IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE (Wilmington)

TRANSCEND MEDICAL, INC.,	:	
	:	
Plaintiff,	:	**CIVIL ACTION**
	:	
v.	:	**No. 13-830**
	:	
GLAUKOS CORPORATION,	:	
	:	
Defendant.	:	

January 16, 2015

Goldberg, J.

MEMORANDUM OPINION

I. Introduction

This case involves a patent dispute regarding devices designed to treat glaucoma. Presently before me is a claim construction pursuant to Markman v. Westview, Inc., 517 U.S. 370 (1996).

Plaintiff Transcend Medical, Inc. has developed a technology called "CyPass Micro-Stent" for use in the treatment of glaucoma. This technology has not been approved by the United States Food and Drug Administration ("FDA") for general use. CyPass is currently only available for use in the United States through Transcend's FDA-sanctioned clinical trial. CyPass is, however, available on a limited commercial basis in Europe. (2d Am. Compl. ¶¶ 9-11.)

Defendant Glaukos Corporation markets and sells a technology called "iStent" which is also used in the treatment of glaucoma. In connection with iStent, Glaukos owns four patents, which are the "patents-in-suit."

Transcend explains that it "heard through conversations with various individuals" that Glaukos claimed Transcend could not commercialize CyPass without infringing the patents owned by Glaukos. Thereafter, the parties exchanged letters disagreeing about the scope of Glaukos' patents and whether Transcend's CyPass violates Glaukos' patents. (2d Am. Compl. ¶¶ 9-11.) Unable to resolve the dispute, Transcend filed a complaint seeking declaratory judgment of non-infringement and unenforceability of Glaukos' patents based upon inequitable conduct. (2d Am. Compl. ¶¶ 9-11.) Glaukos in turn filed counterclaims for infringement of its patents. (Ans., Counterclaims ¶¶ 17-33.)

The parties have submitted a Joint Claim Construction Statement outlining their agreed constructions as well as disputed constructions of terms contained in the patents-in-suit. Briefs and reply briefs in support of their proposed constructions have also been submitted. On November 13, 2014, a Markman hearing was held and the parties presented background on the devices in question and argument on their respective claim constructions.

II. Legal Principles

A. Claim Construction

Patent infringement cases typically involve a two-part analysis. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1581-82 (Fed. Cir. 1996). The first step involves proper construction of the asserted claims. Id. The second step involves a determination as to whether the accused method or product infringes the asserted claims as properly construed. Id.

Claim construction requires a determination of the meaning and scope of any disputed terms contained in a patent's claims. Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999). In construing disputed terms, courts initially look to "the intrinsic evidence

of record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history." Vitronics Corp., 90 F.3d at 1582.

The first source of intrinsic evidence is the actual language of the claims. Id. Claim construction begins with and remains focused on the language of the claims because that is what the inventor used to describe his invention. Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001). Claim language is given its "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." Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005). A patentee may, however, "choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." Vitronics Corp., 90 F.3d at 1582.

Claims are not read in isolation because they are "part of a fully integrated written instrument consisting principally of a specification that concludes with the claims." Phillips, 415 F.3d at 1315 (internal citations omitted). As such, the second source of intrinsic evidence courts consider is the patent specification. Vitronics Corp., 90 F.3d at 1582. In fact, the specification "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." Id.

Third, courts consider the patent's prosecution history, when in evidence, to assess whether the inventor disclaimed a particular interpretation of a term during the prosecution of the patent. Ventana Med. Sys., Inc. v. Biogenex Labs., Inc., 473 F.3d 1173, 1182 (Fed. Cir. 2006). The doctrine of prosecution disclaimer requires "a clear and unmistakable disavowal of scope during prosecution. This may occur, for example, when the patentee explicitly characterizes an aspect of his invention in a specific manner to overcome prior art." Purdue Pharma L.P. v. Endo

Pharm. Inc., 438 F.3d 1123, 1136 (Fed. Cir. 2006). Therefore, 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." Phillips, 415 F.3d at 1317.

In most circumstances, consideration of these sources of intrinsic evidence will resolve a dispute as to a claim's meaning. Vitronics Corp., 90 F.3d at 1583. Where a claim can be properly construed through intrinsic evidence, it is improper for the court to consider extrinsic evidence, such as "expert testimony, inventor testimony, dictionaries, and technical treatises and articles." Phillips, 415 F.3d at 1317 (internal citations omitted). Examination of extrinsic evidence is, however, appropriate where an assessment of all intrinsic evidence fails to resolve the meaning of a disputed term. Vitronics Corp., 90 F.3d at 1583. While extrinsic evidence may be considered, it "may be used only to help the court come to the proper understanding of the claims; it may not be used to vary or contradict the claim language." Id. at 1584.

B. § 112(f) – Means-plus-function Analysis

The patent statute provides that an "element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure . . . and such claim shall be construed to cover the corresponding structure . . . described in the specification and equivalents thereof." 35 U.S.C. § 112(f).[1] In other words, this section applies "to purely functional limitations that do not provide the structure that performs the recited function." Phillips, 415 F.3d at 1311.

The use of the term "means" in a claim element creates a rebuttable presumption that § 112(f) applies. Inventio AG v. ThyssenKrupp Elevator Ams. Corp., 649 F.3d 1350, 1356 (Fed.

[1] In 2011, Congress reformatted the paragraphs of § 112 as subsections. Leahy–Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011). Former § 112 ¶ 6 is now codified as § 112(f).

Cir. 2011). Conversely, the failure to use "means" creates a rebuttable presumption that § 112(f) does not apply. Id. When a claim term lacks the word "means," the presumption is rebutted and § 112(f) applies "if the challenger demonstrates that the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function." Id. (internal citations omitted).

Where § 112(f) applies, the first step is to define the function. Golight, Inc. v. Wal-Mart Stores, Inc., 355 F.3d 1327, 1333-34 (Fed. Cir. 2004). In doing so, the court must construe the function of a means-plus-function limitation to include only those limitations contained in the claim language. Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 296 F.3d 1106, 1113 (Fed. Cir. 2002).

The second step "is to look to the specification and identify the corresponding structure for that function." Golight, Inc., 355 F.3d at 1333-34. The "structure disclosed in the specification is 'corresponding' structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim." Id. (quoting Med. Instrumentation & Diagnostics Corp. v. Elekta AB, 344 F.3d 1205, 1210 (Fed. Cir. 2003). The claim is then construed to be limited to those corresponding structures. Id.

C. Claim Differentiation

The doctrine of claim differentiation provides that every claim in a patent is "presumptively different in scope." Ecolab, Inc. v. Paraclipse, Inc., 285 F.3d 1362, 1375 (Fed. Cir. 2002) (internal citations omitted). The doctrine is based on "the common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope." Andersen Corp. v. Fiber Composites, LLC, 474 F.3d 1361, 1369

(Fed. Cir. 2007) (quoting Karlin Tech. Inc. v. Surgical Dynamics, Inc., 177 F.3d 968, 971–72 (Fed. Cir. 1999)).

The claim differentiation presumption is especially strong where "there is a dispute over whether a limitation found in a dependent claim should be read into an independent claim, and that limitation is the only meaningful difference between the two claims." Wenger Mfg., Inc. v. Coating Mach. Sys., Inc., 239 F.3d 1225, 1233 (Fed. Cir. 2001).[2] Claim differentiation, however, is not a "hard and fast rule of construction" and cannot be used to broaden claims beyond their proper scope. Id.

III. Background – Glaucoma/Aqueous Humor

Glaucoma is associated with elevated pressure in the eye. The eye contains fluid called aqueous humor. An imbalance in the rate at which aqueous humor is produced in the eye and the rate at which it exits the eye causes elevated eye pressure. This elevated intraocular pressure can cause vision loss and eventually blindness. (Pl.'s Br. p. 2; Def.'s Br. pp. 3-4.)

Aqueous humor exits the eye through different pathways. Several of the disputed terms relate to the number, composition and outflow route of these pathways. Regarding the general anatomy of the eye, Glaukos explains that there are only two outflow pathways. According to Glaukos, the primary pathway is through Schlemm's canal and the trabecular meshwork. This is called the "canalicular route." Glaukos further explains that the secondary pathway is called the "uveoscleral" or "uveal scleral" route because the fluid passes between the uvea and the sclera. The uvea consists of the iris, ciliary body and choroid. (Def.'s Br. p. 4.) Transcend's general view of the eye's anatomy is that there are more than two pathways and that the uveal scleral route is not a singular well-defined pathway. (Pl.'s Br. pp. 2-3, 15-16.)

[2] Independent claims do not reference any other claim. Dependent claims reference another claim and are considered subsets of the referenced claim.

IV. Claim Construction

As noted previously, Glaukos owns the four patents-in-suit. US Patent No. 7,850,637 ("Patent '637") was granted to Drs. Mary G. Lynch and Reay H. Brown for their work developing an implant for the treatment of glaucoma. US Patent No. 7,857,782 ("Patent '782"), US Patent No. 8,075,511 ("Patent '511") and US Patent No. 8,579,846 ("Patent '846") (naming Hosheng Tu and others as inventors) claim implant systems that involve both an implant and a device for placing the implant in the eye. The parties collectively refer to these three patents as the "Tu Patents."[3] The parties dispute the meaning of five claim terms.[4]

A. Disputed Term 1: "physiological outflow path"

Term	Claims-at-Issue	Glaukos' Proposed Construction	Transcend's Proposed Construction
"physiological outflow path of the eye"	Patent '637 - Claims: 1, 3, 12, 26, 27 and 33	plain and ordinary meaning, namely a naturally occurring outflow path	The canalicular pathway for aqueous humor to flow from the anterior chamber through the trabecular meshwork and Schlemm's canal. An artificially created space is not a physiological outflow path.

Claims 1, 3, 12, 26, 27, and 33 of Patent '637 use the disputed term "physiological outflow path of the eye." In these claims, the length, shape, location and size of the implant are described in terms of fitting into the eye's "physiological outflow path." (Patent '637 12:5-18, 23-25, 44-47; 13:12-29; 14:3-7.)

[3] The Tu Patents contain identical specifications. The line numbering in the specifications, however, is not consistent. The parties reference the line numbering in Patent '782. For clarity, I will do the same when citing to the specifications in the Tu Patents.

[4] The parties initially disputed the meaning of a sixth term. That term is "the ocular implant is positioned entirely within the confines of a cornea and a sclera of the eye." (Claim Chart p. 5.) Transcend withdrew its proposed construction and no longer disputes Glaukos' construction which is "the ocular implant is positioned within the boundary defined by the cornea and sclera." (Pl.'s Br. p. 28 n.18.)

This term is subject to two disputes. First, the parties disagree as to the general construction of the term "physiological outflow path of the eye." Glaukos contends that it should be afforded its plain and ordinary meaning which is "a naturally occurring outflow path." Although Transcend acknowledges the term is broad in scope, it nonetheless urges that the term, as used in the patent, should be construed to mean the canalicular route only, which includes a pathway through the trabecular meshwork and the Schlemm's canal. The second dispute involves Transcend's proposal to include a negative limitation that states "an artificially created space is not a physiological outflow path." I will first address the dispute regarding the general construction and then turn to the second dispute regarding Transcend's proposed negative limitation.

Regarding the general construction of the term, Transcend proposes "the canalicular pathway for aqueous humor to flow from the anterior chamber through the trabecular meshwork and Schlemm's canal." Transcend primarily relies upon the fact that the specification consistently defines "the present invention" as a shunt placed in Schlemm's canal. Transcend argues that these statements delineate the invention and make clear that the disputed term, as used in the patent, is limited to Schlemm's canal and does not include other pathways such as the uveal scleral route.

Glaukos proposes that the term "physiological outflow path of the eye" be given its plain and ordinary meaning and construed as "a naturally occurring outflow path." Glaukos asserts that those of skill in the art know there are two "naturally occurring outflow paths" – the uveal scleral route and the canalicular route. In support, Glaukos offers the declaration of Dr. Jay Katz which states that there are "two physiological or naturally existing outflow paths for aqueous humor to flow out of a healthy human eye." (Katz Decl. ¶ 13.)

Glaukos also asserts that its construction is consistent with a general dictionary definition of "physiological" as the natural or normal functioning of an organism. Glaukos notes that this construction is consistent with the fact that the "BACKGROUND OF INVENTION" section of the specification references both outflow pathways. (Patent '637 1:54-60.)

Finally, Glaukos posits that Transcend's construction would render claims 10 and 29 superfluous. Claims 1 and 26 disclose an implant with "an outlet section shaped to be disposed in a physiological outflow path." (Patent '637 12:13-14; 13:18-19.) Claims 10 and 29 state the outlet of the implants disclosed in Claims 1 and 26 are to be "disposed in Schlemm's canal." (Patent '637 12:39-40; 13:31-32.) Glaukos argues that if Transcend were correct that "physiological outflow path of the eye" means Schlemm's canal, claims 10 and 29 would be redundant. As such, Glaukos argues that the doctrine of claim differentiation requires that Transcend's construction be rejected.[5]

For the following reasons, I will adopt Transcend's proposed construction and construe the term "physiological outflow path" as used in Patent '637 to mean "the canalicular pathway for aqueous humor to flow from the anterior chamber through the trabecular meshwork and Schlemm's canal." Transcend's construction is amply supported by the multiple references in the specification defining "the present invention" as an implant placed in Schlemm's canal. "When a

[5] Glaukos also points out that the inventors claimed devices specific to Schlemm's canal in earlier patents. Thus, according to Glaukos, these earlier patents reflect that the inventors knew how to claim a device specific to Schlemm's canal and if they had intended to claim a similarly limited device in Patent '637 they would have specifically done so. (Def.'s Br. pp. 11-14; Def.'s Reply Br. pp. 1-3.)

This argument fails. Except as documented in the prosecution history, the "subjective intent of the inventor when he used a particular term is of little or no probative weight in determining the scope of a claim." Markman v. Westview Instruments, Inc., 52 F.3d 967, 985 (Fed. Cir. 1995) aff'd, 116 S. Ct. 1384 (1996). Therefore, claims must be construed for "what they actually recite" not by considering what was subjectively intended by the inventors. Superior Fireplace Co. v. Majestic Prods. Co., 270 F.3d 1358, 1375 (Fed. Cir. 2001).

patentee consistently describes one embodiment as 'the present invention,' the public is entitled to take the patentee at his word." Lydall Thermal/Acoustical, Inc. v. Fed.-Mogul Corp., 344 F. App'x 607, 613 (Fed. Cir. 2009) (internal citations omitted); Honeywell Int'l, Inc. v. ITT Indus., Inc., 452 F.3d 1312, 1318 (Fed. Cir. 2006) (limiting term based on multiple descriptions of "this invention" or "the present invention").

In Honeywell, the United States Court of Appeals for the Federal Circuit considered a claim for a "fuel injection component." Id. at 1318. The specification repeatedly referred to a fuel filter as "this invention" and "the present invention." Id. Although the ordinary meaning of the term was not limited to a fuel filter, in light of the repeated definitions of "the invention," the court construed the "fuel injection component" narrowly to be limited to a fuel filter. Id. The court reasoned that the "public is entitled to take the patentee at his word and the word was that the invention is a fuel filter." Id.

Like Honeywell, Patent '637 contains multiple references that define "the present invention." The "TECHNICAL FIELD" section states "the present invention is generally directed to a surgical treatment for glaucoma, and relates more particularly to a device and method for continuously decompressing elevated intraocular pressure in eyes affected by glaucoma by diverting aqueous humor from the anterior chamber of the eye into Schlemm's canal." (Patent '637 1:24-29.) The "SUMMARY OF INVENTION" section states "the present invention is directed to a novel shunt and an associated surgical method for the treatment of glaucoma in which the shunt is placed to divert aqueous humor from the anterior chamber of the eye into Schlemm's canal." (Patent '637 5:19-22, 26-30.) Similarly, the "DETAILED DESCRIPTION OF THE PRESENT INVENTION" section states "[t]he present invention provides an aqueous humor shunt device to divert aqueous humor in the eye from the anterior

chamber into Schlemm's canal" and "[t]he invention contemplates many different configurations for an aqueous humor directing channel, provided that each assists in channeling aqueous humor from the anterior chamber to Schlemm's canal." (Patent '637 6:56-58; 7:19-22.) Under Honeywell, the repeated references to the "present invention" as a device to divert aqueous humor into Schlemm's canal weigh in favor of Transcend's proposed construction.

The first sentence of Transcend's proposed construction is also consistent with the purpose of the invention as stated in the specification. A specification's emphasis on a particular feature of an invention in solving the problems of the prior art is an important factor in defining the claims. Inpro II Licensing, S.A.R.L. v. T-Mobile USA, Inc., 450 F.3d 1350, 1354 (Fed. Cir. 2006); Honeywell, 452 F.3d at 1318 (construing a term in light of "[t]he written description's detailed discussion of the prior art problem addressed by the patent invention").

Consistent with this principle, in Inpro II Licensing, the Federal Circuit narrowly construed the general term "host interface" to mean a single particular type of interface – "a direct parallel bus interface." 450 F.3d at 1354-55. In doing so, the court rejected a broad construction of the term that included all types of interfaces. Id. Among the factors the court stressed in reaching this conclusion was that "the specification emphasizes the importance of a parallel connection in solving the problems of the previously used [types of interfaces]." Id. at 1354-56.

Like Inpro II Licensing, Patent '637's specification catalogues the shortcomings of various prior art and emphasizes a particular feature of the present invention as important to remedying those shortcomings. For example, the specification states

> Most of the problems that have developed with current glaucoma treatment devices and procedures have occurred because aqueous fluid is drained from inside of the eye to the surface of the eye. A need exists, then, for a more

> physiologic system to enhance the drainage of aqueous fluid from the anterior chamber into Schlemm's canal.

(Patent '637 4:6-5:3.) In other words, the specification emphasizes that the prior art fails to address the specific need for drainage into Schlemm's canal. Therefore, the stated need the device seeks to address weighs in favor of Transcend's proposed construction.

Glaukos' arguments that the term "physiological outflow path" should be construed to include both the canalicular route and the uveal scleral route are unavailing. According to Glaukos, the reference to the uveal scleral route in the "BACKGROUND OF THE INVENTION" section supports its proposed construction. This section, in relevant part, states:

> Once in the anterior chamber, the fluid drains out of the eye through two different routes. In the "uveoscleral" route, the fluid percolates between muscle fibers of the ciliary body. This route accounts for approximately ten percent of the aqueous outflow in humans. The primary pathway for aqueous outflow in humans is through the "canalicular" route that involves the trabecular meshwork and Schlemm's canal.

(Patent '637, 1:54-60.) Following this passage, a detailed account of the anatomy of the canalicular route is set forth which explains that glaucoma is caused by decreased outflow through the canalicular pathway. (Patent '637 1:60-2:34.)

The single reference to the uveal scleral route in the "BACKGROUND OF THE INVENTION" section merely describes the anatomy of the eye. This general anatomic explanation serves only to clarify that glaucoma involves resistance in the canalicular route, and, therefore, the implant is to be placed in the canalicular route – i.e. the "primary pathway." (See Patent '637 2:21-34; 4:64-5:4.) While the cited passage does reference two routes by which fluid can drain out of the eye, it does not define the term "physiological outflow pathway" as used in the claims.

Glaukos also urges that its construction finds support in Dr. Katz's affidavit. However, expert reports 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." Phillips, 415 F.3d at 1318. Dr. Katz has close ties to and significant financial interests in Glaukos. He sits on the Scientific Advisory Board for Glaukos, owns 70,000 shares of Glaukos stock, served as the clinical monitor for all clinical trials of iStent over the past ten years, presented to the FDA in connection with efforts to gain approval for iStent, and has earned approximately one-half million dollars from Glaukos. (Doc. No. 146). In light of this evidence, I give little weight to Dr. Katz's declaration.

Glaukos' reliance on the dictionary definition of "physiological" also lends little support to its proposed construction. As an initial matter, the Federal Circuit has cautioned against relying too heavily on general usage dictionaries. Phillips, 415 F.3d at 1321-24 (Fed. Cir. 2005) ("heavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification.") Both the dictionary definition and Dr. Katz's declaration constitute extrinsic evidence. The construction that Glaukos derives from this extrinsic evidence would give the disputed term a broader definition than the specification and claims disclose. This is impermissible because extrinsic evidence "may not be used to vary, contradict, expand, or limit the claim language from how it is defined, even by implication, in the specification or file history." Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc., 262 F.3d 1258, 1269 (Fed. Cir. 2001).

Similarly, Glaukos' reliance on claim differentiation is improper given the specific language limiting the invention to Schlemm's canal. Claim differentiation is not a "hard and fast rule of construction" and cannot be used to broaden a claim beyond its proper scope. Seachange

Int'l, Inc. v. C-COR, Inc., 413 F.3d 1361, 1369 (Fed. Cir. 2005) (internal citations omitted); Kraft Foods, Inc. v. Int'l Trading Co., 203 F.3d 1362, 1368 (Fed. Cir. 2000) ("the written description and prosecution history overcome any presumption arising from the doctrine of claim differentiation.") As discussed above, the proper scope of the term is limited to the canalicular route. I decline to expand the term to include other pathways.

For all of the reasons set forth above, I will adopt the first part of Transcend's proposed construction regarding the term "physiologic outflow path of the eye."

Regarding the second dispute, I now consider Transcend's proposal that the construction should make clear that "an artificially created space is not a physiological outflow path." Transcend argues that this negative limitation is supported by the prosecution history. Transcend notes that the United States Trademark and Patent Office ("USTPO") initially rejected claims in Patent '637 in light of the prior art disclosed in U.S. Patent No. 6,544,249 ("the Yu Patent"). The Yu Patent teaches a tube that facilitates the flow of aqueous humor from the anterior chamber of the eye to the subconjunctival space. In order to overcome this rejection, Glaukos asserted that it is "well known in the art" that the subconjunctival space is "an artificially created space for aqueous drainage as opposed to a naturally occurring and existing physiologic outflow path as required by Applicants' claims." (emphasis in original). In her Notice of Allowance, the USTPO examiner noted "the closest prior art teaches providing an artificially created space comprising a flow passage created from an anterior chamber of an eye to a subconjunctival space but does not teach or fairly suggest . . . an implant comprising a flow path within a physiologic outflow path." Transcend asserts that Glaukos, having distinguished prior art and gained allowance on the basis that an artificially created space is not a physiologic outflow path, cannot now assert that the

term "physiologic outflow path of the eye" includes such a space. (Pl.'s Br. pp. 7-13; Pl.'s Surreply pp. 1-4.)

Glaukos counters that the inventors did not disclaim the ordinary meaning of "physiologic outflow path of the eye" when they pointed out that Yu teaches opening a hole through the sclera to the subconjunctival space. According to Glaukos, in distinguishing Yu, the inventors also acknowledged that Schlemm's canal was a physiologic outflow path not the physiologic outflow path. (Def.'s Br. pp. 13-14; Def.'s Reply Br. pp. 2-4) ("Any disclosure in Yu relating to a physiologic outflow path of the eye, such as Schlemm's canal, is minimal and not enabling.")

I find that Transcend's proposed negative limitation – that the term "physiological outflow path of the eye" does not include "an artificially created space" – is supported by the prosecution history. In order to overcome rejection by the USTPO, Glaukos explicitly stated that it is "well known in the art" that the subconjunctival space is "an artificially created space for aqueous drainage as opposed to a naturally occurring and existing physiologic outflow path as required by Applicants' claims." (Pl.'s Br., Ex. 2 p. 7) (emphasis in original). This statement is a clear and explicit representation that the disputed term does not include an artificially created space. This disclaimer is reflected in the USTPO examiner's Notice of Allowance. (Pl.'s Br., Ex. 3 p. 2.) Therefore, the second sentence of Transcend's proposed construction is necessary to ensure that the disputed term is construed consistently with the disavowal made during the prosecution of Patent '637.

B. Disputed Term 2: "uveal scleral outflow path"

Term	Claims-at-Issue	Glaukos' Proposed Construction	Transcend's Proposed Construction
"uveal scleral outflow path" Synonymous with "uveoscleral outflow pathway" / "uveoscleral outflow path/route"	Patent '782 – Claim 1; Patent '511 – Claims 1, 24, 25 and 29; Patent '846 – Claims 1, 16 and 25	Plain and ordinary meaning, namely an outflow path that drains aqueous humor from the anterior chamber through the intermuscular spaces of the ciliary muscle, into the supraciliary-suprachoroidal space, and then out of the eye through the substance of the sclera, through the emissarial channels, or by absorption into the uveal vessels.	The naturally existing outflow path for aqueous humor to flow from the anterior chamber through the intermuscular spaces of the ciliary muscle, into the supraciliary-suprachoroidal space, and out of the eye through the substance of the sclera or through the perivascular spaces of the emissarial channels in the sclera. A uveal scleral outflow path does not include (1) an artificial drainage site or (2) a separation of a portion of the ciliary body from the sclera for fluid to flow from the anterior chamber to the supraciliary/suprachoroidal space.

The disputed term "uveal scleral outflow path" appears in each of the three Tu Patents. The parties agree that this term refers to the outflow path that drains fluid through the ciliary body into the "supraciliary-suprachoroidal space" and then out of the eye. The parties also agree that fluid exits the eye via the uveal scleral outflow path through: 1) the substance of the sclera or 2) through the emissarial channels that pass through the sclera. The parties disagree, however, on two points. The first disagreement is whether the term "uveal scleral outflow path" should be further construed to include absorption into the uveal vessels (Glaukos' construction) or whether absorption in the uveal vessels occurs in a different pathway called the uveovortex pathway

(Transcend's construction). The second area of disagreement is whether two negative limitations on the disputed term should be included. (Discussed infra pp. 21-24.)

Regarding the first issue, Glaukos asserts that, in addition to the two agreed upon outflow methods described above, fluid also exits the eye via the uveal scleral outflow path by absorption in the uveal vessels. Glaukos states that this construction is consistent with the view of those skilled in the art and points to the treatise The Glaucomas and language in a chapter titled "Uveoscleral Outflow." This language states that "[o]nce fluid has passed from the anterior chamber into the suprachoroidal space, it may be osmotically absorbed by uveal vessels, may leave the sclera through the emissarial channels, or may flow through the substance of the sclera itself." (Katz Decl., Ex. B, Robert Ritch, M.D., et al., The Glaucomas 340 (Kathryn H. Falk eds., 2d ed. 1996). [6]

Transcend disagrees that the term "uveal scleral outflow path of the eye" should be construed to include absorption by the uveal vessels. According to Transcend, The Glaucomas treatise does not indicate that absorption by the uveal vessels occurs in the uveal scleral outflow path. Transcend points out that when prosecuting a related "child application" (U.S. Application

[6] Glaukos posits that its proposed construction is also consistent with representations that Transcend made regarding its CyPass device in The Journal of Cataract and Refractive Surgery, where a figure in that journal shows aqueous humor passing both into the sclera as well as the uvea in the uveal scleral outflow path. (Def.'s Br. pp. 14-16.) Glaukos seems to assert that this figure shows absorption by the uveal vessels occurring in the "uveal scleral outflow path."

According to Transcend, the journal article was written by clinicians, not Transcend. Regardless of authorship, Transcend asserts that the article is irrelevant as it was published in 2013 "more than a decade after the proper date for interpreting the Tu Patents." (Pl.'s Surreply p. 6.)

Even assuming that the publication is fairly attributable to Transcend and supports Glaukos' construction, I agree with Transcend that the publication is nonetheless not persuasive evidence of the meaning of the disputed term. First, the journal was published more than a decade after the time of the invention which is the proper date for interpreting the Tu Patents. See Phillips, 415 F.3d at 1313 ("the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention"). Second and more importantly, it is extrinsic evidence and cannot be used to contradict intrinsic evidence such as the specification.

No. 13/786,357) ("Application '357"), Glaukos directed the USTPO to a different definition of uveal scleral outflow path contained in The Glaucomas treatise than the definition it now relies upon. The definition Glaukos previously provided to the USTPO reads "[u]veoscleral outflow is defined as aqueous outflow from the anterior chamber through the intermuscular spaces of the ciliary muscle, into the supraciliary-suprachoroidal space." (Pl.'s Br., Ex. 5 p. 39.) The above definition is only a portion of the sentence as it appears in The Glaucomas. This sentence ends with the phrase "and out through the substance of the sclera or through the perivascular spaces of the emissarial channels." (Katz Decl., Ex. B p. 337.) Transcend notes that this complete sentence does not include absorption by the uveal vessels as part of the uveal scleral outflow path of the eye. In fact, the complete sentence forms the first portion of Transcend's proposed construction. (Pl.'s Br. pp. 14-16.) As will be discussed in greater detail below, a review of the language in The Glaucomas treatise seems to support Transcend's construction.

Transcend also argues its construction is consistent with the Tu Patents which recognize that there are at least three separate outflow pathways. In particular, Transcend notes that the Tu Patents' "SUMMARY OF THE INVENTION" section states, aqueous humor may exit "through the trabecular meshwork (major route) or uveal scleral outflow (minor route) or other route effective to reduce intraocular pressure (IOP)." (Patent '782 4:19-23; Pl.'s Br. p. 16.)

Glaukos counters that the distinction Transcend draws between the uveovortex pathway and uveal scleral outflow pathway is meaningless as uveovortex is simply another term for the uveal scleral outflow path. Glaukos points to exhibits submitted by Transcend which Glaukos contends are consistent with this proposition. In particular, Glaukos notes that Transcend cited a chapter of Diagnosis and Therapy of the Glaucomas, titled "Aqueous Humor Outflow." A section of this chapter titled "Uveoscleral flow" states "[t]his alternative pathway is called by a

number of terms including uveoscleral, unconventional, extracanalicular, secondary, and uveovortex flow." (Pl.'s' Br., Ex. 6 p. 52.)[7]

According to Glaukos, Transcend's assertion of a distinct uveovortex pathway is also inconsistent with the Tu Patents as the Tu Patents do not mention "uveovortex" and only recognize two pathways – the uveal scleral and canalicular routes. Therefore, according to Glaukos, regardless of any dispute that may exist in the literature, the Tu Patents identify only two natural outflow paths and the language of the specification prevails over extrinsic evidence. (Def.'s Br. p. 5.)

Having carefully considered the parties' proposed constructions, I will adopt the first part of Transcend's proposed construction and construe the term "uveal scleral outflow path" to mean "[t]he naturally existing outflow path for aqueous humor to flow from the anterior chamber through the intermuscular spaces of the ciliary muscle, into the supraciliary-suprachoroidal space, and out of the eye through the substance of the sclera or through the perivascular spaces of the emissarial channels in the sclera." I find that one of skill in the art would understand the term "uveal scleral outflow path" to be distinct from the uveovortex pathway. I also find that one of

[7] Glaukos also notes that a portion of a journal article that Transcend submitted as an exhibit to its brief states "[t]he uveo-scleral pathway and the uveovortex pathway, as proposed, are essentially the same" (Pl.'s Br. Ex. 7 p. 171.) Glaukos argues that this sentence supports its contention that uveal scleral and uveovortex are essentially synonyms.

However, a reading of the complete passage does not support Glaukos' position. The complete passage reads,

> The uveo-scleral pathway and the uveovortex pathway, as proposed, are essentially the same within the uvea since, in each, tracer moves from the anterior chamber into the ciliary body. However, the tracer following the uveo-scleral route is then thought to pass out of the eye through the sclera, whereas that following the uveo-vortex route leaves the eye by the vortex veins.

(Pl.'s' Br., Ex. 7 p. 171.) Contrary to Glaukos' position, the complete passage recognizes that fluid exits the uveal scleral route and the uveovortex route through distinct pathways.

skill in the art would understand that absorption by the uveal vessel occurs in the distinct uveovortex pathway not the uveal scleral pathway. I thus find that the term in question must be construed so to exclude absorption by the uveal vessels. I reach these conclusions for the following reasons.

First, the Tu Patents' specifications do not state that there are only two pathways and, in fact, reference at least one "other route" in addition to the canalicular and uveal scleral routes. (Patent '782 4:19-23.) Glaukos' assertion that there are only two pathways is thus inconsistent with the language of the specifications.

Second, I agree with Transcend's position that based on the extrinsic evidence,[8] the uveal scleral and uveovortex pathways are distinct. As noted previously, Glaukos argues that the scientific literature indicates that the uveal scleral outflow path and the uveovortex pathway are essentially one pathway and that this singular pathway encompasses fluid absorption by the uveal vessels. However, the portion of The Glaucomas cited by Glaukos does not support this reading. The definition Glaukos proposes is taken from a section of The Glaucomas which details the results of studies tracing fluid absorption in the eyes of different animals. These passages do not purport to offer an anatomical definition of the term uveal scleral. Furthermore, when summarizing the results of the studies, the text recognizes that absorption by the uveal vessels occurs in the distinct uveovortex pathway. (See Katz Decl., Ex. B p. 339) (in some cases dye penetrated "blood vessels in the iris stroma and anterior ciliary body, leading to the designation 'uveovortex pathway.'")

[8] In presenting their arguments on this issue, the parties properly rely upon extrinsic evidence as the intrinsic evidence fails to resolve the ambiguity regarding the parameters of the "uveal scleral outflow path of the eye."

Transcend urges that the literature supports a narrower reading in which the uveal scleral and uveovortex pathways are distinct and fluid absorption by the uveal vessels occurs in the distinct and separate uveovortex pathway. Although there is some inconsistency in the texts cited by the parties, I agree with Transcend's reading that one of skill in the art would understand the "uveal scleral outflow path of the eye" as used in the Tu Patents to be a distinct and separate outflow pathway from the uveovortex pathway. Unlike the portion of The Glaucomas cited by Glaukos, the portion cited by Transcend explicitly defines the term as it provides a general anatomical definition of uveal scleral outflow path. Transcend is correct that this definition does not include absorption by the uveal vessels as part of the uveal scleral route.

I next turn to the disagreement about the two negative limitations Transcend includes in its proposed construction. Transcend urges that the term "uveal scleral outflow path" should be further construed to state that it does not include 1) "an artificial drainage site" or 2) "a separation of a portion of the ciliary body from the sclera for fluid flow from the anterior chamber to the supraciliary/suprachoroidal space." (Claim Chart pp. 2-3.)

In support of the first disclaimer, Transcend posits that similar to Patent '637, Glaukos disclaimed "an artificial drainage site" during prosecution of the Tu Patents and that this disclaimer should be reflected in the claim construction. During prosecution of Patent '511 (one of the three Tu Patents), the USTPO rejected claims as anticipated by U.S. Patent No. 5,041,081 ("Odrich"). Transcend notes that, in distinguishing Odrich, Glaukos stated:

> Odrich is directed to an ocular implant configured to allow fluid to flow from the anterior chamber of the eye to the subconjunctival space and not to the uveal scleral outflow path . . . As is known to one of ordinary skill in the art the subconjunctival space is an artificial drainage site as opposed to the uveal scleral outflow path.

(Pl.'s Br. pp. 17-18; Pl.'s Surreply p. 6) (emphasis in original). According to Transcend, the proposal to exclude "an artificial drainage site" ensures that the term is construed in a manner consistent with this disclaimer. (Id.)[9]

Glaukos asserts that, like "artificial drainage space," "artificial drainage site" would itself require construction and could be read to exclude the inventors' disclosed embodiments. (Def.'s Br. pp. 17-18; Def.'s Reply p. 6.)

In support of its second negative limitation, Transcend argues that Glaukos also disclaimed "a separation of a portion of the ciliary body from the sclera" when prosecuting U.S. Patent Application 09/549,350 (Application '350) which the Tu Patents incorporate by reference. (See Patent '782 4:66-5:2.) According to Transcend, in Application '350, Glaukos distinguished its invention from prior art, including Patent No. 4,521,210 ("Wong"), on the basis that the prior art did not employ "normal physiologic outflow pathways." Transcend notes that the Wong device drains aqueous humor by maintaining a separation of a portion of the ciliary body away from the sclera. Thus, Transcend asserts that Glaukos cannot now claim that such a separation is a normal physiological outflow pathway, in general, or part of the uveal scleral outflow path, in particular. Transcend urges that its second negative limitation is necessary to prevent Glaukos from now claiming a feature that it previously disavowed.

[9] Glaukos counters that this negative limitation is not supported by the prosecution history of Patent '511. Glaukos contends that it was "criticizing a prior art device [Odrich] that extended through a hole cut in the sclera." Glaukos' contention that it distinguished Odrich on the general basis that Odrich teaches placement through a hole cut in the sclera is inconsistent with the clear language of the prosecution history.

In further response to Transcend's prosecution history argument, Glaukos asserts that Transcend's CyPass device "has nothing to do with the Odrich patent distinguished during prosecution." This argument is non-responsive. What matters is how Glaukos articulated its claims in order to distinguish prior art and avoid rejection.

On a similar basis, Transcend notes that in prosecuting U.S. Patent Application 13/786,357 ("Application '357"), a related child of the Tu Patents, Glaukos attempted to add a claim in which the delivery device is configured to "detach at least a portion of the ciliary body from the sclera to form an internal space between the ciliary body and the sclera." (Pl.'s Br., Ex 5 p. 3.) The USTPO rejected the claim on the ground that the "[s]pecification as originally filed, and as amended, lacks any reference to a step or an apparatus configured to detach a ciliary body from the sclera." (Pl.'s Br., Ex 13 p. 13.) In further support of its second negative limitation, Transcend contends that there is no support in the Tu Patents' specifications for an interpretation of uveal scleral outflow path that would include such a separation. (Pl.'s Br. pp. 19-20.)

Glaukos also disagrees with Transcend's second negative limitation that the uveal scleral outflow path does not include "a separation of a portion of the ciliary body from the sclera for fluid flow." Glaukos asserts that Application '350 cannot be fairly read as distinguishing Wong from the Tu Patent claims in issue. First, Glaukos notes that Wong is but one of thirty nine references listed in a portion of Application '350 generally discussing the drawbacks of various prior art. Second, Glaukos argues that Transcend inaccurately describes Wong because Wong actually discloses a device placed in an ab externo manner via a complicated surgical procedure. Glaukos notes that the claims as written do not encompass what Wong actually discloses and Transcend's attempt to rewrite the claim language on the basis of its inaccurate characterization is unnecessary.[10]

Having carefully considered the parties' positions on the proposed negative limitations, I find that Transcend's first negative limitation – that the uveal scleral outflow does not include an

[10] Glaukos also contends that Transcend's second negative limitation would exclude an embodiment disclosed in Patent '782 Figure 43 which teaches an implant being placed in the exact location the negative limitation seeks to exclude. (Def.'s Br. pp.18-19; Def.'s Reply pp. 6-8.)

artificial drainage site – is supported by the prosecution history. Glaukos made a clear and explicit statement that the uveal scleral outflow path is not an artificial drainage site in order to avoid rejection. For example, Glaukos stated, "[a]s is known to one of ordinary skill in the art the subconjunctival space is an artificial drainage site as opposed to the uveal scleral outflow path which is a naturally existing 'physiologic outflow pathway.'" (Def.'s Br., Ex. 10 pp. 8) (emphasis in original.)

I, however, find that Transcend's second proposed negative limitation – that the uveal scleral outflow path does not include a separation of the ciliary body from the sclera – is not supported by a fair reading of the prosecution history. The Tu Patents incorporate by reference a prior Glaukos application. That application in turn distinguishes thirty nine inventions in the prior art, including Wong, on the general basis that they do not use physiological outflow pathways. Transcend contends that Wong involves maintaining a separation of a portion of the ciliary body away from the sclera. Transcend connects these propositions in order to create a disclaimer that the uveal scleral outflow path does not include a separation of a portion of the ciliary body away from the sclera.

Glaukos correctly responds that Wong actually discloses a device placed in an ab externo manner via a complicated surgical procedure and that it distinguished Wong from the invention disclosed in the Tu Patents on this basis. Glaukos' explanation of Application '350 is reasonable and consistent with the general survey of the prior art contained therein. As such, I find that this is not the sort of unambiguous statement warranting a finding of a prosecution disclaimer. See SanDisk Corp. v. Memorex Products, Inc., 415 F.3d 1278, 1287 (Fed. Cir. 2005) (there is no "clear and unmistakable disclaimer if a prosecution argument is subject to more than one

reasonable interpretation, one of which is consistent with a proffered meaning of the disputed term.")

C. Disputed Term 3: "Ciliary tissue"

Term	Claims-at-Issue	Glaukos' Proposed Construction	Transcend's Proposed Construction
"Ciliary tissue"	Patent '782 - Claim 18; Patent '846 - Claims 15, 20, and 29.	The tissue of the ciliary body. The ciliary body consists of the ciliary muscle and ciliary processes.	Tissue of the ciliary body. The ciliary body consists of the ciliary muscle and ciliary processes and is the portion of uveal tissue between the iris and choroid. The posterior portion of the ciliary body joins the choroid at the ora serrata.

Claim 18 of Patent '782 and Claims 15, 20 and 29 of Patent '846 use the disputed term "ciliary tissue." The parties agree that "ciliary tissue" means "the tissue of the ciliary body" and that "the ciliary body consists of the ciliary muscle and ciliary processes." Glaukos asserts that the foregoing definition is complete. (Def.'s Reply Br. p. 10.)

Transcend proposes that the term should also note that the ciliary body is "the portion of uveal tissue between the iris and choroid." Transcend asserts that the declaration of Glaukos' own expert, Dr. Jay Katz, is consistent with this additional clarification. This declaration states "[t]he uvea consists of the iris, the ciliary body, and the choroid, going from anterior (front) to posterior (back.)" (Katz Decl. ¶ 12.)

Transcend also proposes that the term "ciliary tissue" should be construed to state that "[t]he posterior portion of the ciliary body joins the choroid at the ora serrata." Transcend notes that this proposition is an "anatomical fact." According to Transcend, Glaukos' proposed construction attempts to avoid delineating where the ciliary body terminates and the choroid begins because the Tu Patents' specifications are inconsistent in defining where the choroid ends

and begins. Transcend argues that this inconsistency renders the term "choroid" in the Tu Patents indefinite.[11] (Pl.'s Br. pp. 26-28; Pl.'s Surreply p. 10.)

Glaukos concedes that Transcend's proposed construction is accurate but contends that it is unnecessary because it goes beyond explaining the disputed term "ciliary tissue" and introduces new terms such as the "ora serrata" that a jury would not understand. (Def.'s Reply Br. p. 10.)

I will adopt Glaukos' proposed construction and construe the term "ciliary tissue" to mean "[t]he tissue of the ciliary body. The ciliary body consists of the ciliary muscle and ciliary processes." I agree with Glaukos' point that Transcend's proposed construction introduces new terms that a jury would not understand without further construction. Transcend does not offer a compelling reason why these additional phrases are necessary. Transcend's assertion that the term "choroid" must be defined so as to avoid indefiniteness misses the mark. "Ciliary tissue" not "choroid" is the disputed term to be construed and disputes regarding indefiniteness can be resolved at a later date. Although the terms may have an anatomical relationship, neither the term choroid nor the relationship between the choroid and the ciliary tissue are presently at issue.

D. Disputed Term 4: "configured to access . . . through . . ."

Term	**Claims-at-Issue**	**Glaukos' Proposed Construction**	**Transcend's Proposed Construction**
"configured to access . . . through . . ."	Patent '511 - Claims 1 and 29.	Plain and ordinary meaning.	Designed to access and implant into position through . . .

[11] Indefiniteness is a validity defense which arises from the requirement that a patent's specification "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112(b). "When a claim is not amenable to construction, the claim is invalid as indefinite" under 35 U.S.C. § 112(b). Aero Prods. Int'l, Inc. v. Intex Recreation Corp., 466 F.3d 1000, 1016 (Fed. Cir. 2006).

Claims 1 and 29 of Patent '511 disclose an implant and delivery device. The parties dispute the meaning of the following phrase, a "delivery device being configured to access the anterior chamber through a corneal incision having a size less than about 1 mm." (Patent '511 24:30-32.)

According to Glaukos, no construction of this phrase is necessary because the language of the disputed term is straightforward and will be understandable to the jury without explanation. (Def.'s Br. pp. 19-20.)

Transcend proposes that the term be construed to mean a "delivery device designed to access the anterior chamber and implant into position through a corneal incision having a size less than about 1 mm." (Emphasis added). Transcend argues that its construction clarifies that the delivery device must be capable of implanting the shunt at a particular location. Under Transcend's construction, the term does not simply mean that the delivery device must be less than 1 mm in diameter.

According to Transcend, this clarification is consistent with how Glaukos distinguished its device from the Odrich device during prosecution of Patent '511. Transcend explains that "there is no dispute that the Odrich patent discloses an implant with a maximum width of less than 1 mm that could, in theory, be pushed through a 1 mm incision."[12] Transcend notes that, during prosecution, Glaukos argued that unlike its device, "it would be exceptionally complicated, if not surgically impossible for any implant delivery device used by Odrich to access the anterior chamber through a corneal incision having a size less than 1 mm and locating

[12] Transcend cites page 10 of the Response to Office Action for the proposition that Odrich "discloses an implant with a maximum width of less than 1 mm." I agree with, Glaukos, that the document does not support that assertion. In fact the Response to Office Action, states that given Odrich's "large size" it would be "extremely difficult, if not surgically impossible" for the Odrich implant to be delivered in the method and location required by Patent '511's claims. (Pl.'s Br., Ex. 10 pp. 9-10.)

the implant at the specific anatomic position within the eye" (Pl.'s Br., Ex. 10 p. 10.) As such, Transcend concludes that Glaukos distinguished Odrich on the grounds that it did not disclose a delivery device 1) configured to access the uveal scleral outflow path and 2) capable of implanting the device in communication with the uveal scleral outflow path. Therefore, Transcend asserts the term must be construed to mean a device capable of implantation through an incision of 1mm. (Pl.'s Br. pp. 21-22.)

Glaukos responds that Transcend's proposed construction is confusing and impermissibly rewrites the claim language. Glaukos argues that Transcend does not adequately explain why it is changing "configured" to "designed," and asserts Transcend's characterization of the prosecution history is, at best, incomplete. (Def.'s Reply Br. pp. 8-9.)

I will adopt Glaukos' construction concluding that the term is to be accorded its plain and ordinary meaning. Transcend seeks to rewrite the language of the claim and fails to offer a persuasive reason for doing so. Transcend's proposed construction is not supported by a fair reading of the prosecution history. The doctrine of prosecution disclaimer requires "a clear and unmistakable disavowal of scope during prosecution." Purdue Pharma L.P., 438 F.3d 1123 at 1136. There is no such disavowal here. Glaukos distinguished Odrich on the general basis that it did not disclose a delivery device. (Pl.'s Br., Ex. 10 p. 10) ("Odrich fails to provide any discussion of a delivery device to advance the implant"). Glaukos further explained that if Odrich did disclose a delivery device it would be markedly different from the delivery device recited in claim 1 of Patent '511. In doing so, Glaukos did not clearly and unmistakably distinguish any feature of its device from the features of a hypothetical delivery device that would be compatible with the Odrich implant. Therefore, I find Transcend's rewriting of the disputed term based on its characterization of the prosecution history unavailing.

For these reasons, the term will be accorded its plain and ordinary meaning as reflected in Glaukos' proposed construction.

E. Disputed Term 5: "deployment mechanism"

Term	Claims-at-Issue	Glaukos' Proposed Construction	Transcend's Proposed Construction
"deployment mechanism"	Patent '782 - Claims 1 and 13; Patent '846: Claims 1 and 12.	Not governed by 35 U.S.C. §112(f) so plain and ordinary meaning should govern. If governed by 35 U.S.C. §112(f): Function: Act upon the ocular implant so as to deploy the ocular implant from the elongated member and into the ocular tissue through the opening formed by the distal portion of the elongated member. Structure: The patent describes many and varied structures for a deployment mechanism. One structure includes a holder configured to hold and release the implant and an actuator on a handpiece that actuates the holder to release the implant. See e.g., '782 patent at 17:20-23; 17:59-63. Another structure includes a holder with a clamp. See e.g., '782 patent at 17:29. Another structure includes a spring configured to be loaded when the implant is being held and at least partially unloaded upon actuation of an actuator to release the implant. See e.g., '782 patent at 17:29-34. In another structure, the clamp can include claws configured to exert a clamping force on the implant. See e.g., '782 patent at 17:35-36. In another structure the holder may include a plurality of flanges. See e.g., '782 patent at 17:37-39. In another structure, the deployment mechanism can be a push-pull type plunger. See e.g., '782 patent at 17:26-28; 17:67 – 18:2.	Governed by 35 U.S.C. § 112(f). Function: Act upon the ocular implant so as to deploy the ocular implant from the elongated member and into the tissue through the opening formed by the distal portion of the elongated member via relative movement between the deployment mechanism and the elongated member. Structure: The push-pull type plunger as disclosed in Figure 31 of U.S. Pat. No. 7,857,782.

Claims 1 and 13 of Patent '782 and Claims 1 and 12 of Patent '846 recite an ocular implant and its delivery system, comprised of an elongated member and a "deployment mechanism." (Patent '782 24:61-67, 25:40-42; Patent '846 24:47-52, 25:16-18.) The parties dispute the meaning of the term "deployment mechanism."

Glaukos proposes that "deployment mechanism" should be given its ordinary meaning as recited in the claim and urges that the claim is not a means-plus-function element governed by 35 U.S.C. § 112(f). Glaukos stresses that the claim does not use the term "means" and, therefore, a rebuttable presumption attaches that § 112(f) does not apply. Glaukos argues that this presumption is not rebutted as the claim recites ample structure for performing the function. In support, Glaukos points to the statement "the deployment mechanism and the elongated member being movable relative to each other." (Patent '782 24:61-67.) According to Glaukos, "relative movement" describes the structural relationship between the deployment mechanism and the elongated member. Additionally, Glaukos contends that "deployment mechanism" is similar to other broad non-means terms like "height adjustment mechanism,"[13] "digital detector,"[14] "eyeglass hanger member,"[15] "reciprocating member,"[16] and "sealing connecting joints;"[17] all instances where the Federal Circuit has found that § 112(f) does not apply. (Def.'s Br. pp. 21-22; Def.'s Reply pp. 9-10.)

[13] Flo Healthcare Solutions, LLC v. Kappos, 697 F.3d 1367, 1373-75 (Fed. Cir. 2012).

[14] Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n, 161 F.3d 696, 703-04 (Fed. Cir. 1998).

[15] Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 1318-19 (Fed. Cir. 1999).

[16] CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1369-70 (Fed. Cir. 2002).

[17] Watts v. XL Sys., Inc., 232 F.3d 877, 880-81 (Fed. Cir. 2000).

Transcend counters that § 112(f) does apply because "mechanism" is no different than a "means for deploying" and the term "deployment" connotes no structure. Transcend points to Webster's Third New International Dictionary 605 (3d ed. 1993) which defines "deployment" as "the act or movement of deploying or the state of being deployed." (Pl.'s Br., Ex. 15.) Transcend argues that "relative movement" does not connote a structural relationship but rather describes part of the deployment mechanism's function. Transcend contends that the claims only explain that the mechanism deploys the implant in a particular fashion and that is a function, not a structure. Accordingly, Transcend asserts that § 112(f) governs this claim construction. (Pl.'s Br. pp. 23-24; Pl.'s Surreply pp. 9-10.)

The parties also disagree as to the definition of the particular function and corresponding structures in the event that § 112(f) does apply. According to Transcend, the claimed function is "deploying the implant via relative movement from (i) the elongated member (ii) into the ocular tissue, (iii) through the opening formed by the distal portion of the elongated member." Transcend argues that the only structure in the specification that actually performs the full three-part function as claimed is the push-pull type plunger depicted in Figure 31 of Patent '782. Transcend argues that none of the other structures identified by Glaukos such as a "clamp with clamping jaws," a "holder that holds and releases" or a "spring that is actuated to release" are described as performing the three-part function nor are they capable of doing so. (Pl.'s Br. pp. 24-25; Pl.'s Surreply pp. 9-10.)

Glaukos responds that even if § 112(f) applies, Transcend is incorrect in including "relative movement" as part of the deployment mechanism's function. Rather, Glaukos urges that "relative movement" refers to the structural relationship between the member and the deployment mechanism not the deployment mechanism's function.

According to Glaukos, if § 112(f) applies, the claimed function is to act upon the ocular implant to deploy the implant. Glaukos asserts that each type of deployment mechanism described in the specification is capable of performing this function and, therefore, must be included within the scope of the claim. Glaukos concludes that Transcend's proposed construction is incorrect because it is limited to only one of the preferred embodiments in the specification (i.e. the push-pull type plunger). (Def.'s Br. pp. 22-23; Def.'s Reply pp. 9-10.)

As a threshold matter, the claim in question does not use the term "means" and, as such, there is a presumption that § 112(f) does not apply. "[T]he presumption flowing from the absence of the term 'means' is a strong one that is not readily overcome." Lighting World, Inc. v. Birchwood Lighting, Inc., 382 F.3d 1354, 1358 (Fed. Cir. 2004). However, the use of the "unadorned term 'mechanism' can overcome the presumption that 112(f) does not apply." Welker Bearing Co. v. PHD, Inc., 550 F.3d 1090, 1096 (Fed. Cir. 2008). This is because the term "mechanism" is "simply a nonce word or a verbal construct that is not recognized as the name of structure and is simply a substitute for the term 'means for.'" Id.

Nonetheless, "[c]laim language that further defines a generic term like 'mechanism' can sometimes add sufficient structure to avoid 112 ¶ 6." Massachusetts Inst. of Tech. v. Abacus Software, 462 F.3d 1344, 1354 (Fed. Cir. 2006). "Sufficient structure exists when the claim language specifies the exact structure that performs the functions in question." TriMed, Inc. v. Stryker Corp., 514 F.3d 1256, 1259-60 (Fed. Cir. 2008). However, consideration of the "written description, prosecution history, and extrinsic evidence" is permitted to determine if a challenger has rebutted the presumption that a limitation lacking the word "means" connotes sufficiently definite structure to those of skill in the art. Inventio AG, 649 F.3d at 1357.

The Federal Circuit has considered whether various limitations reciting a "mechanism" possessed sufficient structure to avoid application of § 112(f). For example, the Federal Circuit determined that the modifier "height adjustment" provided sufficient structure to the word "mechanism" to avoid application of § 112(f). Flo Healthcare Solutions, 697 F.3d at 1373-75. The court reasoned that "adjustment" has a "reasonably well-understood meaning as a name for a structure." Id. at 1375. In reaching this conclusion, the court relied on the general dictionary definition[18] of adjustment as "a device, as a knob or lever, for adjusting: the adjustments on a television set." Id. at 1374.

Similarly, the term "detent mechanism" has been found to possess sufficient structure to avoid application of § 112(f). Greenberg v. Ethicon Endo-Surgery, Inc., 91 F.3d 1580, 1583 (Fed. Cir. 1996). The court found that "[d]ictionary definitions make clear that the noun 'detent' denotes a type of device with a generally understood meaning in the mechanical arts." Id. For example, the court noted that one dictionary defined "detent" as a "catch or checking device, the removal of which allows machinery to work such as the detent which regulates the striking of a clock." Id.

On the other hand, the Federal Circuit determined that "colorant selection mechanism" did not possess sufficient structure and, therefore, was governed by § 112(f). Abacus Software, 462 F.3d at 1354. The court reasoned that "the term 'colorant selection,' which modifies 'mechanism' here, is not defined in the specification and has no dictionary definition, and there is no suggestion that it has a generally understood meaning in the art." Id.

[18] Although recent precedent cautions against heavy reliance on dictionary definitions, the Federal Circuit notes that it continues to consult dictionary definitions to determine whether a disputed term connotes sufficient structure under § 112(f). See Williamson v. Citrix Online, LLC, 770 F.3d 1371, 1379 (Fed. Cir. 2014).

As noted above, the use of the word "mechanism" in the disputed term may rebut the presumption that § 112(f) does not apply in the absence of the word "means." The issue then is whether "deployment" adds sufficient structure to the term "mechanism" to avoid application of § 112(f). Transcend relies on the dictionary definition of "deployment" as the "act," "movement," or "state" of deploying. The "act" "movement," or "state" of doing something describe functions and cannot be interpreted as disclosing structure. Therefore, the dictionary definition suggests that "deployment" does not connote a reasonably well understood structure to avoid application § 112(f).

Glaukos has failed to identify any evidence that would, to the contrary, demonstrate that deployment has a generally well understood structural meaning in the art. This failure coupled with the dictionary definition indicates that "deployment mechanism" is more akin to "colorant selection mechanism" than "detent mechanism" or "adjustment mechanism."

Glaukos presses that the statement "the deployment mechanism and the elongated member being movable relative to each other" connotes sufficient structure to avoid application of § 112(f). As noted above, movement is not fairly characterized as structure. Therefore, I agree with Transcend that "relative movement" does not connote structure but rather describes the deployment mechanism's function. As such, I find that the term "deployment mechanism" is a means-plus-function element governed by § 112(f).

The first step under § 112(f) is to identify the claimed function. The parties agree that the deployment mechanism's function includes "acting upon the ocular implant . . . so as to deploy the ocular implant from the elongated member and into the ocular tissue through the opening formed by the distal portion of the elongated member." The parties disagree as to whether the phrase "the deployment mechanism and the elongated member being movable relative to each

other" should be included as part of the claimed function. As discussed above, I agree with Transcend that "relative movement" describes the deployment mechanism's function. Therefore, it must be included in the claimed function. Thus, the properly identified function set forth in the last element of Claim 1 of Patent '782 is "acting upon the ocular implant, the deployment mechanism and the elongated member being movable relative to each other so as to deploy the ocular implant from the elongated member and into the ocular tissue through the opening formed by the distal portion of the elongated member." (Patent '782 24:62-67.)

The second step under § 112(f) is to identify the corresponding structures in the specification that actually perform the properly identified claimed function. I agree with Transcend that only the push-pull type plunger operates via relative movement between the deployment mechanism and the elongated member and is capable of performing the entire function as properly identified. Glaukos fails to explain how the other structures it names are capable of performing the entire function as properly identified.

For all of the reasons set forth above, I will adopt Transcend's proposed construction regarding the term "deployment mechanism."

V. Conclusion

For the foregoing reasons, the claims shall be construed as stated in the following Order.