

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SIGHT SCIENCES, INC.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 21-1317-GBW-SRF
)	
IVANTIS, INC., ALCON RESEARCH)	
LLC, ALCON VISION, LLC, & ALCON)	
INC.,)	
)	
Defendants.)	

REPORT AND RECOMMENDATION

Pending before the court are the parties’ claim construction disputes. Plaintiff Sight Sciences, Inc. (“Plaintiff”) asserts five patents against defendants Ivantis, Inc., Alcon Research LLC, Alcon Vision, LLC, and Alcon Inc. (collectively, “Defendants”): United States Patent Nos. 8,287,482 (“the ’482 patent”), 9,370,443 (“the ’443 patent”), 9,486,361 (“the ’361 patent”), 10,314,742 (“the ’742 patent”), and 11,389,328 (“the ’328 patent;” collectively, the “Asserted Patents”). (D.I. 59 at ¶¶ 24-29) All of the asserted patents share substantially identical specifications and generally relate to devices, methods, and kits for reducing intraocular pressure in the treatment of glaucoma. (D.I. 119, Exs. 1-5) This decision sets forth the court’s recommendations of constructions following a review of the parties’ joint claim construction brief and consideration of the arguments presented at the *Markman* hearing held on February 9, 2023. (D.I. 118)

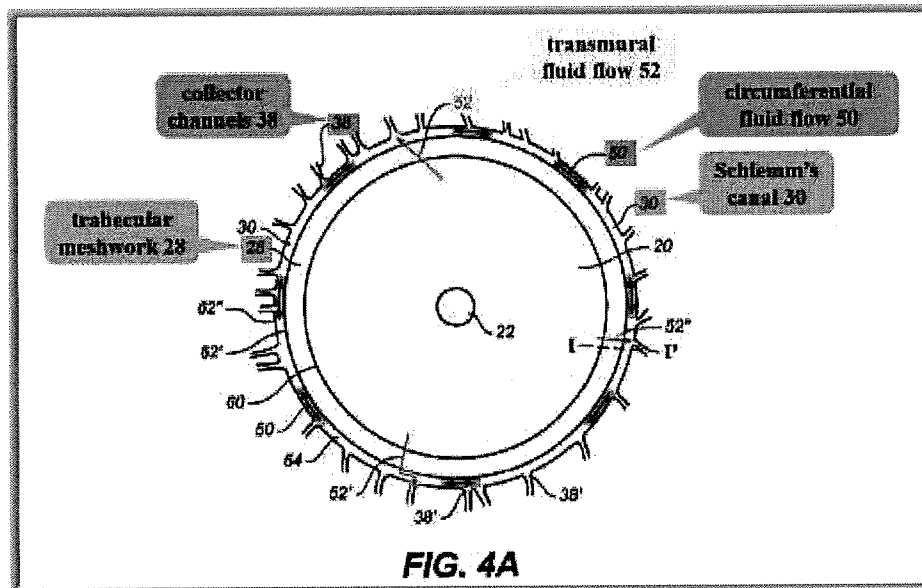
The parties present argument on ten disputed claim terms. For the reasons set forth below, I recommend that the court adopt the following constructions for the disputed terms:

Term	Recommended Construction
<p>“support” ('482 patent, claims 1, 32, 63; '443 patent, claims 1, 58; '361 patent, claim 1; '742 patent, claim 1; '328 patent, claim 1)</p>	<p>Plain and ordinary meaning, i.e., “a structure that props something open” or “a prop.”</p>
<p>“arcuate member” ('443 patent patent, claims 1, 58; '361 patent, claim 1; '742 patent, claim 1; '328 patent, claim 1)</p>	<p>“a structure having one or more curved portions”</p>
<p>“fluid may traverse the canal without substantial interference from the support” / “support does not substantially interfere with the [longitudinal / transmural] flow” / “does not significantly block fluid outflow” ('482 patent, claims 1, 32; '443 patent, claims 1, 56, 57, 58; '361 patent, claims 6, 7, 8; '742 patent, claims 17, 18; '328 patent, claims 7, 8)</p>	<p>“the support does not significantly block either fluid outflow from the trabecular meshwork or fluid outflow to the collector channels.”</p>
<p>“wherein when the support is [disposed/inserted] within a cylindrical section of the lumen of the canal having an internal wall surface area C, the support contacts less than 30% of [the surface area of] C” ('482 patent, claims 1, 32, 63; '443 patent, claims 1, 58; '742 patent, claim 13; '328 patent, claim 21)</p>	<p>“wherein when the support is disposed within a section of Schlemm’s canal, the internal wall surface area C of that section is estimated by viewing the inside of Schlemm’s canal as a slightly arcuate cylinder having length L, extending circumferentially from a first end X₁ to a second end X₂ of the support, and inside radius R_i, and the support contacts less than 30% of [the surface area of] C.”</p>
<p>“wherein at least a portion of the arcuate member has a radius of curvature smaller than the radius of curvature of Schlemm’s canal [such that at least a portion of the arcuate member extends out of Schlemm’s canal]” ('443 patent, claims 1, 58; '361 patent, claim 1; '742 patent, claim 1; '328 patent, claim 1)</p>	<p>Plain and ordinary meaning, i.e., at least a portion of the arcuate member has a radius of curvature smaller than the radius of curvature of Schlemm’s canal (which persons of ordinary skill in the art knew or could measure) [such that at least a portion of the arcuate member extends out of Schlemm’s canal].</p>
<p>“discontinuous along a perimeter of the lumen of the canal” ('482 patent, claims 1, 63)</p>	<p>Plain and ordinary meaning, i.e., that contact between the support and a wall of the canal is “interrupted by a non-contact point along a perimeter of the lumen of the canal.”</p>

“only a portion of the exterior surface of the support contacts an inner periphery of the lumen of the canal” (’482 patent, claim 32)	Plain and ordinary meaning, i.e., “only a portion of the exterior surface of the support contacts an inner wall of the lumen of the canal.”
“periodic contact” (’482 patent, claims 7, 38, 69)	“contact that is interrupted by a non-contact point”
“fluted edges” (’482 patent, claims 5, 36, 68)	“edges that are uneven”
“multiple connected elements” (’482 patent, claims 18, 49, 73)	No construction of this term is necessary.

I. BACKGROUND OF THE TECHNOLOGY

The Asserted Patents cover devices, methods, and kits for treating glaucoma, a potentially blinding disease characterized by elevated intraocular pressure (“IOP”) that occurs when fluid cannot properly drain from the eye. (D.I. 119, Ex. 1 at 24:24-39) This fluid, known as aqueous humor, is continuously replenished in the eye and then flows out of the eye sequentially through the trabecular meshwork, Schlemm’s canal, and collector channels. (*Id.*, Ex. 1 at 1:40-52) In Schlemm’s canal, aqueous humor flows both circumferentially around the circular canal, and transmurally from the trabecular meshwork, across Schlemm’s canal, and out through the collector channels. (*Id.*, Ex. 1 at 6:62-7:16) The flow of aqueous humor through each of these three structures is depicted in an annotated version of Figure 4A from the ’482 patent:



(D.I. 118 at 3 (depicting annotated version of D.I. 119, Ex. 1 at Fig. 4A))

Elevated IOP can be caused by obstructions that reduce the drainage of fluid, such as blockages or constriction in the trabecular meshwork and/or Schlemm's canal. (D.I. 119, Ex. 1 at 1:57-59) Efforts to reduce IOP can prevent or slow down damage to the optic nerve. (*Id.*, Ex. 1 at 1:27-35) The Asserted Patents describe ways to reduce IOP by implanting supports into Schlemm's canal that keep the canal open without interfering with the transmural flow of fluid across the canal. (*Id.*, Ex. 1 at Abstract; 2:56-63)

II. LEGAL STANDARDS

A. Claim Construction

The purpose of the claim construction process is to “determin[e] the meaning and scope of the patent claims asserted to be infringed.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 388-90 (1996). Construing the claims of a patent presents a question of law, although subsidiary fact finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015) (citing *Markman*, 52 F.3d at

977-78). An actual dispute regarding the proper scope of a claim term must be resolved by a judge, as opposed to the jury. *Markman*, 52 F.3d at 979.

“[T]here is no magic formula or catechism for conducting claim construction.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1324 (Fed. Cir. 2005). Instead, the court may attach the appropriate weight to appropriate sources “in light of the statutes and policies that inform patent law.” *Id.* The words of the claims “are generally given their ordinary and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Id.* at 1312-13 (internal citations and quotation marks omitted). If the meaning of a claim term is not readily apparent, the court considers sources including “the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004).

“It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). Accordingly, “the claims themselves provide substantial guidance as to the meaning of particular claim terms.” *Id.* at 1314. Claim terms are typically used consistently throughout the patent, and “usage of a term in one claim can often illuminate the meaning of the same term in other claims.” *Id.* Also, “[d]ifferences among claims can also be a useful guide For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15 (internal citation omitted).

The claims must be read in view of the specification, which “is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). “[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). The specification may also contain a disclaimer or disavowal of claim scope. *Id.* However, “[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted). The specification “is not a substitute for, nor can it be used to rewrite, the chosen claim language.” *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004).

The court should also consider the patent’s prosecution history, which is intrinsic evidence and “consists of the complete record of the proceedings before the [Patent and Trademark Office] and includes the prior art cited during the examination of the patent.” *Phillips*, 415 F.3d at 1317. “[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.* Statements made during inter partes review (“IPR”) may also be considered. *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1362 (Fed. Cir. 2017).

A court may sometimes rely on “extrinsic evidence,” which “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980. Expert testimony can be useful “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” *Id.* Nonetheless, courts must not lose sight of the fact that “expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.” *Id.* Overall, extrinsic evidence is less reliable than intrinsic evidence, and its consideration “is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Phillips*, 415 F.3d at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

B. Indefiniteness

“Definiteness is a statutory requirement for patentability.” *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, 30 F.4th 1339, 1346 (Fed. Cir. 2022). The primary purpose of the definiteness requirement articulated in 35 U.S.C. § 112(b) “is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public . . . can determine whether or not they infringe.” *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779-80 (Fed. Cir. 2002). Definiteness is a question of law, although the court must sometimes make factual findings based on extrinsic evidence. *See Sonix Tech. Co. v. Publications Int’l, Ltd.*, 844

F.3d 1370, 1376 (Fed. Cir. 2017). “Any fact critical to a holding on indefiniteness . . . must be proven by the challenger by clear and convincing evidence.” *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1366 (Fed. Cir. 2003).

Like claim construction, definiteness should be evaluated from the viewpoint of a person of ordinary skill in the art at the time the patent was filed. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 908 (2014); *Nature Simulation Sys. Inc. v. Autodesk, Inc.*, 50 F.4th 1358, 1360 (Fed. Cir. 2022). A patent claim is indefinite “if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Id.* at 901. The reasonable certainty standard is intended to strike a balance between providing clear notice of what is claimed and recognizing the “inherent limitations” of language. *Niazi*, 30 F.4th at 1346 (quoting *Nautilus*, 572 U.S. at 909).

III. CONSTRUCTION OF DISPUTED TERMS

A. “support”

Claim term	Plaintiff’s proposal	Defendants’ Proposal	Court’s construction
“support” (’482 patent, claims 1, 32, 63; ’443 patent, claims 1, 58; ’361 patent, claim 1; ’742 patent, claim 1; ’328 patent, claim 1)	No construction of this term is necessary. If construed, the term should be construed according to its plain and ordinary meaning, i.e., “a structure that props something open” or “a prop.”	“structure that occupies at least a portion of the central core of Schlemm’s canal”	Plain and ordinary meaning, i.e., “a structure that props something open” or “a prop.”

I recommend that the court construe the term “support” in accordance with its plain and ordinary meaning, i.e., “a structure that props something open” or “a prop.” The focus of the parties’ dispute is on whether the claimed support’s occupation of at least a portion of the central

core of Schlemm's canal is a required feature. (D.I. 118 at 5) Defendants concede there is no lexicography by the patentee to include this limitation in the definition of the term "support," but they maintain that the term is defined by implication in the specification. (2/9/2023 Tr. at 38:23-39:3) However, the intrinsic evidence supporting Defendants' narrower proposal falls short of a "clear and unmistakable" disclaimer as required to limit the scope of the claims. *See Thorner v. Sony Computer Ent'mt Am. LLC*, 669 F.3d 1362, 1366-67 (Fed. Cir. 2012).

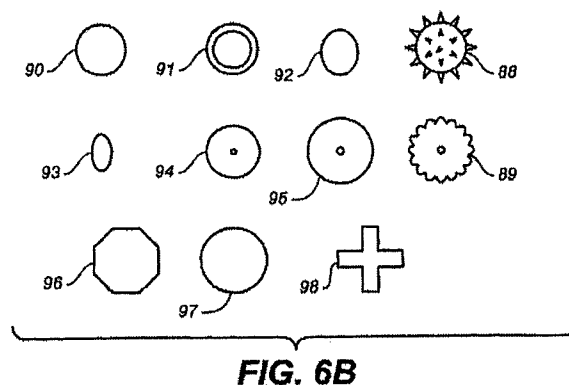
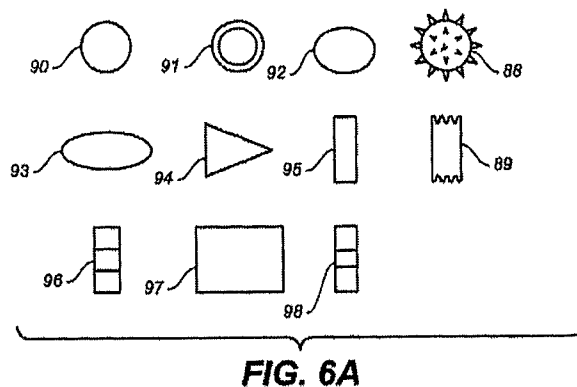
There is no meaningful dispute that the specification discloses supports occupying at least a portion of the central core of Schlemm's canal as preferred embodiments and disparages open-ended tubular supports that do not occupy the central core of the canal. (2/9/2023 Tr. at 37:12-19) The Summary of the Invention discloses that "[t]he support occupies at least a portion of a central core of Schlemm's canal." (D.I. 119, Ex. 1 at 2:61-63) The specification reiterates this characteristic in its description for each of the claimed devices, kits, and methods, describing "variations" only in whether the support occupies "the majority of the central core of the canal" or "a small portion of the central core of the canal." (D.I. 119, Ex. 1 at 12:23-54; *see also* 2:55-61, 4:30-36, 4:50-56; 7:22-27, 15:4-11, 17:1-8) But the court cannot redefine words or read limitations from the specification into the claims in the absence of a clear and unmistakable disclaimer, even when all the disclosed embodiments contain a particular limitation. *See Thorner*, 669 F.3d at 1366-67. Here, the written description as a whole confirms that none of these statements amounts to an "expression[] of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Continental Circuits LLC v. Intel Corp.*, 915 F.3d 788, 797 (Fed. Cir. 2019) (quoting *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1306 (Fed. Cir. 2011)).

The specification's disparagement of hollow tubular supports is not absolute. *See Thorner*, 669 F.3d at 1366 ("Mere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal.") (citing *Epistar Corp. v. Int'l Trade Comm'n*, 566 F.3d 1321, 1335 (Fed. Cir. 2009)). In fact, the specification implies open-ended tubular supports may sometimes satisfy the goals of the claimed invention. By explaining that open-ended tubular supports "can lose functionality over time as a result of occlusion or scarring," "can be prone to failure and collapse," "can be difficult or expensive to design and manufacture," and "can result in blockage of the meshwork or collector channels" due to the amount of surface area contact with the trabecular meshwork, the patentee implies that these drawbacks do not arise every time an open-ended tubular support is used. (D.I. 119, Ex. 1 at 2:29-47; 7:63-67) Instead, this permissive language suggests that a tubular support may be designed in a manner to permit sufficient transmural flow. Other portions of the specification describe ways to achieve the goal of promoting transmural flow, such as adding fluted edges or fenestrations to reduce surface area contact with the canal walls and using permeable materials such as mesh. (*Id.*, Ex. 1 at 3:47-51, 9:21-28, 11:5-7) Nothing in the specification precludes the application of these design features to open-ended tubular supports.

The specification also alludes to the viability of at least some open-ended tubular supports by explaining that the "devices described here need not comprise an open-ended tubular support placed longitudinally along Schlemm's canal, i.e., the devices and supports can be non-tubular." (*Id.*, Ex. 1 at 7:48-50) By stating that the support is not required to be open-ended and tubular, the specification implies that open-ended tubular supports fall within the scope of the invention. *See Continental Circuits*, 915 F.3d at 797 (finding disclosure providing that "the present invention can be carried out by a new use" of a preferred material did not exclude prior

art embodiments disparaged therein). This language distinguishes the present case from the Federal Circuit's decision in *Indivior Inc. v. Dr. Reddy's Labs., S.A.*, 930 F.3d 1325 (Fed. Cir. 2019). There, the Federal Circuit found an unmistakable disclaimer of conventional top air drying because the claims recited a film that is "capable of being dried without loss of substantial uniformity," and the specification made clear that top air drying did not yield uniform films. *Id.* at 1337. By contrast, the specification in this case disparages hollow, open-ended tubular supports without suggesting it is impossible to achieve acceptable results with those supports under any circumstances. Limiting the term "support" to require its occupation of at least a portion of the central core of Schlemm's canal would therefore be inconsistent with the Federal Circuit's admonition that the claims and embodiments in the specification are not always strictly coextensive. *Phillips*, 415 F.3d at 1323.

Similarly, the Figures do not clearly and unmistakably foreclose the use of a support that does not occupy at least a portion of the central core of Schlemm's canal. It is true that many of the Figures depict supports that occupy at least a portion of the central core of the canal. (*See, e.g.*, D.I. 119, Ex. 1 at Figs. 8A-8B, 10C, 12A-12D, 12G-12H) But the specification describes the scope of the supports more broadly: "Elements or beads used in a support may be hollow and closed structures, open structures, solid structures, porous structures, or any combination thereof, and may be of any suitable shape." (*Id.*, Ex. 1 at 9:25-28) Figures 6A and 6B illustrate non-exclusive "exemplary elements" shown below. (*Id.*, Ex. 1 at 9:28-30)



(*Id.*, Ex. 1 at Figs. 6A-6B)

During the *Markman* hearing, the parties paid particular attention to element 95, which is described in the specification as “disk-shaped.” (*Id.*, Ex. 1 at 9:30-32; 2/9/2023 Tr. at 14:20-15:7) Plaintiff suggested that element 95 can be a ring element which is hollow and open-ended, yet also avoids the problems associated with significant surface area contact with the walls of the canal. (2/9/2023 Tr. at 14:20-15:7; 15:14-25, 16:8-22) Defendants conceded that the elements of a support may be hollow and open, as long as these embodiments occupy at least a portion of the central core of the canal. (*Id.* at 31:21-32:8) According to Defendants, element 95 may depict a tubular structure that is hollow in the center, but the small diameter of the hollow center and the thick walls of the support are such that the support still occupies at least a portion of the central core of the canal. (*Id.* at 32:18-33:6)

Nothing in the specification provides any dimensions for the hollow center in element 95 or for the requisite thickness of the support's walls. More broadly, the specification explains "[s]upports can have variable lengths and thicknesses." (D.I. 119, Ex. 1 at 11:39) Although the specification describes hollow tubular stents with thin walls as being "especially prone to failure," it does not clearly and unmistakably require hollow, open-ended supports to have walls thick enough to occupy a portion of the central core of the canal. (*Id.*, Ex. 1 at 2:40-41) Even if the court were to find Defendants' interpretation of element 95 in Figures 6A and 6B more plausible, the outcome would remain the same because the specification describes these shapes as non-exclusive "exemplary elements." (D.I. 119, Ex. 1 at 9:28-30)

The language of the claims also supports Plaintiff's broader construction. Under the doctrine of claim differentiation, the language of a patent's dependent claims "gives rise to a presumption that the limitation in question is not present in the independent claim." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-1315 (Fed. Cir. 2005). Here, dependent claims 29, 60, and 86 of the '482 patent recite the device or method of the associated independent claim, "wherein the support occupies at least a portion of a central core of the canal." (D.I. 119, Ex. 1 at cls. 29, 60, 86) These dependent claims would be superfluous if the claimed "support" in the independent claims included a limitation requiring the support to occupy at least a portion of the central core of Schlemm's canal. See *SunRace Roots Enters. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1302 (Fed. Cir. 2003). The presumption is particularly strong where, as here, "the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *Id.* at 1303 (citing *Ecolab Inc. v. Paraclipse, Inc.*, 285 F.3d 1362, 1375 (Fed. Cir. 2002)).

Plaintiff's proposed construction is supported by the intrinsic record. The Abstract states a primary purpose of the support is to "maintain[] the patency of the canal," a point that is reiterated throughout the specification. (D.I. 119, Ex. 4 at Abstract, 8:21-25, 8:53-65) The claim language also confirms that the features of the support must "at least partially prop open" the canal. (*Id.*, Ex. 1 at cls. 1, 63) Defendants correctly note that Plaintiff's proposed construction poses its own claim differentiation issues because dependent claim 6 of the '328 patent recites the method of independent claim 1, "wherein the support at least partially props open Schlemm's canal." (D.I. 118 at 11-12; 2/9/2023 Tr. at 34:21-35:2; D.I. 119, Ex. 5 at cl. 6) But the presumption of claim differentiation is not as strong in this instance. Defendants do not meaningfully challenge the position that a primary purpose of the claimed supports is to open Schlemm's canal, nor do they cite any embodiments or language in the specification indicating an intent by the patentee to leave the door open to supports which do not open the canal. Because a support that does not prop open the canal would broaden the claims beyond their correct scope in light of the specification, the presumption of claim differentiation does not apply to Plaintiff's proposed construction. *See Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1369 (Fed. Cir. 2005).

The authority cited by Defendants to support an implicit disavowal of scope is not on all fours with the intrinsic record for the Asserted Patents. Defendants argue that the Federal Circuit's decision in *GPNE Corp. v. Apple Inc.* is analogous to this case because the specification consistently and repeatedly described the claimed "node" as a "pager" or "pager unit." 830 F.3d 1365, 1370 (Fed. Cir. 2016). But the repetition of the description in *GPNE* was more significant because the specification characterized the "node" as a pager more than 200 times. *Id.* And as previously discussed, the specifications of the Asserted Patents in this case lack the consistency

of the specification in *GPNE*. (See, e.g., D.I. 119, Ex. 1 at 7:48-51) (“[D]evices described here need not comprise an open-ended tubular support . . . , i.e., the devices and supports can be non-tubular.”). Other cases finding disavowal of scope are similarly distinguishable. See *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1343 (Fed. Cir. 2001) (finding disavowal of scope where the specification described the favored configuration as the basic structure for “all embodiments of the present invention contemplated and disclosed herein.”); *Profectus Tech. LLC v. Huawei Techs. Co., Ltd.*, 823 F.3d 1375, 1381 (Fed. Cir. 2016) (finding proper limitation of scope where the plaintiff “fail[ed] to pinpoint in the intrinsic record where the patent contemplates a situation where *no* mounting features exist.”); *Astrazeneca AB v. Mutual Pharm. Co., Inc.*, 384 F.3d 1333, 1339 (Fed. Cir. 2004) (concluding that inventors deliberately acted as their own lexicographers).

The Federal Circuit has acknowledged “the difficulty in drawing the fine line between construing the claims in light of the specification and improperly importing a limitation from the specification into the claims.” *Continental Circuits*, 915 F.3d at 797 (internal quotation marks and citations omitted). This term presents such a challenge, as demonstrated by both parties’ comprehensive and well-reasoned arguments. Ultimately, the intrinsic evidence in support of Defendants’ proposed construction does not rise to the level of a clear and unmistakable limitation on the scope of the term, and the case law cited by Defendants is distinguishable in this regard. See *Continental Circuits*, 915 F.3d at 797 (concluding that none of the statements in the specification rose to the level of “a clear and unmistakable disclaimer”). For these reasons, I recommend that the court adopt the plain and ordinary meaning of the term “support” as proposed by Plaintiff.

B. “arcuate member”

Claim term	Plaintiff’s proposal	Defendant’s Proposal	Court’s construction
“arcuate member” (’443 patent patent, claims 1, 58; ’361 patent, claim 1; ’742 patent, claim 1; ’328 patent, claim 1)	“a structure that is arced or bowed [along the length of the structure]”	“bent or curved portion”	“a structure having one or more curved portions”

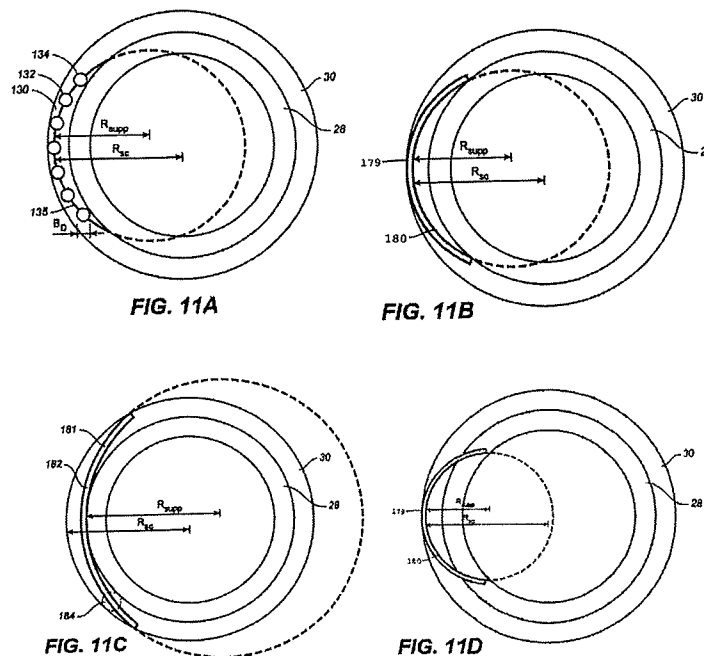
The parties’ arguments on the term “arcuate member” have evolved over the course of claim construction briefing and the *Markman* hearing. The parties are now in agreement that the arcuate member is not required to have only one single arc, and instead may have multiple arcs and multiple radii of curvature. (2/9/23 Tr. at 43:3-9; 46:10-20) This is consistent with the claim language, which states that “at least a portion of the arcuate member has a radius of curvature smaller than the radius of curvature of Schlemm’s canal so that at least a portion of the arcuate member is configured to extend out of Schlemm’s canal[.]” (D.I. 119, Ex. 2 at cl. 1)

Turning to the parties’ competing constructions, I recommend that the court reject both parties’ proposals and construe the term “arcuate member” to mean “a structure having one or more curved portions.” Plaintiff’s proposed construction is likely to lead to confusion because it suggests the entire arcuate member must be arced or bowed, even though the claim language requires only a portion of the arcuate member to have a radius of curvature and does not limit the arcuate member to having only a single arc. (D.I. 119, Ex. 2 at cl. 1; 2/9/23 Tr. at 43:3-9) Defendants’ proposed construction defines the entire arcuate member as the “bent or curved portion,” without accounting for the claim language indicating that the portion having a radius of curvature does not constitute the entire arcuate member. (D.I. 119, Ex. 2 at cl. 1; 2/9/2023 Tr. at

46:24-47:1 (Defendants' counsel explaining the claim language "implies that other portions of the arcuate member may not have a radius of curvature.")).

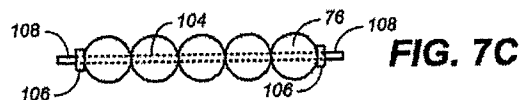
The recommended construction is consistent with the intrinsic evidence and resolves the parties' disputes regarding whether the arcuate member may be bent, and whether the radius of curvature must be measured over the length of the support. The relevant portion of the claim recites "wherein the support comprises an arcuate member, wherein at least a portion of the arcuate member has a radius of curvature smaller than the radius of curvature of Schlemm's canal so that at least a portion of the arcuate member is configured to extend out of Schlemm's canal[.]" (D.I. 119, Ex. 2 at cl. 1) The recommended construction accounts for the entire structure of the arcuate member, at least a portion of which is curved.

The intrinsic record does not support Defendants' position that the arcuate member may be bent. Figures 11A to 11D show examples and variations of arcuate members having a single curved or bowed shape:

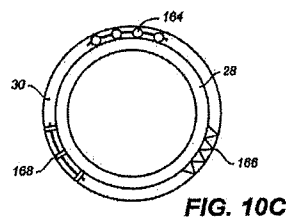
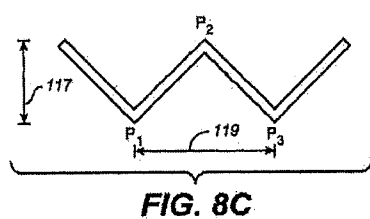


(D.I. 119, Ex. 2 at Figs. 11A-11D) These Figures are described as examples or variations and are therefore not limiting. *See Phillips*, 415 F.3d at 1323 (explaining that “persons of ordinary skill in the art rarely would confine their definitions of terms to the exact representations depicted in the embodiments.”). However, the balance of the intrinsic record does not support Defendants’ position that the portion of the arcuate member having a radius of curvature may be “bent.”

The excerpts of the specification cited by Defendants in support of this proposed limitation do not address embodiments having an arcuate member. (D.I. 118 at 63-64) Defendants cite Figure 7C featuring “guide element” 104, which can be made of “one or more shapeable metal wires that can be bent into a desired position[.]”



(D.I. 119, Ex. 2 at Fig. 7C; 9:52-67) But the specification does not suggest that the guide element is equivalent to the arcuate member, nor does it state that the “guide element” must have a radius of curvature. Likewise, Figures 8C and 10C depict supports which appear to feature bends but are not described as comprising an arcuate member:



(*Id.*, Ex. 2 at Figs. 8C, 10C) Not every support described in the specification comprises an arcuate member, and a comprehensive review of the specification confirms the inventor

expressly indicated when the claimed support comprises an arcuate member and described those embodiments in the context of the radius of curvature. (*Id.*, Ex. 2 at 11:60-12:22)

Defendants express concern that the exclusion of “bent” would allow Plaintiff to exclude small radii of curvature from the scope of the term “arcuate member.” (2/9/2023 Tr. at 54:2-8) The specification provides an exemplary range of 3 mm to 8 mm for the radius of curvature of the arcuate member, without imposing any strict limits on the boundary. (D.I. 119, Ex. 2 at 12:16-22) The claims provide a cap on the upper boundary of the range by specifying that the radius of curvature of the arcuate member must be smaller than that of Schlemm’s canal. (*Id.*, Ex. 2 at cl. 1) However, neither the claims nor the specification articulates a firm limit on the lower boundary of the range. The parties’ proposed constructions for this term do not impose any restrictions on the range of measurements for the radius of curvature, and the court’s recommended construction for the term “arcuate member” is consistent with the parties’ proposals in this regard.

At the *Markman* hearing, Plaintiff also raised a dispute and a proposed modification to the construction of “arcuate member” to limit the measurement of the radius of curvature along the length of the structure, as opposed to a cross-sectional dimension. (2/9/2023 Tr. at 45:3-10) The proposed modification finds some support in the specification, which discloses the measurement of a cross-sectional dimension as B_D , whereas the measurement of the radius of curvature is indicated by F_{supp} . (D.I. 119, Ex. 2 at 11:64-67) Figure 11A demonstrates the difference between these measurements:

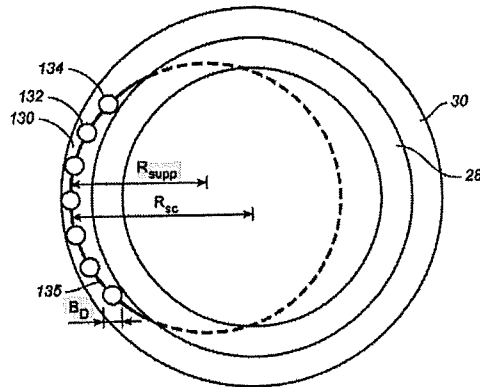


FIG. 11A

(*Id.*, Ex. 2 at Fig. 11A)

Plaintiff’s proposed modification is not likely to provide greater clarity because defining “arcuate member” to mean “a structure that is arced or bowed [along the length of the structure]” raises ambiguity regarding the relationship between the arcuate member and the support. During the *Markman*, Plaintiff argued that the claim language “talks about the arcuate member having a radius of curvature and how that radius of curvature is across the length of the *support*.”

(2/9/2023 Tr. at 55:21-24) In this regard, Plaintiff’s proposal appears to use the word “structure” to signify both the arcuate member and the support. The claim language expressly states that “the support *comprises* an arcuate member,” signifying that the support can have additional elements beyond the arcuate member, and the arcuate member and the support are not necessarily coextensive. (D.I. 119, Ex. 2 at cl. 1) Similarly, the written description describes a support that “can be configured” as an arcuate member, where the support “comprises” but is not limited to an arcuate member. (*Id.*, Ex. 2 at 4:13-15, 11:60-12:9) Because Plaintiff’s proposed modification is ambiguous, and because the specification clearly distinguishes between the cross-sectional dimension B_D and the radius of curvature measurement F_{supp} , inclusion of the newly-proposed modification in the court’s construction is not justified.

C. “fluid may traverse the canal without substantial interference from the support” / “support does not substantially interfere with the [longitudinal / transmural] flow” / “does not significantly block fluid outflow”

Claim term	Plaintiff’s proposal	Defendants’ Proposal	Court’s construction
“fluid may traverse the canal without substantial interference from the support” / “support does not substantially interfere with the [longitudinal / transmural] flow” / “does not significantly block fluid outflow” (’482 patent, claims 1, 32; ’443 patent, claims 1, 56, 57, 58; ’361 patent, claims 6, 7, 8; ’742 patent, claims 17, 18; ’328 patent, claims 7, 8)	No construction of this term is necessary, and the term is not indefinite. Definitional language from specification: “the support does not significantly block either fluid outflow from the trabecular meshwork or fluid outflow to the collector channels.”	Indefinite	“the support does not significantly block either fluid outflow from the trabecular meshwork or fluid outflow to the collector channels.”

I recommend that the court construe the terms “fluid may traverse the canal without substantial interference from the support” / “support does not substantially interfere with the [longitudinal / transmural] flow” / “does not significantly block fluid outflow” in accordance with Plaintiff’s proposed construction to mean “the support does not significantly block either fluid outflow from the trabecular meshwork or fluid outflow to the collector channels.” The crux of the parties’ dispute is whether these terms are indefinite due to the inclusion of the words “substantial,” “substantially,” and “significantly.” The evidence of record is not sufficient to establish by clear and convincing evidence that the term is indefinite.¹ *See Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014).

¹ This recommendation is without prejudice, and Defendants may raise their indefiniteness argument at the summary judgment stage within the applicable page limitations.

It is well-established that terms of degree are not inherently indefinite, and “a patentee need not define his invention with mathematical precision in order to comply with the definiteness requirement.” *Sonix Tech. Co., Ltd. v. Publications Int’l, Ltd.*, 844 F.3d 1370, 1377 (Fed. Cir. 2017) (quoting *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1384 (Fed. Cir. 2005)). Rather, terms of degree are definite when they “provide reasonable certainty to a skilled artisan when read in the context of the patent.” *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1290 (Fed. Cir. 2017). The Federal Circuit has applied these principles in holding that the clause “not interfering substantially” was not indefinite because the intrinsic evidence provided sufficient guidance on the scope of the claims. *See Sonix*, 844 F.3d at 1377 (citing *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1336 (Fed. Cir. 2010)). More recently, the Federal Circuit held that the term “enlarged chamber” was not indefinite even though the specification did not recite a specific standard of measurement because a skilled artisan would understand that the enlarged chamber must be large enough to achieve a particular purpose. *Grace Instrument Indus., LLC v. Chandler Instruments Co., LLC*, 57 F.4th 1001, 1010-11 (Fed. Cir. 2023). Consistent with this line of cases, the specification in the present case informs a skilled artisan of the objective boundaries of the claim term by describing the particular purpose of the claimed support.

The specification provides express guidance on the meaning of the claim language “does not substantially interfere,” explaining “it is meant that the support does not significantly block either fluid outflow from the trabecular meshwork or fluid outflow to the collector channels.” (D.I. 119, Ex. 1 at 7:35-39) This definition acknowledges the competing goals of the invention and explains to a person of ordinary skill what is required by the claim language. (2/9/2023 Tr. at 70:7-18) The disclosure describes how implanting a support to maintain the patency of

Schlemm's canal is key to reducing IOP. (*Id.*, Ex. 1 at 2:56-59) However, the support is preferably designed in a manner to minimize contact with the walls of Schlemm's canal because such contact "can result in blockage of the meshwork or collector channels[.]" (*Id.*, Ex. 1 at 2:41-46; *see also id.* at 8:12-16, 10:61-65; Ex. 19 at ¶ 21) A person of ordinary skill reading this disclosure would understand the relationship between the support's contact with the canal walls and the amount of fluid outflow and would appreciate that the support can be designed in a manner to minimize the impact. (*Id.*, Ex. 1 at 11:30-38; Ex. 19 at ¶¶ 23-24)

A person of ordinary skill would be able to distinguish between supports that substantially interfere and those that do not based on a review of the Asserted Patents' written description. As in *Enzo*, the specification provides examples of both interfering and non-interfering supports and identifies criteria to distinguish them. *See Enzo*, 599 F.3d at 1333-34. For example, the specification describes hollow tubular stents placed lengthwise along Schlemm's canal as having "significant surface area contact with the trabecular meshwork and/or the collector channels, which can result in blockage of the meshwork or collector channels, substantially interfering with transmurial flow" across the canal. (D.I. 119, Ex. 1 at 2:41-47) While this design may allow for longitudinal flow, "the eye may not be effectively drained unless the fluid eventually traverses the canal." (*Id.*, Ex. 1 at 7:51-55, 7:63-67) Other designs may inhibit longitudinal flow while allowing transmurial flow across the canal, thereby effectively reducing IOP. (*Id.*, Ex. 1 at Fig. 5B, 5:21-23, 8:54-63)

Claim language such as "does not substantially interfere" denotes "language of magnitude" because it "purports to describe *how much* interference can occur" in fluid outflow. *Enzo*, 599 F.3d at 1333. Here, the intrinsic record provides guidance on how much fluid outflow and how much of a reduction in IOP levels is considered tolerable by setting forth ranges of

measurement for aqueous outflux and IOP. The specification discloses that, “[i]n many variations, the support allows between about 0.1 and about 5 microliters per minute aqueous outflux from the eye through the trabecular meshwork and collector channels.” (D.I. 119, Ex. 1 at 7:39-42) The specification also describes exemplary reductions in the level of IOP by 1-40 mm Hg. (*Id.*, Ex. 1 at 8:6-17)

Defendants take issue with the fact that these ranges are only exemplary, arguing that nothing in the specification informs a skilled artisan whether measurements outside of those ranges may not be substantially interfering. (2/9/2023 Tr. at 77:11-22) But mathematical precision is not required if the claim language informs those skilled in the art about the scope of the invention. *See Niazi*, 30 F.4th at 1347 (citing *Nautilus*, 572 U.S. at 901). Here, both parties’ experts confirm a skilled artisan would know how to determine whether a support substantially interferes with fluid outflow by testing the aqueous outflux and IOP metrics to establish the net effect of the support on outflow facility and IOP. (D.I. 119, Ex. 19 at ¶ 25; Ex. 20 at 133:24-134:7; D.I. 120, Ex. 34 at 161:22-162:8) The experts explained that a skilled artisan would be able to test fluid outflow in cadaver experiments and could measure both fluid flow and IOP using the Goldmann equation. (*Id.*) Using these standards to compare eyes with an implanted support and eyes without a support, the skilled artisan can ascertain the net effect of the support on fluid outflow facility and/or IOP. (D.I. 120, Ex. 34 at 163:16-21); *see Exmark Mfg. Co. v. Briggs & Stratton Power Prods. Grp., LLC*, 879 F.3d 1332, 1346 (Fed. Cir. 2018) (“All that is required is some standard for measuring the term of degree.”). A skilled artisan would understand the support “substantially interferes” with outflow facility when there is no net improvement in these metrics. (D.I. 119, Ex. 20 at 136:6-15)

Defendants object to the use of functional language in the asserted claims, arguing that it “creates problems figuring out where the bounds are for the claim.” (2/9/2023 Tr. 59:9-16) But the case cited by Defendants for this proposition acknowledges “there is nothing intrinsically wrong with” using functional language in the claims if the disclosure in the specification and the knowledge of a person of ordinary skill provide clear guidance on the scope of the claims. *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1255 (Fed. Cir. 2008). For these reasons, Defendants have failed to establish by clear and convincing evidence that the terms are indefinite.

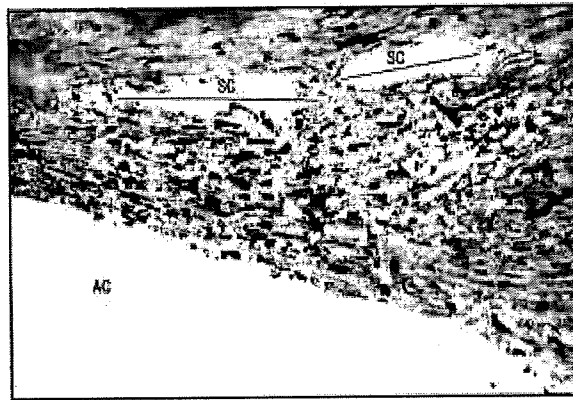
D. “wherein when the support is [disposed/inserted] within a cylindrical section of the lumen of the canal having an internal wall surface area C, the support contacts less than 30% of [the surface area of] C”

Claim term	Plaintiff’s proposal	Defendants’ Proposal	Court’s construction
“wherein when the support is [disposed/inserted] within a cylindrical section of the lumen of the canal having an internal wall surface area C, the support contacts less than 30% of [the surface area of] C” (’482 patent, claims 1, 32, 63; ’443 patent, claims 1, 58; ’742 patent, claim 13; ’328 patent, claim 21)	“wherein when the support is disposed within a section of Schlemm’s canal, the internal wall surface area C of that section is estimated by viewing the inside of Schlemm’s canal as a slightly arcuate cylinder having length L, extending circumferentially from a first end X ₁ to a second end X ₂ of the support, and inside radius R _i , and the support contacts less than 30% of [the surface area of] C.”	Indefinite	“wherein when the support is disposed within a section of Schlemm’s canal, the internal wall surface area C of that section is estimated by viewing the inside of Schlemm’s canal as a slightly arcuate cylinder having length L, extending circumferentially from a first end X ₁ to a second end X ₂ of the support, and inside radius R _i , and the support contacts less than 30% of [the surface area of] C.”

I recommend that the court construe the term “wherein when the support is [disposed/inserted] within a cylindrical section of the lumen of the canal having an internal wall surface area C, the support contacts less than 30% of [the surface area of] C” in accordance with

Plaintiff's proposed construction. The issue is whether it is possible for a skilled artisan to calculate whether the support contacts less than 30% of the interior wall surface area as required by the claims, or whether those claims are indefinite. The evidence of record is not sufficient to establish by clear and convincing evidence that the term is indefinite.² See *Nautilus*, 572 U.S. at 901.

The parties agree that the actual surface area contact with Schlemm's canal cannot be precisely calculated due to the irregular shape of the canal, which can vary anatomically from person to person:



(D.I. 120, Ex. 29 at 1253; see also D.I. 119, Ex. 19 at ¶ 28; Ex. 20 at 120:25-121:2) To account for this variability, the specification sets forth an equation for calculating an estimate of the canal wall surface area in contact with the support: “The fraction of canal wall surface area in contact with a support can be estimated by viewing the inside of Schlemm’s canal as a slightly arcuate cylinder C having length L, extending circumferentially from a first end X_1 to a second end X_2 of support 152, and inside radius R_i .” (D.I. 119, Ex. 1 at 11:16-20) This explanation is further illustrated in Figures 9A and 9B:

² This recommendation is without prejudice, and Defendants may raise their indefiniteness argument at the summary judgment stage within the applicable page limitations.

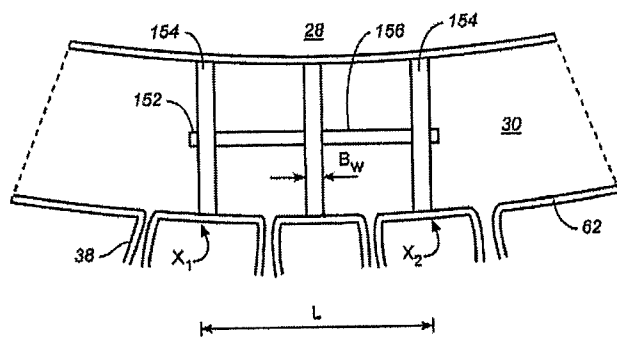


FIG. 9A

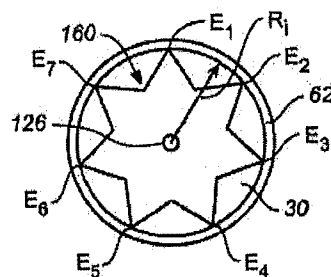


FIG. 9B

(*Id.*, Ex. 1 at Figs. 9A-9B)

Plaintiff's proposed construction tracks this formula and is therefore supported by the intrinsic record. *See Masimo Corp. v. Philips Elecs. N. Am. Corp.*, C.A. No. 11-742-LPS, 2015 WL 7737308, at *6 (D. Del. Dec. 1, 2015) (finding claim term was not indefinite where the specification explained how to calculate two estimates and how a skilled artisan could use those estimates to arrive at the resulting indication). Defendants' suggestion that the phrase "slightly arcuate" injects uncertainty into Plaintiff's proposed construction is not persuasive because the Figures illustrate the "slightly arcuate" nature of the cylinder to account for the curvature of Schlemm's canal. (D.I. 118 at 38; D.I. 119, Ex. 1 at Figs. 9A-B)

The extrinsic evidence also indicates that one skilled in the art would know with reasonable certainty how to calculate an estimate of the surface area as required by the claims. The testimony of Plaintiff's expert confirms that a skilled artisan would interpret the claim language to refer to an estimate of the surface area, rather than an actual measurement, due to the difficulty of obtaining an actual measurement. (*Id.*, Ex. 20 at 44:1-45:16, 46:21-47:4) Plaintiff's expert explains that the internal surface wall area of Schlemm's canal ("C") "has no meaning unless you start talking about this as a cylinder. . . . there is no literature that says, 'Oh, C is the actual in-vivo surface area of the real Schlemm's Canal.'" (D.I. 119, Ex. 20 at 120:13-17)

Despite this variability, Plaintiff's expert confirms that a skilled artisan reading the specification could use the mathematical construct of an arcuate cylinder to estimate the shape of Schlemm's canal and calculate surface area contact between the canal wall and the claimed support with reasonable certainty. (*Id.*, Ex. 20 at 43:20-44:20, 64:4-17) The anatomical realities of Schlemm's canal do not render this term indefinite where, as here, the intrinsic and extrinsic evidence "reasonably apprise[s] those skilled in the art both of the utilization and scope of the invention, and [] the language is as precise as the subject matter permits." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385 (Fed. Cir. 1986).

Defendants argue that the prosecution history confirms the claim limitation requires determining the actual surface area contact between the support and the canal wall, as opposed to an estimate. (D.I. 118 at 35) But the prosecution history of the '482 patent shows that applicants distinguished the prior art Shadduck reference by observing that Shadduck did not make any disclosure about the amount of contact, either actual or estimated, between the apparatus and the surrounding tissue. (D.I. 120, Ex. 35 at 14-15) As previously stated, a person of ordinary skill would understand that the calculations described in the Asserted Patents are estimates due to the anatomical irregularities of Schlemm's canal, and the prosecution history simply states that the prior art Shadduck reference did not contemplate the impact of the amount of surface area contact on the stent's functioning.

Defendants also contend that Plaintiff's proposed construction does not adequately inform a person of ordinary skill because it fails to clarify critical details about the calculation, such as when or how to make the estimation. (D.I. 118 at 37) But the testimony of Plaintiff's expert shows that a person of ordinary skill would understand how to determine the size of the cylinder, the contact points, and the length of the support to perform a surface area calculation

based on the guidance in the specification. (D.I. 119, Ex. 20 at 69:14-24, 72:17-21, 75:14-16, 111:6-15) Defendants have not shown by clear and convincing evidence that a skilled artisan would not be able to calculate the estimate with reasonable certainty. *See Nautilus*, 134 S. Ct. at 2124.

The parties also dispute whether Defendants’ own modeling approach for its product supports Plaintiff’s position that a hypothetical cylinder may be used to measure surface area contact in Schlemm’s canal. (D.I. 118 at 42, 45) The Federal Circuit has indicated that “evidence of a challenger’s own ability to apply a term without unreasonable uncertainty counts against an indefiniteness contention.” *Liqwd, Inc. v. L’Oreal USA, Inc.*, 720 F. App’x 623, 631 (Fed. Cir. 2018) (citing *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1368) (Fed. Cir. 2017)). But the court need not consider evidence regarding Defendants’ own product to reach the conclusion that the claim term is not indefinite. For the reasons previously discussed, the specification’s disclosure and the testimony of Plaintiff’s expert regarding the understanding of a skilled artisan are sufficient to preclude a ruling of indefiniteness.

E. “wherein at least a portion of the arcuate member has a radius of curvature smaller than the radius of curvature of Schlemm’s canal [such that at least a portion of the arcuate member extends out of Schlemm’s canal]”

Claim term	Plaintiff’s proposal	Defendant’s Proposal	Court’s construction
“wherein at least a portion of the arcuate member has a radius of curvature smaller than the radius of curvature of Schlemm’s canal [such that at least a portion of the arcuate member extends out of Schlemm’s canal]” (’443 patent, claims 1, 58; ’361 patent, claim	No construction of this term is necessary, and the term is not indefinite. If the court decides to construe this term, it should be construed according to its plain and ordinary meaning, i.e., at least a portion of the arcuate member has a radius of curvature smaller than the radius of curvature	Indefinite	Plain and ordinary meaning, i.e., “at least a portion of the arcuate member has a radius of curvature smaller than the radius of curvature of Schlemm’s canal (which persons of ordinary skill in the art knew or could measure) [such that at

1; '742 patent, claim 1; '328 patent, claim 1)	of Schlemm's canal (which persons of ordinary skill in the art knew or could measure) [such that at least a portion of the arcuate member extends out of Schlemm's canal].		least a portion of the arcuate member extends out of Schlemm's canal]."
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I recommend that the court construe the term “wherein at least a portion of the arcuate member has a radius of curvature smaller than the radius of curvature of Schlemm’s canal [such that at least a portion of the arcuate member extends out of Schlemm’s canal]” in accordance with the plain and ordinary meaning proposed by Plaintiff. The issue is whether the term is indefinite. Defendants describe three layers of uncertainty in this claim term: (1) how to measure the radius of curvature of the arcuate member; (2) how to measure the radius of curvature of Schlemm’s canal; and (3) whether the “configured to extend out of Schlemm’s canal” limitation injects a method step into a device claim. (2/9/2023 Tr. at 101:17-102:12) The evidence of record is not sufficient to establish by clear and convincing evidence that the term is indefinite.³ See *Nautilus*, 572 U.S. at 901.

Plaintiff’s proposal is consistent with the evidence of record. The specification explains and illustrates how arcuate members having a radius of curvature smaller than Schlemm’s canal can be used to “urge the canal open” beyond the cross-sectional dimension of the canal, indicated by B_D . (D.I. 119, Ex. 4 at 12:15-23) In Figures 11A and 11D, for instance, the radius of curvature of Schlemm’s canal is indicated by R_{SC} , and the radius of curvature of the arcuate member is indicated by R_{supp} :

³ This recommendation is without prejudice, and Defendants may raise their indefiniteness argument at the summary judgment stage within the applicable page limitations.

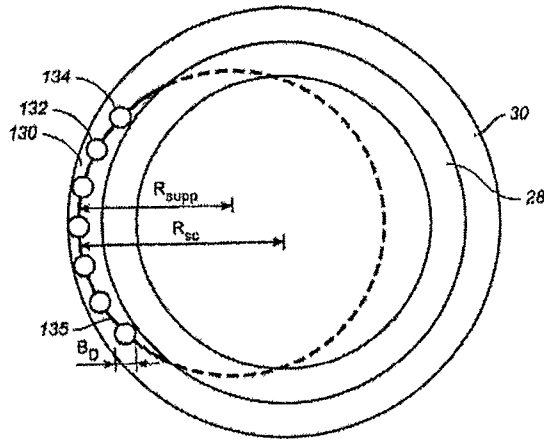


FIG. 11A

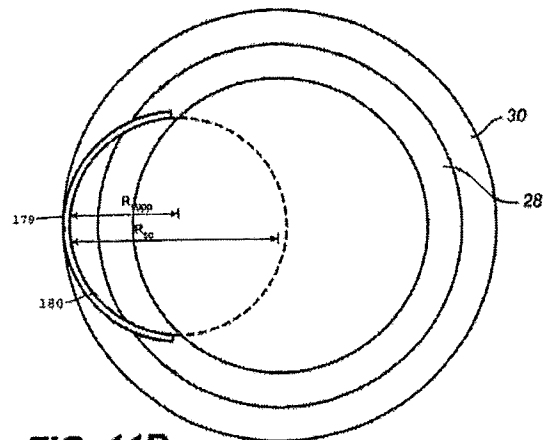


FIG. 11D

(*Id.*, Ex. 4 at Figs. 11A, 11D) The specification provides an exemplary range for the radius of curvature of the arcuate member between 3 mm and 8 mm, and the claim language provides an additional parameter by requiring that the radius of curvature of the arcuate member must be smaller than the radius of curvature of Schlemm's canal. (*Id.*, Ex. 4 at 12:33-39, cl. 1) While the range disclosed in the specification is not limiting, it provides objective guidance to a person of ordinary skill in determining the scope of the claims when considered in the context of the radius of curvature of Schlemm's canal. (*Id.*, Ex. 4 at 12:30-33; Ex. 19 at ¶¶ 38-39); see *United Access Techs., LLC v. AT&T Corp.*, 757 F. App'x 960, 969-71 (Fed. Cir. 2019) (concluding that "high frequency band" range was reasonably clear and not indefinite where the specification and extrinsic evidence supported a numerical approximation of the lower range of the band and there was no limit on the upper range of the band).

A skilled artisan would understand that the radius of curvature of the arcuate member cannot readily be disclosed with greater specificity due to the inherent variability of the radius of curvature of Schlemm's canal. (D.I. 119, Ex. 19 at ¶¶ 39-40) This anatomical variability does not render a claim term indefinite. The Federal Circuit has held that electrodes claimed "in spaced relationship" with each other were not indefinite even though the "spaced relationship"

was not specifically defined in the patents because the electrodes were to collect electrical signals on a user's hand and was implicitly defined by "the width of a user's hands." *Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374, 1382-83 (Fed. Cir. 2015); *see also Young v. Lumenis, Inc.*, 492 F.3d 1336, 1346 (Fed. Cir. 2007) (concluding that the term "near" was not indefinite for lack of a precise numerical measurement because it described a location on an animal that would vary based on the animal's size). Similarly, the claims here are not indefinite because they define the radius of curvature of the arcuate member by reference to the radius of curvature of Schlemm's canal.

A person of ordinary skill would also be able to determine the radius of curvature of Schlemm's canal with reasonable certainty based on the disclosure in the specification, which indicates that the radius of curvature of the arcuate member is generally 3 mm to 8 mm and provides that this dimension is about 10 to 50% smaller than that of Schlemm's canal. (D.I. 119, Ex. 4 at 12:30-39) Applying this guidance, a skilled artisan would have understood that a 3 mm radius of curvature for an arcuate member 50% smaller than the radius of Schlemm's canal would correspond to a dimension of 6 mm for Schlemm's canal. (*Id.*; Ex. 19 at ¶ 40) The extrinsic evidence also establishes that a skilled artisan would have been familiar with the radius of curvature of Schlemm's canal and would have understood that it is typically about 6 mm. (D.I. 119, Ex. 19 at ¶ 40; Ex. 15 at [0074]; D.I. 120, Ex. 34 at 59:18-60:2) The variability in this anatomical dimension would not prevent a person of ordinary skill from calculating the radius of curvature of Schlemm's canal with reasonable certainty. *See Biosig Instruments*, 783 F.3d at 1382-83.

Defendants' own documents on the accused Hydrus® Microstent product further confirm that a person of ordinary skill can ascertain both the radius of curvature of Schlemm's canal and

that of a device inserted into the canal having a smaller radius so that the device protrudes into the anterior chamber. (D.I. 119, Ex. 16 at IVANTIS_SS_00001281; Ex. 19 at ¶ 42) Although these features of the accused product do not guide the court's chosen construction of the disputed term, they do support a conclusion that the term is not indefinite. *See Exigent Tech., Inc. v. Atrana Sols., Inc.*, 442 F.3d 1301, 1309 n.10 (Fed. Cir. 2006) (explaining that the court may "consider the accused device when determining what aspect of the claim should be construed."); *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1368 (Fed. Cir. 2017) (citing expert's own work as implicit confirmation that the terms would be understood with reasonable certainty by a skilled artisan).

Defendant relies on the Federal Circuit's unpublished decision in *Saso Golf, Inc. v. Nike, Inc.*, which held that a claim requiring a comparison of two radii of curvature on the "toe" and "heel" sides of a wood type golf club was indefinite because the boundaries of those measurements were not reasonably known. 843 F. App'x 291, 292, 297 (Fed. Cir. 2021). According to Defendants, the specification and claims in this case similarly fail to identify start or end points on the arcuate member to determine the radius of curvature. (D.I. 118 at 68-69) But in *Saso*, the Federal Circuit focused on the fact that the sides of the golf club were "more complex than a segment of a perfect circle," and the experts did not consider the "toe" and "heel" portions of the club to have a single definition or established boundaries. *Saso*, 843 F. App'x at 295-97. Here, in contrast, the specification illustrates the portions of an arcuate member having a radius of curvature as portions of a perfect circle. (D.I. 119, Ex. 4 at Figs. 11A-11D) And Plaintiff's expert testified that any portion of the arcuate member having a radius of curvature smaller than Schlemm's canal would satisfy the claim language. (*Id.*, Ex. 20 at 178:2-179:11)

For the reasons previously discussed at § III.B, *supra*, the radii of curvature R_{supp} and R_{SC} are distinct from the cross-sectional dimension of the canal B_D .

Finally, Defendants take issue with the portion of the term requiring the arcuate member to be “configured to extend out of Schlemm’s canal” because the specification provides no guidance on how the arcuate member should be configured. (D.I. 118 at 67-70) To the extent that the device must be implanted in the canal before it can be determined whether the device is “configured to extend out” of the canal, Defendants maintain this improperly imports a method step into the device claim, rendering the claims indefinite. (*Id.* at 70) But Defendants do not establish how a device “configured to extend out” of the canal covers both an apparatus and a method of use. In *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, the claim recited a system in which “the user uses the input means” to change or accept the transaction, covering both a system and a method step on its face. 430 F.3d 1377, 1384 (Fed. Cir. 2005). Defendants cite no authority suggesting that a claim limitation requiring a device to be “configured” in a specific way connotes a method step. The extrinsic evidence confirms that a person of ordinary skill would understand how to configure the portion of the arcuate member having a radius of curvature to extend out of Schlemm’s canal, despite the irregularities in the size of the canal itself. (D.I. 119, Ex. 20 at 207:6-208:17; Ex. 16 at IVANTIS_SS_00001281)

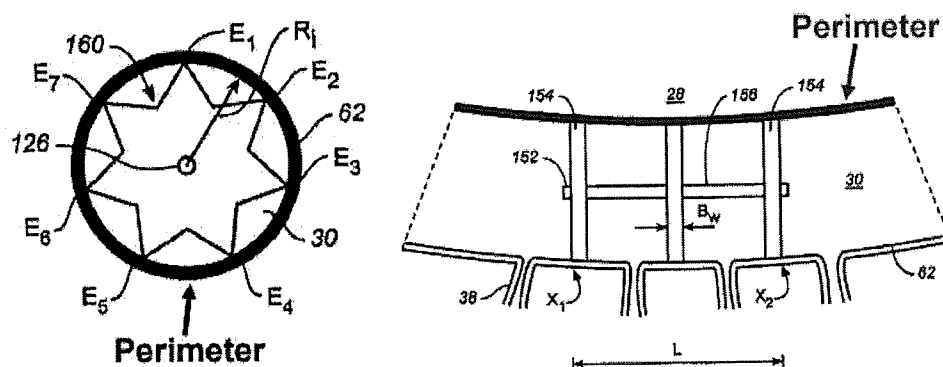
F. “discontinuous along a perimeter of the lumen of the canal”

Claim term	Plaintiff’s proposal	Defendants’ Proposal	Court’s construction
“discontinuous along a perimeter of the lumen of the canal” (’482 patent, claims 1, 63)	No construction of this term is necessary. If the court decides to construe this term, it should be construed according to its plain and ordinary meaning, i.e., that contact between the support and a wall of the canal is “interrupted by a non-contact point along a perimeter of the lumen of the canal.”	“interrupted by a non-contact point along the support”	Plain and ordinary meaning, i.e., that contact between the support and a wall of the canal is “interrupted by a non-contact point along a perimeter of the lumen of the canal.”

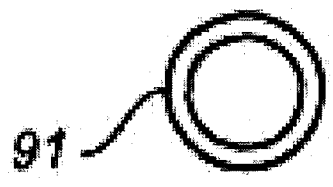
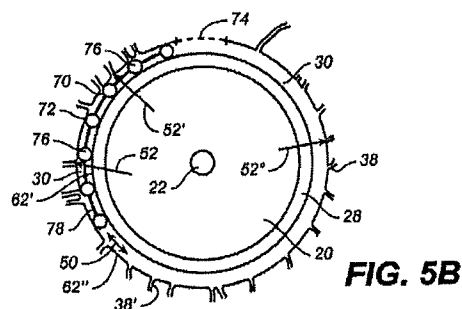
I recommend that the court construe the term “discontinuous along a perimeter of the lumen of the canal” in accordance with Plaintiff’s proposed construction, which is consistent with the claim language and the specification. During the *Markman* hearing, the parties confirmed their agreement that the claimed “perimeter” could refer to either a perimeter of the cross-section or a perimeter along the length of the canal. (2/9/2023 Tr. at 118:10-119:3) The parties also agree that “discontinuous contact” means contact that is interrupted by a noncontact point. (*Id.* at 119:18-21) However, the parties disagree about whether the non-contact point is located along the support or along the perimeter of the lumen of the canal. (D.I. 118 at 30-31)

Both parties focus on the language of the claims themselves to support their proposed constructions. Claim 1 of the ’482 patent recites that “when the support is disposed within a lumen of Schlemm’s canal, contact between the support and a wall of the canal is discontinuous along a perimeter of the lumen of the canal[.]” (D.I. 119, Ex. 1 at cl. 1) Although the claim discusses contact between the support and the wall of the canal, the claim specifies that the discontinuity of that contact occurs “along a perimeter of the lumen of the canal.” (*Id.*; *see*

2/9/2023 Tr. at 123:2-13) Defendants' demonstratives on Figures 9A and 9B confirm the parties' agreement regarding where the claimed perimeter is located:



Defendants argue that Plaintiff's proposed construction would read out multiple beaded embodiments that make continuous contact around the cross-sectional perimeter of Schlemm's canal. (D.I. 118 at 32-33) But these beaded embodiments still fall within the scope of the claims precisely because "a perimeter of the lumen of the canal" may refer to either the cross-sectional dimension or the longitudinal dimension of the canal. (2/9/2023 Tr. at 124:2-8) For instance, Figure 5B depicts a beaded embodiment which would have continuous contact around the cross-sectional perimeter as shown by element 91 in Figure 6A, but this embodiment would still satisfy the claim language because the beads have discontinuous contact along the length of the canal:



(D.I. 119, Ex. 1 at Figs. 5B, 6A) For these reasons, Plaintiff's proposed construction finds more support in the intrinsic record.

G. "only a portion of the exterior surface of the support contacts an inner periphery of the lumen of the canal"

Claim term	Plaintiff's proposal	Defendants' Proposal	Court's construction
"only a portion of the exterior surface of the support contacts an inner periphery of the lumen of the canal" ('482 patent, claim 32)	No construction of this term is necessary. If the court decides to construe this term, it should be construed according to its plain and ordinary meaning, i.e., "only a portion of the exterior surface of the support contacts an inner wall of the lumen of the canal."	"contact between the support and the canal is interrupted by a non-contact point"	Plain and ordinary meaning, i.e., "only a portion of the exterior surface of the support contacts an inner wall of the lumen of the canal."

I recommend that the court construe the term "only a portion of the exterior surface of the support contacts an inner periphery of the lumen of the canal" in accordance with Plaintiff's proposal, which is consistent with the intrinsic record. The parties dispute whether the phrase "inner periphery" refers to the entire interior surface of Schlemm's canal, or whether it instead refers to a specific portion of the canal.

The specification discloses that the "inner periphery of the lumen of the canal" refers to the portion of the canal bordering the trabecular meshwork. (D.I. 119, Ex. 1 at 7:6-8) In this regard, the specification distinguishes the inner peripheral surface of Schlemm's canal from its outer peripheral surface, where the apertures leading to the collector channels are located. (*Id.*, Ex. 1 at 7:13-15) The inner periphery of the canal is depicted at element 62' in Figure 4A, bordering the outer peripheral surface of the trabecular meshwork 28:

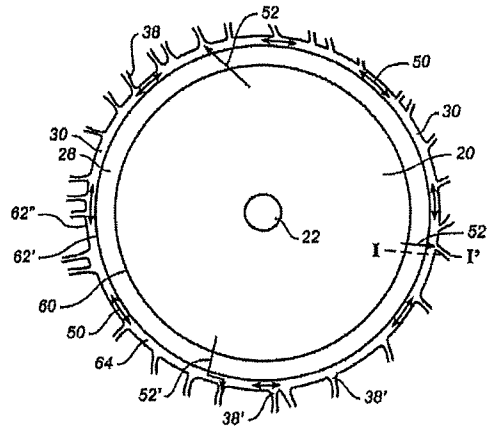


FIG. 4A

(*Id.*, Ex. 1 at Fig. 4A) Defendants’ proposed construction is not as true to the intrinsic record because it does not distinguish between the inner and outer peripheral surfaces of Schlemm’s canal or otherwise meaningfully address “the inner periphery of the lumen.”

H. “periodic contact”

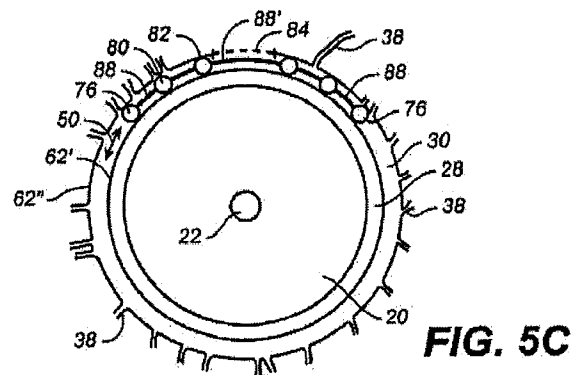
Claim term	Plaintiff’s proposal	Defendants’ Proposal	Court’s construction
“periodic contact” (’482 patent, claims 7, 38, 69)	No construction of this term is necessary. If the court decides to construe this term, it should be construed according to its plain and ordinary meaning, i.e., “contact at regular intervals.”	“contact that is interrupted by a non-contact point”	“contact that is interrupted by a non-contact point”

I recommend that the court adopt Defendants’ proposed construction and construe the term “periodic contact” to mean “contact that is interrupted by a non-contact point.” The parties dispute whether the term requires the points of contact between the support and the canal wall to occur at regular intervals. Defendants’ proposal is consistent with the specification.

Both sides discuss the “tangential, periodic, sporadic” language in the specification. (D.I. 119, Ex. 1 at 10:61-65) The word “sporadic” only appears once in the entire specification and

never appears in the claims. Nothing in the specification describes the difference between “sporadic” and “periodic.” Moreover, the parties agree that none of the embodiments disclosed in the specification is explicitly described as having periodic contact. (2/9/2023 Tr. at 140:9-17) The specification only states that “[t]here is no contact with the canal walls where connectors space apart beads, and no contact in fluted regions of beads,” without specifying the intervals of no contact. (*Id.*, Ex. 1 at 11:28-30)

The Figures support Defendants’ position that the claimed contact is interrupted by non-contact points, but these Figures do not specify any particular interval at which the points of no contact occur. (*Id.*, Ex. 1 at Figs. 5B-C, 9A-B, 10A-C, 11A, 12A-B, 12E-H; 10:61-65, 11:28-33) Nothing in the intrinsic evidence restricts “periodic contact” to “regular intervals.” To the contrary, the space between the supports 82 at incision site 84 in Figure 5C suggests that non-contact points may occur at irregular intervals because the supports may be connected with connectors 88 and 88’ having different lengths:



(*Id.*, Ex. 1 at Fig. 5C; 9:11-16, 11:39-42) On this record, there is insufficient evidence to support a requirement that the points of contact must occur at regular intervals.

I. “fluted edges”

Claim term	Plaintiff’s proposal	Defendants’ Proposal	Court’s construction
“fluted edges” (’482 patent, claims 5, 36, 68)	No construction of this term is necessary. Following <i>Markman</i> : “edges that are uneven”	“grooves” Following <i>Markman</i> : “edges that are uneven or have grooves”	“edges that are uneven”

I recommend that the court adopt Plaintiff’s modified construction proposed during the *Markman* hearing and construe the term “fluted edges” to mean “edges that are uneven.” (2/9/2023 Tr. at 144:21-145:1; D.I. 132) Defendants’ construction of “fluted edges” to mean “edges that are uneven or have grooves” is unnecessary because construing the term to mean “edges that are uneven” does not exclude grooves, and there is nothing in the intrinsic record to support the inclusion of the term “grooves.” (D.I. 130)

J. “multiple connected elements”

Claim term	Plaintiff’s proposal	Defendants’ Proposal	Court’s construction
“multiple connected elements” (’482 patent, claims 18, 49, 73)	No construction of this term is necessary. If the court decides to construe this term, it should be construed according to its plan and ordinary meaning, i.e., “multiple elements exist along the length of the support.”	“elements joined or fastened together by a distinct connecting means”	No construction of this term is necessary.

No construction of the term “multiple connected elements” is necessary. The parties dispute whether the “connected” language in the claims should be limited to elements that are “joined or fastened together by a distinct connecting means” as proposed by Defendants, or whether the “connected” language is readily understood without these additional limitations. The latter conclusion is supported by the intrinsic record.

Both parties agree the specification describes many ways in which the claimed elements may be connected. (D.I. 118 at 54-55) These include the use of adhesives, chemical bonding, mechanical interlocking, welding, threading, knots, or any combination of these techniques. (D.I. 119, Ex. 1 at 9:49-51, 10:11-14, 10:18-23) The written description leaves the means of connection open-ended, explaining that “[j]unctions 102 between beads as shown in FIG. 7B can be made using any suitable technique”:



(*Id.*, Ex. 1 at 9:49-50; Fig. 7B) Plaintiff correctly observes that Defendants’ proposed construction requiring “a distinct connecting means” would exclude embodiments connecting the elements by casting the entire support out of a single piece of material. (D.I. 118 at 56) In such an embodiment, the connecting means cannot accurately be described as “distinct.”

IV. CONCLUSION

For the reasons set forth above, I recommend that the court construe disputed terms as follows:

Term	Recommended Construction
“support” (’482 patent, claims 1, 32, 63; ’443 patent, claims 1, 58; ’361 patent, claim 1; ’742 patent, claim 1; ’328 patent, claim 1)	Plain and ordinary meaning, i.e., “a structure that props something open” or “a prop.”
“arcuate member” (’443 patent patent, claims 1, 58; ’361 patent, claim 1; ’742 patent, claim 1; ’328 patent, claim 1	“a structure having one or more curved portions”
“fluid may traverse the canal without substantial interference from the support” / “support does not substantially interfere with the [longitudinal / transmural] flow” / “does not significantly block fluid outflow”	“the support does not significantly block either fluid outflow from the trabecular meshwork or fluid outflow to the collector channels.”

(’482 patent, claims 1, 32; ’443 patent, claims 1, 56, 57, 58; ’361 patent, claims 6, 7, 8; ’742 patent, claims 17, 18; ’328 patent, claims 7, 8)	
“wherein when the support is [disposed/inserted] within a cylindrical section of the lumen of the canal having an internal wall surface area C, the support contacts less than 30% of [the surface area of] C” (’482 patent, claims 1, 32, 63; ’443 patent, claims 1, 58; ’742 patent, claim 13; ’328 patent, claim 21)	“wherein when the support is disposed within a section of Schlemm’s canal, the internal wall surface area C of that section is estimated by viewing the inside of Schlemm’s canal as a slightly arcuate cylinder having length L, extending circumferentially from a first end X ₁ to a second end X ₂ of the support, and inside radius R _i , and the support contacts less than 30% of [the surface area of] C.”
“wherein at least a portion of the arcuate member has a radius of curvature smaller than the radius of curvature of Schlemm’s canal [such that at least a portion of the arcuate member extends out of Schlemm’s canal]” (’443 patent, claims 1, 58; ’361 patent, claim 1; ’742 patent, claim 1; ’328 patent, claim 1)	Plain and ordinary meaning, i.e., at least a portion of the arcuate member has a radius of curvature smaller than the radius of curvature of Schlemm’s canal (which persons of ordinary skill in the art knew or could measure) [such that at least a portion of the arcuate member extends out of Schlemm’s canal].
“discontinuous along a perimeter of the lumen of the canal” (’482 patent, claims 1, 63)	Plain and ordinary meaning, i.e., that contact between the support and a wall of the canal is “interrupted by a non-contact point along a perimeter of the lumen of the canal.”
“only a portion of the exterior surface of the support contacts an inner periphery of the lumen of the canal” (’482 patent, claim 32)	Plain and ordinary meaning, i.e., “only a portion of the exterior surface of the support contacts an inner wall of the lumen of the canal.”
“periodic contact” (’482 patent, claims 7, 38, 69)	“contact that is interrupted by a non-contact point”
“fluted edges” (’482 patent, claims 5, 36, 68)	“edges that are uneven”
“multiple connected elements” (’482 patent, claims 18, 49, 73)	No construction of this term is necessary.

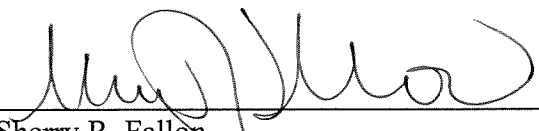
Given that the court has relied upon material that technically remains under seal, the court is releasing this Report and Recommendation under seal, pending review by the parties. In the unlikely event that the parties believe that certain material in this Report and Recommendation should be redacted, the parties shall jointly submit a proposed redacted version

by no later than **March 16, 2023**, for review by the court, along with a motion supported by a declaration that includes a clear, factually detailed explanation as to why disclosure of any proposed redacted material would “work a clearly defined and serious injury to the party seeking closure.” See *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019) (quoting *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994) (internal quotation marks omitted)). If the parties do not file a proposed redacted version and corresponding motion, or if the court determines the motion lacks a meritorious basis, the documents will be unsealed within fourteen (14) days of the date the Report and Recommendation issued.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The objections and responses to the objections are limited to ten (10) pages each. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the District Court. See *Sincavage v. Barnhart*, 171 F. App’x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the court’s Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated March 7, 2022, a copy of which is available on the court’s website, <http://www.ded.uscourts.gov>.

Dated: March 9, 2023


Sherry R. Fallon
UNITED STATES MAGISTRATE JUDGE