UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IVANTIS, INC.,
Petitioner

v.

GLAUKOS CORP.,
Patent Owner.

U.S. Patent No.: 9,827,143
Issue Date: Nov. 28, 2017
Title: SHUNT DEVICE AND METHOD
FOR TREATING OCULAR DISORDERS

Inter Partes Review No.: {unassigned}

PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 9,827,143

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Exhibit 1033	Mark C. Gillies & Tao Su, *Cytokines, fibrosis and the failure of glaucoma filtration surgery*, 19 AUSTL. AND N.Z. J. OF OPHTHALMOLOGY 299, 300 (1991)

I. MANDATORY NOTICES

A. Real Party-In-Interest (§ 42.8(b)(1))

Ivantis, Inc. is the real party-in-interest for the instant petition.

B. Related Matters (§42.8(b)(2))

1. Related Litigations

On April 16, 2018, Ivantis was served with a complaint for patent infringement on U.S. Patent No. 9,827,143 (the "'143 patent") (Ex. 1001). The case is currently pending before the District Court for the Central District of California in the case captioned *Glaukos Corp. v. Ivantis Inc.*, Civ. Case No. 8:18- cv-00620.

2. Related Proceedings Before the Board

Petitioner has previously filed a separate petition for *inter partes* review challenging the claims of U.S. Patent No. 6,626,858, which claims priority from the same provisional application and the same utility application as U.S. Patent No. 9,827,143.

C. Lead and Backup Counsel (§ 42.8(b)(3))

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D. Service Information (§ 42.8(b)(4))

In accordance with 37 C.F.R. § 42.8(b)(4), Petitioners identify the following service information:

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II. PAYMENT OF FEES (37 C.F.R. § 42.103)

The required *inter partes* review fee specified in 37 C.F.R. § 42.15(a) is being paid at the time of filing of this petition. If there are any additional fees due in connection with the filing of this paper, please charge them to Deposit Account No. 502387.

III. REQUIREMENTS FOR IPR (37 C.F.R. § 42.104)

A. CERTIFICATION OF GROUNDS FOR STANDING

As required by 37 C.F.R. § 42.104(a), Petitioner certifies that the patent for which review is sought is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review on the grounds identified herein.

B. IDENTIFICATION OF CHALLENGED CLAIMS AND STATEMENT OF THE PRECISE RELIEF REQUESTED

Petitioner respectfully requests *inter partes* review under 35 U.S.C. §§ 311-318 and 37 C.F.R §§ 42.100-42.123, and the cancellation of claims 1-42 of the ’143 patent for the following reasons:

(i) Claims **1**, **3-8**, **11-16**, **20-24**, **26-29**, **31**, and **38-42** are anticipated under 35 U.S.C. § 102(b) and/or rendered obvious under 35 U.S.C. § 103(a) by Australian Patent Application No. 199876197 B2 (issued as Australian Patent No. 746903) (“Grieshaber”) (Ex. 1002);

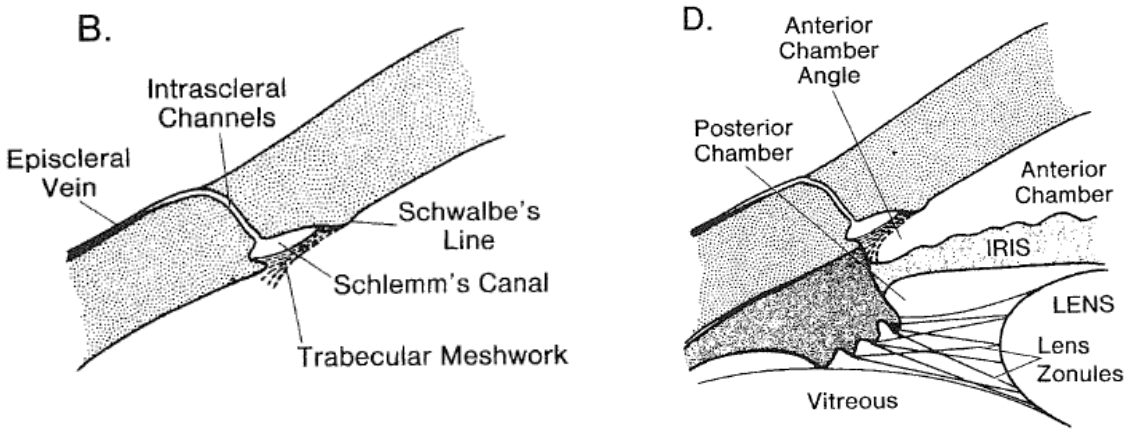
(ii) Claims **2**, **9**, **10**, **17-19**, **25**, and **32-37** are rendered obvious under 35 U.S.C. § 103(a) by Grieshaber in view of Detlev Spiegel, *Surgical Glaucoma Therapy*, in Benefits and Risks of Ophthalmological Therapy: Main Presentations of the 33rd Essen Continued Education for Ophthalmologists 79-82 (Herausgegeben von Anselm Kampik & Franz Grehn ed., 1998) (“Spiegel”) (Ex. 1003; certified translation at Ex. 1004).

(iii) Claim **30** is rendered obvious under 35 U.S.C. § 103(a) by Grieshaber and/or by Grieshaber in view of "Hypothesis for Improving Accessory Filtration by Using Geometry," by Michael J. Wilcox and Donald S. Minckler and published in 1994 in the *Journal of Glaucoma* ("Minckler") (Ex. 1005).

The claim construction, reasons for unpatentability, and specific evidence supporting this request are detailed below and in the supporting Declarations of Dr. Andrew Iwach, M.D. (Ex. 1006) and Dr. James Moore, Ph.D. (Ex. 1007).

IV. BACKGROUND ANATOMY AND TECHNOLOGY

The '143 patent is directed to the treatment of glaucoma, an eye disease linked to elevated intraocular pressure. Ex. 1006 ¶ 22. Elevated intraocular pressure stems from the build-up in the eye of a fluid called "aqueous humor," which is produced by ciliary bodies located in the posterior chamber of the eye. *Id.* ¶¶ 15, 18. The relevant anatomy of the eye is shown below:



Id. ¶ 16.

Generally, aqueous humor drains from the anterior chamber of the eye through the "canalicular" route. *Id.* ¶ 15. In passing through this route, aqueous humor flows from the anterior chamber, across the trabecular meshwork, and into a fragile, tube-like structure encircling the cornea known as Schlemm's canal. *Id.* ¶¶ 15, 17. Aqueous humor then drains out of the eye through collecting channels located on the outer wall of Schlemm's canal, which connect to the episcleral venous system, as shown below.

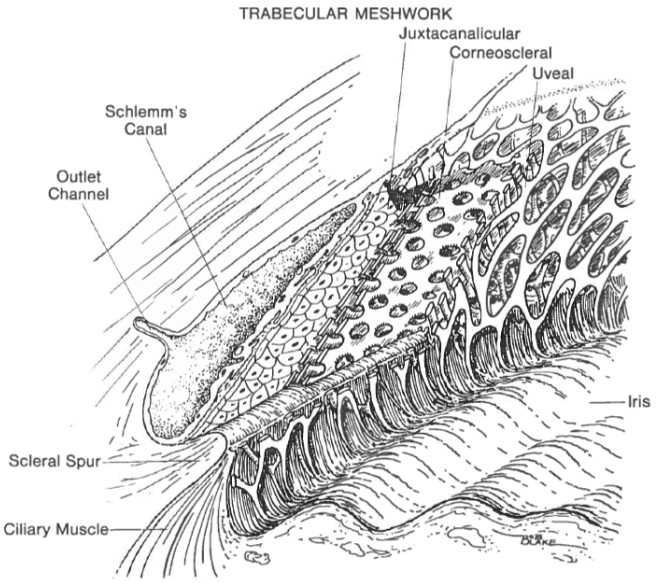


Figure 2.10. Three layers of trabecular meshwork (shown in cutaway views): (1) uveal; (2) corneoscleral; and (3) juxtacanalicular.

Id. ¶ 16.

In eyes afflicted with glaucoma, this process of natural outflow is compromised, leading to a decrease in the outflow of aqueous humor and a consequent increase in intraocular pressure ("IOP"). *Id.* ¶¶ 14-18. Treatments for glaucoma focus on relieving IOP, whether through medication, laser treatments, or surgery. *Id.* ¶ 19.

For decades, in an attempt to avoid the recovery time and complications associated with traditional glaucoma surgery, surgeons have employed minimally invasive glaucoma surgery ("MIGS"). Ex. 1006 ¶ 20. For instance, since at least the 1940s, glaucoma surgeons performed MIGS in pediatric and uveitic (inflammatory) glaucoma cases. *Id.* In MIGS, surgeons operate inside the eye through small clear corneal incisions that

cause less tissue trauma as compared to traditional operations. *Id.* MIGS procedures often involve implantation of small medical devices that facilitate a decrease in intraocular pressure. *Id.*

V. OVERVIEW OF THE '143 PATENT AND ITS PROSECUTION HISTORY

The '143 patent issued on November 28, 2017 and, on its face, claims priority to U.S. Provisional Patent App. No. 60/131,030 ("the '030 Provisional") (Ex. 1016), which was filed on April 26, 1999.[1] The '143 patent issued from the seventh utility application in a chain of applications dating back to the '030 Provisional.[2]

The '143 patent is directed to a surgical treatment and device for continuously decompressing elevated IOP by diverting aqueous humor from the anterior chamber of the eye into Schlemm's canal and the natural outflow pathways of the eye. Ex. 1001 at 1:32-42; *see also id.* at Abstract, 5:30-44. The '143 patent acknowledges that, at the time of filing, it was known that the primary pathway for aqueous outflow in humans is through the "canalicular" route—*i.e.*, from the anterior chamber across the trabecular

[1] As noted in Section V.A below, however, the '030 Provisional does not provide written description support for the claims of the '143 patent.

[2] *See* Ex. 1001 at 1:7-24. This petition will refer to the patents in the priority chain collectively as the "Lynch family." U.S. Patent No. 9,492,320 (Ex. 1017), which issued from the immediate parent application, is referred to in this petition as "the '320 Parent Patent."

meshwork, into Schlemm's canal and out through the collecting channels that drain into the episcleral venous system of the eye. *Id.* at 1:67-2:3, 2:21-28.

The '143 patent also acknowledges that "[t]he prior art includes a number of such aqueous shunt devices," and that "[s]ome prior art references for glaucoma management have been directed at Schlemm's canal[.]" *Id.* at 4:36-45, 4:57-5:9. According to the Applicant, however, the prior art "[did] not involve[] the placement of long-term, indwelling shunts." *Id.* at 4:58-59.

In each of the first five patents to issue in the Lynch family, the claims were directed to an ocular shunt placed partially in the eye's anterior chamber and partially within Schlemm's canal. *See, e.g.*, claim 1 of Exs. 1018, 1019, 1020, 1021, 1022. These related patents encompass and, in some cases, expressly claim "tubular" ocular implants. For instance, independent claims 1, 19, and 32 in U.S. Patent 6,827,700 each recite a "solid-walled tubular body." Ex. 1020 at 12:23, 13:20, 13:59.

In contrast, the independent claims of the '143 patent require an implant that is (1) "**non-tubular**"; (2) "**non-luminal open**"; and/or (3) has a channel which is at least "**partially open**" along its length.

The claims of the ’143 patent appear to derive support from certain discrete embodiments in the specification. For instance, Figure 3A discloses “[an] embodiment of the present invention in which the inventive shunt is comprised of elements that are partially tubular and partially open in their configuration.” Ex. 1001 at 6:8-11; *see also id.*at 8:50-62.

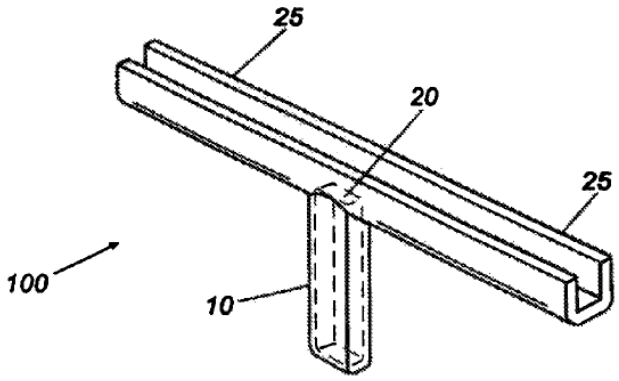


Fig. 3A

Figure 3D shows “another embodiment of the present invention in which the inventive shunt is comprised of elements that are partially open and trough-like in their configuration.” *Id.* at 6:18-21.

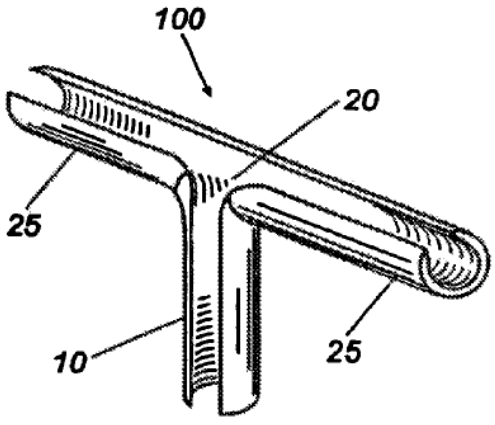


Fig. 3D

Figure 5D shows "an alternative embodiment of the inventive shunt comprised of a partially open trough-like element which is placed within Schlemm's canal but contains a portal to maintain fluid egress of aqueous humor from the anterior chamber to Schlemm's canal." *Id.* at 6:43-47.

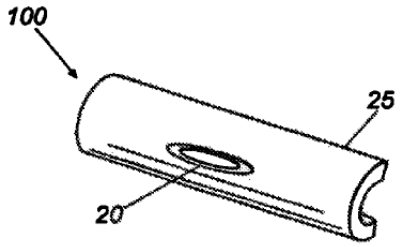


Fig. 5D

The '143 patent refers to these various implants as "aqueous humor directing channels." For instance, in order to "facilitate the passage of aqueous humor from the anterior chamber into Schlemm's canal," the shunts of the '143 patent comprise "aqueous humor directing channel[s]." *Id*. at 7:24-33. These channels form the interior of the device and provide for "fluid communication" of aqueous humor within the shunt. *Id*. at 7:9-11. "For example, the aqueous humor directing channel can be a fully enclosed lumen, a partially enclosed lumen, or a trough-like channel that is partially open." *Id*. at 7:33-36; *see also id.* at 8:50-54 (describing FIG. 3A embodiment as a "channeling device"), 9:4-8 (describing "an aqueous

humor directing channel that is both open and curved in a continuous trough-like configuration").

A. Priority Date

The independent claims of the '143 patent all require a stent that is "non-tubular," "non-luminal," or has a channel that is "partially open." The '143 patent is not entitled to an April 26, 1999 priority date because no such embodiments were disclosed in the '030 Provisional, either expressly or inherently.

Under 35 U.S.C. § 112 ¶ 1, for a utility application to be entitled to the priority date of a provisional application, the provisional application must contain an adequate written description of the claimed invention of the non-provisional application. *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). More generally, "to satisfy the written description requirement, the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and demonstrate that by disclosure in the specification of the patent." *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1348 (Fed. Cir. 2011) (quotations omitted). "[A]n applicant complies with the written description requirement by describing the invention, *with all its claimed limitations*, not that which

makes it obvious." *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997) (emphasis added) (quotations omitted).

The '030 Provisional discloses six different embodiments, only two of which concern stent-like implants. Neither of the two stent-like embodiments are depicted or described as "non-tubular," "non-luminal," or "partially open." Instead, one of the stent-like embodiments of the '030 Provisional is a "t-bar tube device" or shunt and the other is a "luminal mesh tube." Ex. 1016 at 11, 16. None of the terms "non-tubular," "non-luminal," or "partially open" even appears in the '030 Provisional. Thus, the '030 Provisional does not provide adequate written description to support the claims of the '143 patent. Consequently, the claims of the '143 patent are not entitled to the filing date of the '030 Provisional. *See Dynamic Drinkware*, 800 F.3d at 1378; *see also Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1344 (Fed. Cir. 2013) ("claims added during prosecution must find support sufficient to satisfy § 112 in the written description of the original priority application").

The concept of a "non-tubular," "non-luminal," or "partially open" implant appeared for the first time in the text and figures of U.S. Patent App. No. 09/558,505, the first non-provisional application in the priority chain of the '143 patent, which was filed on April 26, 2000, and issued as U.S. Patent

No. 6,450,984. *See*, *e.g.*, Ex. 1022 at 8:35-47, 9:35-42, Figures 3A, 3D and 5D. Therefore, the earliest priority date to which the '143 patent is entitled is April 26, 2000.

B. Prosecution History

The application giving rise to the '143 patent was filed with an initial set of claims that did not include any "non-tubular," "non-luminal," or "partially open" limitations. Ex. 1023 at 24-27. Instead, like the claims of other patents in the Lynch family, the initial claims were all directed generally to implants having a flow path to convey fluid from the anterior chamber of the eye into Schlemm's canal. *Id.* In a preliminary amendment filed on April 24, 2017, the Applicant introduced new claims that required the implant's body to be "non-tubular," "non-luminal," or "partially open." *Id.* at 62-65.

During an in-person interview on July 13, 2017, the Applicant presented these new claims to the Examiner, drawn mostly to the embodiment depicted in Figure 5D, which shows a "partially open trough-like element." *Id.* at 869; Ex. 1001 at 6:43-47.

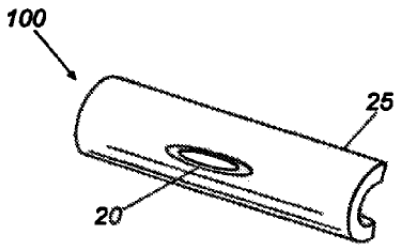


Fig. 5D

The Examiner noted that the claims were similar to those of the '320 Parent Patent. Ex. 1023 at 869. The Applicant subsequently filed a Terminal Disclaimer to the '320 Parent Patent on August 16, 2017. Ex. 1023 at 885-889. A Notice of Allowance was issued on October 17, 2017, and the '143 patent issued shortly thereafter. *Id.* at 1297.

VI. OVERVIEW OF THE PRIOR ART

As discussed above, the '143 patent acknowledges that ocular implants existed in the prior art and also recognizes that Schlemm's canal was a known target for glaucoma treatment. Ex. 1001 at 4:36-5:9. By 1999, it was understood in the art that drainage problems with the trabecular meshwork contributed to elevated intraocular pressure and glaucoma. Ex. 1006 ¶ 19. In fact, the '143 patent expressly acknowledged that "[i]n primary open angle glaucoma, which is the most common form of glaucoma, the abnormal resistance [through the canalicular outflow system] is believed to be along the outer aspect of the trabecular meshwork and the inner wall of

Schlemm's canal." Ex. 1001 at 2:30-33. Thus, the trabecular meshwork was a well-recognized focus for treating elevated intraocular pressure and glaucoma in the art. It was also known in the art that IOP and glaucoma—particularly congenital pediatric glaucoma or uveitic glaucoma—could be addressed by removing or bypassing the trabecular meshwork and providing access directly to Schlemm's canal using minimally invasive glaucoma surgery. Ex. 1006 ¶ 19; *see* Ex. 1004 at 81.

Moreover, contrary to the assertion in the '143 patent, indwelling shunts or stents for Schlemm's canal to facilitate improved drainage of aqueous humor across the trabecular meshwork and to the outflow connector channels were also known in the prior art. Ex. 1006 ¶ 19.

A. Australian Patent Application Publication AU 199876197 ("Grieshaber")

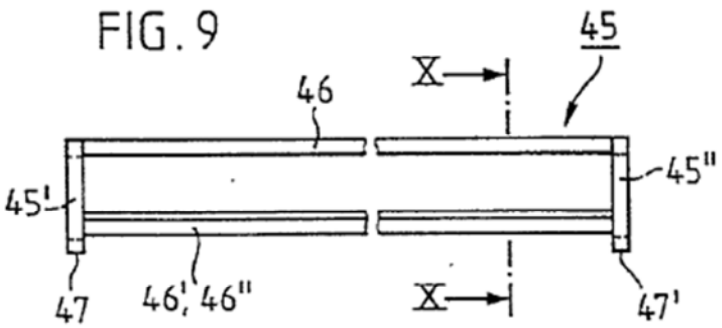
The Grieshaber Australian patent application was published on February 25, 1999, more than a year before the earliest priority date of the'143 patent (April 26, 2000), and therefore constitutes prior art under 35 U.S.C. § 102(b). *See* Ex. 1002.

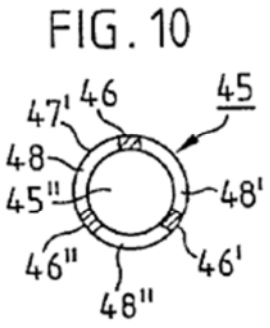
Other members of the Grieshaber patent family were listed in Information Disclosure Statements ("IDS") by the Applicant, among 851 references. There was neither discussion in the file relating to any

Greishaber publication nor any indication that the Examiner considered the arguments now being presented.

Grieshaber describes an indwelling ocular implant for treatment of ophthalmic disorders and, specifically, for the treatment of glaucoma. For instance, Grieshaber discloses "a support element (35) subsequently implanted in the lumen (16) of the canal of Schlemm, the inner walls of this canal are supported and permanently held in an expanded position, whereby unimpeded drainage of the aqueous humor from the canal of Schlemm (15) through the subsequent outflow pathways (20) is ensured." Ex. 1002 at Abstract. Like the devices disclosed in the '143 patent, Grieshaber describes implants designed to treat intraocular pressure by maintaining the patency of Schlemm's canal. *Compare* Ex. 1001 at 9:20-22 *with* Ex. 1002 at 2.

Grieshaber describes several embodiments of the ocular implant, one of which includes a "substantially hollow cylindrical support element." Ex. 1002 at 8, 10. This embodiment is shown in Figures 9 and 10:





The overall device of Figures 9 and 10 is the "support element 45." Ex. 1002 at 8. At one end is "opening 45'" and at the other is opening 45". *Id.* at 8. These openings are defined by "end portions 47, 47'," which are made up of "axially spaced toruses"—rings—that are linked to each other by "two, but preferably three webs, 46, 46', and 46" placed circumferentially at intervals . . . ." *Id.* The portions marked 48, 48', and 48" represent open gaps or "recesses" designed to "serve . . . as outflow openings for the aqueous humor to be drained . . . ." *Id.* In other words, the implant is formed of two rings ("toruses" designated 45' and 45") linked by longitudinally extending pieces ("webs" designated 46, 46' and 46"). The gaps between these narrow pieces ("recesses" designated 48, 48' and 48") are open to allow drainage of aqueous humor from the trabecular meshwork to Schlemm's canal and the natural outflow pathways of the eye. Ex. 1006 ¶ 45. The body of the device may be "curved" longitudinally to approximate the curvature of Schlemm's canal encircling the cornea. Ex. 1002 at 9 ("In a variant embodiment not depicted, there is also the possibility that the support element 35; 40; 45; 50 or 55 is designed longitudinally somewhat arcuate.").

Moreover, Grieshaber teaches that two webs may be used instead of the three depicted in Figures 9 and 10: "between which are placed at least

two, but preferably three webs 46,46’ and 46” placed circumferentially at intervals and linking the end portions 47,47’ to each other.” Ex. 1002 at 8.

Grieshaber also discloses Figure 4 and Figure 7 embodiments, each of which comprise a support element (35, 40) that contains a number of throughholes (38, 38’, 40, 41’). Ex. 1002 at 6-7. The support element is preferably positioned and implanted in Schlemm’s canal so that “at least one of the throughholes 38, 38’ connects with the small collector channels 21’, 22’ of the natural outflow pathways 20’.” *Id.*

Figures 4 and 7 depict this alignment of openings to collector channels:

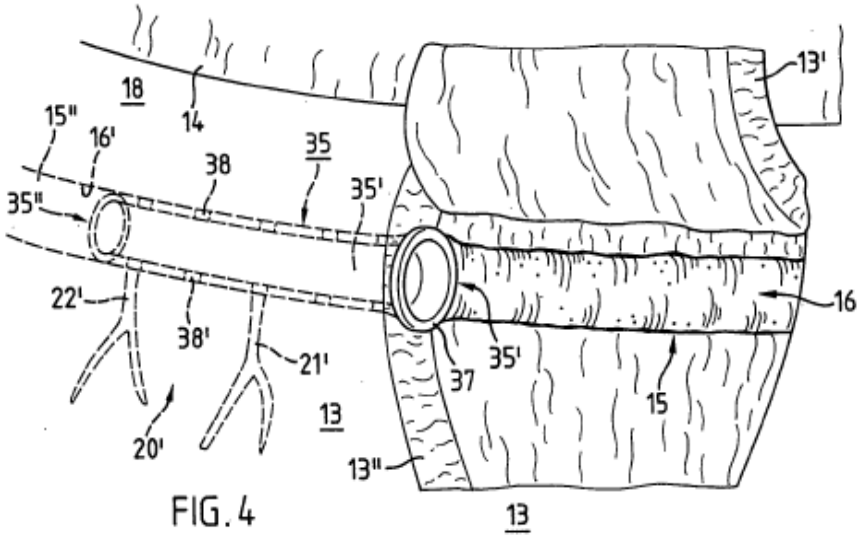


FIG. 4

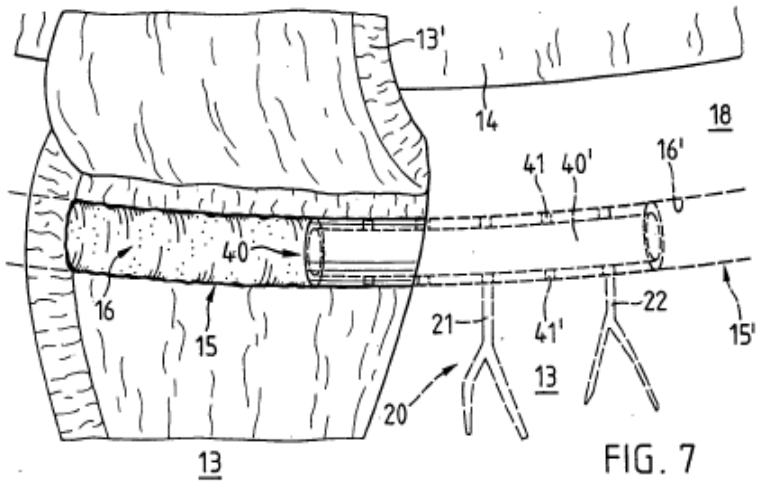


FIG. 7

Grieshaber reports that "[t]he aqueous humor penetrating through the trabecular meshwork 18 exits through the canal of Schlemm 15 or through the interior 40' of the support element 40 and through the openings 41' and collector channels 21, 22 of the subsequent natural outflow pathways." Ex. 1002 at 7. Thus, Grieshaber teaches various configurations of stents that facilitate aqueous humor flow from the trabecular meshwork, into Schlemm's canal, and out through collector channels and the natural outflow pathways of the eye. Grieshaber Figure 5 provides additional detail on the pipe (36) or tube of support element (35) disclosed in Figure 4 above. Ex. 1002 at 6. Most notably, Figure 5 shows that the implant has "throughholes" (designated 38 and 38'), or fenestrations, which are "distributed axially and circumferentially" along its body and "connect[] with the small collector channels . . . of the natural outflow pathways." *Id.* at 6-7.

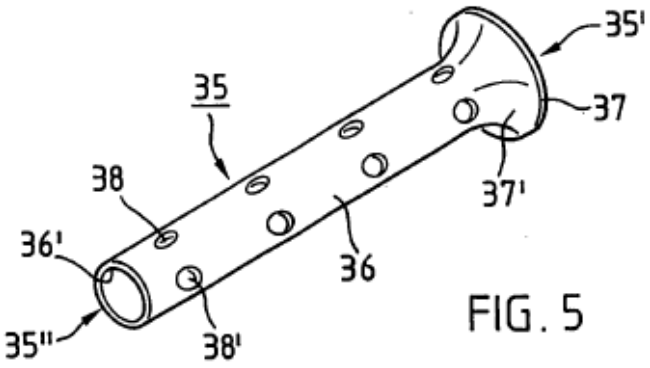


FIG. 5

A. Detlev Spiegel, *Surgical Treatment of Glaucoma*, in Benefits and Risks of Ophthalmologic Therapy: Main Presentations from the 33rd Ophalmology Continuing Education Seminar in Essen

Spiegel was published on or before August 1998, more than a year before the priority date of the '143 patent, and was publicly available by October 1998. Ex. 1008 ¶ 5. As such, the Spiegel reference is prior art under 35 U.S.C. § 102(b). While Spiegel was submitted as prior art in an IDS by the applicant, it was never cited by the Examiner and did not form the basis for any rejection during prosecution.[3]

[3] *See* Ex. 1023 at 893. Spiegel was also submitted in an earlier related application, U.S. App. No. 09/558,505, first in an IDS (where it was not cited by the Examiner and did not form the basis for any rejection) and later by a third party pursuant to 37 C.F.R. § 1.291. Ex. 1025 at 262, 307-11. However, the protest was filed after a notice of allowance and was never addressed by the Examiner.

In the Introduction, Spiegel notes that there were two approaches in the art to reduce intraocular pressure by surgical methods: (1) "reducing the production of aqueous humor by using cyclodestructive procedures" (thereby destroying the ciliary bodies); and (2) "increasing aqueous outflow." Ex. 1004 at 79. With respect to increasing aqueous outflow, Spiegel states that improved drainage "can be achieved by either improving aqueous outflow via the existing outflow pathways, or by creating a new outflow pathway that connects the anterior chamber with the subconjunctival space." *Id.*

Spiegel teaches that "[t]reating the cause of glaucoma requires improving aqueous outflow via existing outflow pathways" and then describes a number of approaches in the art to improving aqueous humor drainage via existing channels: "This can be accomplished by surgical iridectomy, argon laser trabeculoplasty, selective laser trabeculoplasty, trabeculotomy, as well as by the experimental methods of viscocanalostomy and drainage of Schlemm's canal." *Id.* at 80.

Spiegel recognizes that the trabecular meshwork is often responsible for the increase in intraocular pressure: "The increase in intraocular pressure . . . is generally believed to be caused by a decrease in the ability of trabecular meshwork to facilitate aqueous outflow due to pathological

changes." *Id.* at 81. Moreover, Spiegel recognizes that the best solution to this reduced drainage across the trabecular meshwork is "to bypass the trabecular meshwork and create a direct connection from the anterior chamber into the aqueous veins, which would allow for [decreased pressure] resulting from outflow through Schlemm's canal." *Id.*

To that end, Spiegel describes placing an indwelling shunt into Schlemm's canal at one end with the other end of the shunt in the anterior chamber to improve aqueous humor drainage from the anterior chamber into the eye's natural outflow pathways. Specifically, Speigel describes "insert[ing] a silicone tube with an outer diameter of 150 μm . . . into Schlemm's canal" wherein "[o]ne end of the tube was seated in Schlemm's canal, while the other end was slid into the anterior chamber once the inner wall of Schlemm's canal was opened." *Id.*

Spiegel Figure 7.1 depicts a tube inserted into Schlemm's canal, while Figure 7.2 shows the positioning of the other end of the tube inside the anterior chamber of the eye. *See id.* at 82.

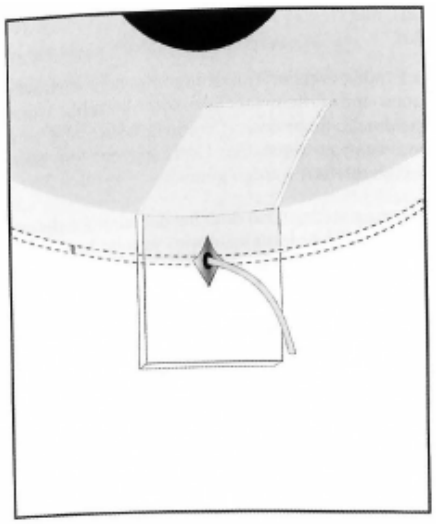


Figure 7.1

Figure 7.2

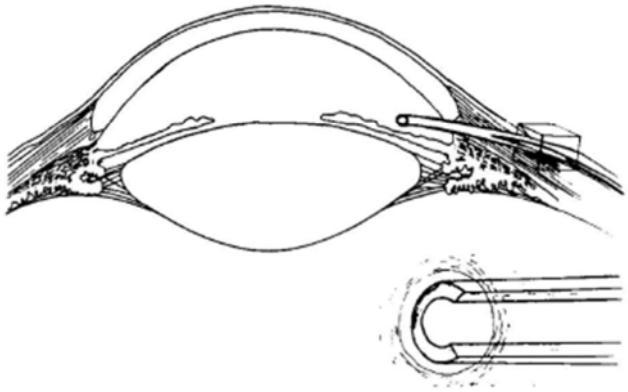
B. Michael J. Wilcox and Donald S. Minckler, "Hypothesis for Improving Accessory Filtration by Using Geometry"

The idea of using an open "trough-like" shape for an intraocular shunt was known in the art. For example, an article published in 1994 by Michael J. Wilcox and Donald S. Minckler in the *Journal of Glaucoma*, "Hypothesis for Improving Accessory Filtration by Using Geometry" ("Minckler"), expressly taught using a C-shaped trough-like stent to drain fluid from the

eye. *See* Ex. 1005 at 246. Minckler was published in 1994, six years before the filing date of the '143 patent and constitutes 35 U.S.C. § 102(b) prior art.

Minckler describes a shunt that is used to provide a conduit for aqueous humor away from the anterior chamber and thus control intraocular pressure. *Id.* at 244. Minckler identifies fibrous tissue scarring as one of the causes for the failure of tube shunt procedures. *Id.* Essentially, "[i]mplanting a tube provides a conduit for aqueous humor to bypass angle structures and enter a large blister-like cavity called a bleb. The fibrous capsule formed around the cavity provides resistance to outflow of aqueous that filters into the adjacent extracellular space." *Id.* Over time, fibrous tissue builds up in the capsule, decreasing the flow of aqueous humor and leading to a re-elevation in intraocular pressure and failure of the device. *Id.*

Minckler describes a small-diameter "trough-like" tube, with a C-shaped cross section, which is used to minimize fibrous build-up, as shown in Figure 2, below.



Id. at 246. The C-shaped cross section, is particularly important to Minckler's described device: "[t]he entire side is open so that aqueous has access to the filtering surface. There are no slits, holes or valves to occlude." *Id.* This minimizes fibrous build-up and consequent re-elevation of intraocular pressure. *Id.*

Thus, the prior art taught a trough-like ocular implant as an alternative to a tubular shunt, and a trough-like implant was known to have certain advantages, including the promotion of unhampered fluid flow and the reduction of occlusion along the flow path of the shunt.

VII. CLAIM CONSTRUCTION

A. Legal Principles

A claim subject to *inter partes* review receives the "broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b). That construction must be consistent with the specification, and the claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010). "Negative claim limitations are adequately supported when the specification describes a reason to exclude the relevant limitation. Such written description support

need not rise to the level of disclaimer." *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1351 (Fed. Cir. 2012).

B. Person of Ordinary Skill in the Art

The '143 patent acknowledges that the prior art teaches aqueous implants for glaucoma, including some devices directed to Schlemm's canal. *See* Ex. 1001 at 4:36-45, 4:57-59. The claimed inventions are ocular stents with particular characteristics. Accordingly, one of ordinary skill in the art would have either (1) a medical degree and at least two years' experience in ophthalmology; or (2) an undergraduate or graduate degree in biomedical or mechanical engineering and at least two years of work experience, including familiarity with ophthalmic anatomy. *See* Ex. 1006 ¶ 38; Ex. 1007 ¶ 22.

C. Petitioner's Proposed Constructions

1. "Non-tubular" (claims 1, 12, 21, 24)

Independent claim 1 recites an ocular implant that comprises a body that is "non-tubular." Independent claim 24 similarly recites "a non-tubular open shape." Ex. 1001 at claims 1 and 24. In addition, claim 12 (which depends from claim 5) and claim 21 (which depends from claim 16) recite that a distal end of the body of the implant is "non-tubular." Ex. 1001 at claims 12 and 21.

The plain language of claim 24, which explicitly refers to "a non-tubular open shape," suggests that the term "non-tubular" implies something about the enclosure or openness of the shape. Ex. 1001 at claim 24.

The '143 patent specification is in accord. It uses the term "non-tubular" only twice, and in each instance, the term is used in contrast with an implant that is "tubular." *Id.* at 8:50-62, 9:23-34. Furthermore, the '143 patent uses the term "tubular" to refer not to a specific kind of shape (*e.g.*, a round cylinder), but rather to the fact that the implant is "enclosed," as made clear in the following passage:

> FIG. 3A shows an embodiment of the inventive shunt in which a portion of the channeling device is ***enclosed and tubular*** in configuration at the junction of the proximal portion 10 and the distal portion 25, ***but where the distal portion 10 is a trough-like channel***. The distal portion portal 20 is also shown. The invention contemplates that any portion of the device 100 can be semi-tubular, open and trough-like, or a wick-like extension. ***Tubular channels can be round, ovoid, or any other enclosed geometry***. Preferably the ***non-tubular trough-like*** aspects are oriented posteriorly on the outer wall of the canal to facilitate aqueous humor drainage to the collecting channels of the eye, as shown in FIG. 3A.

Id. at 8:50-62 (emphasis added). This passage also indicates that a non-tubular shunt may be partially enclosed—that is, enclosed along a portion of its length—insofar as it discloses a shunt in which "a portion of the channeling device is enclosed and tubular" with at least one other portion

that is "semi-tubular, open [or] trough-like." *Id.* Thus, a shunt that is trough-like at one end and enclosed at the other would nonetheless be "non-tubular." In contrast, a shunt that is enclosed along its length would be "tubular."

The '143 patent contrasts such "tubular" and "enclosed geometr[ies]" with "non-tubular" implants possessing "trough-like aspects . . . on the outer wall of the canal," as shown in Figure 3A. As noted in the passage quoted above, tubular channels can be "round, ovoid, or any other enclosed geometry." Ex. 1001 at 8:57-58. Likewise, the '143 patent teaches that "non-tubular" trough-like terminal openings may be round, ovoid or any other shape:

> FIG. 5A shows another embodiment of the inventive shunt in which the proximal portion 10 joins a single, curved distal portion 25 in a "V-shaped," ***tubular*** configuration. . . . ***Fenestrations and non-tubular, trough-like terminal openings*** 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 within the anatomic spaces involved.

Id. at 9: 23-34. Notably, each of the embodiments in the '143 patent that are described as "tubular" without further qualifiers (*e.g.*, partially tubular, perforated tubular, etc.) are also depicted as enclosed structures. *See id.* at 8:4-16, Figures 1A, 1B; *see also id.* at 9:44-48, Figure 5C.

Thus, based on the plain language of the claims and the disclosure of the specification, one of ordinary skill in the art would have understood "non-tubular" to mean "not enclosed along its length." Ex. 1006 ¶ 64.

The prosecution history of the '320 Parent Patent also supports this construction. During prosecution, the Applicant amended then-pending claim 86, which recited a "***partially*** tubular" ocular implant, to recite a "***non***-tubular" ocular implant in response to a restriction requirement. *See* Ex. 1024 at 150 (emphasis added). The Applicant explained that claims 86-94 of Species C, all of which were directed to "***partially*** tubular" implants, covered Species B, which claims were directed to "***non***-tubular" implants. *Id.* at 152 (emphasis added). The Applicant thus made it clear that an implant that is only "partially" enclosed (that is, with one portion enclosed and another not enclosed) is, in fact, "non-tubular."

2. "Non-luminal" (claims 32 and 38)

Independent claim 32 requires a "non-luminal open stent," while independent claim 38 recites an implant comprising a "non-luminal, elongated body." Ex. 1001 at claims 32 and 38.

The '143 patent uses the term "lumen" in describing Figure 1B, which is shown below:

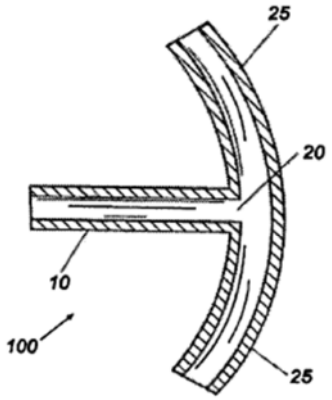


Fig. 1B

The specification states, "Figure 1B is an overhead view of the embodiment of the present invention shown in FIG. 1A, with phantom lines detailing the internal communication between the ***lumens*** of the tubular elements comprising the inventive device." Ex. 1001 at 5:52-55. In other words "the lumens of the tubular elements" are the enclosed spaces or cavities within them. The '143 specification goes on to say that "***[t]he lumen or channeling space defined by the walls*** of the proximal portion 10 and the distal portion(s) 25 are continuous at their junction[.]" *Id.* at 8:14-16 (emphasis added). The enclosed cavities in these portions thus lead into one another. This is consistent with how one of ordinary skill in the art at the time of patent would have understood the term "lumen" or "luminal" to refer

to a "cavity or channel within a tube," *i.e.* a cavity or channel ***enclosed*** by a tube.[4] Ex. 1006 ¶ 70.

The '143 patent specification is sparing in its references to "non-luminal" body shapes. The specification states that "***non-luminal, non-trough-like***" portions of the implant's body can act as "wicking extensions" that direct aqueous humor along the extensions' length. Ex. 1001 at 10:28-31, 11:17-20. That is, they may draw off aqueous humor away from the implant. One of ordinary skill in the art would understand that "wicking extensions" have no interior space or channel. Ex. 1006 ¶ 72. This is consistent with a wicking extension being "non-luminal."

For all of these reasons, one of ordinary skill in the art would understand the term "non-luminal," in the context of the '143 patent, to mean "not having an enclosed space or cavity." *Id.* ¶ 73.

3. "Portal" (claims 5, 7-8, and 38-40)

Independent claim 5 requires that the channel has "one or more portals." Independent claim 38 requires that the implant comprises "a portal." Dependent claims 8 and 39 require that the "portal" is "ovoid" or

[4] Ex. 1026 at 956 (Lumen: 1. the cavity or channel within a tube or tubular organ; Luminal: pertaining to the lumen of a tubular structure).

"oval-shaped" and dependent claims 7 and 40 required "multiple portals" or "multiple oval-shaped portals."

The '143 patent uses the term "portal" to refer to an "opening" on the body of the implant. For instance, in describing Figure 5D, the '143 patent states that it represents "an alternative embodiment of the inventive shunt comprised of a partially open trough-like element which is placed within Schlemm's canal but contains a portal to maintain fluid egress of aqueous humor from the anterior chamber to Schlemm's canal." Ex. 1001 at 6:43-47.

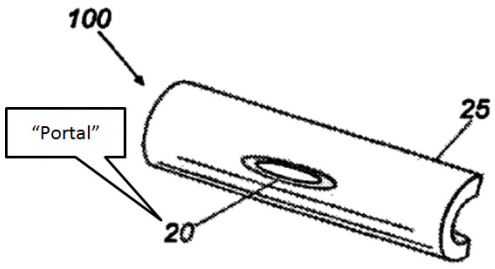


Fig. 5D

Similarly, Figure 4 shows "another embodiment of the present invention, in which the inventive shunt is comprised of distal elements having wicking extensions at their terminal ends, and in which the proximal portion has a sealed, blunted tip with a portal continuous with the lumen of the proximal portion . . . ." *Id.* at 6:22-28.

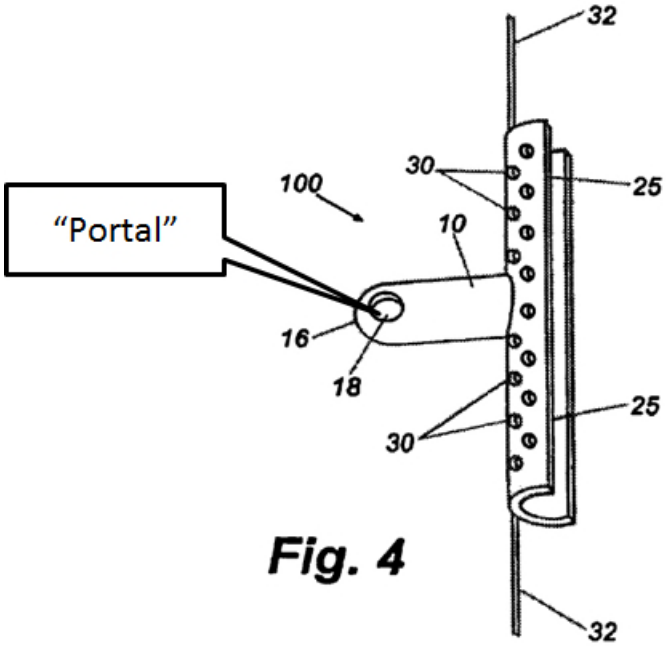


Fig. 4

These figures indicate that a "portal" may be a window or aperture on the body of the device. Ex. 1006 ¶ 80. For instance, with reference to Figure 2, the portal (18) is a point of entry near the iris in the anterior chamber and the aqueous humor is diverted to the portion of the implant residing in Schlemm's canal (25). Ex. 1001 at 8:43-47 ("FIG. 2 further shows an alternate embodiment of the present invention in which the terminal aspect 16 of the proximal portion is angulated toward the iris 40 with respect to the main axis of the proximal portion 10, with the portal 18 of the proximal portion directed toward the iris 40.").

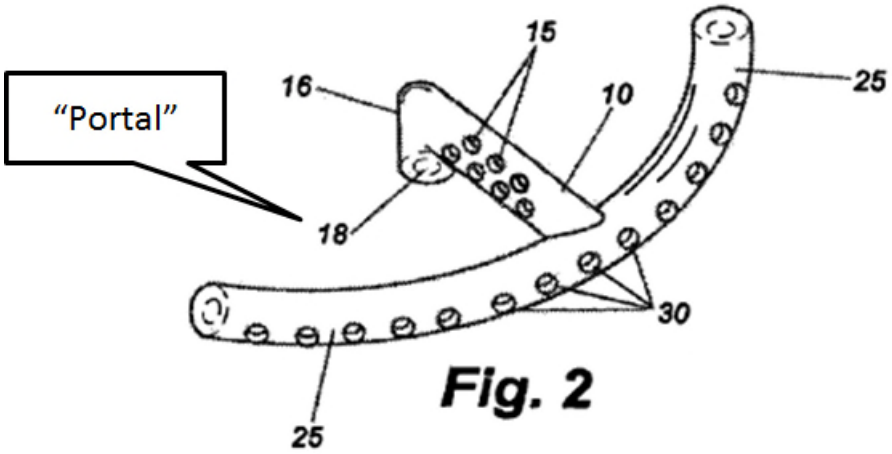


Fig. 2

Under the broadest reasonable interpretation, and in view of the various ways "portal" is used in the '143 patent, one of ordinary skill in the art would have understood "portal" to mean an "opening." Ex. 1006 ¶ 80.

VIII. GROUNDS FOR UNPATENTABILITY

A. Claims 1, 3-8, 11-16, 20-24, 26-29, 31, and 38-42 Are Anticipated and/or Rendered Obvious By Grieshaber

Disclosure that anticipates under 35 U.S.C. § 102 also renders the claim invalid under 35 U.S.C. § 103 because "anticipation is the epitome of obviousness." *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983). As shown below, Grieshaber anticipates and/or renders obvious each of claims 1, 3-8, 11-16, 20-24, 26-29, 31, and 38-42 of the '143 patent.

1. Independent Claim 1

Grieshaber anticipates, or at least renders obvious, claim 1 of the '143 patent.

Claim 1
An ocular implant configured to maintain patency of Schlemm's canal in a stenting fashion, the ocular implant comprising:

Grieshaber teaches that, in eyes afflicted by glaucoma, Schlemm's canal "may close such that the drainage of the aqueous humor is inhibited or completely blocked." Ex. 1002 at 4. The ocular implant of Grieshaber therefore "provides an axially oriented support element which supports the inner wall of the canal of Schlemm in the region of the locally expanded lumen and which is placed such that aqueous humor can permanently drain from the canal of Schlemm through the subsequent natural outflow pathways of the eye." *Id.* at 2. The Grieshaber ocular implant is thus a support element placed inside Schlemm's canal that acts as a scaffold to maintain the patency of the canal. Ex. 1006 ¶ 81.

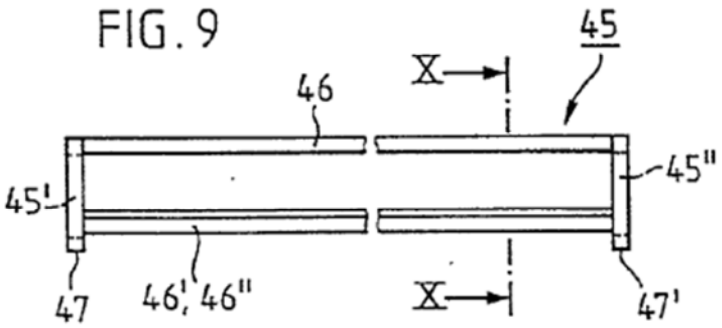
Claim 1
a body of biocompatible material of a size and shape adapted to be at least partially circumferentially retained within a portion of Schlemm's canal,

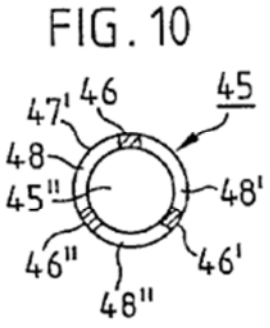
Grieshaber teaches that the support element will be "made of a suitable biocompatible material," which will "enable, in particular, due to their inherent flexibility, optimal adaptation to the natural canal of Schlemm 15." Ex. 1002 at 9. More specifically, the support element of Grieshaber is "implanted in the expanded lumen of the canal of Schlemm and thus [the canal] permanently held in an expanded position." *Id.* at 2. In fact,

Grieshaber Figures 9 and 10 depict a stent that is inserted axially into Schlemm's canal such that it is circumferentially retained by and maintains the patency of Schlemm's canal. Ex. 1002 at 8; Ex. 1006 ¶ 82.

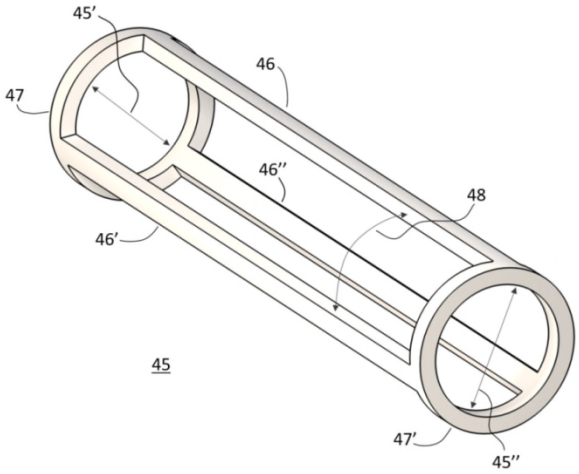
Claim 1
wherein the body is non-tubular,

As discussed above, the broadest reasonable construction of "non-tubular" is "not enclosed along its length." Grieshaber Figures 9 and 10 (shown below) depict an ocular implant comprising several longitudinal webs or panels connected at each end to a torus, or ring. Ex. 1002 at 8. The wide openings shown between each of the webs or panels allow for aqueous humor to pass from the anterior chamber/trabecular meshwork through to the back wall of the Schlemm's canal where collector channels are located. *Id.*; Ex. 1006 ¶ 83.





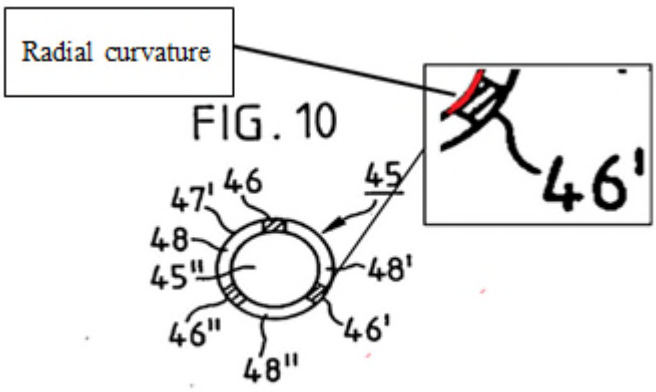
When viewed from an angle, the embodiment disclosed in Figures 9 and 10 has the shape shown below.



Ex. 1007 ¶ 26. Figures 9 and 10 thus disclose an implant with a non-tubular body. Ex. 1006 ¶ 84.

Claim 1
wherein the body is curved, and

Grieshaber teaches ocular implants that are curved, both radially and longitudinally. As shown in Figure 10, Grieshaber's implant is radially curved. Ex. 1006 ¶¶ 45-46, 85.



Grieshaber also teaches that "the support element 35; 40; 45; 50 or 55 is designed longitudinally somewhat arcuate." Ex. 1002 at 9. This is consistent with other disclosure in Grieshaber that provides that the support element will be "made of a suitable biocompatible material" which will "enable, in particular, due to their inherent flexibility, optimal adaptation to the natural canal of Schlemm 15." *Id*; Ex. 1006 ¶ 85.

Claim 1
wherein the body comprises at least one opening along its length configured to facilitate passage of aqueous humor.

Grieshaber discloses openings in the body of the ocular implant to facilitate passage of aqueous humor. As noted above, the wide openings between each of the longitudinal webs or panels in Figures 9 and 10 allow aqueous humor to pass from the anterior chamber and trabecular meshwork through Schlemm's canal and out to collector channels of the eye. Ex. 1002 at 8; Ex. 1006 ¶ 86. Specifically, Grieshaber teaches that "the recesses 48, 48' and 48" provided between the webs 46, 46' and 46" serve in each case as outflow openings for the aqueous humor to be drained substantially through the openings 45' and 45"." Ex. 1002 at 8.

Thus, claim 1 is anticipated or, at least rendered obvious by, Grieshaber.

2. Independent Claims 5 and 38

Grieshaber anticipates, or at least renders obvious, independent claims 5 and 38 of the ’143 patent.

Claim 5	Claim 38
An implant designed to relieve excessive intraocular pressure, the implant comprising:	*An implant for relieving excessive intraocular pressure, the implant comprising:*

Grieshaber teaches that “it would be desirable to provide a method and device by means of which improved, pressure-regulating circulation of the aqueous humor is achieved and its drainage from the eye is permanently maintained. . . . With regard to the device aspect, the present invention provides an axially oriented support element which supports the inner wall of the canal of Schlemm in the region of the locally expanded lumen and which is placed such that the aqueous humor can permanently drain from the canal of Schlemm through the subsequent natural outflow pathways of the eye.” Ex. 1002 at 2; Ex. 1006 ¶ 87.

Claim 5	Claim 38
a flexible, elongate body of biocompatible material for implantation in a living human eye comprising a curved channel shaped to be at least partially positioned within a circumferential length of Schlemm’s canal;	*a non-luminal, elongated body of biocompatible material for implantation in a living human eye, the body comprising, a channel shaped to be at least partially positioned within a circumferential length of Schlemm’s canal,*

First, the support elements of Grieshaber are "flexible" and "elongate." For example, Grieshaber describes "a support element 35 with a long tube 36, which is inserted with its distal end 35'' into the canal of Schlemm 15." Ex. 1002 at 6; *see id.* at Figs. 4-7. Figures 9-12 of Grieshaber also clearly disclose implants that are "elongate." Ex. 1006 ¶ 88.

Grieshaber also discloses implants made of biocompatible material for implantation in a human eye. Grieshaber notes that "[t]he support elements 35, 40, 45, 50 or 55 designed, for example, as tubes or spirals made of suitable biocompatible material enable, in particular, due to their inherent flexibility, optimal adaptation to the natural shape of the canal of Schlemm." Ex. 1002 at 9. Moreover, given the goal of Grieshaber to maintain flow of aqueous humor, it is clear the implants of Grieshaber are for use in a "living human eye." *See, e.g.*, Ex. 1002 at Abstract; Ex. 1006 ¶ 89.

Further, the Figures 9 and 10 embodiment of Grieshaber comprises a curved channel for aqueous humor. As noted above, the '143 patent uses the term "aqueous humor directing channel" to refer to the various implants disclosed in the patent. Here, the implants of Grieshaber, too, are aqueous humor directing "channels." For example, the Figure 9 and 10 embodiment shows an implant with an aqueous humor "channel" extending from one end of the implant to the other (from 45' to 45") . Ex. 1002 at 8 (noting

"aqueous humor to be drained substantially through the openings 45' and 45"); Ex. 1006 ¶ 91. Moreover, according to Grieshaber, the channel is both radially and longitudinally curved: "In a variant embodiment not depicted, there is also the possibility that the support element 30; 40; 45; 50 or 55 is designed longitudinally somewhat arcuate." Ex. 1002 at 9; Ex. 1006 ¶ 90.

The curved channel, or implant, of Grieshaber is designed to be positioned within a circumferential length of Schlemm's canal. *See supra* claim 1. For example, Grieshaber describes "in the lumen 16 of the canal of Schlemm 15 at least one axially oriented support element 30;40;45;50;55 supportingly contacting the inner wall 16' of the canal of Schlemm 15 is implanted. Ex. 1002 at 11.

Claim 38 additionally requires that the implant be "non-luminal." As discussed in Section VII(C)(2) above, one of ordinary skill in the art would understand the term "non-luminal," in the context of the '143 patent, to mean "not having an enclosed space or cavity." *See* Ex. 1006 ¶ 73. Figures 9 and 10 of Grieshaber depict an ocular implant with longitudinal openings "or recesses" along the body of the stent. *See* Ex. 1002 at 8; Ex. 1006 ¶ 95. Because of these "recesses" or outflow openings, the stent depicted in Figures 9 and 10 of Grieshaber lacks an enclosed cavity, rendering it "non-luminal." Ex. 1006 ¶ 93.

Claim 5	Claim 38
wherein the channel is at least partially open along its length to facilitate flow of aqueous humor from Schlemm's canal into one or more collecting channels;	*wherein the channel is at least partially open along a length of the body and is oriented to open toward one or more collecting channels when implanted in the eye; and*

The channel of Grieshaber is "partially open" along its length, as shown by the recesses between the webs in Figures 9 and 10. *See* Ex. 1006 ¶ 94. This feature enables the flow of aqueous humor from Schlemm's canal into the collecting channels. *Id.* Grieshaber's implants "provide an axially oriented support element which supports the inner wall of the canal of Schlemm . . . which is placed such that the aqueous humor can permanently drain from the canal of Schlemm through the subsequent natural outflow pathways of the eye," which are the collecting channels. Ex. 1002 at 2. "[T]he recesses 48, 48' and 48'' provided between the webs 46, 46' and 46'' serve as "outflow openings for the aqueous humor . . . ." *Id.* at 8. Grieshaber also teaches that "it is advantageous if the respective implanted support element ensures a connection of the canal of Schlemm 15 with at least one collector channel 21, 22 or 21', 22' of the subsequent natural outflow pathways 20 or 20'." *Id.* at 11-12.

Claim 5	Claim 38
the channel further having one or more portals oriented to allow flow of aqueous humor from an anterior chamber of the eye into Schlemm's canal.	*a portal that is generally adjacent to an inner wall of Schlemm's canal when the body is implanted in the eye, so as to allow flow of aqueous humor from an anterior chamber through trabecular meshwork and into Schlemm's canal.*

Grieshaber discloses that the flow of aqueous humor in a "healthy eye" starts from the anterior chamber of the eye, through the trabecular meshwork, and into Schlemm's canal. Ex. 1002 at 4. In several embodiments directed to restoring aqueous humor flow, Grieshaber discloses the use of implants with "throughholes" and "outflow openings" that are "distributed axially and circumferentially spaced" or "axially and arbitrarily distributed circumferentially." *Id.* at 6-7 (Figs. 4-5), 7 (Figs. 7-8). Grieshaber depicts some of the outflow openings facing the trabecular meshwork to allow for the flow of aqueous humor from the anterior chamber into the Schlemm's canal implant. *See id.* at Fig. 4 (label 38) and Figs. 7-8 (label 41); *id.* at 11 ("The aqueous humor penetrating into the trabecular meshwork 18 exits via the canal of Schlemm 15 or via the lumen 36' or 40' of the support element 35 or 40 . . . ."); Ex. 1006 ¶ 95.

The embodiment of Figures 9 and 10 similarly includes "recesses 48, 48' and 48" " to serve as "outflow openings for the aqueous humor," just as in the other embodiments. Ex. 1002 at 8; Ex. 1006 ¶ 96. One or more of these openings also constitute "portals" in the channel of the Figures 9 and 10 embodiment of Grieshaber. *Id.* Indeed, when the Figure 9 and 10 embodiment is inserted in Schlemm's canal, at least one recess would face toward the anterior chamber, adjacent to the trabecular meshwork. *Id.* Thus, the last limitations of both claims 5 and 38 are taught by Grieshaber.

Alternatively, it would have been obvious to add "portals" to webs 46, 46' and/or 46" of Grieshaber Figures 9 and 10. Ex. 1007 ¶ 37. Grieshaber notes that there can be "at least two, but preferably three webs," but does not specify the size or width of the disclosed webs. Ex. 1002 at 8. For example, in several other embodiments, Grieshaber discloses the use of implants with "throughholes" and "outflow openings" that are "portals," "distributed axially and circumferentially spaced" or "axially and arbitrarily distributed circumferentially." *Id.* at 6-7 (Figs. 4-5), 7 (Figs. 7-8). Grieshaber shows some of the outflow openings facing the trabecular meshwork to allow for the flow of aqueous humor from the anterior chamber into the Schlemm's canal implant. *See id.* at Fig. 4 (label 38) and Figs. 7-8 (label 41); *id.* at 11 ("The aqueous humor penetrating into the trabecular meshwork 18 exits via

the canal of Schlemm 15 or via the lumen 36' or 40' of the support element 35 or 40 . . . .").

Depending on the size of the webs in a Figure 9/10 embodiment, one of ordinary skill in the art would have reason to introduce portals or openings along the web to provide for additional lateral flow from the anterior chamber and trabecular meshwork into Schlemm's canal. Ex. 1007 ¶ 37.

Thus, claims 5 and 38 are anticipated or, at least rendered obvious by, Grieshaber.

3. Independent Claim 16

Grieshaber anticipates, or at least renders obvious, independent claim 16 of the '143 patent.

Claim 16
An implant designed to relieve excessive intraocular pressure, the implant comprising:

As discussed above with respect to claim 5, Grieshaber teaches an implant designed to relieve excessive intraocular pressure. *See supra* Section VIII(A)(2).

Claim 16
a body of biocompatible material for implantation in a living human eye, wherein the body has a non-linear shape before insertion into the eye;

Grieshaber teaches that the implant will be "made of a suitable biocompatible material" and further teaches the use of an implant in a living human eye. *See supra* Claim 5; *see also* Ex. 1002 at Abstract, 9.

Also, the implant of Grieshaber may be designed to be curved (or non-linear) prior to insertion: "In a variant embodiment not depicted, there is also the possibility that the support element 30; 40; 45; 50 or 55 is designed longitudinally somewhat arcuate." Ex. 1002 at 9; Ex. 1006 ¶ 100; Ex. 1007 ¶ 32.

Claim 16
the body comprising a channel shaped to be at least partially positioned within a circumferential length of Schlemm's canal;

As with claim 5, the support element of Grieshaber comprises a channel, extending from 45' to 45" in Figures 9 and 10, shaped to be at least partially positioned within a circumferential length of Schlemm's canal. *See supra* Section VIII(A)(2); *see also* Ex. 1006 ¶ 103.

Claim 16
wherein the channel is at least partially open along its length and oriented to facilitate flow of aqueous humor from Schlemm's canal into one or more collecting channels.

The support element of Grieshaber is "partially open" along its length, as defined by openings between the webs depicted in Figures 9 and 10. *See* Ex. 1006 ¶ 104. Grieshaber further discloses that the "recesses" between the webs in the Figures 9 and 10 embodiment (46, 46', and 46")

"serve in each case as outflow openings for aqueous humor." Ex. 1002 at 8. The implant of Grieshaber "is placed such that the aqueous humor can permanently drain from the canal of Schlemm through the subsequent natural outflow pathways of the eye," which are the collecting channels. *Id.* at 2.

Thus, claim 16 is anticipated or, at least rendered obvious by, Grieshaber.

4. Independent Claim 24

Grieshaber renders obvious claim 24 of the '143 patent.

Claim 24
An implant designed to relieve excessive intraocular pressure, the implant comprising:

As discussed above with respect to claim 5, Grieshaber teaches an implant designed to relieve excessive intraocular pressure. *See supra* Section VIII(A)(2); *see also* Ex. 1006 ¶ 106.

Claim 24
a biocompatible metal stent shaped to be partially circumferentially positioned within a length of Schlemm's canal in a living human eye;

Grieshaber teaches the use of "suitable biocompatible materials" for the various disclosed "support elements 35; 40; 45; 50 or 55." Ex. 1002 at 9. Grieshaber expressly discloses that plastic and metal are among such biocompatible materials. *See, e.g.*, *id.* at 8 ("the support element 50 . . .

produced from relatively stiff plastic or metal threads…"); *id.* at 9 ("the support element 55 . . . produced from relatively stiff plastic or metal threads 56 or made of a noble metal, for example, a silver, gold or platinum wire."). Indeed, metal was a well-known biocompatible material and one of ordinary skill would have understood these metal could be used to design such an implant. Ex. 1006 ¶ 107; Ex. 1007 ¶¶ 28-29.

The support element of Grieshaber is designed to be "implanted in the expanded lumen of the canal of Schlemm and thus [the canal] permanently held in an expanded position." Ex. 1002 at 2. Grieshaber explains that the "suitable biocompatible materials" will "enable, in particular, due to their inherent flexibility, optimal adaptation to the natural canal of Schlemm 15." *Id.* at 9. Thus, the support element is positioned circumferentially within Schlemm's canal. Ex. 1006 ¶ 108.

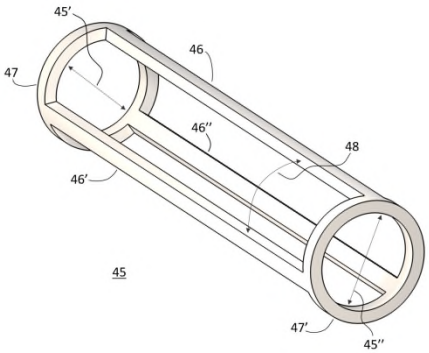
Claim 24
wherein the stent comprises a non-tubular open shape to provide stenting support for the patency of Schlemm's canal and to improve flow of aqueous humor into Schlemm's canal after implantation of the stent;

As discussed above with respect to claim 1, Grieshaber provides several embodiments that teach a non-tubular ocular implant, including the embodiment of Figures 9 and 10. *See supra* Section VII(A)(1); *see also* Ex. 1006 ¶ 110. This embodiment has an "open shape," including recesses 48, 48' and 48''. Ex. 1002 at 8; Ex. 1006 ¶ 110.

The implant of Grieshaber provides stenting support to maintain the patency of Schlemm's canal and to improve the flow of aqueous humor: "With a support element (35) subsequently implanted in the lumen (16) of the canal of Schlemm, the inner walls of the canal are supported and permanently held in an expanded position, whereby unimpeded drainage of the aqueous humor from the canal of Schlemm through the subsequent outflow pathways (20) is ensured." Ex. 1002 at Abstract; Ex. 1006 ¶ 110.

Claim 24
wherein at least one cross-section of the stent approximates a partial circumference of a circle having an inner diameter between about 100 micrometers and 500 micrometers.

The embodiment of Figures 9 and 10 of Grieshaber is illustrated below from a perspective angle:



Ex. 1007 ¶ 26. As the implant of Grieshaber is non-tubular, a cross section between the two tori will approximate a partial circumference. *Id.* ¶ 27; Ex. 1006 ¶ 111.

There is no disclosure in the specification or file history of the '143 patent attributing any particular significance to a diameter of 100-500 micrometers (or 1.0 to 5.0 mm). However, as was known in the art, the interior diameter of Schlemm's canal averages 190-370 micrometers. Ex. 1009 at 15. Because Grieshaber's stent is designed to be "circumferentially positioned" within Schlemm's canal, as discussed above, one of ordinary skill in the art would have understood Grieshaber to disclose stents with a diameter that is smaller than the circumference of Schlemm's canal. Ex. 1006 ¶ 112. Consistent with this, Grieshaber describes that "the support elements have, for example . . . an external diameter D = 0.2 mm," or 200 micrometers. Ex. 1002 at 9.

Moreover, as the Examiner noted during prosecution of the parent '858 patent noted, "manufacturing the distal portion to have an outer diameter of about 0.30 mm is also a design choice . . . since in order for the device to be placed into Schlemm's canal, certain dimensions of the distal portion must be maintained." Ex. 1027 at 148; *see also id.*at 129-30 (noting that the dependent claim "merely recites a more specific outer diameter

dimension (0.30 mm) of the distal portion, which is included in the range of 0.1 to 0.5 mm").

Similarly, an inner diameter within the claimed range was well-known in the art for Schlemm's canal implants. Ex. 1006 ¶ 113; *see, e.g.*, Ex. 1028 at 2:59-62 (using a tube with "an interior diameter of between 100 and 200 μm"). It therefore would have been obvious to design an implant for Schlemm's canal (including the implants of Grieshaber) with a diameter between 1.0 mm and 5.0 mm. *See* Ex. 1006 ¶ 113.

Thus, claim 24 would have been obvious in light of Grieshaber.

5. Dependent Claims 3, 13, 29, and 31

Claim 3 depends from claim 1 and recites the further limitation "*wherein the body is shaped to facilitate flow of aqueous humor from Schlemm's canal into one or more collecting channels*."

Claim 13 depends from claim 5 and claims 29 and 31 depend from claim 24. They recite:

Claim 13 (additional limitation)	**Claim 29 (additional limitation)**	**Claim 31 (additional limitation)**
wherein the opening along the length of the channel is oriented toward one or more of the collecting channels when located within Schlemm's canal	*wherein the non-tubular open shape of the stent is disposed to facilitate flow of aqueous humor into one or more collecting channels in the eye.*	*wherein the stent is oriented so as to open toward one or more of the collecting channels when located within Schlemm's canal.*

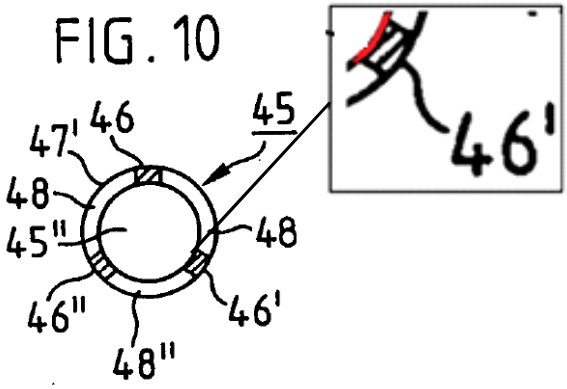
As discussed above with respect to claim 5, the recesses of Grieshaber Figures 9 and 10—which provide the implant's "open" shape—are oriented toward one or more collecting channels when located within Schlemm's canal. *See supra* Section VIII(A)(2); *see also* Ex. 1006 ¶ 116.

Specifically, Grieshaber teaches that "it is advantageous if the respective implanted support element ensures a connection of the canal of Schlemm 15 with at least one collector channel 21, 22 or 21', 22' of the subsequent natural outflow pathways 20 or 20'." Ex. 1002 at 11-12. The Figures 9 and 10 embodiment is such a "support element", with the "recesses" between the webs serving as "outflow openings" for aqueous humor. *Id.* at 3-4; Ex. 1006 ¶ 117. Grieshaber also instructs that the implant is preferably positioned and implanted so that at least one of the outflow openings of the implant connects with the small collector channels of the natural outflow pathways. Ex. 1002 at 6-7; *see also id.* at Figs. 4 and 7. Thus, Grieshaber anticipates and/or renders obvious claims 3, 13, 29, and 31.

6. Dependent Claim 6

Claim 6 depends from claim 5 and recites the additional limitation "*wherein the channel has a trough-like shape to provide stenting support for the patency of Schlemm's canal*."

As depicted in Figure 10 below, Grieshaber's longitudinal webs are arranged along the circumference of the torus, creating a concavity along their lengths, as shown in Figures 9 and 10 below:



While the inner length of the web defines a trough-like channel, the outer length of the web is in contact with the internal surface of Schlemm's canal and provides internal support ("in a stenting fashion") to the canal. Grieshaber describes "in the lumen 16 of the canal of Schlemm 15 at least one axially oriented support element 30;40;45;50;55 supportingly contacting the inner wall 16' of the canal of Schlemm 15 is implanted. Ex. 1002 at 11; Ex. 1006 ¶ 120.

Thus Grieshaber anticipates or renders obvious claim 6.

7. Dependent Claims 7 and 27

Claim 7 depends from claim 5 and recites the following additional limitation "*wherein the channel includes multiple portals along its length*."

Claim 27 depends from claim 24 and recites the following additional limitation: "*wherein the stent is elongate and further includes multiple holes along its length*."

Grieshaber explicitly discloses three "portals" or "holes" in the form of recesses along its length. Ex. 1002 at 8. Alternatively, as discussed above with respect to claim 5, one of ordinary skill in the art would have had reason to include multiple holes or portals in the channel of Grieshaber Figures 9 and 10. *See supra* Section VIII(A)(2); Ex. 1006 ¶ 122.

Finally, the support elements of Grieshaber are "elongate," including Figures 9 and 10. *See supra* Section VIII(A)(2); Ex. 1006 ¶ 122. Thus, Grieshaber renders obvious claims 7 and 27.

8. Dependent Claims 11 and 20

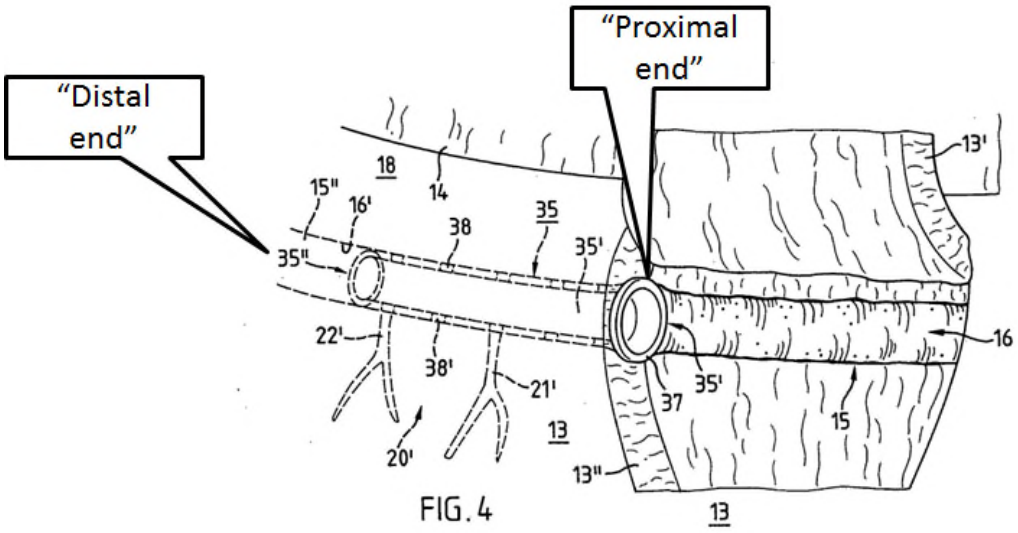
Claim 11 depends from claim 5 and claim 20 depends from claim 16. Both recite the following additional limitation: "*wherein the biocompatible material comprises metal.*"

As discussed above with respect to claim 24, Grieshaber teaches the use of "suitable biocompatible materials" which one of ordinary skill in the art would have understood would include metal. *See supra* Section VIII(A)(4); *see also* Ex. 1006 ¶ 124; Ex. 1007 ¶¶ 28-29. Thus, Grieshaber anticipates and/or renders obvious claims 11 and 20.

9. Dependent Claims 12 and 21

Claim 12 depends from claim 5 and claim 21 depends from 16 and recite the further limitation "*wherein a distal end of the body is non-tubular.*"

In describing Figure 4, Grieshaber teaches that "a support element 35 with a long tube 36, which is inserted with its distal end 35" into the canal of Schlemm 15." Ex. 1002 at 6. On the other end, there is a "proximal end 35'" as shown below. *Id.*; Ex. 1006 ¶ 126.



The implantation procedure according to Grieshaber involves inserting the stent axially into Schlemm's canal, thereby rendering one end of the stent depicted in Figures 9 and 10 the "distal end." *See* Ex. 1002. at 10; Ex. 1006 ¶ 127.

As discussed above with respect to claim 1, the implant of Grieshaber Figures 9 and 10 is non-tubular. *See supra* Section VIII(A)(1); *see also* Ex. 1006 ¶ 128. This is true throughout the length of the implant, including at the distal end. Ex. 1006 at ¶ 128. Thus, Grieshaber anticipates and/or renders obvious claims 12 and 21.

10. Dependent Claim 26

Claim 26 depends on claim 24 and recites the following additional limitation: *"wherein the stent has a non-linear shape before insertion into the eye."*

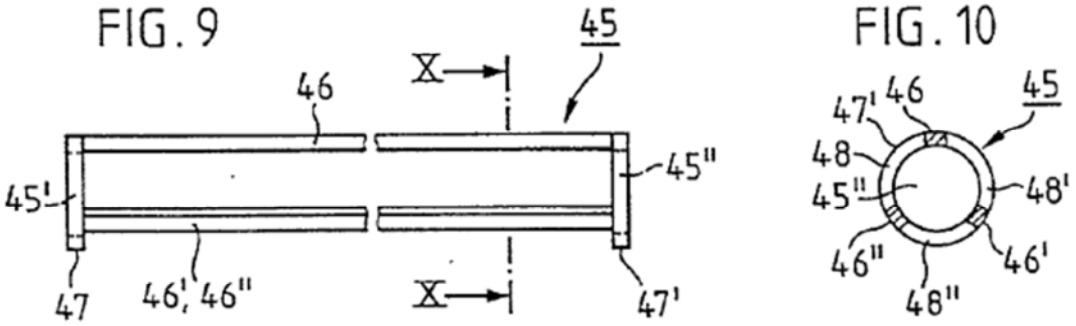
Grieshaber discloses that the implant may be designed to be curved or non-linear prior to insertion: "In a variant embodiment not depicted, there is also the possibility that the support element 30; 40; 45; 50 or 55 is designed longitudinally somewhat arcuate." Ex. 1002 at 9; *see* Ex. 1006 ¶ 130; Ex. 1007 ¶¶ 30-32. Thus, Grieshaber anticipates or renders obvious claim 26.

11. Dependent Claims 14-15, 22-23, and 42

Claims 14 and 15 each depend from claim 5, claims 22 and 23 each depend from claim 16, and claim 42 depends from claim 38. They recite the following additional limitations which appear to have nearly the same scope:

Claims 14 and 22	**Claims 15, 23, and 42**
wherein the opening along the length of the channel extends to a distal end of the body.	*wherein the channel is open along a length that extends to a distal end of the body.*

Grieshaber discloses a "distal end." *See supra* Section VIII(A)(9). The webs of Grieshaber Figures 9 and 10 have "openings" that extend the entire length of the body of the implant.



See Ex. 1006 ¶ 132. Thus, Grieshaber anticipates and/or renders obvious claims 14, 15, 22, 23, and 42.

12. Dependent Claims 4, 8, 28, 39, and 40

Claim 4 depends from claim 1, claim 8 depends from claim 7, claim 28 depends from claim 27, claim 39 depends from claim 38, and claim 40 depends from claim 39. Each recites the following, substantially identical, additional limitation:

Claim 4	**Claim 8**
wherein the body is elongate and comprises multiple ovoid openings along its length.	*wherein at least some of the portals are ovoid in shape.*

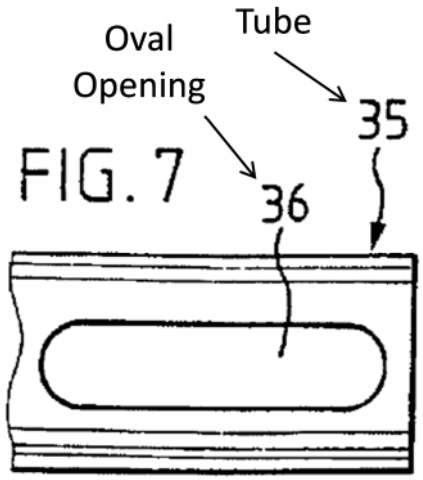
Claim 28	**Claim 39**	**Claim 40**
wherein at least some of the holes are oval-shaped.	*wherein the portal in the body is oval-shaped.*	*wherein the body includes multiple oval-shaped portals along the length of the channel.*

As discussed above with respect to claim 5, Grieshaber discloses support elements with an "elongate" body. *See supra* Section VIII(A)(2); Ex. 1006 ¶ 135.

Moreover, Grieshaber discloses embodiments where the openings that permit the flow of aqueous fluid are circular holes, trough-like openings, and/or gaps in spiral or helicoidal support elements. *See, e.g.*, Ex. 1002 at Figures 4, 7, 9-10, 11, and 12; *see also id.* at 6-11. For instance, Figures 4-7 of Grieshaber depicts an alternate embodiment of a stent with "a number of throughholes 38, 38' distributed axially and circumferentially spaced." *Id.* at 6. Grieshaber teaches that the stent should be positioned such that the "throughholes 38, 38' connects with the small collector channels 21', 22' of the natural outflow pathways 20'." *Id.* at 6-7.

The use of an ovoid portal or hole rather than any of the particular shapes explicitly depicted in the Grieshaber figures would have been a simple matter of design choice. Ex. 1006 ¶ 137; Ex. 1007 ¶ 40. While the '143 patent does not disclose any particular advantage to using an ovoid-shaped portal (Ex. 1007 ¶ 40), Grieshaber demonstrates that portals could be designed in many shapes and sizes (*id.* ¶ 41) and one of ordinary skill in the art would have understood that he or she could design any shape opening that was desired. *Id.* ¶ 42.

For example, the prior art explicitly teaches the use of ovoid portals in intraocular devices. *Id.* ¶ 43; *see* Ex. 1029 at Fig. 7 (annotated):



Moreover, one of ordinary skill in the art would have had reason to modify the circular portals of Grieshaber to be ovoid because such modification could theoretically reduce fluid resistance and enhance fluid flow across the ocular implant without compromising structural integrity. Ex. 1007 ¶ 45. One of ordinary skill in the art would have had a reasonable expectation of success in doing so. *Id.*; *see also* Ex. 1029 at Fig. 7.

Thus, claims 4, 8, 28, 39, and 40 are obvious based on Grieshaber.

13. Dependent Claim 41

Claim 41 depends from claim 38 and recites the following additional limitation: *"wherein at least one cross-section of the body approximates a partial circumference of a circle having an inner diameter between about 100 micrometers and 500 micrometers."*

As discussed above with respect to claim 24, the cross-section of the implant described by Grieshaber approximates the partial circumference of a circle, and it would have been obvious to design the stent of Grieshaber with an inner diameter within the claimed range. *See supra* Section VIII(A)(4); *see also* Ex. 1006 ¶ 141. Thus, Grieshaber renders obvious claim 41.

B. Claims 2, 9, 10, 17-19, 25, and 32-37 Are Rendered Obvious By Grieshaber in View of Spiegel

1. Independent Claim 32

The combination of Grieshaber and Spiegel renders obvious claim 32 of the '143 patent.

Claim 32
A surgical method for relieving excessive intraocular pressure by implanting a medical device in an eye, the method comprising:

Grieshaber describes a method for relieving excessive intraocular pressure by implanting a medical device in an eye: "The present invention relates to a method to improve aqueous humor drainage in an eye with a canal of Schlemm in which eye the aqueous humor secreted by the ciliary body is drained through the subsequent outflow pathways and to a device to maintain aqueous humor drainage." Ex. 1002 at Abstract; Ex. 1006 ¶ 146.

Claim 32
inserting a non-luminal open stent into a living human eye, wherein at least one cross-section of the stent approximates a partial circumference of a circle having an inner diameter between about 100 micrometers and 500 micrometers;

Grieshaber describes inserting a non-luminal open stent into a living human eye. As discussed in Section VII(C)(2) above, one of ordinary skill in the art would understand the term "non-luminal" to mean "not having an enclosed space or cavity." *See also* Ex. 1006 ¶ 73. Figures 9 and 10 of Grieshaber depict an ocular implant with longitudinal openings "or recesses" around the body of the stent. *See* Ex. 1002 at 8; Ex. 1006 ¶ 147. Because of these "recesses," the stent depicted in Figures 9 and 10 of Grieshaber lacks an enclosed cavity, rendering it "non-luminal." Ex. 1006 ¶ 147. For the same reason, the Grieshaber stent is "open." *Id.* Moreover, given the desire to maintain flow of aqueous humor, the implants of Grieshaber are for a "living human eye." *See, e.g.*, Ex. 1002 at Abstract; Ex. 1006 ¶ 147.

As discussed above with respect to claim 24, one of ordinary skill would have been motivated to use a stent or implant for insertion into Schlemm's canal with an inner diameter between about 100 and 500 micrometers. *See supra* Section VIII(A)(4); *see also* Ex. 1006 ¶ 148.

Claim 32
creating an incision in a trabecular meshwork of the eye; *positioning the stent through the incision so that the stent is partially located in an anterior chamber of the eye and partially located within a circumferential length of Schlemm's canal in the eye;* *leaving the stent in the eye as a permanent implant to permit increased flow of aqueous humor from the anterior chamber into Schlemm's canal.*

Both Grieshaber and Spiegel recognize that poor drainage through the trabecular meshwork is a source of elevated intraocular pressure. Ex. 1006 ¶ 143. Grieshaber teaches that the drainage of aqueous humor may be impeded by changes in the trabecular meshwork "which [] completely or only partially obstruct the drainage of the aqueous humor." Ex. 1002 at 1a-2. Spiegel likewise recognizes that "[t]he increase in intraocular pressure in primary open-angle glaucoma and secondary open-angle glaucoma . . . is generally believed to be caused by a decrease in the ability of trabecular meshwork to facilitate aqueous outflow due to pathological changes." Ex. 1004 at 81.

Moreover, both Grieshaber and Spiegel propose as a solution an implant in Schlemm's canal that permits increased flow of aqueous humor from the anterior chamber into Schlemm's canal and out of the natural collecting channels of the eye. *See* Ex. 1002 at 4-5; Ex. 1004 at 81; Ex. 1006 ¶¶ 143, 149.

Grieshaber discloses an implant for Schlemm's canal that permanently holds open the lumen of the canal to provide unimpeded drainage from the trabecular meshwork, through Schlemm's canal, to the subsequent outflow pathways of the eye. *See* Ex. 1002 at Abstract, 6-7.

Spiegel teaches that "[t]he optimal solution to this problem would be to bypass the trabecular meshwork and create a direct connection from the anterior chamber into the aqueous veins." Ex. 1004 at 81. Spiegel teaches that a silicone tube can be used to improve aqueous humor drainage. Spiegel goes on to describe "insert[ing] a silicone tube of 150 μm through a scleral flap incised into Schlemm's canal (Fig. 7.1). One end of the tube was seated in Schlemm's canal, while the other end was slid into the anterior chamber once the inner wall of Schlemm's canal was opened (Fig. 7.2)." *Id*. One of ordinary skill in the art would understand that Spiegel's tube with one end positioned inside the Schlemm's canal and the other in the anterior chamber necessarily involves creating an incision in a trabecular meshwork of the eye. Ex. 1006 ¶ 150. Thus, Spiegel teaches making an incision in the trabecular meshwork through which the stent, partially located in the anterior chamber and partially located in Schlemm's canal, is positioned.

It was well known in the art, and acknowledged by the '143 patent, that "[i]n primary open angle glaucoma, which is the most common form of glaucoma, the abnormal resistance is believed to be along the outer aspect of trabecular meshwork and the inner wall of Schlemm's canal." Ex. 1001 at 2:30-32. For this reason, one of ordinary skill in the art would have had reason to combine Grieshaber with the analogous art of Spiegel to extend the

indwelling stent of Grieshaber beyond Schlemm's canal, across the trabecular meshwork, and into the anterior chamber to provide a direct conduit between the site of fluid build-up in the anterior chamber (and the cause of IOP) and the natural outflow pathways from Schlemm's canal as taught by both Spiegel and Grieshaber. Ex. 1006 ¶ 144. *See, e.g., Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prods*, 16-2616, Slip Op. at 19 (Fed. Cir. May 16, 2018) ("Where the level of ordinary skill in the art is high, and the claim applies a known solution to a known problem, it is likely the product not of innovation but of ordinary skill and common sense.") (citations omitted).

As the Federal Circuit has made clear, "[a] suggestion or motivation to modify prior art teachings may appear in the content of the prior art, in the nature of the problem addressed by the invention, or even in the knowledge of one of ordinary skill in the art." *Princeton Biochems., Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332, 1338 (Fed. Cir. 2005) (citation omitted). Further, one of ordinary skill would have had a reasonable expectation of success in combining Spiegel with Grieshaber, since the modifications suggested by Spiegel to Grieshaber were a simple matter of design choice in the fabrication of an ophthalmic implant. Ex. 1006 ¶ 144.

Thus, the combination of Grieshaber and Spiegel renders claim 32 obvious.

2. Dependent Claims 2 and 25

Claim 2 depends from claim 1, and claim 25 depends from claim 24. Both claims 1 and 24 were addressed above in Section VIII(A).

Claim 2 (additional limitation)	Claim 25 (additional limitation)
wherein a portion of the body is oriented to be positioned in the anterior chamber after implantation.	*wherein a portion of the stent is oriented to be positioned in an anterior chamber of the eye after implantation.*

Spiegel teaches that"[t]he increase in intraocular pressure in primary open-angle glaucoma and secondary open-angle glaucoma . . . is generally believed to be caused by a decrease in the ability of trabecular meshwork to facilitate aqueous outflow due to pathological changes." Ex. 1004 at 81. Spiegel describes "insert[ing] a silicone tube with an outer diameter of 150 µm through a scleral flap incised into Schlemm's canal (Fig. 7.1). One end of the tube was seated in Schlemm's canal, while the other end was slid into the anterior chamber once the inner wall of Schlemm's canal was opened (Fig. 7.2)." *Id*. Figure 7.1 of Spiegel shows one end of the tube positioned inside Schlemm' s canal:

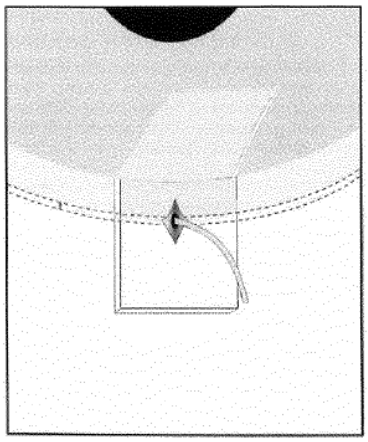


Fig. 7.1 Drainage implant in the Schlemm's canal (schematic drawing).
The implant is inserted into the Schlemm's canal after the preparation of a deep scleral flap.

Id. at 82. Figure 7.2 of Spiegel shows the other end of the implant positioned in the anterior chamber:

Fig. 7.2 Drainage implant in the Schlemm's canal - site in the autopsy eye
After opening the anterior chamber, the free end is positioned inside the anterior chamber (arrow).

As discussed above with respect to claim 32, one of ordinary skill would have been motivated to combine the teachings of Grieshaber and Spiegel. *See also* Ex. 1006 ¶¶ 142-44. Thus, for the same reasons as

described above in Section VIII(B)(1), Spiegel and Grieshaber renders claims 2 and 25 obvious.

3. Dependent Claims 9 and 17

Claim 9 depends from claim 5, and claim 17 depends from claim 16. Claims 5 and 16 are discussed above in Section VIII(A)(2) and (3).

Claim 9 (additional limitations)	Claim 17 (additional limitations)
wherein a distal portion of the elongate body comprises the curved channel, and wherein the elongate body further comprises a proximal portion that is oriented to be positioned at least partially in the anterior chamber after implantation.	*wherein a distal portion of the body comprises the channel, and wherein the body further comprises a proximal portion that is oriented to be positioned at least partially in an anterior chamber of the eye after implantation.*

The '143 patent uses the terms "proximal" and "distal" in reference to shunts described in the specification that extend from Schlemm's canal into the anterior chamber. Ex. 1001 at 6:37-42, 6:57-63; *see also id.* at 12:7-15. Grieshaber teaches that "a support element 35 with a long tube 36, which is inserted with its distal end 35" into the canal of Schlemm 15." Ex. 1002 at 6. The implantation procedure according to Grieshaber involves inserting the stent—the curved channel—axially into Schlemm's canal, rendering one end of the stent depicted in Figures 9 and 10 the "distal end." *See id.* at 10; Ex. 1006 ¶ 155. Moreover, Spiegel discloses a tube positioned inside Schlemm's canal, with "the other end [] slid into the anterior chamber." Ex. 1004 at 81. As discussed above with respect to claim 32, one of ordinary

skill in the art would have had reason to combine the teachings of Grieshaber and Spiegel. *See also* Ex. 1006 ¶¶ 142-44. Thus, claims 9 and 17 are rendered obvious by the combination of Grieshaber and Spiegel.

4. Dependent Claims 10 and 18

Claim 10 depends from claim 9 and Claim 18 depends from claim 17. They recite the following additional limitations:

Claim 10 (additional limitations)	Claim 18 (additional limitations)
wherein the proximal portion is at least partially open to receive aqueous humor from the anterior chamber, and wherein the proximal portion is in fluid communication with the distal portion to facilitate flow of aqueous humor into Schlemm's canal.	*wherein the proximal portion comprises an opening to receive aqueous humor from the anterior chamber, and wherein the proximal portion is in fluid communication with the distal portion to facilitate flow of aqueous humor into Schlemm's canal.*

As discussed above, Spiegel teaches "bypass[ing] the trabecular meshwork and creat[ing] a direct connection from the anterior chamber into the aqueous veins" using a silicon tube. Ex. 1004 at 81. It is clear from Spiegel that the proximal portion of the silicon tube, which is "open" at its end, is in fluid communication with the distal portion to facilitate flow of aqueous humor into Schlemm's canal. Ex. 1006 ¶ 157. Moreover, as discussed above with respect to claim 32, one of ordinary skill would have had reason to combine the teachings of Grieshaber and Spiegel. *See also* Ex.

1006 ¶ 142-44. Thus, Grieshaber and Spiegel render obvious claims 10 and 18.

5. Dependent Claim 19

Claim 19 depends from claim 18 and recites the following additional limitation: *"wherein the proximal portion is shorter in length than the distal portion."*

Spiegel discloses that "[o]ne end of the tube was seated in Schlemm's canal, while the other end was slid into the anterior chamber once the inner wall of Schlemm's canal was opened (Fig. 7.2)." Ex. 1004 at 81. It is apparent from Figure 7.1 of Spiegel that the proximal portion of Spiegel, within the anterior chamber, is shorter than the distal portion within Schlemm's canal. Ex. 1006 ¶ 159.

Indeed, in contrast to the portion sitting in Schlemm's canal, one of ordinary skill in the art would also have known that the length of the proximal portion of an implanted shunt must be narrowly limited by the anatomy of the angle, the space between the cornea and the iris, and by the length of the iris. *Id.* ¶ 160. A shunt with a proximal portion that is too long could contact the cornea, thereby causing corneal damage. *Id.*; *see also* Ex. 1030 at 203. In contrast, an ordinarily skilled artisan would have had reason to extend the length of the distal portion of the implant (the portion residing

in Schlemm's canal) to provide better stenting function along a length of the trabecular meshwork. Ex. 1006 ¶ 161. Moreover, as discussed in Section VIII(B)(1) above, one of ordinary skill would have had reason to combine the teachings of Grieshaber and Spiegel. *See id.* ¶¶ 142-44. Thus, claim 19 is rendered obvious by Grieshaber and Spiegel.

6. Dependent Claim 33

Claim 33 depends from claim 32 and recites the following additional limitation: *"wherein the stent provides stenting support for the patency of Schlemm's canal."*

As discussed above with respect to claim 1, the implant of Grieshaber is a support element placed inside Schlemm's canal that acts as a scaffold to maintain the patency of the canal. *See supra* Section VIII(A)(1). Furthermore, an ordinarily skilled artisan would have had reason to combine Grieshaver and Spiegel. *See* Ex. 1006 ¶¶ 142-44. Thus, claim 33 is rendered obvious by the combination of Grieshaber and Spiegel.

7. Dependent Claim 34

Claim 34 depends from claim 32 and recites the following additional limitation: *"wherein the stent is oriented to open toward one or more collecting channels of the eye to facilitate flow of aqueous humor."*

As discussed above with respect to claim 16, the stent of Grieshaber "is placed such that the aqueous humor can permanently drain from the canal of Schlemm through the subsequent natural outflow pathways of the eye," which are the collecting channels. *See supra* Section VIII(A)(3). The recesses of the Figure 9 and 10 embodiment serve this purpose. *Id*; *see also* Ex. 1006 ¶ 163. One of ordinary skill would have had reason to combine Grieshaber and Spiegel. *See id.* ¶¶ 142-44. Thus, Grieshaber and Spiegel render obvious claim 34.

8. Dependent Claim 35

Claim 35 depends from claim 34 and recites the following additional limitation: "*wherein the portion of the stent positioned in Schlemm's canal further includes multiple openings along its length through which aqueous humor is permitted to flow from the anterior chamber into Schlemm's canal.*"

As discussed above with respect to claims 5 and 38, Grieshaber includes multiple openings along its length for the flow of aqueous humor from the anterior chamber to Schlemm's canal. *See supra* Section VIII(A)(2); *see also* Ex. 1006 ¶ 164. Moreover, one of ordinary skill would have had reason to combine Grieshaber and Spiegel. *See id.* ¶¶ 142-44. Thus, claim 35 is rendered obvious by Grieshaber and Spiegel.

9. Dependent Claim 36

Claim 36 depends from claim 32 and recites the following additional limitation: *"wherein the stent is flexible and comprises a biocompatible material."*

Grieshaber provides that "[t]he support elements 35;40;45;50 or 55 designed, for example, as tubes or spirals made of suitable biocompatible material enable, in particular, due to their inherent flexibility, optimal adaptation to the natural shape of the canal of Schlemm 15." Ex. 1002 at 9. One of ordinary skill would have had reason to combine Grieshaber and Spiegel. *See* Ex. 1006 ¶¶ 142-44. Thus, Grieshaber and Spiegel render obvious claim 36.

10. Dependent Claim 37

Claim 37 depends from claim 32, and recites the following additional limitation: *"wherein the stent has a non-linear shape before insertion into the eye."*

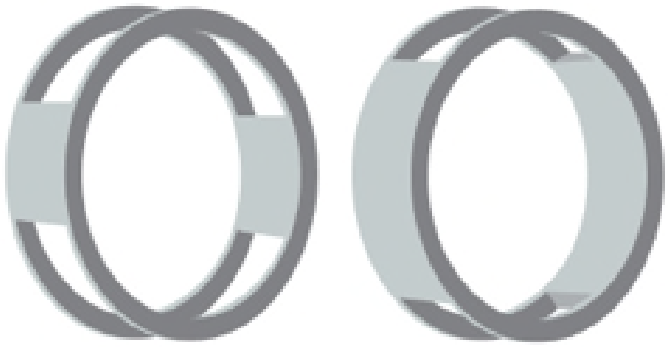
Grieshaber discloses that the implant may be designed with a preformed curvature and, as such, would be non-linear prior to insertion: "In a variant embodiment not depicted, there is also the possibility that the support element 30; 40; 45; 50 or 55 is designed longitudinally somewhat arcuate." Ex. 1002 at 9; *see* Ex. 1006 ¶ 167; Ex. 1007 ¶¶ 31-32. Moreover,

as discussed above, one of ordinary skill would have had reason to combine Grieshaber and Spiegel. *See* Ex. 1006 ¶¶ 142-44. Thus, claim 37 is rendered obvious by Grieshaber and Spiegel.

C. Dependent Claim 30 is Rendered Obvious By Grieshaber and/or Grieshaber in View of Minckler

Claim 30 depends from claim 24 and recites the following additional limitation: *"wherein the at least one cross-section is approximately semi-circular."* As discussed above, claim 24 is rendered obvious by Grieshaber. *See supra* Section VIII(A)(4); *see also* Ex. 1006 ¶ 111.

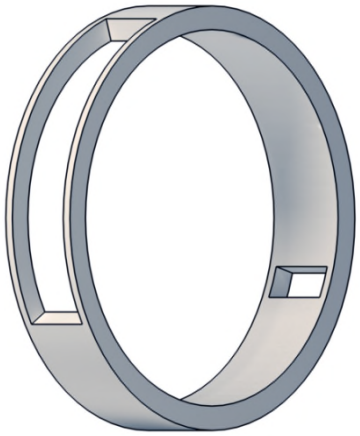
One goal of Grieshaber's invention is to ensure patency of Schlemm's canal. Ex. 1002 at Abstract, 2. Grieshaber expressly teaches that two webs may be used instead of three webs (or panels), as depicted in the Figures 9 & 10 embodiment. *Id.* at 8. One of ordinary skill in the art would have appreciated that, if two webs were used instead of webs, the panels would be larger for structural stability reasons. Ex. 1007 ¶¶ 36, 47. One of ordinary skill thus would have been motivated to employ larger panels to offer more support to the ocular implant and to ensure that it would continue to function post-implantation as a scaffold structure, as shown in the following figures from Dr. Moore's declaration.



Id. ¶ 36.

As Dr. Moore points out, Grieshaber does not teach that any particular size web or panel is necessary nor does Grieshaber even recommend a particular size or width for the spacing between the webs. *Id*. ¶ 48. The Figure 9 and 10 embodiment depicts equally sized intervals between the webs. *Id.* However, an ordinarily skilled artisan who designs medical devices would recognize that there could be advantages to having different intervals between webs. *Id*. As Dr. Moore notes, Grieshaber's use of the plural "intervals" indicates that it anticipated this design variation. *Id*. Thus, one could vary the intervals such that some intervals are very small and others are larger. *Id*. ¶ 49. This would result in an embodiment in which two of the webs are nearly adjacent, while others might be quite far apart. *Id*. In such an embodiment, shown below, the two webs form an approximately semi-circular shape, with only a small opening through

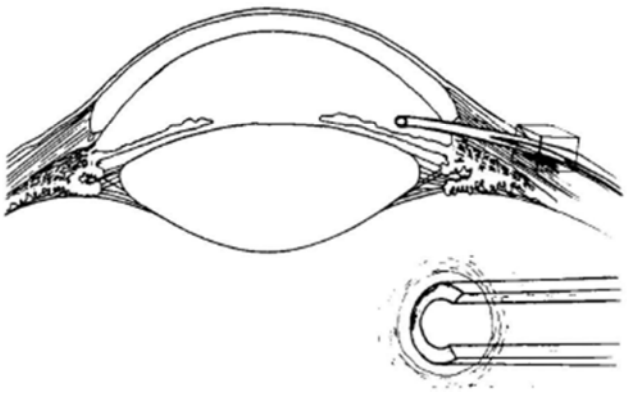
which, for example, fluid could flow outward into collector channels. *Id.* ¶ 49.



These are straightforward design modifications that would be well-within the capability of an ordinarily skilled artisan. *Id.* ¶ 50. Thus, claim 30 is rendered obvious by Grieshaber.

Alternatively, Grieshaber in view of Minckler renders obvious claim 30. Minckler describes a non-tubular shunt that is used to provide a conduit for aqueous humor from the anterior chamber to help control intraocular pressure. Ex. 1005 at 244. Because Minckler discloses a non-tubular implant and is from the same field of endeavor (the treatment of excessive intraocular pressure) as the ’143 patent (and Grieshaber), it is analogous prior art. *Comaper Corp. v. Antec, Inc.*, 596 F.3d 1343, 1351 (Fed. Cir. 2010); *see also* Ex. 1006 ¶ 169.

Minckler demonstrates that a semi-circular cross-section was a known design option for non-tubular implants in the prior art. Ex. 1005 at 246. Minckler discloses a shunt where "[t]he entire side is open so that aqueous has access to the filtering surface[,]" as shown below:



Id. Moreover, Minckler teaches that providing a lateral opening to a tube-like structure (thereby creating a semi-circular cross-section) may provide a functional advantage, i.e., to help promote drainage and avoid occlusion in an indwelling shunt. Ex. 1005 at 246. The '143 patent recognizes the same problem. *See* Ex. 1001 at 4:18-24 ("The outside end of the tube is protected from fibroblasts and scarring by the plastic plate. Many complications are associated with aqueous shunt devices. A thickened wall of scar tissue that develops around the plastic plate offers some resistance to outflow and in many eyes limits the reduction in eye pressure.").

Minckler thus teaches that opening a tube in an ocular shunt to create a semi-circular cross section will promote greater movement of aqueous

humor out of the anterior chamber of the eye and can help prevent obstruction or occlusion by opening the shunt along its length. Ex. 1006 ¶ 172. As Minckler explains, "there are no slits holes or valves to occlude." Ex. 1005 at 246. This minimizes fibrous build-up and consequent re-elevation of intraocular pressure. *Id.*

Thus, one of ordinary skill in the art would have known a semi-circular cross-section was a design option for ophthalmic implants. Ex. 1006 ¶ 173; Ex. 1007 ¶¶ 49-50. Furthermore, an ordinarily skilled artisan would have had reason to modify the ocular implants of Grieshaber to include an opening along the length of the implant, forming a semi-circular cross section, to enhance aqueous humor flow across Schlemm's canal. Ex. 1006 ¶ 173; *see also* Ex. 1007 ¶¶ 49-50.

Thus, claim 30 is rendered obvious by Grieshaber and Minckler.

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Respectfully submitted,

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CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24 (d), I certify that the present paper contains 13,968 words as counted by the word-processing program used to generate the Petition.

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a) and (b), I certify that on the date listed below, a copy of this paper and every exhibit filed with this paper was served on the patent owner at the correspondence address of record and elsewhere, as listed below:

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