through a cannula, in which "[t]he distal section of the cannula portion 55 has…a distal space for holding the device 31." Ex.1007 (¶186, Figure 3); Ex.1001 (¶185).

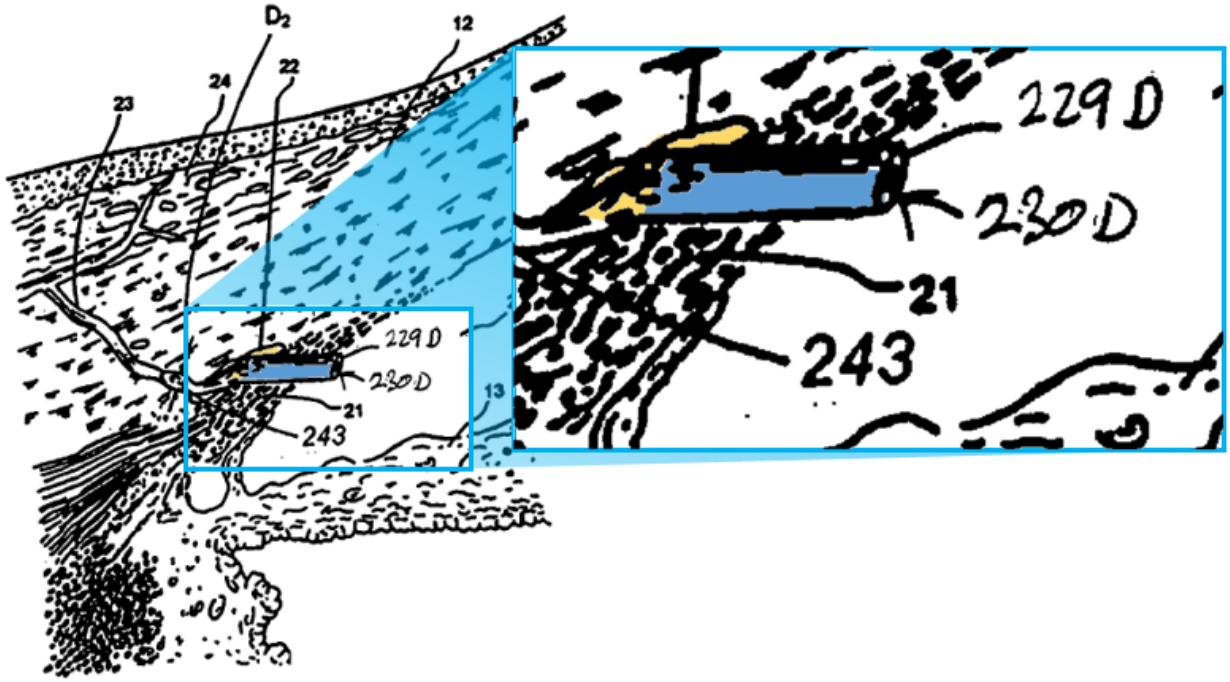


Burns Figs.3, 31

Burns' introducer is configured to hold and release a preloaded ocular stent into Schlemm's canal. Ex.1007 (¶188); Ex.1001 (¶186). By preloading and using a marked introducer, a user can ensure proper orientation for implantation of the support, which can then be delivered into Schlemm's canal by pushing it from the introducer. Ex.1007 (¶¶182, 252); Ex.1001 (¶186).



Ex.1007 Fig.31



Ex.1007 Fig.50B

Burns also teaches "[a]mong the advantages of [the invention] is its simplicity. The microsurgery may potentially be performed on an outpatient basis with rapid visual recovery and greatly decreased morbidity," lower infection risk, and faster recovery. Ex.1007 (¶37); Ex.1001 (¶187).

Accordingly, a POSITA would have been motivated to preload an introducer with Lynch's support, as taught by Burns, to improve the ease of delivery, safety, and recovery time for patients. Ex.1001 (¶188). Moreover, a POSITA would have had a reasonable expectation of success in preloading Lynch's support with Burns' introducer at least because Burns discloses that very combination and doing so would not modify any device or impede implantation. Ex.1001 (¶188). Combining devices into a single package or kit would have been obvious to a POSITA. *See*

Ormco Corp. v. Align Techs., Inc., 463 F.3d 1299, 1309 (Fed. Cir. 2006) (providing devices in one package "is not a novel or patentable feature in the light of the well-known practice of packaging items in the manner most convenient to the purchaser.").

2. Dependent Claim 20

The method of claim 19, wherein the support is delivered from the introducer using a pusher.

As discussed in §XI.I.1 above, Lynch in view of Burns teaches supports that can be pushed from the introducer into Schlemm's canal. Ex.1001 (¶189)

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 '742 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 12, 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 13,999 (14,000 limit) words.

/s/ *Kat Li*
Kat Li (Reg. No. 64,857)

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 12th day of September, 2022, via Federal Express® directed to PO at the correspondence address of record:

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