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.

IPR2022-01533
U.S. Patent No. 8,287,482

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

TABLE OF CONTENTS

Page

I. Introduction....1

II. Mandatory Notices....2

A. 37 C.F.R. § 42.8(b)(1): Real Parties-in-Interest....2

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

C. 37 C.F.R. § 42.8(b)(3) &(4): Lead and Back-up Counsel and Service Information....2

III. Payment of Fees Pursuant to 37 C.F.R. § 42.103....3

IV. Certification of Standing Under 37 C.F.R. § 42.104....3

V. Overview of Challenge and Relief Requested....3

A. 37 C.F.R. § 42.104(b)(1): Claims for Which IPR Is Requested....3

B. 37 C.F.R. § 42.104(b)(2): Grounds for Challenge....4

C. 37 C.F.R. § 42.104(b)(3): Claim Construction....5

D. 37 C.F.R. § 42.104(b)(4): How the Claims Are Unpatentable....7

E. 37 C.F.R. § 42.104(b)(5): Evidence Supporting Challenge....7

VI. Background of the Technology....7

A. Glaucoma....7

B. Surgical Glaucoma Treatments Were Well Known....10

C. Schlemm's Canal Implants Were Well Known....11

VII. The '482 Patent....13

A. Alleged Problem....13

B. Alleged Invention....14

C. Prosecution History 15

VIII. Discretionary Denial Is Not Appropriate Here 16

A. The Presented Grounds and Argument are Dissimilar to the Art and Arguments Previously Presented to the Office 16

1. *Becton Dickinson* Factors 16

B. Efficiency, Fairness, and the Merits Support the Exercise of the Board's Authority to Grant the Petition 17

1. *Fintiv* Factors 17

IX. Level of Ordinary Skill in the Art 19

X. Overview of the Primary Prior Art 19

A. Grieshaber 19

B. Lynch 20

XI. Each of the Challenged Claims Is Unpatentable 20

A. Ground 1: Grieshaber alone, or in combination with Bergheim renders obvious Claims 1-2, 5, 7-8, 10-11, 15, 18, 21, 23, 32-33, 36, 38-39, 41-42, 46, 49, 52, 54, 63, 65, 68-70, 73, 77, and 79-80. 20

1. Independent Claim 1 20

2. Dependent Claim 2 35

3. Dependent Claim 5 38

4. Dependent Claim 7 39

5. Dependent Claim 8 41

6. Dependent Claim 10 41

7. Dependent Claim 11 43

8. Dependent Claim 15 43

9. Dependent Claim 18 44
10. Dependent Claim 21 47
11. Dependent Claim 23 47
12. Independent Claim 32 48
13. Dependent Claim 33 50
14. Dependent Claim 36 51
15. Dependent Claim 38 51
16. Dependent Claim 39 51
17. Dependent Claim 41 51
18. Dependent Claim 42 52
19. Dependent Claim 46 52
20. Dependent Claim 49 52
21. Dependent Claim 52 52
22. Dependent Claim 54 53
23. Independent Claim 63 53
24. Dependent Claim 65 54
25. Dependent Claim 68 54
26. Dependent Claim 69 54
27. Dependent Claim 70 55
28. Dependent Claim 73 55
29. Dependent Claim 77 55
30. Dependent Claim 79 55
31. Dependent Claim 80 55

B. Ground 2: Lynch alone, or in combination with Bergheim render obvious Claims 1-2, 5, 7-8, 15, 18, 21, 23, 32-33, 36, 38-39, 46, 49, 52, 54, 63, 65, 68-70, 73, and 77 56

1. Independent Claim 1 56

2. Dependent Claim 2 67

3. Dependent Claim 5 69

4. Dependent Claim 7 72

5. Dependent Claim 8 74

6. Dependent Claim 15 74

7. Dependent Claim 18 78

8. Dependent Claim 21 81

9. Dependent Claim 23 81

10. Independent Claim 32 81

11. Dependent Claim 33 83

13. Dependent Claim 38 84

14. Dependent Claim 39 84

15. Dependent Claim 46 84

19. Independent Claim 63 85

20. Dependent Claim 65 86

22. Dependent Claim 69 87

23. Dependent Claim 70 87

25. Dependent Claim 77 87

C. Ground 3: Lynch alone, or in combination with Bergheim, further in view of Gharib render obvious claims 8, 10, 11, 39, 41, 42, 77 and 79-80 88

1. Dependent Claim 8 88
2. Dependent Claim 10 90
3. Dependent Claim 11 90
4. Dependent Claim 39 90
5. Dependent Claim 41 91
6. Dependent Claim 42 91
7. Dependent Claim 77 91
8. Dependent Claim 79 91
9. Dependent Claim 80 92

XII. Secondary Considerations of Nonobviousness.....92

XIII. Conclusion 93

*All emphases and coloring added, unless otherwise noted.

TABLE OF AUTHORITIES

Page(s)

Cases

Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH,
IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020).....16

In re Aller,
220 F.2d 454 (C.C.P.A. 1955).....66

Apple Inc. v. Samsung Electronics Co., Ltd.,
839 F.3d 1034 (Fed. Cir. 2016).....92

Apple v. Fintiv,
IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020).....17, 18, 19

Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.,
672 F.3d 1335 (Fed. Cir. 2012).....*passim*

Becton, Dickinson, & Co. v. B. Braun Melsungen AG,
IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017).....16

Bio-Rad Lab'ys. Inc. v. 10X Genomics, Inc.,
18-1679-RGA, 2020 WL 2849989 (D. Del. June 2, 2020).....18

Bowtech Inc. v. MCP IP, LLC,
IPR2019-00383, Paper 14 (PTAB Aug. 6, 2019).....17

Ethicon LLC v. Intuitive Surgical, Inc.,
17-871-LPS, 2019 WL 1276029 (D. Del. Mar. 20, 2019).....19

Fasteners for Retail, Inc. v. RTC Indus., Inc.,
IPR2019-00994, Paper 9 (PTAB Nov. 5, 2019).....16

Galderma Lab'ys, L.P. v. Tolmar, Inc.,
737 F.3d 731 (Fed. Cir. 2013).....34, 67

In re Geisler,
116 F.3d 1465 (Fed. Cir. 1997).....34, 67

Hicks v. Kelsey,
85 U.S. 670 (1873).....43, 90

Iron Grip Barbell Co. v. USA Sports, Inc.,
392 F.3d 1317 (Fed. Cir. 2004) 93

KSR Int'l Co. v. Teleflex Inc.,
550 U.S. 398 (2007).....43, 90

Merck & Co. Inc. v. Biocraft Lab. Inc.,
874 F.2d 804 (Fed. Cir. 1989) 34, 67

Paice LLC v. Ford Motor Co.,
722 Fed. App'x 1015 (Fed. Cir. 2018) 30

Phillips v. AWH Corp.,
415 F.3d 1303 (Fed. Cir. 2005) 5

Powers-Kennedy Contracting Corp. v. Concrete Mixing & Conveying Co.,
282 U.S. 175 (1930).....34, 67

SEVEN Networks, LLC v. Apple Inc.,
C.A. No. 2:19-cv-00115-JRG, Dkt. 313 (E.D. Tex. Sept. 22, 2020) 19

Sight Sciences, Inc. v. Ivantis, Inc.,
C.A. No. 21-1317-GBW (D. Del.).....1

Sinclair & Carrolll Co. v. Interchemical Corp.,
325 U.S. (1945).....43, 90

Statutes

35 U.S.C. §112.....6

35 U.S.C. § 325(d) 16

America Invents Act 13

Other Authorities

37 C.F.R. § 1.68 7

37 C.F.R. § 42.8 2

37 C.F.R. § 42.10(b) 3

37 C.F.R. § 42.100(b) 5

37 C.F.R. § 42.103 3

37 C.F.R. § 42.104 .....3, 4, 5, 7

TABLE OF EXHIBITS

Exhibit No.	Description
1001	Declaration of Dr. Michael Reynard
1002	Curriculum Vitae of Dr. Michael Reynard
1003	U.S. Patent No. 8,287,482
1004	File History of U.S. Patent No. 8,287,482
1005	U.S. Pub. No. 2002/0165478 ("Gharib")
1006	U.S. Pub. No. 2003/0060752 ("Bergheim")
1007	RESERVED
1008	U.S. Pub. No. 2005/0038334 ("Lynch '334")
1009	RESERVED
1010	U.S. Pub. No. 2004/0193262 ("Shadduck")
1011	U.S. Pub. No. 2006/0195187 ("Stegmann")
1012	CA 2244646 ("Grieshaber")
1013	"A History of the Surgical Management of Glaucoma," Razeghinejad & Spaeth
1014	"An Operation for Glaucoma," Stefansson
1015	"How Does Nonpenetrating Glaucoma Surgery Work? Aqueous Outflow Resistance and Glaucoma Surgery," Johnson & Johnson
1016	U.S. Patent No. 7,192,412 ("Zhou")
1017	WO 2006/066103 ("Stegmann")
1018	Excerpts of Sight Sciences Inc.'s Corrected Initial Infringement Contentions (Aug. 26, 2022)

Exhibit No.	Description
1019	Sight Sciences Inc.'s Second Amended Complaint (D.I 59)
1020	Exhibits A-P for Sight Sciences Inc.'s Second Amended Complaint (D.I. 59-1)
1021	2022-03-28 D27 ORAL ORDER Case assigned to District of Delaware's VAC (D.I. 27)
1022	2022-04-11 D30 ORAL ORDER referring case to Magistrate Judge S. Fallon (D.I. 30)
1023	LexMachina Statistics
1024	Merriam Webster Collegiate Dictionary
1025	U.S. Pub. No. 2004/0254520 ("Porteous")
1026	Docket, *Sight Sciences, Inc. v. Ivantis, Inc.*, 1:21-cv-01317-GBW (D. Del)
1027	"Glaucoma drainage implants: a critical comparison of types," Schwartz et al. (2006)
1028	"Glaucoma drainage implants," Sidoti & Baerveldt (1994)
1029	U.S. Pub. No. 2005/0266047 ("Tu")
1030	WO 2000064391 ("Lynch '391")
1031	WO 2001097727 ("Hosheng")
1032	Sight Sciences, Inc.'s Answer to Ivantis, Inc.'s Counterclaims (D.I. 26), *Sight Sciences, Inc. v. Ivantis, Inc.*, C.A. No. 21-1317-GBW (D. Del.)
1033	Sight Sciences, Inc.'s Responses and Objections to Defendant Ivantis, Inc.'s First Set of Interrogatories (Nos. 1-7) (May 23, 2022), *Sight Sciences, Inc. v. Ivantis, Inc.*, C.A. No. 21-1317-GBW (D. Del.)

I. INTRODUCTION

U.S. Patent No. 8,287,482 ("'482 patent") is one of several patents in a family directed to a concept 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 '482 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 ("PO") assertion of the '482 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. Given 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 requests *inter partes* review ("IPR") of '482 claims 1-2, 5, 7-8, 10-

11, 15, 18, 21, 23, 32-33, 36, 38-39, 41-42, 46, 49, 52, 54, 63, 65, 68-70, 73, 77, 79-80 ("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

PO asserted the '482 against Petitioners in the Delaware Litigation. Petitioners are concurrently filing IPR petitions for three other patents in the same family as the '482 patent, all of which are asserted in the Delaware Litigation: U.S. Patent Nos. 9,370,443; 9,486,361; and 10,314,742.[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

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

	W. Todd Baker Reg. No. 45,265 todd.baker@kirkland.com Justin Bova Reg. No. 70,336 justin.bova@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

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 '482 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 1-2, 5, 7-8, 10-11, 15, 18, 21, 23, 32-33, 36, 38-39, 41-42, 46, 49, 52, 54, 63, 65, 68-70, 73, 77, and 79-80 of the '482 patent.

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

Petitioners challenge the claims based on the following references:

1. 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).

2. 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).

3. 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).

4. 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).

Petitioners request IPR on the following grounds:

Ground	Basis	Claims	Reference(s)
1	§ 103	1-2, 5, 7-8, 10-11, 15, 18, 21, 23, 32-33, 36, 38-39, 41-42, 46, 49, 52, 54, 63, 65, 68-70, 73, 77, and 79-80	Grieshaber alone, or in combination with Bergheim
2	§ 103	1-2, 5, 7-8, 15, 18, 21, 23, 32-33, 36, 38-39, 46, 49, 52, 54, 63, 65, 68-70, 73, and 77	Lynch alone, or in combination with Bergheim
3	§ 103	8, 10-11, 39, 41-42, 77 and 79-80	Lynch alone, or in combination with Bergheim, further in view of Gharib

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 PO submits.

The ’482 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 PO'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 '482 patent states "[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." Ex.1003 (11:16-20). There is nothing in the '482 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 discussed in the '482 Patent (estimated as a slightly arcuate cylinder), Sight Sciences' Delaware Complaint ignores the specification and assumes Schlemm's canal is a regular cylinder.[3] *See* Ex.1020 (Ex.L at 19 (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 *Inter Partes* Review, Petitioners adopt PO's construction of this term, which assumes the scope

[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.

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 details how the Challenged Claims are unpatentable.

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

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

VI. BACKGROUND OF THE TECHNOLOGY

A. Glaucoma

Glaucoma is an ophthalmic condition characterized by elevated intraocular pressure, which in turn places increased pressure on the optic nerve and can lead to loss of vision if left untreated. Ex.1001 (¶23) (citing Ex.1008 (¶6)). Elevated pressure results from an internal imbalance of 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.* (citing Ex.1008 (¶7)). The fluid then flows through the trabecular meshwork, 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.* (citing Ex.1008 (¶8)). After passing through the trabecular meshwork, aqueous humor flows into

Schlemm's canal, which abuts the trabecular meshwork and encircles the posterior junction of the cornea and sclera. *Id.* In general, Schlemm's canal is a flexible, continuous passage (or vessel) that goes 360-degrees around the eye. *Id.* The cross-section of Schlemm's canal, therefore, varies as well. After aqueous humor flows into Schlemm's canal, it exits through collector channel openings in the wall of Schlemm's canal and is cleared by the venous system. *Id.* (citing Ex.1008 (¶9)). Figure 2 of '482 patent itself shows the general flow of aqueous humor from ciliary body 12 between lens 16 and iris 18, through pupil 22 into the anterior chamber 20, across the trabecular meshwork 28, and into Schlemm's canal 30. Ex.1003 (6:39-48).

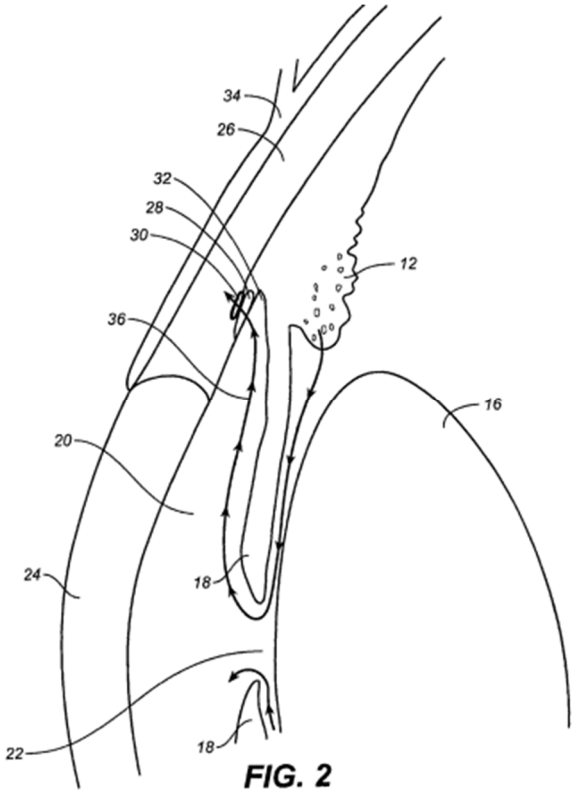


FIG. 2

Ex.1003 Fig.2

In healthy eyes, aqueous humor production approximately equals aqueous humor outflow, keeping intraocular pressure fairly constant. Ex.1001 (¶24) (citing Ex.1008 (¶7)). In primary open angle glaucoma—the most common form of glaucoma—ocular pressure can increase due to decreased aqueous humor outflow across the trabecular meshwork and through Schlemm's canal. Ex.1001 (¶24) (citing Ex.1008 (¶8-9)). Schlemm's canal can also collapse, which prevents aqueous humor outflow into the collector channels and out through the body's normal outflow pathways. Ex.1001 (¶24) (citing Ex.1012 (5:11-17)); *see also* Ex.1003 (1:60-63). Thus, many glaucoma treatments seek to improve aqueous humor outflow across these structures. Ex.1001 (¶24) (citing Ex.1008 (¶¶13-19)).

B. Surgical Glaucoma Treatments Were Well Known

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

The trabecular meshwork and inner wall of Schlemm's canal are understood to be the sites of increased resistance in glaucoma patients, and therefore, treatments are generally directed at bypassing diseased tissue. Ex.1001 (¶26) (citing Ex.1015 (Abstract)). In 1925, Stefansson invented gold wire implants designed to channel aqueous out of the anterior chamber (figures below). Ex.1001 (¶26) (citing Ex.1014 (681, 683)). The perpendicular ends of the supports below (the twisted ends of 1, 2, and 4 and the vertical tube in 3), inserted into the anterior chamber, provided an outlet for excess aqueous humor to exit the chamber through the resulting opening. Ex.1001 (¶26) (citing Ex.1014 (683-684)).

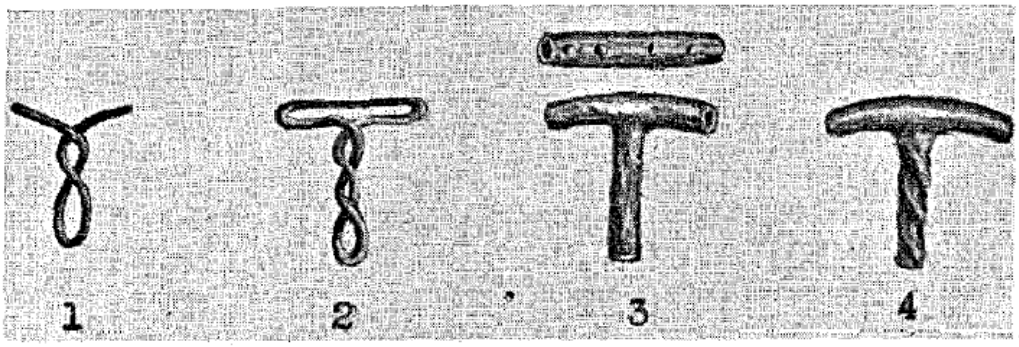
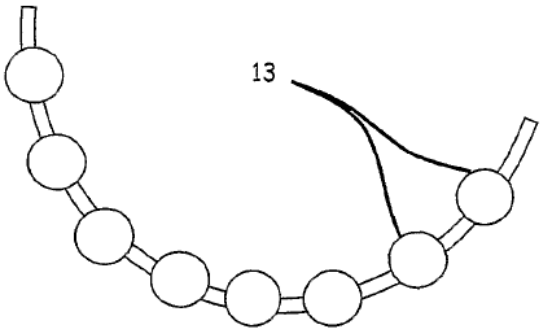


Fig. 3. Different types of inserts used in order of design. Base of No. 3 perforated to facilitate drainage.

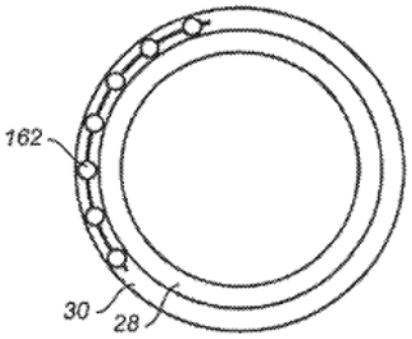
Many known devices, such as shunts and stents, channel aqueous humor out of the anterior chamber to reduce pressure very similarly to Dr. Stefansson's devices. Device designs vary, but generally fall within two categories: (1) treatments that create a new outflow pathway and (2) treatments that encourage 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. Ex.1001 (¶27).

C. Schlemm's Canal Implants 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 bears striking resemblance to the alleged invention. *Id*. (Abstract).

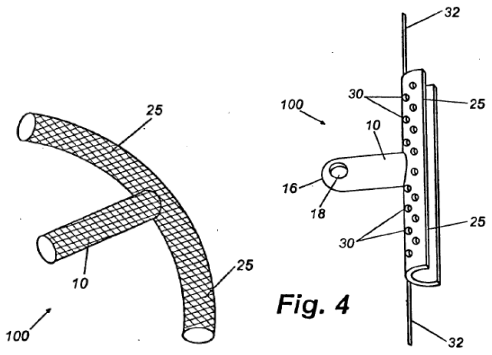


Ex.1017 (Stegmann) Fig.4a.

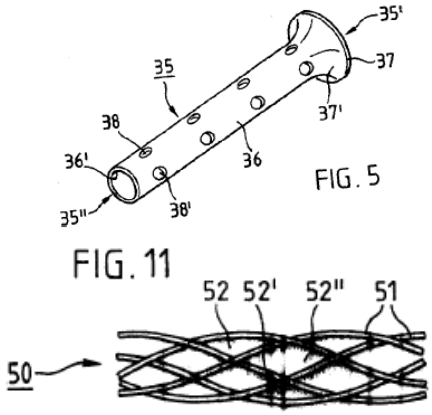


Ex.1003 Fig.10B

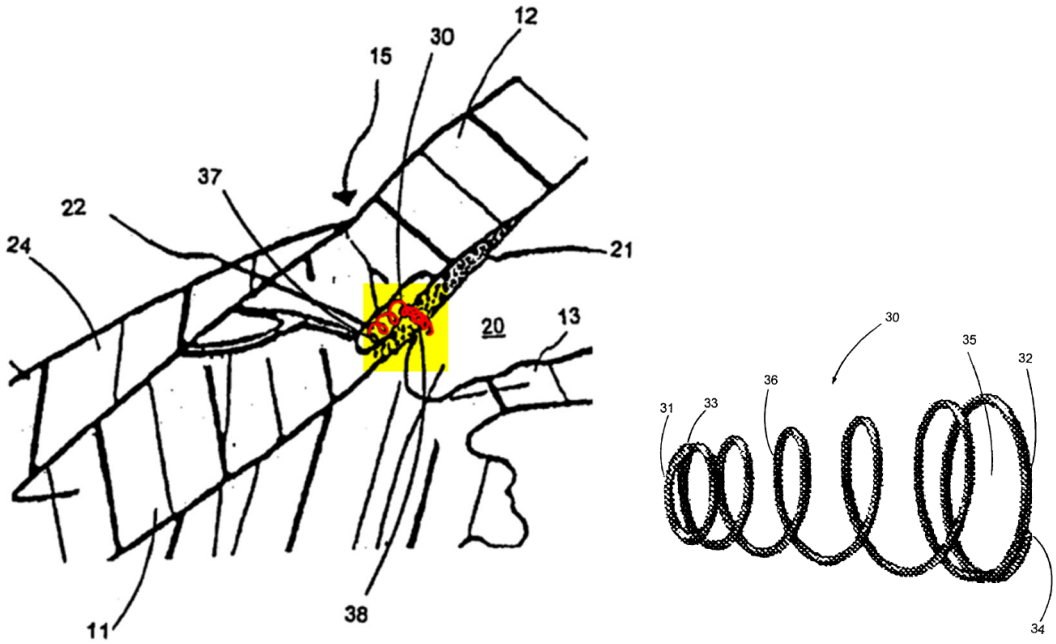
Recognizing these devices can occlude the flow of aqueous into Schlemm's canal and out through the collector channels, it was well known to design Schlemm's canal supports with fenestrations, mesh, or trough-like features to reduce the surface area contact between the implant and the wall of Schlemm's canal. *See, e.g.*, Ex.1012 (8:4-6); Ex.1005 (¶29, 56 (describing mesh, porous, fenestrated, coil, spiral, and permeable supports)); Ex.1008 (¶53, 55, 57, Fig.1C). Some examples are shown here:



Ex.1008 Figs.1C, 4



Ex.1012 Figs.5, 11



Ex.1025 Figs.3 (annotated), 4A

VII. THE '482 PATENT

The '482 patent issued from Application No. 12/695,053, filed January 27, 2010, and claims to be a continuation of application No. 11/475,523, filed June 26, 2006. Ex.1003. Because the application claims priority to an application filed before March 16, 2013, its patentability is not governed by the America Invents Act.

A. Alleged Problem

The '482 patent admits using bypass stents "to bridge a blocked trabecular meshwork" and to connect the anterior chamber to Schlemm's canal were both known. Ex.1003 (2:22-25). Allegedly, "it is difficult to consistently and reliably implant a bypass stent." Ex.1003 (2:25-27). The '482 patent also suggests "stents can become clogged and lose functionality over time," a problem that allegedly

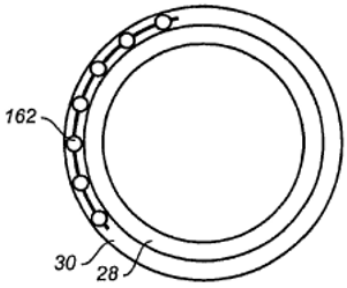
happens even to so-called "tubular elongated cylindrical hollow stents" "as a result of occlusion or scarring." *Id*. (2:27-33). According to the '482 patent, the walls of tubular stents "can have significant surface area contact with the trabecular meshwork and/or the collector channels, which can result 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*. (2:41-47). Finally, the '482 patent states "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*. (2:34-38).

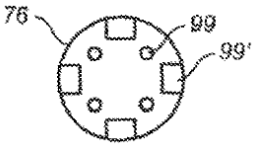
B. Alleged Invention

The '482 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 (2:55-59).

The '482 patent describes traditional Schlemm's canal stent elements: a solid or hollow, biocompatible support inserted into Schlemm's canal to improve aqueous humor flow from the anterior chamber and eventually into the collector channels. Ex.1003 (3:47-52). The support may take a variety of configurations, *e.g.*, having "smooth, rough, spiked, or fluted" surfaces, "made from mesh," or including fenestrations. *Id*. (3:49-50).

The ’482 patent provides the following exemplary embodiments of the devices:





Ex.1003 Fig.7B **Ex.1003 Fig.10B** **Ex.1003 Fig.6C**

Figure 7B shows an exemplary support comprising of beads, labeled 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*. (9:35-38; 14:28-29). Figure 10B shows the support positioned inside Schlemm’s canal. *Id.* (11:53-54).

C. Prosecution History

During prosecution, the ’482 patent examiner rejected the claims as anticipated over U.S. Pub. No. US 2004/0193262 (“Shadduck”) (Ex.1010) and as obvious based on the combination of Shadduck and U.S. Pub. No. 2006/0195187 (“Stegmann”) (Ex.1011). PO amended each independent claim to recite “having at least one fenestration” and “wherein when the support is disposed within a cylindrical section of the lumen of the canal having an internal wall surface area C,

the support contacts less than 30% of C" and argued the prior art does not disclose these limitations or "lead one skilled in the art to think that it would be desirable to adjust the amount of contact with Schlemm's canal, especially contact of less than 30% of the internal wall surface area of Schlemm's canal, as claimed." Ex.1004 (120-126); Ex.1001 (¶38-40).

VIII. DISCRETIONARY DENIAL IS NOT APPROPRIATE HERE

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

1. *Becton Dickinson* Factors

All factors considered by the Board under 35 U.S.C. § 325(d) weigh in favor of institution. *Becton, Dickinson, & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017); *see also Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020). The Board has consistently "held that a reference that 'was neither applied against the claims nor discussed by the Examiner' does not weigh in favor of exercising [] discretion under §325(d)." *Fasteners for Retail, Inc. v. RTC Indus., Inc.*, IPR2019-00994, Paper 9 at 7–11 (PTAB Nov. 5, 2019). The grounds presented in the petition include obviousness challenges applying Grieshaber and Lynch as base references, neither of which was applied against the Challenged Claims or discussed by the Examiner during prosecution of the '482 patent or its parent

applications. In addition, none of the references applied by the examiner in either the '482 patent or its parent applications is cumulative of the references cited here.

During prosecution the '482 patent, the 482 was rejected over Shadduck and Stegmann. PO argued the prior art failed to disclose "having at least one fenestration" and the "30% of C" surface area contact limitation. These distinctions are not applicable to either Grieshaber or Lynch, both of which teach fenestrations and reducing surface area contact.

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

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

1. *Fintiv* Factors

Taking into consideration Director Vidal's recent memorandum, the Board should not exercise its discretion under § 314(a) in light of the Delaware Litigation. This petition presents evidence that the '482 patent claims are met by the prior art such that, if unrebutted at trial, would plainly lead to a conclusion that one or more claims are unpatentable by a preponderance of the evidence. *See* Section XI. Accordingly, the Board should not discretionarily deny institution of this compelling, meritorious challenge to the '482 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. 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.1026. 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.*, 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.,* 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 (¶42-43).

X. OVERVIEW OF THE PRIMARY PRIOR ART

A. Grieshaber

Grieshaber teaches treatments for reducing intraocular pressure in glaucoma patients by propping open Schlemm's canal with a support to 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 (8:6-13; 9:1-18; 10:1-12; 11:9-11; 14:6-15; cls 16, 18). The support can be "designed conically tapering" (Ex.1012 (12:1-2)), can have a torus-shaped transition portion (*Id*. (8:15-17)), or be made of a helicoidal network of threads (*Id*. (10:5-7)).

B. Lynch

Lynch teaches glaucoma treatments using shunt devices that improve aqueous outflow through natural pathways. Ex.1008 (Title, Abstract, ¶¶3, 24). Lynch's devices are implanted within Schlemm's canal to maintain the patency of the canal. *Id*. (¶¶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." *Id*. (¶53, 64).

XI. EACH OF THE CHALLENGED CLAIMS IS UNPATENTABLE

A. Ground 1: Grieshaber alone, or in combination with Bergheim renders obvious Claims 1-2, 5, 7-8, 10-11, 15, 18, 21, 23, 32-33, 36, 38-39, 41-42, 46, 49, 52, 54, 63, 65, 68-70, 73, 77, and 79-80.

1. Independent Claim 1

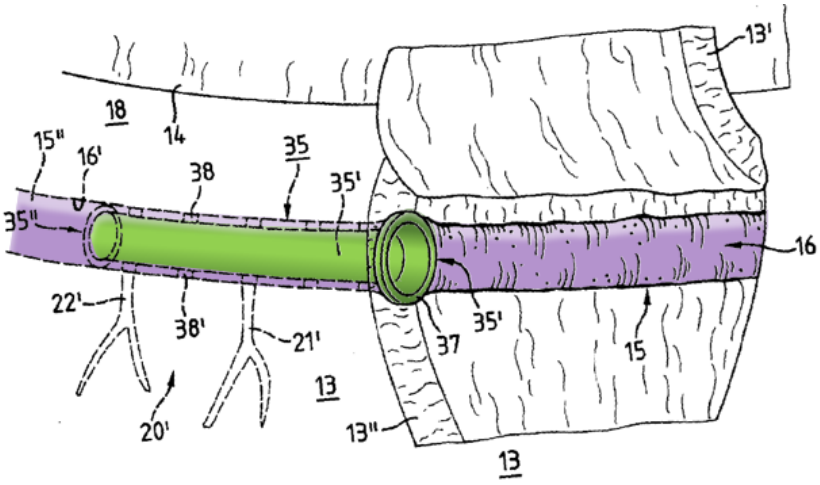
a. "A device comprising"

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, Grieshaber discloses treating glaucoma with a "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 (¶46).

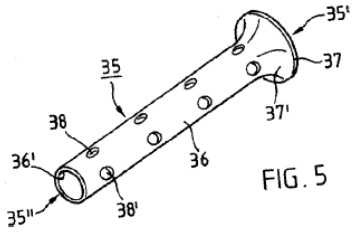
b. **"a support having at least one fenestration that is longitudinally insertable into a lumen of Schlemm's canal;**

Grieshaber discloses inserting supports longitudinally into Schlemm's canal. Ex.1012 (8:18-22, 10:13-15, 12:16-20, 13:8-12). After the support is inserted, Schlemm's canal is "permanently held in an expanded position" by supporting the inner wall 16' of Schlemm's canal as shown in Figure 4 below. Ex.1012 (2:11-21, Fig.4, cls 5-6). Ex.1001 (¶47).

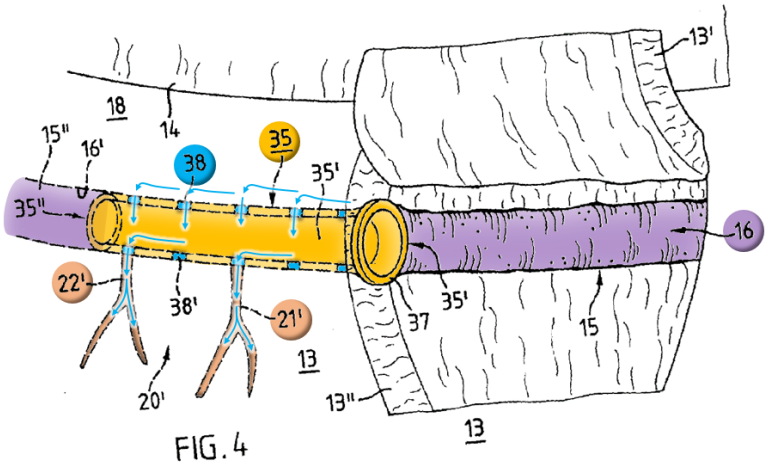


Ex.1012 Fig.4 (annotated)

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, 8:6-9:18, Figs.4-7). Ex.1001 (¶48).

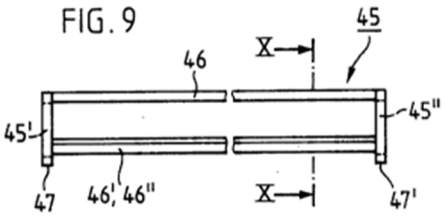


Ex.1012 Fig.5

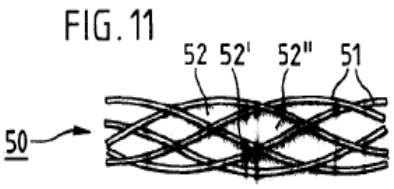


Ex.1012 Fig.4 (annotated)

Grieshaber discloses additional supports having at least one fenestration. These include intertwined helicoidal networks, Ex.1012 (10:5-7, Fig.11), or "axially spaced toruses" that are connected by webs, *id*. (9:18-10:4, Fig.9). The gaps 52,52', and 52'' between the threads 51 in the helicoidal network of threads (Fig.11) and the "recesses" "provided between the webs 46,46', and 46'' in Figure 9" serve as outflow openings to drain aqueous humor. *Id*. (10:2-4, 10:10-12). Ex.1001 (¶49).



Ex.1012 Fig.9

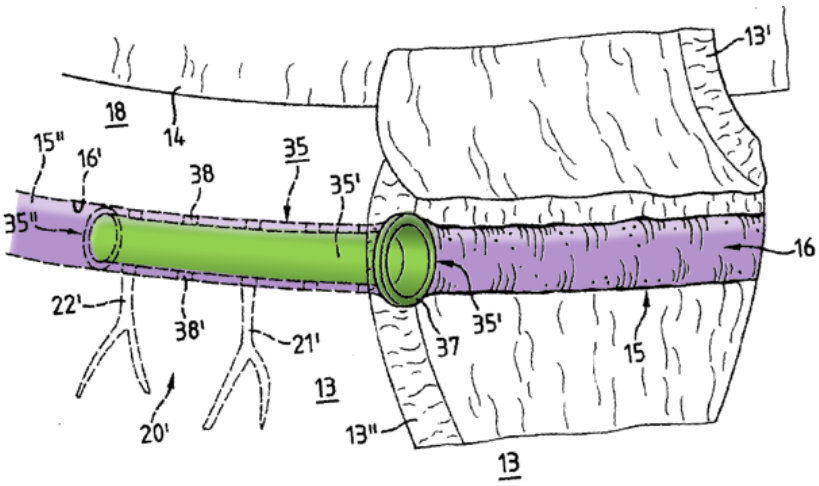


Ex.1012 Fig.11

A POSITA would recognize Grieshaber's "throughholes" in Figures 4 and 5, "gaps" in Figure 11, and "recesses" between the webs in Figure 9 as "fenestrations" in the supports. Ex.1001 (¶50-51).

c. **"the support having a cross-sectional dimension sufficient to at least partially prop open Schlemm's canal upon insertion into the canal, and to thereby maintain patency of at least a portion of the canal so that fluid may traverse the canal without substantial interference from the support"**

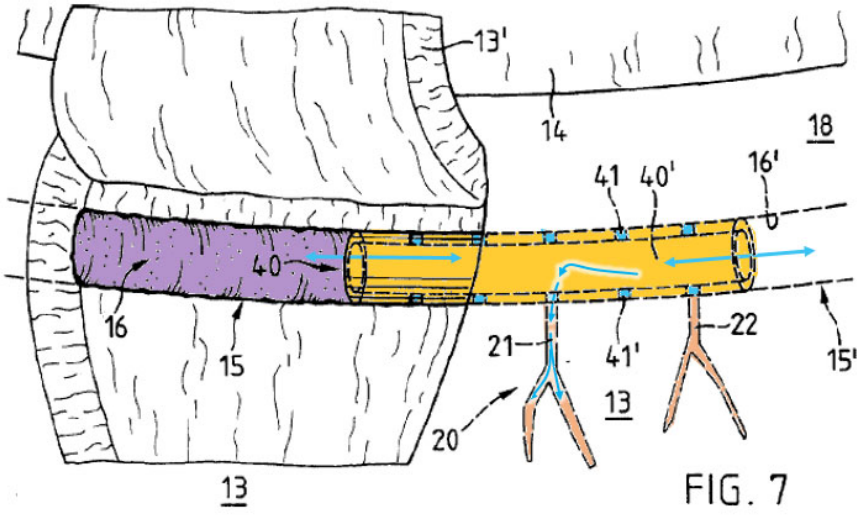
Grieshaber discloses that, after implanting the support, Schlemm's canal is "permanently held in an expanded position." Ex.1012 (2:11-21; *id.* 14:5-10, cls 1, 5-6). Thus, Grieshaber's supports (as depicted, for example, in Figs.4, 9-11) have a cross-sectional dimension sufficient to at least partially prop open Schlemm's canal upon insertion. Ex.1001 (¶52-53). Figure 4 shows a support propping open inner wall 16' of Schlemm's canal:



Ex.1012 Fig.4 (annotated)

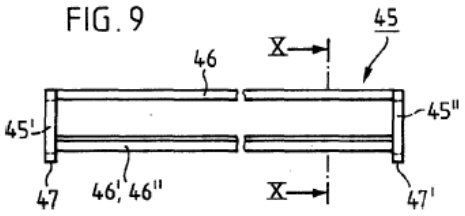
Grieshaber's supports also maintain the patency of at least a portion of the canal so that fluid may traverse the canal without substantial interference from the support. For example, Grieshaber discloses the support can be hollow or "substantially hollow," Ex.1012 (11:16-17; 13:8-11), and that "[t]he 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*." *Id*. (9:3-10, Figs.4-7). Grieshaber emphasizes the importance of including throughholes/openings in the supports for aqueous humor to flow across Schlemm's canal and to the collector channels as shown in Figure 7 below. *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). Thus, Grieshaber's support facilitates, rather than substantially interferes with, fluid traversing the canal. Ex.1001 (¶53-62).



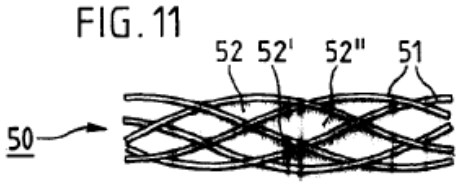
Ex.1012 Fig.7 (annotated)

Similarly, Figures 9 and 11 show supports with openings and hollow centers that would allow fluid to traverse the canal without substantial interference when inserted into Schlemm's canal to prop it open. Ex.1001 (¶54-55).



Ex.1012 Fig.9

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



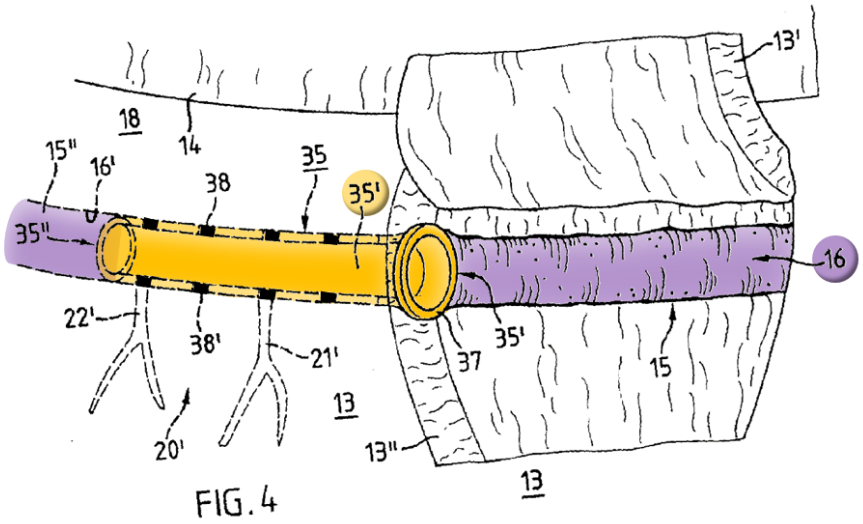
Ex.1012 Fig.11

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

d. **"wherein when the support is disposed within a lumen of Schlemm's canal, contact between the support and a wall of the canal is discontinuous along a perimeter of the lumen of the canal,"**

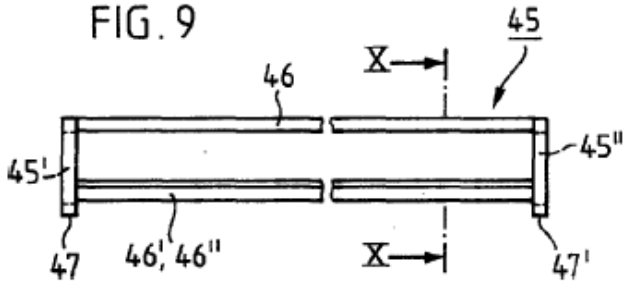
The '482 patent lacks clear guidance regarding what constitutes "discontinuous" contact. For this IPR, Petitioners have adopted PO's interpretation that "discontinuous contact" at least includes a support having any openings or non-contact points. *See, e.g.*, Ex.1018 (26).

As discussed in §XI.A.1.b, Grieshaber discloses supports disposed within a lumen of Schlemm's canal and "provided with a number of throughholes…distributed axially and circumferentially spaced." Ex.1012 (8:4-10); *see also Id.* (7:17-8:6, 8:11-9:10, 9:11-18, Figs.4-7). Ex.1001 (¶64). As illustrated by Figure 4, Grieshaber's throughholes create "discontinuous" contact along the perimeter of the lumen of the canal (consistent with PO's interpretation).

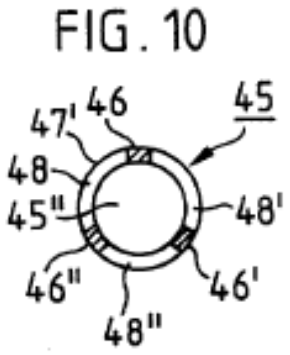


Ex.1012 Fig.4 (annotated, throughholes annotated in black)

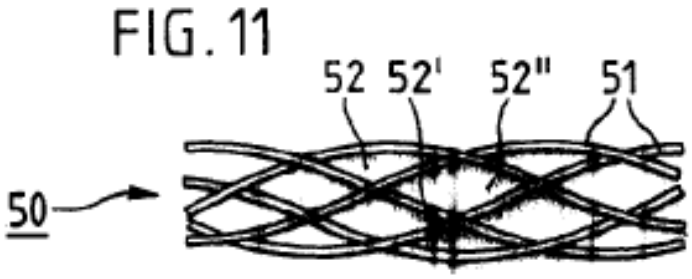
Similarly, the outflow openings between the webs and threads of the supports shown in Figures 9 and 11 create discontinuous contact between the support and the wall of Schlemm's canal along a perimeter of the canal. Ex.1001 (¶65-66).



Grieshaber Fig.9



Grieshaber Fig.10



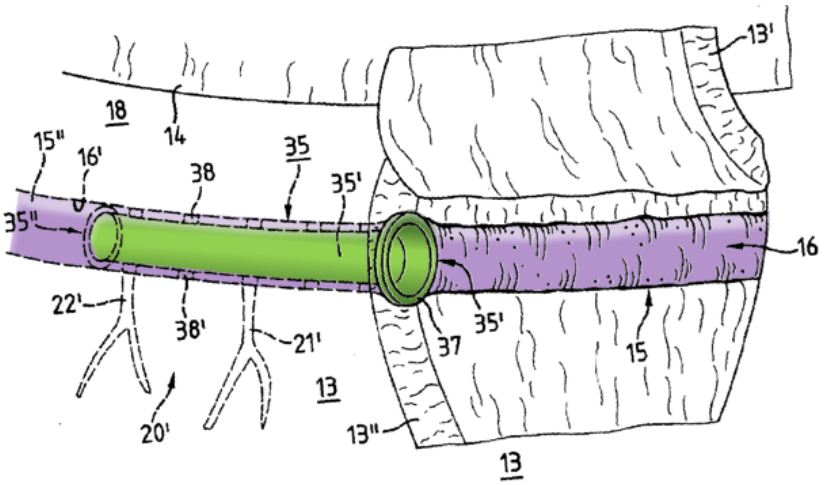
Ex.1012 Fig.11

Thus, consistent with PO's interpretation, Grieshaber's supports with throughholes/outflow openings make "discontinuous" contact along the perimeter of the lumen of the canal. Ex.1001 (¶63-66).

e. **"wherein when the support is disposed within a cylindrical section of the lumen of the canal having an internal wall surface area C, the support contacts less than 30% C."**

As discussed in §V.C, for this IPR, Petitioners have adopted PO's interpretation that Schlemm's canal is cylindrical.[4] Grieshaber's supports are disposed within a cylindrical section of the lumen of Schlemm's canal. Ex.1001 (¶67-68); Ex.1012 (7:17-9:18, 10:13-15, 12:16-20, 13:8-12, Figs.4-7, 9-12).

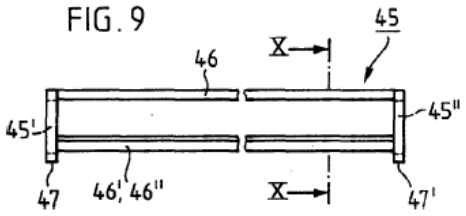
[4] Schlemm's Canal is not in fact cylindrical. Ex.1001 (¶67).



Ex.1012 Fig.4 (annotated)

As discussed in §V.C, for this IPR, Petitioners have adopted PO'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 '482 Patent's description as a "slightly arcuate cylinder"). Adopting PO's approximation, Grieshaber teaches a variety of shapes and designs that would have reduced contact with the inner wall surface of Schlemm's canal when implanted, including below 30% C.

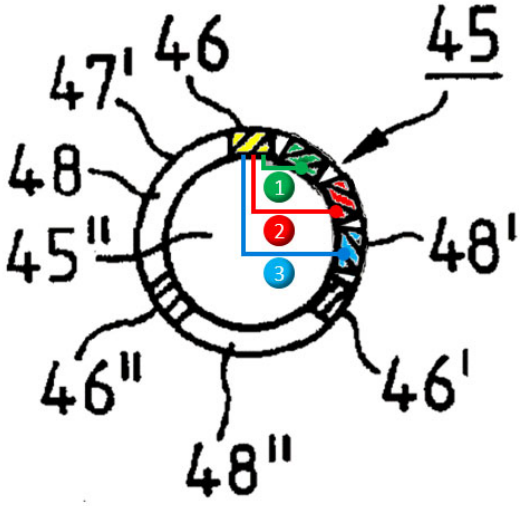
For example, Grieshaber discloses "axially spaced toruses" connected by "at least two, but preferably three webs 46,46', and 46,'' placed circumferentially at intervals linking the end portions 47,47' to each other" where "the recesses 48,48', and 48'' [*i.e.,* empty spaces] provided between the webs 46,46', and 46'' serve in each case as outflow openings for the aqueous humor." Ex.1012 (9:19-10:4, Figs.9, 10); Ex.1001 (¶72).



Ex.1012 Fig.9

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

Figure 10 (a side view of Fig.9) contains three webs (46,46', 46''). Although shown with three webs, as noted above, as few as two webs can connect the round toruses in 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 (¶72).

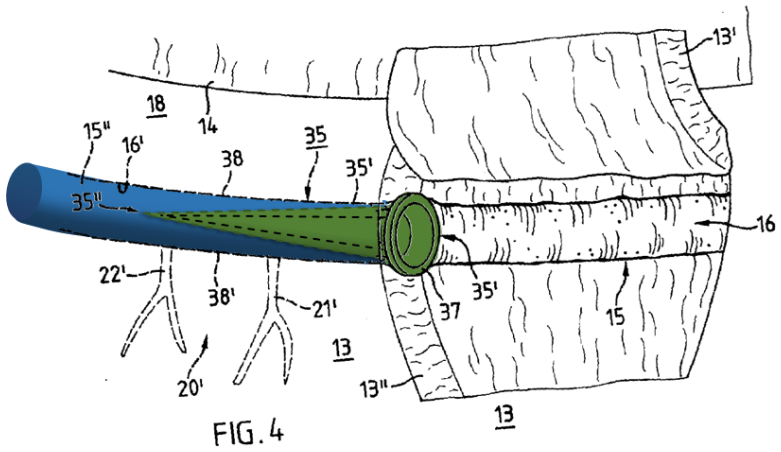


Ex.1012 Fig.10 (annotated and modified)

Accordingly, even assuming the webs were flush against the canal wall when this support is implanted, it would take approximately twelve webs to fill the entire cylindrical-shaped support. *See* Ex.1001 (¶72). Grieshaber's disclosure of three

webs, therefore, would contact at most approximately one fourth (*i.e.,* 3/12 or 25%) of the canal's wall. *See* Ex.1001 (¶72). Grieshaber's disclosure of "at least two" webs would mean even lower surface area contact (*i.e.,* 2/12 or 16.7%). *See* Ex.1001 (¶72). Thus, it would have been immediately apparent to a POSITA that Grieshaber discloses supports that contact less than 30% of the surface area of Schlemm's canal. *See* Ex.1001 (¶72); *see also Paice LLC v. Ford Motor Co.*, 722 Fed. App'x 1015, 1022 (Fed. Cir. 2018) (explaining it was reasonable for an expert to rely on visual inspection of patent figures to scale components relative to each other).

Grieshaber further emphasizes the importance of reducing surface area contact and providing aqueous outflow openings in its supports. For example, Grieshaber teaches a support that is "conically tapered axially" from one end to the other. Ex.1012 (8:18-22). This design, shown in the annotated image below, would contact the inner surface of Schlemm's canal at one end and taper away from the surface toward the other end, necessarily contacting less than 30% of the surface area (over the support's length). Ex.1001 (¶70).

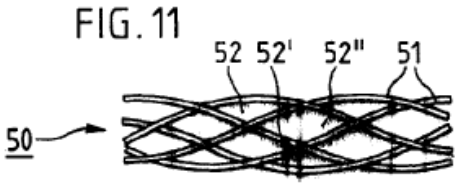


Ex.1012 Fig.4 (annotated and modified)

Moreover, Grieshaber's supports are designed to facilitate aqueous transmission from the anterior chamber into Schlemm's canal, and finally, out through the collector channels, 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, 8:6-9:18, Figs.4-7). A POSITA would have understood that increasing the number of throughholes improves the likelihood of connecting with the collector channels for outflow and therefore a POSITA would have been motivated to further increase the number of throughholes to achieve that goal. Ex.1001 (¶71).

Another Grieshaber support having reduced surface area contact 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, Cl.18, Fig.11). Grieshaber's helicoidal network support is akin

to the ’482 patent’s disclosure that a support may be “made from mesh” and “can have an open network structure,” which the ’482 patent recognizes “will have minimal surface area contact with the walls of Schlemm’s canal.” Ex.1003 (3:49-50; 10:54-55); Ex.1001 (¶71).



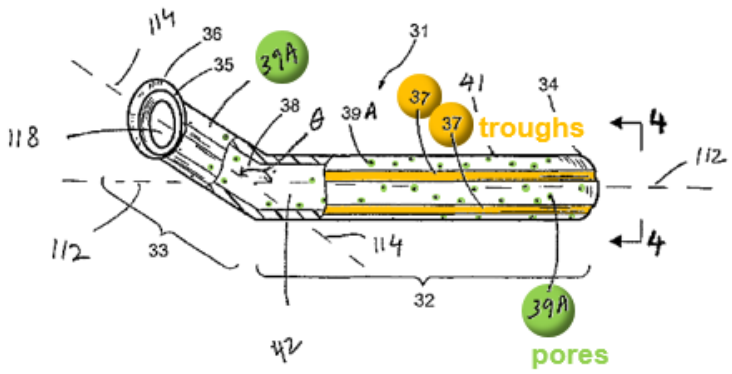
Ex.1012 Fig.11

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

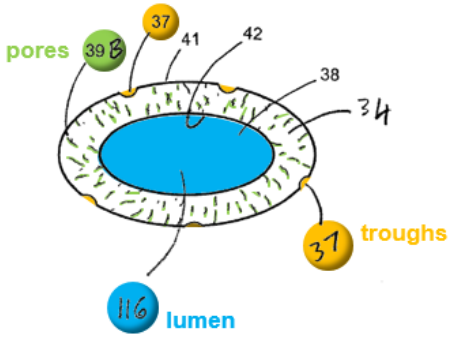
A POSITA, in light of Grieshaber, would have been motivated to increase the number and size of outflow openings in supports (*e.g.*, Figs.4-9), which necessarily reduces the surface area contact with the wall of Schlemm’s canal, to permit better aqueous flow and to avoid blocking collector channels. *See* Ex.1001 (¶73). A POSITA would also have had a reasonable expectation of success in increasing the amount and size of the outflow pathways while maintaining the support function because Grieshaber itself teaches multiple embodiments so designed, including designs necessarily making less than 30% surface area contact. Grieshaber (8:18-22; Figs.9-10). *See* Ex.1001 (¶73-74).

While Grieshaber alone provides sufficient motivation to reduce surface area contact and a reasonable expectation of success, Bergheim provides additional motivation to reduce the surface area contact to improve aqueous humor outflow.

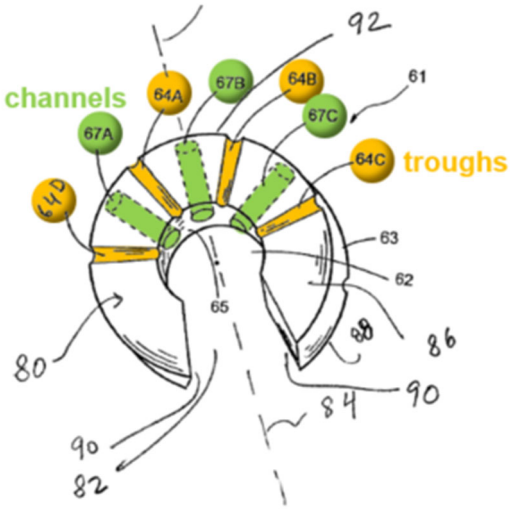
For example, Bergheim discloses devices for reducing intraocular pressure by restoring existing outflow pathways, including Schlemm's canal. Ex.1006 (¶¶3, 35). Bergheim teaches the benefits of increased porosity of devices—to "facilitate efficient transport and/or transfusion of aqueous humor." Ex.1006 (¶71). Bergheim also teaches removing material from the exterior surface of the device, such as including 20+ troughs on the exterior surface, or 20+ channels to improve aqueous transmission. Ex.1006 (¶¶73-76, 100-111; Figs.3, 4 and 7 below). *See* Ex.1001 (¶75-76).



Ex.1006 Fig.3 (annotated)



Ex.1006 Fig.4 (annotated)



Ex.1006 Fig.7 (annotated)

Bergheim would have motivated a POSITA to decrease the amount of material to improve aqueous humor flow, a stated goal of both Bergheim and Grieshaber. *See* Ex.1001 (¶75-76). Moreover, doing so would only have required the obvious step of optimizing the contact ratio between the support and the canal wall to balance the desired aqueous fluid drainage and patency. *See Merck & Co. Inc. v. Biocraft Lab. Inc.*, 874 F.2d 804, 809 (Fed. Cir. 1989); *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"); *Galderma Lab'ys, L.P. v. Tolmar, Inc.*, 737 F.3d 731, 739 (Fed. Cir. 2013) (similar). Balancing the desire to increase aqueous flow with maintaining canal patency is merely an obvious 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* Ex.1001 (¶75-76).

Likewise, a POSITA would also have had a reasonable expectation of success of decreasing the amount of material to improve aqueous humor flow, and therefore reduce 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, and with less surface area contact there is more opportunity for aqueous humor flow. *See* Ex.1001 (¶67-76). Thus, it would have been obvious to a POSITA in light of Grieshaber and Bergheim to use a support that contacts less than 30% of the internal wall of Schlemm's canal.

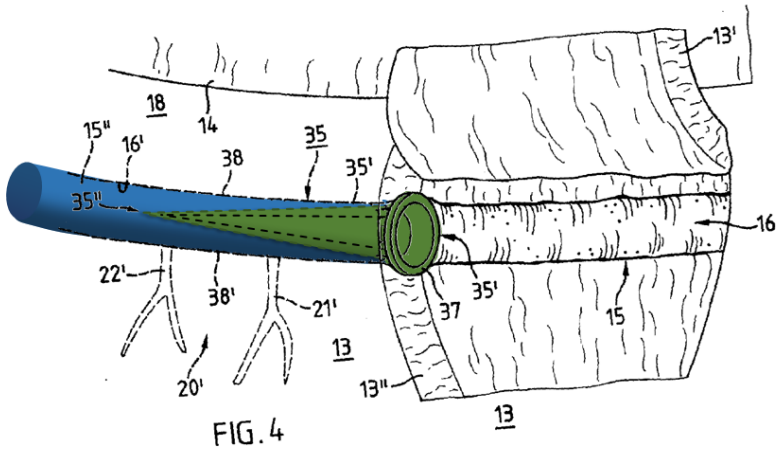
2. Dependent Claim 2

> **The device of claim 1, wherein the support makes minimal contact with the interior surface of the canal wall when the support is disposed within the lumen of the canal.**

As discussed in §XI.A.1.e, the '482 patent contains no clear guidance regarding how one measures the internal wall surface area, the amount of the support that contacts the internal wall surface area, or how much contact constitutes "minimal contact." Nonetheless, Grieshaber's support makes minimal contact with the interior surface of the canal wall when the support is disposed within the lumen of the canal, a design choice that also would have been obvious in light of Grieshaber and Bergheim. Ex.1001 (¶77).

Grieshaber's variety of shapes and designs for its supports, including a "conically tapered" design, would make contact only at one end (nearest the collar

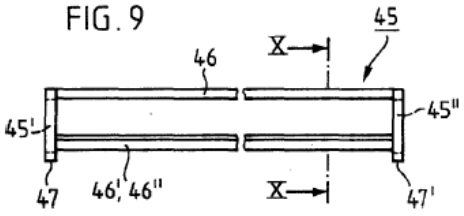
37). Ex.1012 (8:18-22; Fig.4). A POSITA would have understood that a conically tapered support would make only minimal contact with the interior surface of the canal wall. Ex.1001 (¶78).



Ex.1012 Fig.4 (annotated and modified)

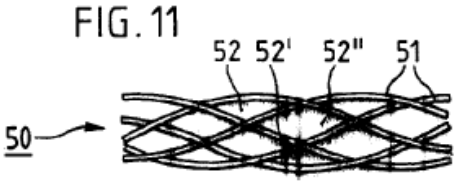
Grieshaber discloses additional support examples that would make only minimal contact with the interior surface of the canal wall. For example, Grieshaber discloses supports "designed essentially as a helicoidal network made of threads" with "gaps provided between the individual threads." Ex.1012 (10:5-13, cl.18, Fig.11). Grieshaber's helicoidal network support is akin to the '482 patent's disclosure that a support may be "made from mesh" and "can have an open network structure," which the '482 patent recognizes "will have minimal surface area contact with the walls of Schlemm's canal." Ex.1003 (3:49-50; 10:54-55); Ex.1001 (¶79). Grieshaber also discloses supports comprising "axially spaced toruses" linked by two to three webs, where "the recesses…provided between the webs…serve in each

case as outflow openings.'' Ex.1012 (9:19-10:4, Figs.9, 10). Ex.1001 (¶79). As explained in §XI.A.1.e, Grieshaber's torus-shaped support with webs would contact at most approximately 16.7-25% of the canal's wall. *See* Ex.1001 (¶72).



Ex.1012 Fig.9

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



Ex.1012 Fig.11

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

Additionally, for the reasons discussed in §XI.A.1.e, a POSITA would have been motivated, in light of Grieshaber and Bergheim to minimize the surface area contact by increasing the number of throughholes/outflow openings, balancing the goal of achieving desired aqueous fluid drainage by avoiding occlusion and maintaining the patency of the canal. Ex.1001 (¶67-82). This is nothing more than an obvious optimization step and design choice. *Id*. A POSITA would also have had a reasonable expectation of successfully doing so at least because both Grieshaber and Bergheim teach removing material to improve aqueous outflow, and

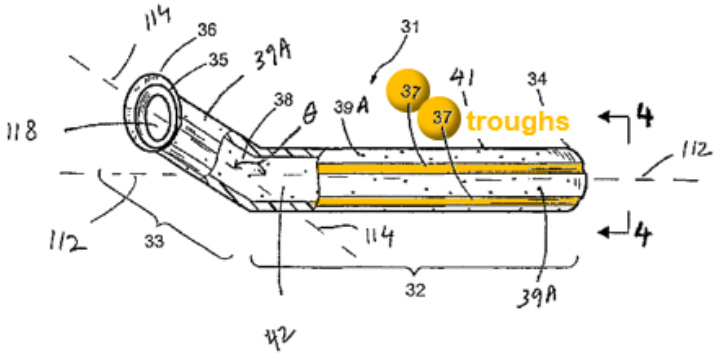
with less surface area contact there is more opportunity for aqueous humor flow. Ex.1001 (¶81-82).

3. Dependent Claim 5

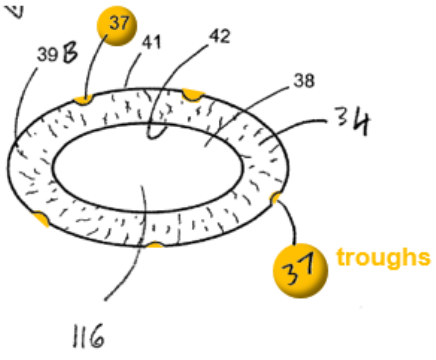
The device of claim 1, wherein the support comprises fluted edges.

The '482 patent does not make clear what is meant by the term "fluted edges." A POSITA would have understood "fluted" means "having grooves." *See* Ex.1024 (483).

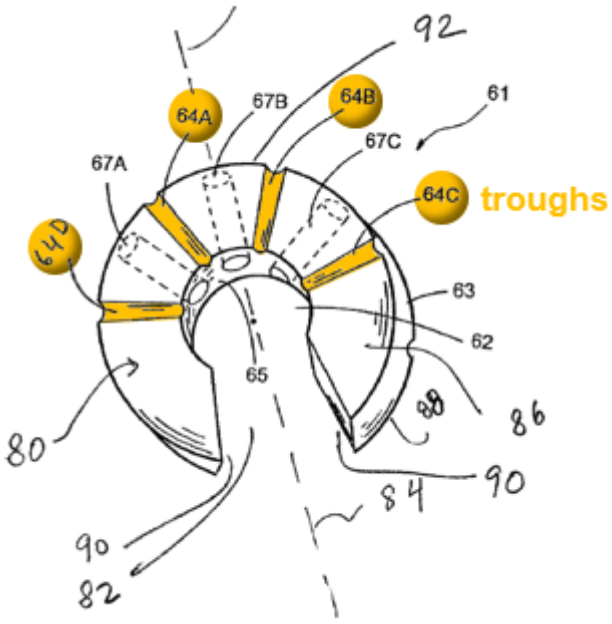
As discussed in §XI.A.1.e, Grieshaber teaches various ways to permit and promote aqueous flow through natural pathways. Ex.1001 (¶84). Additionally, to improve aqueous flow, a POSITA would have been motivated to include grooves on the surface of Grieshaber's supports to improve aqueous flow. Bergheim, for example, teaches including grooves or troughs on the surface of an ophthalmic support to "allow the flow of aqueous humor" and "provid[e] efficient aqueous transmission." Ex.1006 (¶¶ 36, 74). Ex.1001 (¶84-85).



Ex.1006 Fig.3 (annotated)



Ex.1006 Fig.4 (annotated)



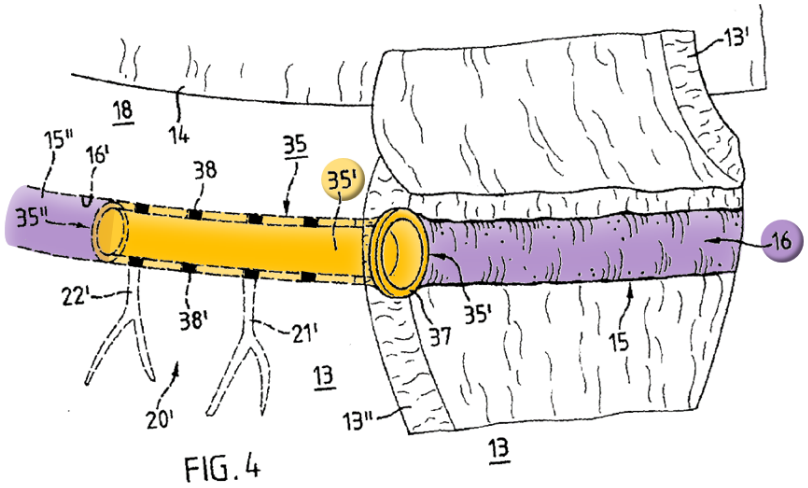
Ex.1006 Fig.7 (annotated)

A POSITA would also have had a reasonable expectation of successfully utilizing grooves on the surface of Grieshaber's supports because both Grieshaber and Bergheim teach removing material to improve aqueous outflow, and with less surface area contact there is more opportunity for aqueous humor flow. Thus, it would have been obvious in light of Bergheim to include fluted edges (*i.e.*, grooves) in supports such as Grieshaber's. Ex.1001 (¶84-86).

4. Dependent Claim 7

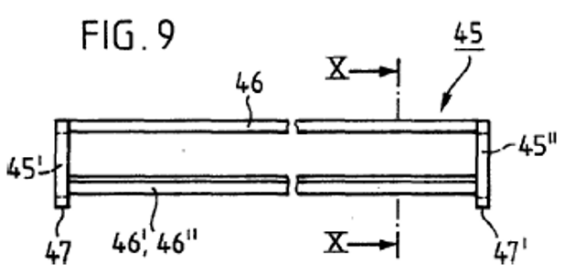
> **The device of claim 1, wherein the support comprises elements that make periodic contact with the canal wall when the support is disposed within the lumen of the canal**

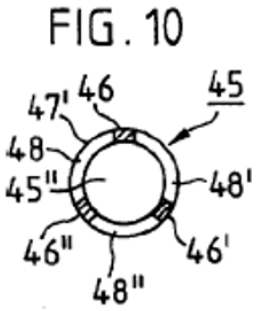
As discussed in §§XI.A.1.d-XI.A.1.e, Grieshaber's supports comprise fenestrations.[5] When implanted in Schlemm's canal, the supports do not make contact with the wall where openings/fenestrations are present. Figs.4-5, 9-11; §XI.A.1.d. Contact between the support's surface and canal wall is, therefore, periodic because the openings/fenestrations along the canal's length or cross section interrupt contact with the wall. Ex.1001 (¶87-89).



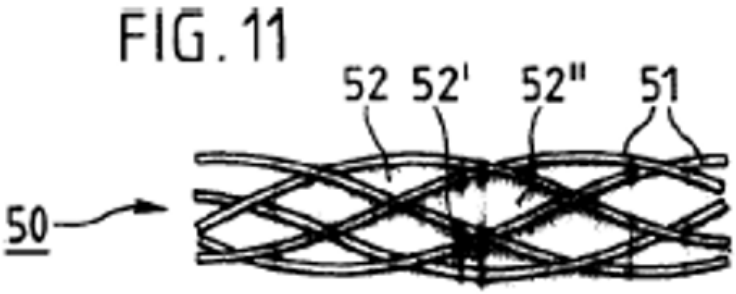
Ex.1012 Fig.4 (annotated)

[5] PO contends "elements" includes at least regions having fenestrations. Ex.1018 (52); *see also* §XI.A.9 above.





Ex.1012 Fig.9 **Ex.1012 Fig.10**



Ex.1012 Fig.11

5. Dependent Claim 8

The device of claim 1, wherein the support comprises a biocompatible metal.

Grieshaber discloses 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); Ex.1001 (¶90-92).

6. Dependent Claim 10

The device of claim 1, wherein the support comprises a shape memory material.

Grieshaber teaches the support may be made using various biocompatible materials, including "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; cls. 7-8, 19-21, 27). The '482 patent recognizes nickel-titanium alloys (e.g., Nitinol) as biocompatible shape memory materials. Ex.1003 (3:5-7; 12:59-62). 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 teaches making supports that comprise shape memory material, and extolls the benefits of using shape memory materials.

Additionally, a POSITA would have been motivated to use a shape memory material like nickel-titanium alloys in Grieshaber's supports because it would improve insertion of the support in a plastically deformed shape, while allowing it to automatically return to its original shape as Grieshaber itself teaches. Ex.1001 (¶94). Further, a POSITA would have had a reasonable expectation of success in using nickel-titanium alloys because Grieshaber teaches using this material in Schlemm's canal supports. Ex.1001 (¶93-95).

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 (¶31, 93-95).

7. Dependent Claim 11

The device of claim 10, wherein the support comprises a nickel titanium alloy.

As discussed in §XI.A.6, Grieshaber teaches making at least a portion of the support using shape-memory material, including nitinol, and doing so would have also been obvious. Ex.1001 (¶96).

8. Dependent Claim 15

The device of claim 1, wherein the support has a unitary structure.

The '482 patent lacks clear guidance regarding what constitutes a "unitary structure". Nonetheless, Grieshaber discloses a support with a unitary structure. Ex.1001 (¶97). For example, Grieshaber's Figure 7 depicts a fenestrated support element 40 implanted in Schlemm's canal, which a POSITA would have understood is made of a singular, unitary tube. Ex.1001 (¶98).

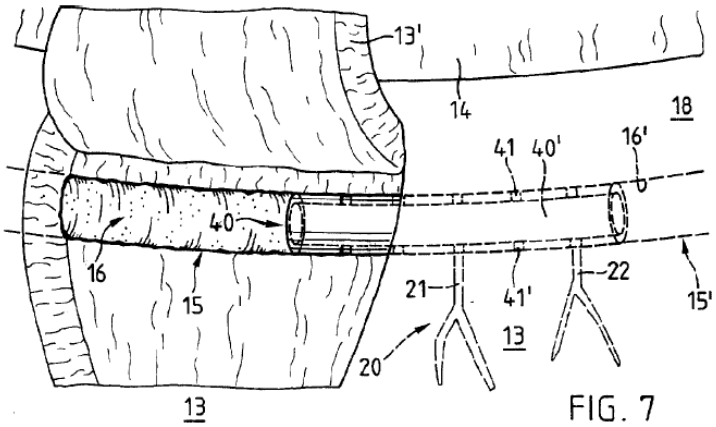


FIG. 7

Ex.1012 Fig.7

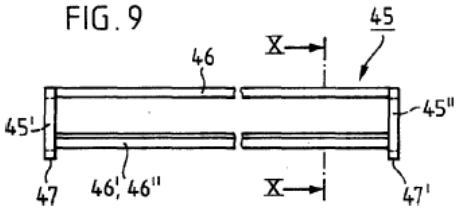
Additionally, a POSITA would have been motivated to make a support with a unitary structure because it would have been easier to manufacture a support from a single-piece mold without introducing weak points. Ex.1001 (¶99). A POSITA would have had a reasonable expectation of success in making a support with a unitary structure because Grieshaber itself teaches unitary supports that achieve the stenting function. Ex.1001 (¶97-99). Thus, a unitary support structure would have been obvious.

9. Dependent Claim 18

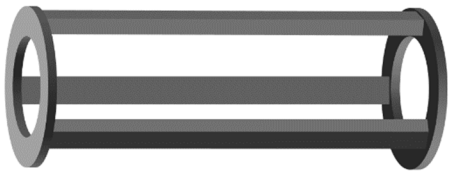
> **The device of claim 1, wherein the support comprises multiple connected elements configured to be distributed longitudinally along Schlemm's canal when the device is in use, and wherein at least one of the connected elements has a cross-sectional dimension sufficient to at least partially prop open Schlemm's canal, and to thereby maintain patency of at least a portion of the canal.**

As explained above in §XI.A.1.b-XI.A.1.c, Grieshaber's Figures 9-10 depict a support with "axially spaced toruses," linked together by webs, that prop open Schlemm's canal to maintain the patency of at least a portion of the canal. Ex.1012 (9:19-10:4, Figs.9, 10). Figure 9 shows end portions 47,47' connected by three webs 46,46', and 46'', rendering them "multiple connected elements." Ex.1001 (¶102). It would have been visually apparent to a POSITA that Figure 9 and the disclosures in Grieshaber show the cross sectional area at the end portions 47,47' would at least

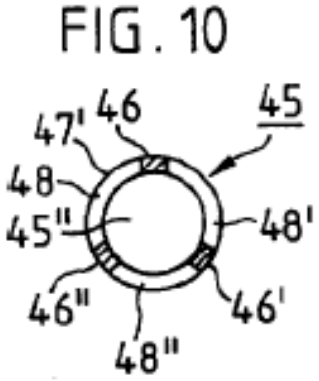
partially prop open Schlemm's canal because the torus-shaped end portions each have an opening 45' and 45'' to allow fluid to flow longitudinally through the support. Ex.1012 (9:19-10:5); Ex.1001 (¶106).



Ex.1012 Fig.9



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

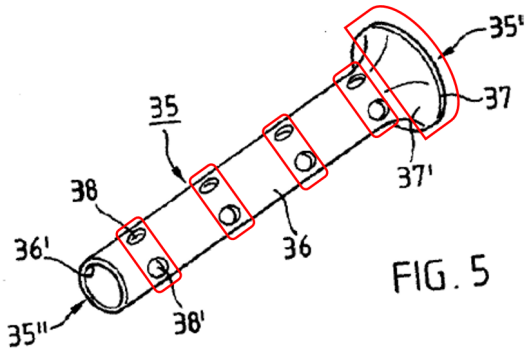


Ex.1012 Fig.10

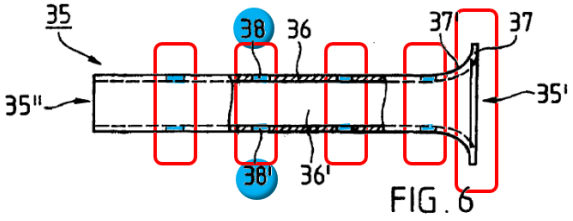
Further, PO contends a support meets this limitation at least if it includes regions containing fenestrations or an "inlet region" connected by the body of the support. *See* Ex.1018 (63-64). Thus, the regions containing recesses 48,48', and 48'' provided between the webs in Figure 9 meet PO's interpretation.

Grieshaber's other disclosures also meet PO's interpretation. As discussed in §XI.A.1.b, Grieshaber teaches a support with "a number of throughholes 38,38'

distributed axially and circumferentially spaced." Ex.1012 (8:4-6); *see also Id.* (7:17-8:6, 8:11-9:10, 9:11-18, Figs.4-7, cl.16). As shown in Figure 5, the fenestrations 38,38' and the collar 37 on Grieshaber's support are "multiple connected elements" connected by the solid portion of the tube 36, as PO contends is claimed in the '482 patent. Ex.1001 ¶103-104. The collar 37 can be "placed on tube 36…by suitable means in the form of a mandrel," Ex.1012 (8:12-22), another demonstration that Greishaber's support can be multiple connected elements. Ex.1001 (¶104).

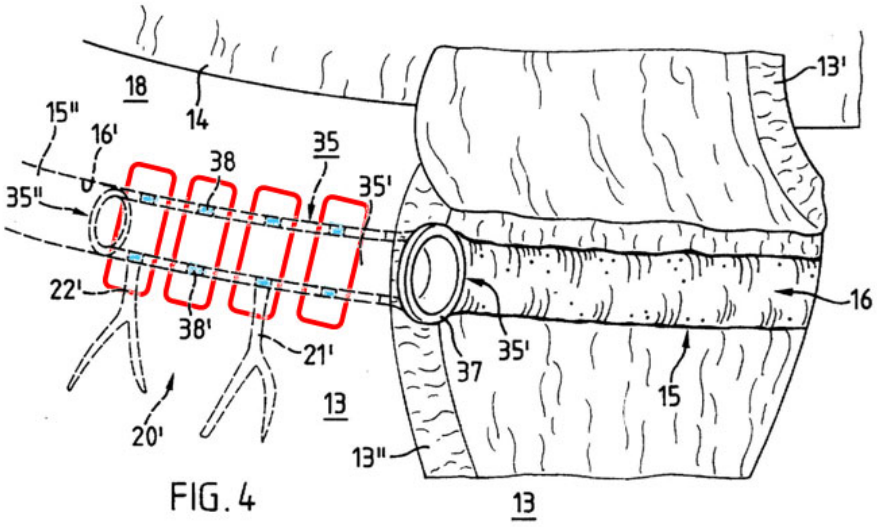


Ex.1012 Fig.5 (annotated)



Ex.1012 Fig.6 (annotated)

Further, Grieshaber discloses that, after implanting the support, 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). Thus, Grieshaber teaches this "multiple connected elements" limitation. Ex.1012 (Abstract, 1:1–6; 2:6–21); *see also Id.* (7:17-8:6, 12:16-20, 3:10-15, Fig.4). Ex.1001 (¶105).



Ex.1012 Fig.4 (annotated)

10. Dependent Claim 21

> **The device of claim 18, wherein the at least one fenestration is included in at least one of the connected elements.**

As discussed in §XI.A.9, XI.A.1.b, consistent with PO's interpretation, Grieshaber's supports with fenestrated regions and webs/recesses meet this limitation.

11. Dependent Claim 23

> **The device of claim 1, wherein at least a portion of the support is porous.**

Grieshaber discloses at least a portion of the support may be porous, teaching 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; Cl.16). Ex.1001 (¶109-113).

12. Independent Claim 32

a. "A device comprising"

Generally, "preamble language is not treated as limiting." *See Aspex*, 672 F.3d at 1347. Nonetheless, as discussed §XI.A.1.a, Grieshaber discloses a device.

b. "a support having at least one fenestration that is longitudinally insertable into a lumen of Schlemm's canal,"

As discussed in §XI.A.1.b, Grieshaber discloses this limitation.

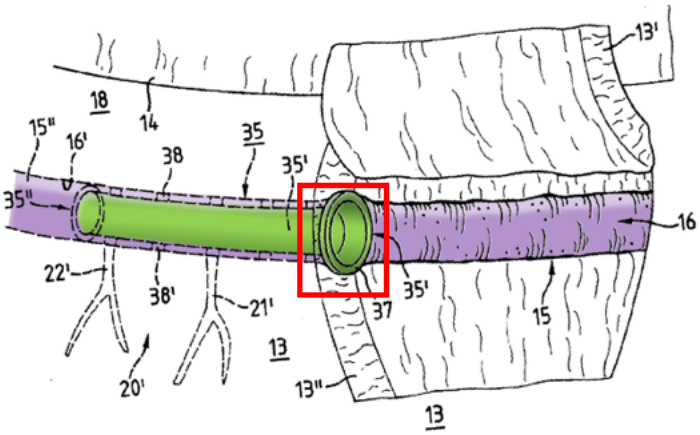
c. "the support comprising an exterior surface and having a cross-sectional dimension sufficient to at least partially prop open Schlemm's canal upon insertion into the canal, and to thereby maintain patency of at least a portion of the canal so that fluid may traverse the canal without substantial interference from the support,"

As discussed in §XI.A.1.c, Grieshaber discloses this limitation. Further, Grieshaber's supports that prop open Schlemm's canal comprise an exterior surface.

d. "wherein when the support is disposed within a lumen of Schlemm's canal, only a portion of the exterior surface of the support contacts an inner periphery of the lumen of the canal,"

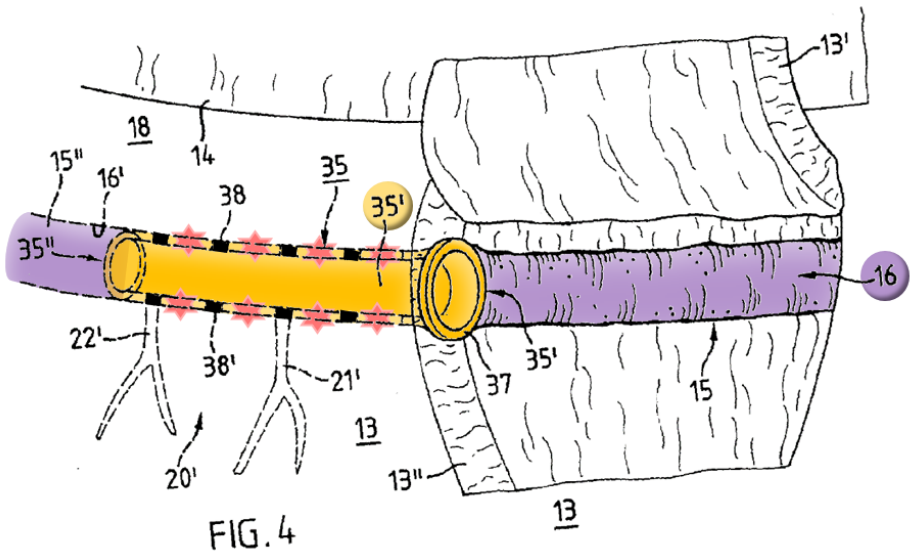
As shown in Figure 4, Grieshaber teaches its support can include a torus-shaped collar 37 of the support element 35, which extends out of Schlemm's canal after insertion. Ex.1012 (Fig.4). A POSITA would have understood that at least a portion of the exterior surface of collar 37, which "fits closely against the…scleral

incision" and designed to prevent "any displacement of the [implanted] support," does not contact the inner periphery of the lumen of the canal. Ex.1001 (¶116).

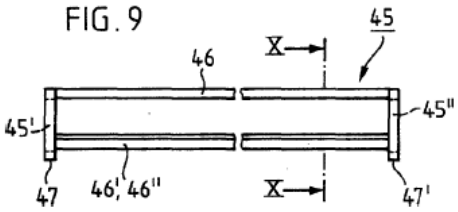


Ex.1012 Fig.4 (annotated)

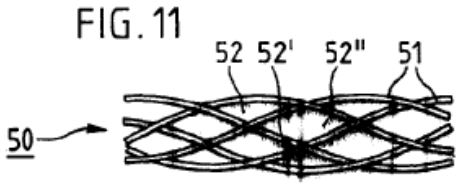
In addition, as discussed in §XI.A.1.d, Grieshaber teaches a support "provided with a number of throughholes 38,38' distributed axially and circumferentially spaced." Ex.1012 (8:4-6); *see also Id.* (7:17-8:6, 8:11-9:10, 9:11-18, Figs.4-7). Grieshaber's Figures 9-11 also depict a support with "recesses 48,48', and 48'' provided between the webs," Ex.1012 (9:19-10:4, Figs.9, 10), and "gaps" between the helicoidal network of threads, Ex.1012 (10:5-13, cl.18, Fig.11). Consistent with PO's interpretation that any openings or non-contact points meet this limitation, Ex.1018 (74), Grieshaber's support does not make contact with the wall where the throughholes, gaps, or recesses exist, and therefore, only a portion of the exterior surface of the support makes contact with the inner periphery of the lumen of Schlemm's canal. Ex.1001 (¶117-120).



Ex.1012 Fig.4 (annotated)



Ex.1012 Fig.9



Ex.1012 Fig.11

e. **"and wherein when the support is disposed within a cylindrical section of the lumen of the canal having an internal wall surface area C, the support contacts less than 30% of C."**

As discussed in §XI.A.1.e, Grieshaber alone and/or in view of Bergheim teaches and/or renders obvious this limitation.

13. Dependent Claim 33

The device of claim 32, wherein the support makes minimal contact with the interior surface of the canal wall when the support is disposed within the lumen of the canal.

As discussed in §XI.A.2, Grieshaber alone and/or in view of Bergheim teaches and/or renders obvious this limitation.

14. Dependent Claim 36

The device of claim 32, wherein the support comprises fluted edges.

As discussed in §XI.A.3, Grieshaber in view of Bergheim renders obvious this limitation.

15. Dependent Claim 38

The device of claim 32, wherein the support comprises elements that make periodic contact with the canal wall when the support is disposed within the lumen of the canal.

As discussed in §XI.A.4, Grieshaber discloses this limitation.

16. Dependent Claim 39

The device of claim 32, wherein the support comprises a biocompatible metal.

As discussed in §XI.A.5, Grieshaber discloses this limitation.

17. Dependent Claim 41

The device of claim 32, wherein the support comprises a shape memory material.

As discussed in §XI.A.6, Grieshaber teaches and/or renders obvious this limitation.

18. Dependent Claim 42

> **The device of claim 41, wherein the support comprises a nickel titanium alloy.**

As discussed in §XI.A.7, Grieshaber teaches and/or renders obvious this limitation.

19. Dependent Claim 46

> **The device of claim 32, wherein the support has a unitary structure.**

As discussed in §XI.A.8, Grieshaber teaches and/or renders obvious this limitation.

20. Dependent Claim 49

> **The device of claim 32, wherein the support comprises multiple connected elements configured to be distributed longitudinally along Schlemm's canal when the device is in use, and wherein at least one of the connected elements has a cross-sectional dimension sufficient to at least partially prop open Schlemm's canal, and to thereby maintain patency of at least a portion of the canal.**

As discussed in §XI.A.9, Grieshaber discloses this limitation.

21. Dependent Claim 52

> **The device of claim 49, wherein the at least one fenestration is included in at least one of the connected elements.**

As discussed in §XI.A.10, Grieshaber discloses this limitation.

22. Dependent Claim 54

The device of claim 32, wherein at least a portion of the support is porous.

As discussed in §XI.A.11, Grieshaber discloses this limitation.

23. Independent Claim 63

a. **"A method for reducing intraocular pressure in an eye, the method comprising"**

Generally, "preamble language is not treated as limiting." *See Aspex*, 672 F.3d at 1347. Nonetheless, Grieshaber discloses treating glaucoma with "a 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 (¶132-133).

b. **"inserting a support having at least one fenestration into a lumen of Schlemm's canal to at least partially prop open the canal and thereby maintain patency of at least a portion of the canal,"**

As discussed in §§XI.A.1.b-XI.A.1.c, Grieshaber discloses this limitation.

c. **"wherein when the support is disposed within the lumen of Schlemm's canal, the support allows fluid to traverse the canal without substantial interference from the support"**

As discussed in §§XI.A.1.b-XI.A.1.c, Grieshaber discloses this limitation.

d. **"and wherein contact between the support and a wall of the canal is discontinuous along a perimeter of the lumen of the canal,"**

As discussed in §XI.A.1.d, Grieshaber discloses this limitation.

e. **"and wherein when the support is disposed within a cylindrical section of the lumen of the canal having an internal wall surface area C, the support contacts less than 30% of C."**

As discussed in §XI.A.1.e, Grieshaber alone and/or in view of Bergheim teaches and/or renders obvious this limitation.

24. Dependent Claim 65

The method of claim 63, wherein the support makes minimal surface area contact with the canal wall when the support is disposed within the lumen of the canal.

As discussed in §XI.A.2, Grieshaber alone and/or in view of Bergheim teaches and/or renders obvious this limitation.

25. Dependent Claim 68

The method of claim 63, wherein the support comprises fluted edges that contact the wall of the canal.

As discussed in §XI.A.3, Grieshaber in view of Bergheim renders obvious this limitation because, after including the grooves as taught by Bergheim, the remaining support portions comprising the fluted edges would contact the canal wall.

26. Dependent Claim 69

The method of claim 63, wherein the support comprises elements that make periodic contact with the canal wall when the support is disposed within the lumen of the canal.

As discussed in §XI.A.4, Grieshaber discloses this limitation.

27. Dependent Claim 70

> **The method of claim 63, wherein the support has a unitary structure.**

As discussed in §XI.A.8, Grieshaber discloses this limitation.

28. Dependent Claim 73

> **The method of claim 63, wherein the support comprises multiple connected elements distributed longitudinally along Schlemm's canal when the support is disposed within the lumen of the canal, and wherein at least one of the elements has a cross-sectional dimension sufficient to at least partially prop open the canal to thereby maintain patency of at least a portion of the canal.**

As discussed in §XI.A.9, Grieshaber discloses this limitation.

29. Dependent Claim 77

> **The method of claim 63, wherein the support comprises a biocompatible metal.**

As discussed in §XI.A.5, Grieshaber discloses this limitation.

30. Dependent Claim 79

> **The method of claim 63, wherein the support comprises a shape memory material.**

As discussed in §XI.A.6, Grieshaber teaches and/or renders obvious this limitation.

31. Dependent Claim 80

> **The method of claim 79, wherein the shape memory material comprises a nickel titanium alloy.**

As discussed in §XI.A.7, Grieshaber teaches and/or renders obvious this limitation.

B. Ground 2: Lynch alone, or in combination with Bergheim render obvious Claims 1-2, 5, 7-8, 15, 18, 21, 23, 32-33, 36, 38-39, 46, 49, 52, 54, 63, 65, 68-70, 73, and 77.

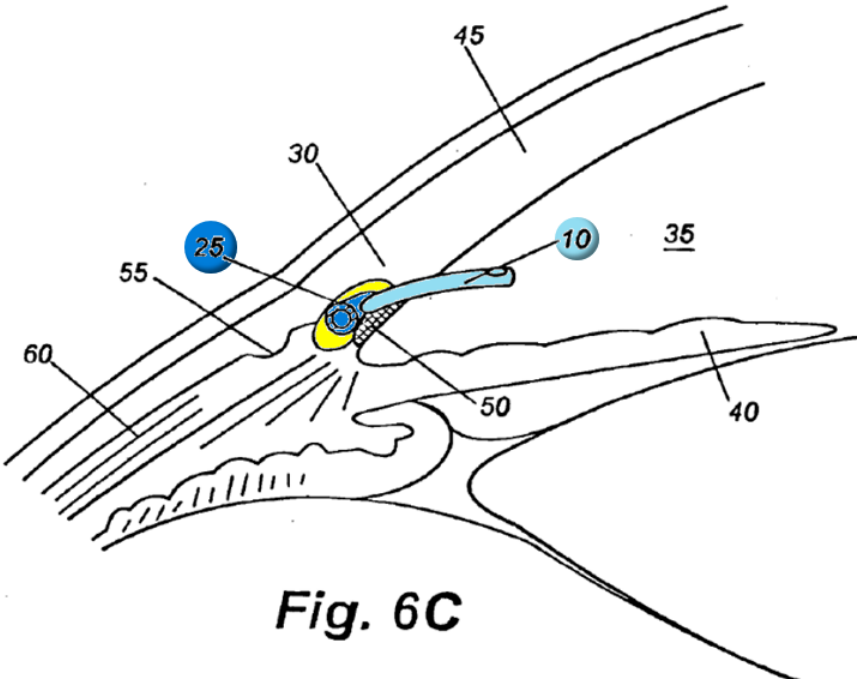
1. Independent Claim 1

a. "A device comprising"

Generally, "preamble language is not treated as limiting." *See Aspex*, 672 F.3d at 1347. Nonetheless, Lynch discloses various intraocular implant devices. Ex.1008 (Title). Ex.1001 (¶147-148).

b. **"a support having at least one fenestration that is longitudinally insertable into a lumen of Schlemm's canal;**

Lynch discloses various devices "sized and shaped to be circumferentially received within a portion of Schlemm's canal." Ex.1008 (¶78); *see also Id.* (¶¶25, 27-28, 35-36, 38, 43, 51-52, 55, 63, 70, 74-75, 79, 84, 113); Ex.1001 (¶147-148). Lynch's devices are "supports" because they "help to maintain the patency of Schlemm's canal in a stenting fashion." Ex.1008 (¶63; Fig.6C). Ex.1001 (¶148).



Ex.1008 Fig.6C (annotated)

Lynch further discloses supports "can be constructed of a solid, matrix, mesh, fenestrated, or porous material." Ex.1008 (¶53). "All or parts of the device may be solid, porous, tubular, trough-like, fenestrated, or pre-curved." *Id*. (¶55). According to Lynch, "[f]enestrations…are contemplated in all embodiments of the invention, and these fenestrations and openings may be round, ovoid, or other shapes as needed for optimum aqueous humor channeling function." *Id.* (¶64). Lynch also discloses an intertwined mesh support (Figure 1C) having gaps that constitute fenestrations. Ex.1001 (¶149-150).

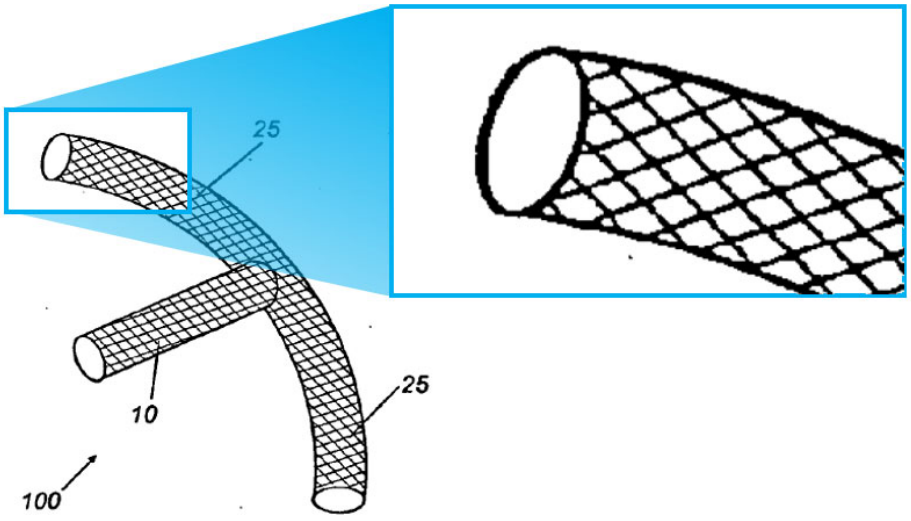
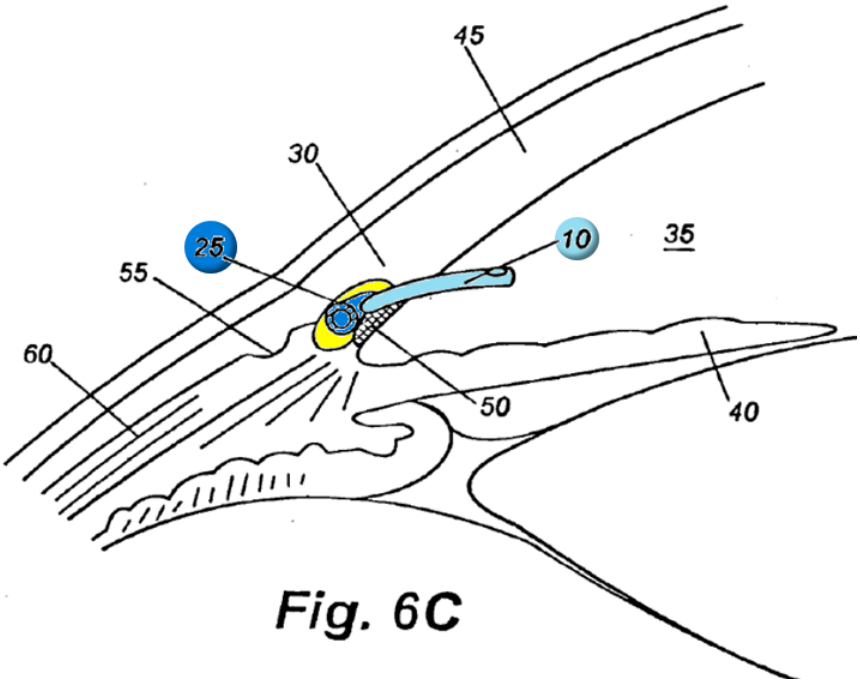


Fig. 1C

Ex.1008 Fig.1C (zoomed in on right)

c. **"the support having a cross-sectional dimension sufficient to at least partially prop open Schlemm's canal upon insertion into the canal, and to thereby maintain patency of at least a portion of the canal so that fluid may traverse the canal without substantial interference from the support"**

Lynch teaches its supports are "sized and shaped to be circumferentially received within a portion of Schlemm's canal," Ex.1008 (¶78), with its exterior surface making contact with Schlemm's canal that "help[s] to maintain the patency of Schlemm's canal in a stenting fashion," Ex.1008 (¶63, Fig.6C). Ex.1001 (¶151-152).



Ex.1008 Fig.6C (annotated)

The ’482 patent acknowledges a support that maintains the patency across the canal enhances transmural flow across the canal, with Fig.5C as an alleged example of a support that enhances flow. Ex.1003 (9:10-24); Ex.1001 (¶155). Lynch’s supports, therefore, likewise enhance transmural flow rather than substantially interfere with fluid traversing the canal.

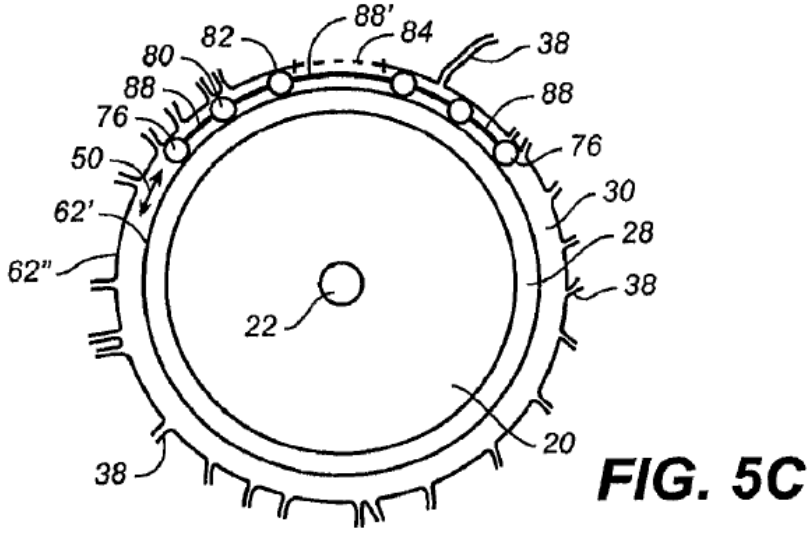


FIG. 5C

Ex.1003 Fig.5C

Lynch also teaches its supports "facilitate[] the normal physiologic pathway for drainage of aqueous humor from the anterior chamber," Ex.1008 (¶24), and that "[f]luid communication can be facilitated by an aqueous humor directing channel in either the proximal or distal portions." *Id*. (¶51). To facilitate flow, Lynch's disclosed fenestrations "allow fluid egress," and "prevent occlusion by the adjacent walls of Schlemm's canal." *Id*. (¶64, 74, Fig.5A). Lynch also teaches "any portion of the device can be semi-tubular, open, and trough-like" and that "[p]referably the non-tubular trough-like aspects are oriented…to facilitate aqueous humor drainage to the collecting channels." Ex.1008 (¶60). Ex.1001 (¶153-154).

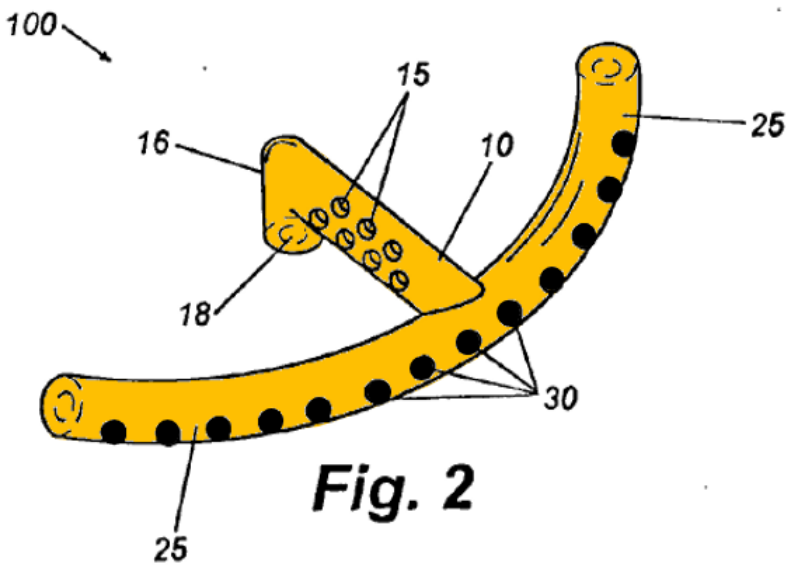
Thus, Lynch's support configurations that stent open the canal and facilitate fluid flow and drainage, in addition to Lynch's taught fenestrations for further

assisted drainage, would enhance, rather than substantially interfere with, fluid traversing the canal. Ex.1001 (¶156-157).

d. **"wherein when the support is disposed within a lumen of Schlemm's canal, contact between the support and a wall of the canal is discontinuous along a perimeter of the lumen of the canal,"**

As explained in §XI.A.1.d, the '482 patent lacks clear guidance regarding what constitutes "discontinuous" contact and that under PO's interpretation, a support that has openings or non-contact points meets the limitation. Ex.1001 (¶158).

Lynch discloses "[a]ll or parts of the device may be porous, tubular, trough-like, fenestrated, or pre-curved" or made of mesh. Ex.1008 (¶55); *see also Id*. (¶53, 55, 57, 59, 64-65, 74, Figs.1C, 2, 3A, 3D, 4, 5A-E). Lynch's fenestrations create "discontinuous" contact along the perimeter of the lumen of the canal (consistent with PO's interpretation). *See, e.g.*, Fig. 2; Ex.1001 (¶159-161).

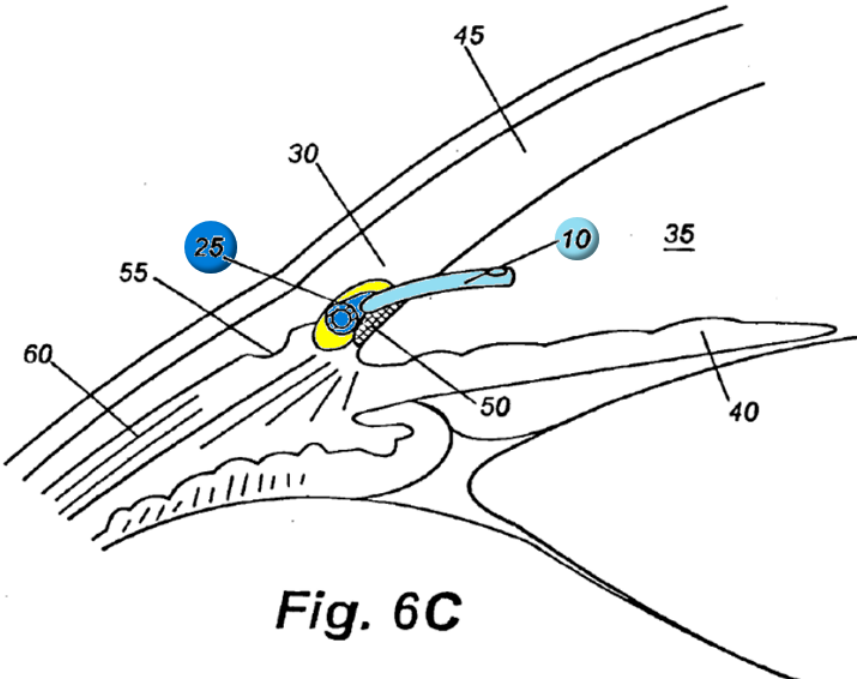


Ex.1008 Fig.2 (annotated, fenestrations annotated in black)

e. **"and wherein when the support is disposed within a cylindrical section of the lumen of the canal having an internal wall surface area C, the support contacts less than 30% C."**

Under PO's interpretation that the canal is cylindrical, *see* §V.C, Lynch's supports are disposed within a cylindrical section of the lumen of Schlemm's canal.[6] Ex.1001 (¶162); Ex.1008 (¶¶51, 55-60, 65, 78, Figs.6B-7B). Lynch's supports are "sized and shaped to be circumferentially received within a portion of Schlemm's canal." Ex.1008 (¶51, Fig.6C).

[6] Schlemm's Canal is not in fact cylindrical.



Ex.1008 Fig.6C (annotated)

With respect to the limitation requiring the support contact less than 30% of the "internal wall surface area," Petitioners have adopted PO's interpretation estimating Schlemm's canal as a cylinder (despite that this contradicts the '482 patent's description as a "slightly arcuate cylinder"). *See* §V.C.

Lynch's various configurations and disclosed materials are aimed at reducing surface area contact. Ex.1001 (¶163-164). 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, *Id*. (¶23), that fenestrations and other openings can be added "as needed for optimum aqueous humor channeling function," *Id*. (¶64), and that additional fenestrations are desirable to allow fluid ingress and to prevent occlusion,

Id. (¶71, 74). Lynch's supports "can be constructed of a solid, matrix, mesh, fenestrated, or porous material." *Id*. (¶53). Figure 1C, for example, 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 (¶165).[7] A POSITA would have understood that Lynch teaches reducing surface area contact either using configurations such as mesh or increasing the number of fenestrations to improve fluid flow, and arranging fenestrations in a scattered fashion helps avoid occlusion, of the openings. Ex.1001 (¶165). Lynch, therefore, encourages using supports that make less than 30% surface area contact with the internal wall of Schlemm's canal. Ex.1001 (¶165).

[7] The '482 patent explains that open network structures, such as mesh, "will have minimal surface area contact with the walls of Schlemm's canal." Ex.1003 (3:54-55, 10:54-55). Ex.1001 (¶173).

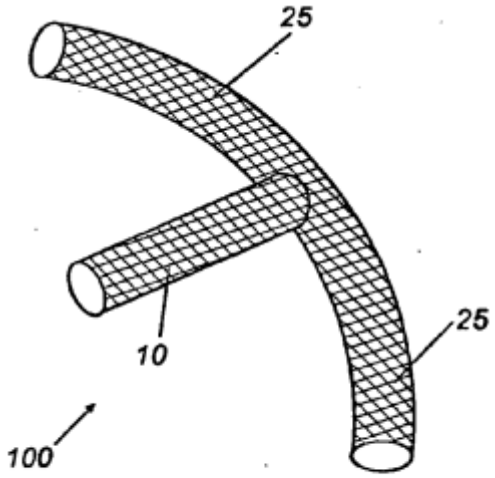


Fig. 1C

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 Figure 4 as having approximately 50% of its exterior removed, are oriented to open toward the collecting channels to facilitate aqueous humor egress. *Id*. (¶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. *Id*. (¶¶71, 74); Ex.1001 (¶164-165). As the collector channels are critical to aqueous outflow from Schlemm's canal, Lynch would have motivated a POSITA to increase the number and size of fenestrations and to decrease the amount of material exposed to the canal wall 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 (¶167); *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 because with less surface area contact there is more opportunity for aqueous humor flow. Ex.1001 (¶167). Thus, the 30% surface area contact limitation would have been obvious in view of Lynch. Ex.1001 (¶167); *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 in §XI.A.1.e, 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 (¶169-170). Doing so would have also necessarily reduced the surface area contact, including below 30%, and 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 Biocraft,* 874 F.2d at 809; *In re Geisler,* 116 F.3d at 1469-70; *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 (¶169-170).

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 material used for the support, and therefore reduce 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 (¶169-170). 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 (¶169-170).

2. Dependent Claim 2

The device of claim 1, wherein the support makes minimal contact with the interior surface of the canal wall when the Support is disposed within the lumen of the canal.

As discussed in §XI.A.1.e, the '482 patent contains no clear guidance regarding how one measures the internal wall surface area, the amount of the support

that contacts the internal wall surface area, or how much contact constitutes "minimal contact." Nonetheless, a POSITA would have found Lynch teaches a support that makes minimal contact with the interior surface of the canal wall when the support is disposed within the lumen of the canal and such a design would have been obvious in light of Lynch alone or in view of Bergheim. Ex.1001 (¶171).

Lynch teaches enhancing drainage and increasing the number of openings, including using open network materials such as mesh—a technique the '482 patent states "will have minimal surface area contact with the walls of Schlemm's canal." Ex.1003 (10:54-55); *see also* §XI.B.1.e. A POSITA, recognizing the collector channels are critical to aqueous outflow would have been motivated to minimize the amount of surface area contacted by the support, balancing (1) the desire to reduce contact inflammation and increase aqueous flow, with (2) maintaining the patency of the canal. Ex.1001 (¶172). Lynch would have also provided a POSITA with a reasonable expectation of successfully increasing fenestrations and reducing material contacting Schlemm's canal to achieve Lynch's stated goal of improving aqueous ingress and egress for drainage and maintaining Lynch's taught stenting capability because with less surface area contact there is more opportunity for aqueous humor flow. Ex.1001 (¶167, 172).

Further, for the reasons discussed in §XI.B.1.e, a POSITA would have been motivated, in light of Lynch and Bergheim to minimize the surface area contact (*e.g.*,

by increasing the number of channels, troughs, or pores), balancing the goal of achieving desired aqueous fluid drainage by avoiding occlusion and maintaining the patency of the canal. Ex.1001 (¶173-174). A POSITA would also have had a reasonable expectation of successfully doing so at least because both Lynch and Bergheim teach removing material to improve aqueous outflow, and with less surface area contact there is more opportunity for aqueous humor flow. Ex.1001 (¶173-174).

3. Dependent Claim 5

The device of claim 1, wherein the support comprises fluted edges.

The '482 patent does not make clear what is meant by the term "fluted edges." A POSITA would have understood "fluted" means "having grooves." *See* Ex.1024 (483).

As discussed in §XI.B.1.e, Lynch teaches "many different configurations…provided that each assists in channeling aqueous humor from the anterior chamber to Schlemm's canal." Ex.1008 (¶53). For example, Lynch discloses trough-like supports that "provide[] an aqueous humor directing channel along the length [of the support]." *Id*. (¶70; Figs.3A, 3D, 4, 5D). A POSITA would have understood these trough-like supports and the grooves formed on the surface of the support, comprise fluted edges as claimed in the '482 patent. Ex.1001 (¶175-177). For example, Figure 3A depicts a support with squared-off edges that bears a

striking resemblance to the '482 patent's Figures 8E and 8F, which are described as "fluted." Ex.1003 (10:49-50).

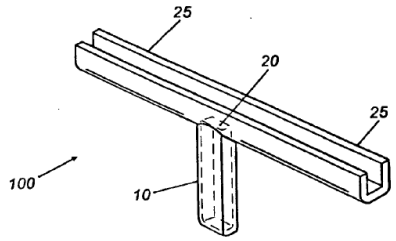


Fig. 3A

Ex.1008 Fig.3A

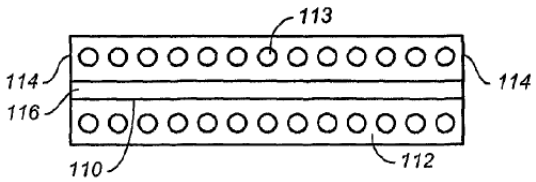


FIG. 8E

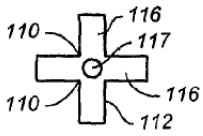


FIG. 8F

Ex.1003 Figs.8E and 8F

Lynch teaches additional shapes and designs that would constitute fluted edges. Ex.1008 (Figs.3D, 4, 5D). Therefore, Lynch discloses a support that comprises "fluted edges." *Id*. (Figs.3A, 3D, 4, 5D). Ex.1001 (¶178-179).

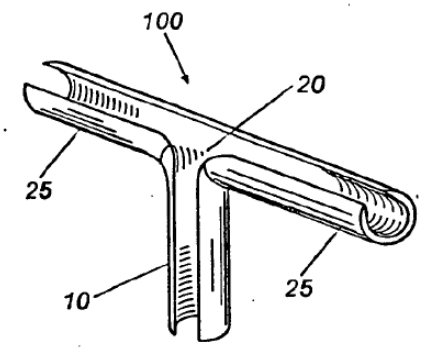


Fig. 3D

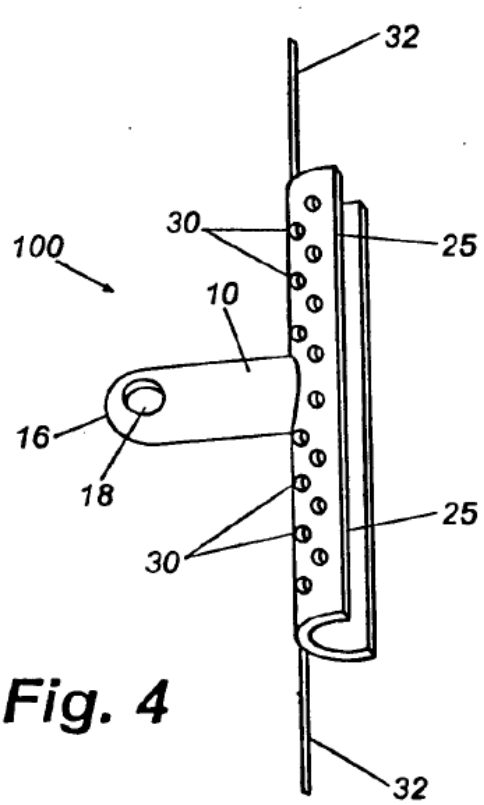


Fig. 4

Ex.1008 Fig.3D **Ex.1008 Fig.4**

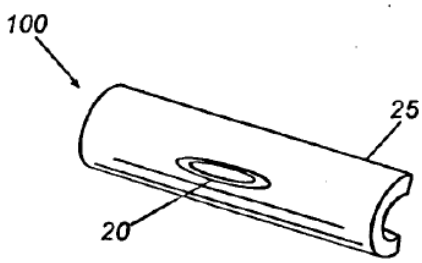
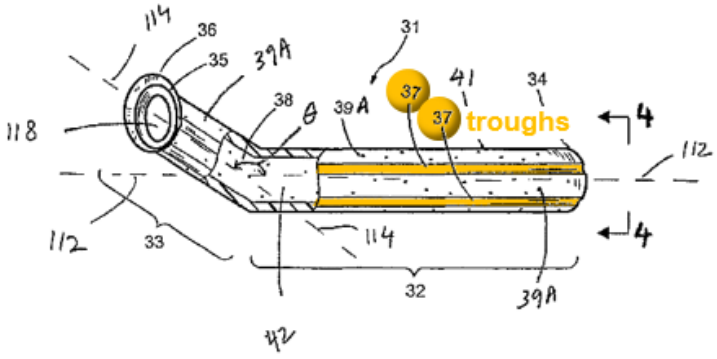


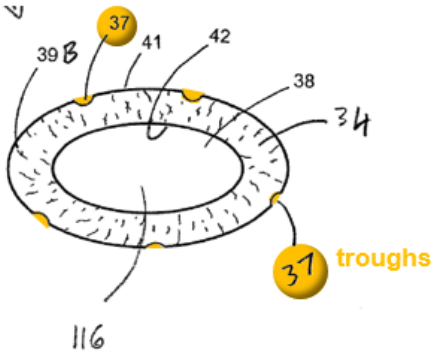
Fig. 5D

Ex.1008 Fig.5D

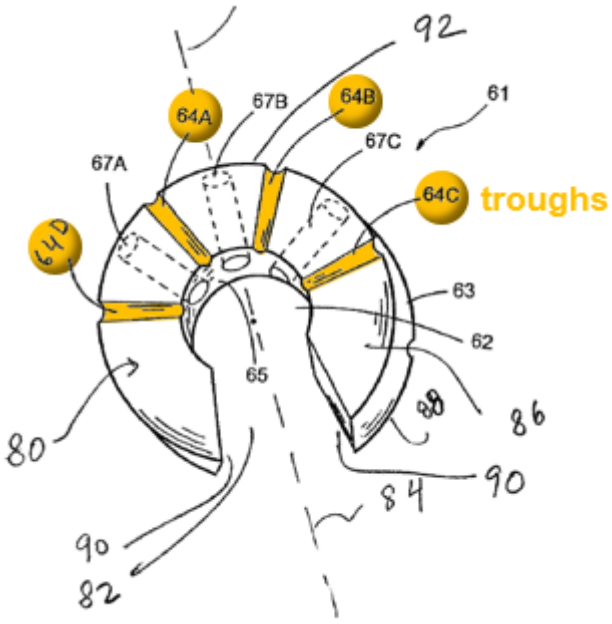
Additionally, to improve the ability to channel aqueous humor into and out of Schlemm's canal through the natural outflow pathways, a POSITA would have been motivated to include grooves on the surface of Lynch's support to improve aqueous flow. Additional prior art references, such as Bergheim, teach including grooves or troughs on the surface of an ophthalmic support to "allow the flow of aqueous humor" and "provid[e] efficient aqueous transmission." Ex.1006 (¶¶36, 74.); Ex.1001 (¶180); §XI.A.3.



Ex.1006 Fig.3 (annotated)



Ex.1006 Fig.4 (annotated)



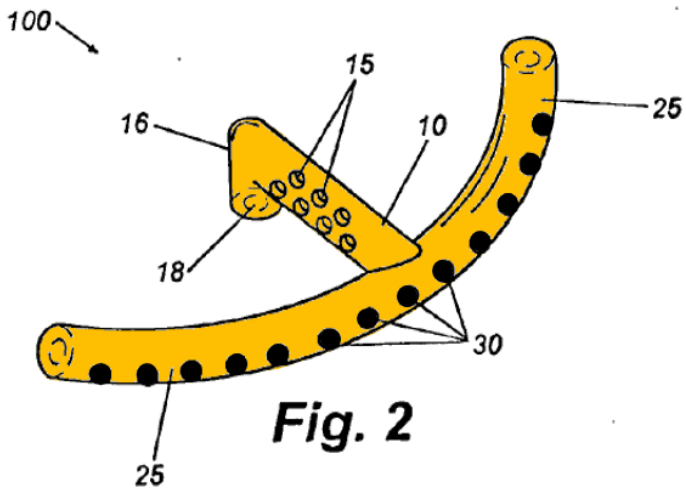
Ex.1006 Fig.7 (annotated)

A POSITA would also have had a reasonable expectation of success of utilizing grooves on the surface of Lynch's supports because both Lynch and Bergheim teach removing material in these ocular devices to improve aqueous outflow, and with less surface area contact there is more opportunity for aqueous humor flow. Thus, it would have been obvious to a POSITA in light of in light of Bergheim to include fluted edges (*i.e.*, grooves) in supports such as Lynch's. Ex.1001 (¶180-181).

4. Dependent Claim 7

> **The device of claim 1, wherein the support comprises elements that make periodic contact with the canal wall when the support is disposed within the lumen of the canal**

As discussed in §XI.B.1.d-XI.B.1.e, Lynch teaches its supports can have fenestrations.[8] When implanted, the supports do not make contact with the wall where fenestrations are present. *See, e.g.*, Fig.2 below. Contact between the surface of the support and the canal wall is, therefore, periodic because fenestrations along the canal's length or cross section interrupt contact of the support with the wall. Ex.1001 (¶182-183). Thus, Lynch teaches this limitation.



Ex.1008 Fig.2 (annotated)

PO has asserted that a support makes periodic contact with the canal wall when the support is trough-like and does not contact the entire cross-section of the canal. *See* Ex.1018 (52-54). Lynch also discloses trough-like supports that "provide[] an aqueous humor directing channel along the length [of the support]."

[8] PO contends "elements" includes at least regions having fenestrations. Ex.1018 (52); *see also* §XI.A.9 above.

Ex.1008 (¶70; Figs.3A, 3D, 4 5D). Contact between the surface of the support and the canal wall is, therefore, periodic on the cross-section of the canal because the opening in the trough portion of the support interrupts contact of the support with the wall. Ex.1001 (¶184-185). Thus, Lynch teaches this limitation.

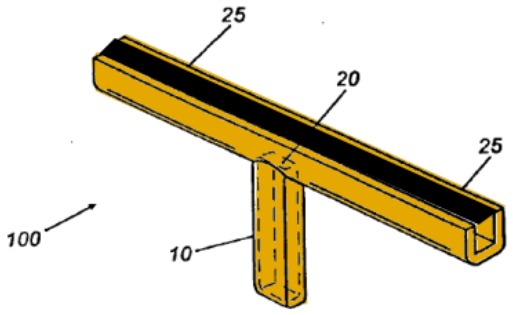


Fig. 3A

Ex.1008 Fig.3A (annotated, black demonstrating trough opening)

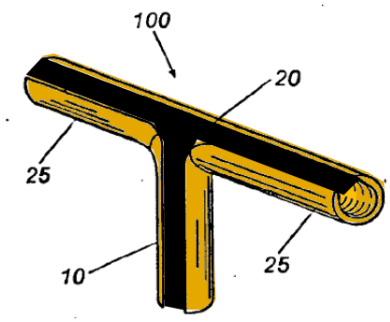


Fig. 3D

Ex.1008 Fig.3D (annotated, black demonstrating trough opening)

5. Dependent Claim 8

The device of claim 1, wherein the support comprises a biocompatible metal.

Lynch discloses 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 (¶186).

6. **Dependent Claim 15**

The device of claim 1, wherein the support has a unitary structure.

The '482 patent lacks clear guidance regarding what constitutes "unitary structure". Nonetheless, Lynch discloses a support that has a unitary structure. Ex.1001 (¶187).

Lynch contemplates "many different configurations…provided that each assists in channeling aqueous humor from the anterior chamber to Schlemm's canal." Ex.1008 (¶53). For example, the support can be a fully enclosed lumen, partially enclosed lumen, or trough-like channel, and can be constructed of a solid, matrix, mesh, fenestrated, or porous material. *Id*. (¶53). Lynch discloses various configurations that have a continuous lumen for aqueous humor to flow into Schlemm's canal. These supports would therefore be "unitary structures" as shown in the exemplary Figures below, Ex.1001 (¶188):

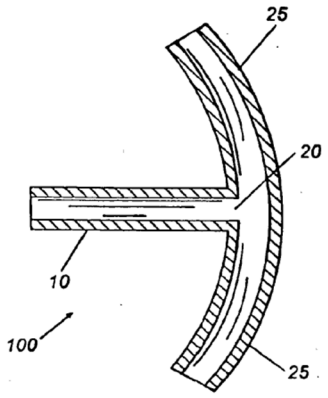


Fig. 1B

Ex.1008 Fig.1B

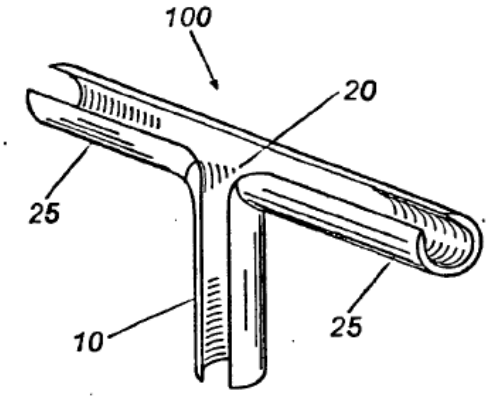


Fig. 3D

Lynch Fig.3D

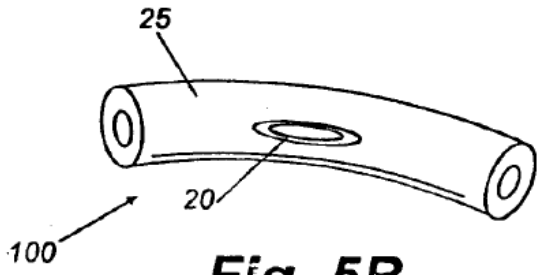


Fig. 5B

Ex.1008 Fig.5B

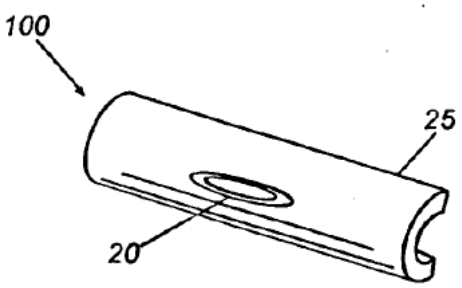


Fig. 5D

Ex.1008 Fig.5D

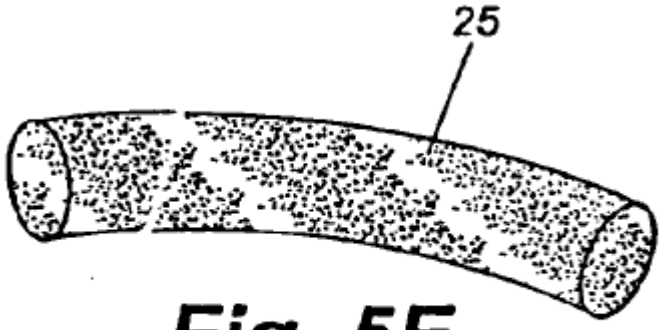
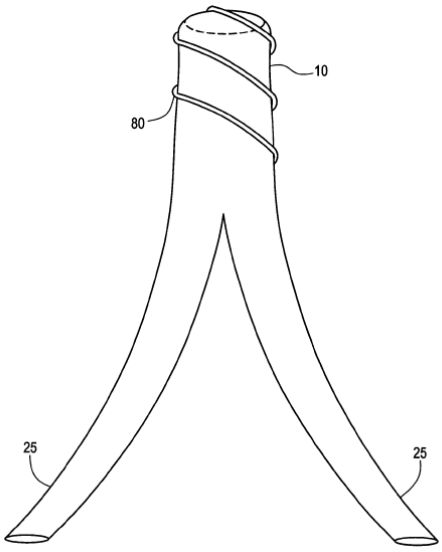


Fig. 5E

Ex.1008 Fig.5E



Ex.1008 Fig.10

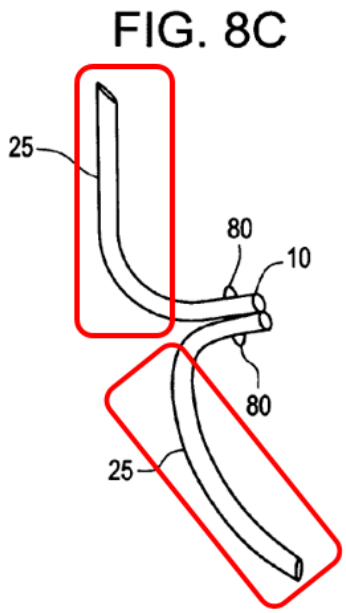
Additionally, a POSITA would have been motivated to make a support with a unitary structure because it would have been easier to manufacture a support from a single-piece mold without introducing weak points. Ex.1001 (¶189). Further, a POSITA would have had a reasonable expectation of success in making a support that has a unitary structure because Lynch teaches multiple supports (as seen above) that have unitary structures that achieve the stenting function.[9] Thus, a unitary structure would have been obvious.

[9] The inventors of Lynch '334 also explicitly contemplated a support with a unitary structure in a related publication, U.S. Pub. No. 2005/0090807, Cl.58 ("wherein the tubular body comprises first and second integrally formed sections disposed transverse to each other.").

7. Dependent Claim 18

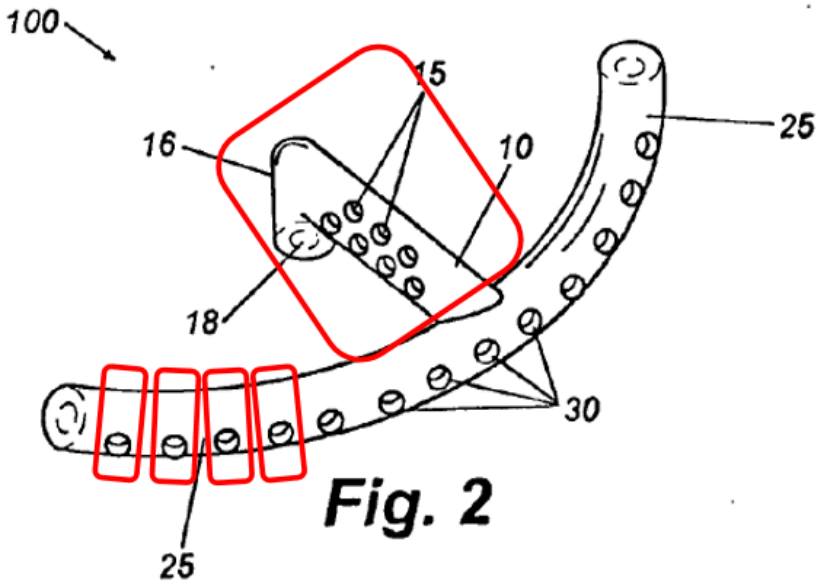
The device of claim 1, wherein the support comprises multiple connected elements configured to be distributed longitudinally along Schlemm's canal when the device is in use, and wherein at least one of the connected elements has a cross-sectional dimension sufficient to at least partially prop open Schlemm's canal, and to thereby maintain patency of at least a portion of the canal.

Lynch discloses a support that "is configured with one distal portion 25 which is tubular to provide a shunting functionality and plurality of proximal portions 10 which provide an anchoring function." Ex.1008 (¶77). For example, Figure 8C depicts "a bidirectional distal portion 25 and an anchor 80 on the proximal portion 10 extending laterally on each side of the device when implanted." *Id*. (¶81). Each of the bi-directional distal portions, connected by anchor 80, extend laterally on each side of the device and constitute multiple elements configured to be distributed longitudinally along Schlemm's canal when the device is in use. Ex.1001 (¶191-192).



Ex.1008 Fig.8C (annotated)

Further, as discussed in §XI.A.9, PO contends a support that includes regions containing fenestrations or an "inlet region" constitute separate elements connected by the body of the support. Ex.1001 (¶193). Each of Lynch's supports can be fenestrated. Ex.1008 (¶53); *see* §XI.B.1.b. Lynch also discloses fenestrations may be placed along "any portion of the device…to facilitate the passage of fluid therethrough." *Id*. (¶59). Thus, as shown in Figure 2, Lynch's fenestrated support 100 comprises "multiple connected elements," according to PO's interpretation, including fenestration regions and an inlet region longitudinally distributed along the support. Ex.1001 (¶194).



Ex.1008 Fig.2 (annotated)

Lynch further discloses its support comprises a distal portion having at least one terminal aspect sized and shaped to be circumferentially received within a portion of Schlemm's canal, which "help[s] to maintain the patency of Schlemm's canal in a stenting fashion." Ex.1008 (¶¶51, 63, 78; Figs.6C, 8C). Ex.1001 (¶195); *see also* §XI.B.1.b. Thus, Lynch teaches this "multiple connected elements" limitation.

8. **Dependent Claim 21**

The device of claim 18, wherein the at least one fenestration is included in at least one of the connected elements.

As discussed in §XI.B.7, XI.B.1.b, contemplates fenestrations in all embodiments, and consistent with PO's interpretation, Lynch's fenestrated supports and supports with fenestrated regions meet this limitation.

9. **Dependent Claim 23**

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

Lynch discloses at least a portion of the support can be porous, teaching the support can be comprised of "porous elements" that also assist in fluid communication. Ex.1008 (¶28); *see also Id*. (Fig.1D, ¶¶53, 55, 57, 69, 71, 85). Ex.1001 (¶198-199). Lynch also teaches including fenestrations. *See* §XI.B.1.b.

10. Independent Claim 32

a. **"A device comprising"**

Generally, "preamble language is not treated as limiting." *See Aspex*, 672 F.3d at 1347. Nonetheless, as discussed in §XI.B.1.a, Lynch discloses a device. Ex.1001 (¶200).

b. **"a support having at least one fenestration that is longitudinally insertable into a lumen of Schlemm's canal,"**

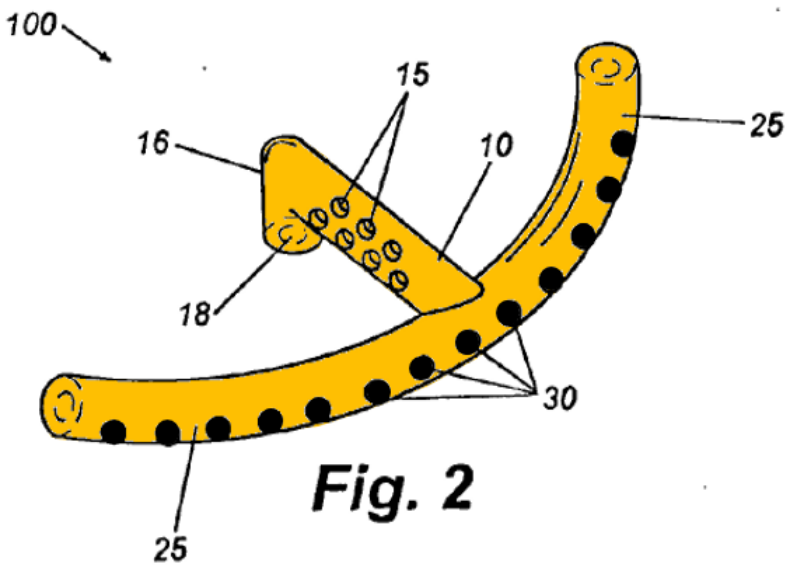
As discussed in §XI.B.1.b, Lynch discloses this limitation.

c. **"the support comprising an exterior surface and having a cross-sectional dimension sufficient to at least partially prop open Schlemm's canal upon insertion into the canal, and to thereby maintain patency of at least a portion of the canal so that fluid may traverse the canal without substantial interference from the support,"**

As discussed in §XI.B.1.c, Lynch discloses this limitation. Further, Lynch's supports that prop open Schlemm's canal comprise an exterior surface.

d. **"wherein when the support is disposed within a lumen of Schlemm's canal, only a portion of the exterior surface of the support contacts an inner periphery of the lumen of the canal,"**

As discussed in §XI.B.1.d, Lynch discloses this limitation. For example, Lynch discloses "[a]ll or parts of the device may be porous, tubular, trough-like, fenestrated, or pre-curved." Ex.1008 (¶55). Lynch contemplates various fenestrations shapes for all embodiments. *Id*. (¶¶53, 55, 59, 64-65, 74; Figs.1C, 2, 3A, 3D, 4, 5A-E). Therefore, consistent with PO's interpretation, as illustrated by Figure 2, Lynch's support makes contact along a perimeter of the lumen of Schlemm's canal at points adjacent to the fenestrations and at least does not make contact at points where fenestrations are present. Thus, only a portion of the external surface of the support makes contact with the inner lumen of Schlemm's canal. Ex.1001 (¶202).



Ex.1008 Fig.2 (annotated)

e. **"and wherein when the support is disposed within a cylindrical section of the lumen of the canal having an internal wall surface area C, the support contacts less than 30% of C."**

As discussed in §XI.B.1.e, Lynch alone and/or in view of Bergheim teaches and/or renders obvious this limitation.

11. Dependent Claim 33

The device of claim 32, wherein the support makes minimal contact with the interior surface of the canal wall when the support is disposed within the lumen of the canal.

As discussed in §XI.B.2, Lynch alone and/or in view of Bergheim teaches and/or renders obvious this limitation.

12. Dependent Claim 36

The device of claim 32, wherein the support comprises fluted edges.

As discussed §XI.B.3, Lynch alone and/or in view of Bergheim teaches and/or renders obvious this limitation.

13. Dependent Claim 38

The device of claim 32, wherein the support comprises elements that make periodic contact with the canal wall when the support is disposed within the lumen of the canal.

As discussed in §XI.B.4, Lynch discloses this limitation.

14. Dependent Claim 39

The device of claim 32, wherein the support comprises a biocompatible metal.

As discussed in §XI.B.5, Lynch discloses this limitation.

15. Dependent Claim 46

The device of claim 32, wherein the support has a unitary structure.

As discussed in §XI.B.6, Lynch teaches and/or renders obvious this limitation

16. Dependent Claim 49

The device of claim 32, wherein the support comprises multiple connected elements configured to be distributed longitudinally along Schlemm's canal when the device is in use, and wherein at least one of the connected elements has a cross-sectional dimension sufficient to at least partially prop open Schlemm's canal, and to thereby maintain patency of at least a portion of the canal.

As discussed in §XI.B.7, Lynch discloses this limitation.

17. Dependent Claim 52

The device of claim 49, wherein the at least one fenestration is included in at least one of the connected elements.

As discussed in §XI.B.8, Lynch discloses this limitation.

18. Dependent Claim 54

The device of claim 32, wherein at least a portion of the support is porous.

As discussed in §XI.B.9, Lynch discloses this limitation.

19. Independent Claim 63

a. **"A method for reducing intraocular pressure in an eye, the method 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, Fig.6A). Ex.1001 (¶213).

b. **"inserting a support having at least one fenestration into a lumen of Schlemm's canal to at least partially prop open the canal and thereby maintain patency of at least a portion of the canal,"**

As discussed in §XI.B.1.b- XI.B.1.c, Lynch discloses this limitation.

c. **"wherein when the support is disposed within the lumen of Schlemm's canal, the support allows fluid to**

traverse the canal without substantial interference from the support"

As discussed in §XI.B.1.b-XI.B.1.c, Lynch discloses this limitation.

d. **"and wherein contact between the support and a wall of the canal is discontinuous along a perimeter of the lumen of the canal,"**

As discussed in §XI.B.1.d, Lynch discloses this limitation.

e. **"and wherein when the support is disposed within a cylindrical section of the lumen of the canal having an internal wall surface area C, the support contacts less than 30% of C."**

As discussed in §XI.B.1.e, Lynch alone and/or in view of Bergheim teaches and/or renders obvious this limitation.

20. Dependent Claim 65

The method of claim 63, wherein the support makes minimal surface area contact with the canal wall when the support is disposed within the lumen of the canal.

As discussed in §XI.B.2, Lynch alone and/or in view of Bergheim teaches and/or renders obvious this limitation.

21. Dependent Claim 68

The method of claim 63, wherein the support comprises fluted edges that contact the wall of the canal.

As discussed in §XI.B.3, Lynch alone and/or in view of Bergheim teaches and/or renders obvious this limitation because Lynch's fluted edges and the

remaining portions of the supports after including grooves taught by Bergheim would contact the canal wall.

22. Dependent Claim 69

> **The method of claim 63, wherein the support comprises elements that make periodic contact with the canal wall when the support is disposed within the lumen of the canal.**

As discussed in §XI.B.4, Lynch discloses this limitation.

23. Dependent Claim 70

> **The method of claim 63, wherein the support has a unitary structure.**

As discussed in §XI.B.6, Lynch discloses this limitation.

24. Dependent Claim 73

> **The method of claim 63, wherein the support comprises multiple connected elements distributed longitudinally along Schlemm's canal when the support is disposed within the lumen of the canal, and wherein at least one of the elements has a cross-sectional dimension sufficient to at least partially prop open the canal to thereby maintain patency of at least a portion of the canal.**

As discussed in §XI.B.7, Lynch discloses this limitation.

25. Dependent Claim 77

> **The method of claim 63, wherein the support comprises a biocompatible metal.**

As discussed in §XI.B.5, Lynch discloses this limitation.

C. Ground 3: Lynch alone, or in combination with Bergheim, further in view of Gharib render obvious claims 8, 10, 11, 39, 41, 42, 77 and 79-80

Claims 8, 10-11 either directly or indirectly depend on claim 1, claims 39, 41-42 either directly or indirectly depend on claim 32, and claims 77, 79-80 either directly or indirectly depend on claim 63. For the reasons presented above in §§XI.B.1a-e, XI.B.10a-e, and XI.B.19a-e, claims 1, 32, and 63 would have been obvious in light of Lynch alone or Lynch in combination with Bergheim. Therefore, this Section addresses only the additional limitations included in dependent claims 8, 10-11, 39, 41-42, 77 and 79-80, which would have been obvious further in view of Gharib.

1. Dependent Claim 8

The device of claim 1, wherein the support comprises a biocompatible metal.

Lynch discloses its support can be made from a "biocompatible material," Ex.1008 (¶52), and the device "can be fabricated from a material that will be compatible with the tissues and fluids with which it is in contact" and can be "biologically inert," *Id.* (¶69). Lynch lists "metals" as one of these biocompatible materials. *Id.* Lynch further teaches making the supports of material that is not "absorbed, corroded, or otherwise structurally compromised during its in situ tenure," and such that the "eye tissues and the aqueous remain non-detrimentally affected by the presence of the implanted device." *Id*. Ex.1001 (¶228-229).

Additionally, it would have been obvious to make Lynch's support such that it comprises a biocompatible metal in light of Gharib. Gharib teaches making at least a portion of a Schlemm's canal support from a biocompatible, shape memory material such as Nitinol. Ex.1005 (¶28, 53, 55, 63). The '482 patent recognizes Nitinol as a shape memory, biocompatible, nickel titanium alloy. Ex.1003 (3:5-7, 12:10-12, 12:59-62, 13:31-33). 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 and desirable material with which to make at least a portion of a Schlemm's canal support because it is biocompatible and allows the device to be delivered in a smaller form and then expand into a preshape post-insertion. Ex.1001 (¶228-230).

A POSITA would have been motivated to use a shape memory material like Nitinol (a nickel-titanium alloy) 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 (¶228-230). A smaller pre-insertion shape would reduce trauma to the eye during insertion while also benefiting from the larger shape post-implantation to allow effective transmission of aqueous through the natural outflow pathways. Ex.1001 (¶228-230).

Further, a POSITA would have had a reasonable expectation of success in using shape memory material, such as Nitinol, in a support because Gharib teaches the benefits and implementation of such materials in Schlemm's canal supports and because Lynch teaches making the supports from a variety of materials, including metals. Ex.1008 (¶69); Ex.1001 (¶228-230).

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 (¶228-230).

2. Dependent Claim 10

The device of claim 1, wherein the support comprises a shape memory material.

As discussed in §XI.C.1, Lynch alone, or in combination with Bergheim, further in view of Gharib renders obvious this limitation.

3. Dependent Claim 11

The device of claim 10, wherein the support comprises a nickel titanium alloy.

As discussed in §XI.C.1, Lynch alone, or in combination with Bergheim, further in view of Gharib renders obvious this limitation.

4. Dependent Claim 39

The device of claim 32, wherein the support comprises a biocompatible metal.

As discussed in §XI.C.1, Lynch alone, or in combination with Bergheim, further in view of Gharib renders obvious this limitation.

5. Dependent Claim 41

> **The device of claim 32, wherein the support comprises a shape memory material.**

As discussed in §XI.C.1, Lynch alone, or in combination with Bergheim, further in view of Gharib renders obvious this limitation.

6. Dependent Claim 42

> **The device of claim 41, wherein the support comprises a nickel titanium alloy.**

As discussed in §XI.C.1, Lynch alone, or in combination with Bergheim, further in view of Gharib renders obvious this limitation.

7. Dependent Claim 77

> **The method of claim 63, wherein the support comprises a biocompatible metal.**

As discussed in §XI.C.1, Lynch alone, or in combination with Bergheim, further in view of Gharib renders obvious this limitation.

8. Dependent Claim 79

> **The method of claim 63, wherein the support comprises a shape memory material.**

As discussed in §XI.C.1, Lynch alone, or in combination with Bergheim, further in view of Gharib renders obvious this limitation.

9. Dependent Claim 80

The method of claim 79, wherein the shape memory material comprises a nickel titanium alloy.

As discussed in §XI.C.1, Lynch alone, or in combination with Bergheim, further in view of Gharib renders obvious this limitation.

XII. SECONDARY CONSIDERATIONS OF NONOBVIOUSNESS

Patent Owner asserts "many factors are relevant to considerations of non-obviousness." Ex.1033 (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 disputes 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 Electronics Co.*, Ltd., 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 '482 patent. Ex.1032

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 requests that the Board institute *inter partes* review and cancel the Challenged Claims.

Date: September 14, 2022

Respectfully submitted,

/s/ Kat Li

Gregg F. LoCascio, P.C. (Reg. No. 55,396)
W. Todd Baker (Reg. No. 45,265)
Justin Bova (Reg. No. 70,336)
gregg.locascio@kirkland.com
todd.baker@kirkland.com
justin.bova@kirkland.com
KIRKLAND & ELLIS LLP
1301 Pennsylvania Ave., N.W.
Washington, D.C. 20004
(202) 389-5000

Kat Li (Reg. No. 64,857)
kat.li@kirkland.com
KIRKLAND & ELLIS LLP
401 Congress Avenue
Austin, TX 78701
(512) 678-9100

Attorneys for Petitioners Ivantis, Inc., Alcon Research, LLC, Alcon Vision, LLC, and Alcon Inc.

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 13,993 (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 served on the 14th day of September, 2022, via Federal Express® directed to PO at the correspondence address of record:

ATTN: IP Docketing Department
1299 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004
UNITED STATES

A courtesy copy was also served by electronic mail on PO's counsel of record in District Court litigation:

Melanie K. Sharp (No. 2501)
James L. Higgins (No. 5021)
Taylor E. Hallowell (No. 6815)
YOUNG, CONAWAY, STARGATT & TAYLOR LLP
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
msharp@ycst.com
jhiggins@ycst.com
thallowell@ycst.com

Orion Armon
COOLEY LLP
1144 15th Street, Suite 2300
Denver, CO 80202
(720)566-4000
oarmon@cooley.com

Michelle S. Rhyu
David Murdter
Deepa Kannappan
Emily M. Ross
Benjamin S. Lin
COOLEY LLP
3175 Hanover Street
Palo Alto, CA 94304-1130
(650) 843-5000
rhyums@cooley.com
dmurdter@cooley.com
dkannappan@cooley.com
eross@cooley.com
blin@cooley.com

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