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

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

Goldberg, J. **September 18, 2015**

MEMORANDUM OPINION

This case involves a patent dispute regarding devices designed to treat glaucoma. Both parties, Transcend Medical, Inc. and Glaukos Corporation, have developed technology designed to drain excess fluid from the eye, a common cause of glaucoma. Glaukos' technology is protected by patents: U.S. Patent Nos. 7,857,782 ("Patent '782"); 8,075,511 ("Patent '511"); and 8,579,846 ("Patent '846"), which are the patents-in-suit.[1]

Transcend explains that it "heard through conversations with various individuals" that Glaukos claimed Transcend could not commercialize its technology without infringing the above referenced patents. Thereafter, the parties exchanged letters disagreeing about the scope of the patents. (2d Am. Compl. ¶¶ 9-11.) Unable to resolve the dispute, Transcend filed a complaint seeking declaratory judgment of non-infringement and invalidity for failure to meet several of the conditions for patentability. Transcend also alleged that the patents are unenforceable due to inequitable conduct. Glaukos filed a counterclaim for infringement. Presently before me is

[1] A fourth patent owned by Glaukos, U.S. Patent No. 7,850,637 ("Patent '637"), was at issue prior to claim construction. Based on the parties' summary judgment submissions, it is clear that the issues as to that patent were resolved by the claims construction. (Pl.'s Mem. p. 2; Def.'s Opp. p. 2 n.1.)

Transcend's motion for summary judgment on the issue of infringement.[2] For the reasons set forth below, I will grant Transcend's motion.

I. FACTUAL RECORD REGARDING NON-INFRINGEMENT

Unless otherwise noted, the following facts are undisputed:

The outer layer of the eye consists of the cornea and the sclera. The middle layer is comprised of the iris, ciliary body and the choroid, while the interior layer consists of the retina. (Pl.'s Mem. Decl. of Julian du Vergier, Ex. 2, Katz Opening Report pp. 8-9; Ex. 4, Caprioli Report p. 5.)[3] The boundaries between the sclera and the ciliary and the sclera and the choroid are, respectively, referred to as the supraciliary and suprachoroidal spaces. (Pl.'s Mem. Ex. 5, Yamamoto Rebuttal Report ¶ 46.)

The patents-in-suit teach an ocular implant to drain aqueous humor to the "uveal scleral outflow pathway." (Pl.'s Mem. Ex. 1, Patent '782, claim 1; Ex. 24, Patent '846 claims 1, 16 and 25; Ex. 28, Patent '511 claims 1 and 29.)[4] After a Markman Hearing, I construed the term "uveal scleral outflow path" to mean:

> 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 an artificial drainage site.

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[2] Transcend has also sought summary judgment on their invalidity claim and Glaukos has sought summary judgment regarding inequitable conduct. These motions are addressed in separate opinions.

[3] In support of its motion for summary judgment, Transcend submitted numerous exhibits as attachments to the Declaration of Julian du Vergier. Hereafter, I will refer to the exhibits attached to the Declaration of Julian du Vergier as "Pl.'s Mem. Ex. ___."

[4] The term "uveal scleral outflow path" is synonymous with "uveoscleral outflow pathway" and "uveoscleral outflow path/route." (Joint Claim Construction Chart, p. 2.)

Transcend Med., Inc. v. Glaukos Corp., 2015 WL 263612, at *9 (D. Del. Jan. 16, 2015) ("Markman Opinion").

The patents-in-suit also recite a "deployment mechanism." (Pl.'s Mem. Ex. 1, Patent '782 claims 1 and 13; Ex. 24, Patent '846 claims 1 and 12.) In construing the claims, I concluded that the deployment mechanism is a means-plus-function element governed by 35 U.S.C. § 112(f). I identified the deployment mechanism's function as follows:

> 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.

Markman Opinion at *16-17. I identified the push-pull type plunger depicted in Figure 31 of Patent '782 as the only structure capable of performing the entire function as identified. Id.

Transcend has developed a technology for use in the treatment of glaucoma called the "CyPass Micro-Stent." This device is designed to sit between the sclera and the ciliary body. (Pl.'s Mem. Ex. 12 ¶15.) According to a scientific journal article offered by Transcend, the CyPass Micro-Stent, once in position, causes aqueous humor to pool in a posterior lake at the end of the stent, a circumferential lake at the front of the stent and a "tented portion" along the length of the stent. (Pl.'s Mem. Ex. 16 pp. 2-4.)

In his report, Glaukos' expert, Dr. Jay Katz, discusses a different scientific journal article which describes a study that found that these features do not occur in large percentages of eyes in which the CyPass Micro-Stent is implanted. Additionally, Dr. Katz opined that, even where present, these features are simply an enlargement of the naturally occurring supraciliary-suprachoroidal space. (Pl.'s Mem. Ex. 2, Katz Opening Report pp. 44-45.)

The CyPass Micro-Stent is implanted into the eye through the use of a device called the "CyPass Applier." This device is comprised of a guidewire, stopper tube, actuator button, spring,

latch catch, piston and tube. The stent is loaded onto the guidewire and then the applier is advanced into location through an incision in the eye. Once in place, the actuator button is depressed and the guidewire retracts into the stopper tube thereby releasing the stent. (Id. at pp. 20-25.)

Glaukos has asserted that Transcend's CyPass Micro-Stent and CyPass Applier infringe claims 1-10 and 12-18 of Patent '782, claims 1, 2, 6, 7, 10, 15, 17, 22-24, 29, 31 and 33 of Patent '511 and claims 1, 4-10, 12-31 of Patent '846. (Id. at p. 2.)

II. STANDARD OF REVIEW

A party moving for summary judgment bears the initial burden of demonstrating that there are no genuine issues of material fact and that judgment is appropriate as a matter of law. Fed. R. Civ. P. 56(a); Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Once a properly supported motion for summary judgment has been made, the burden shifts to the non-moving party, who must set forth specific facts showing that there is a genuine issue of material fact for trial. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986).

An issue is "genuine" if a reasonable jury could rule in favor of the non-moving party based on the evidence presented. Id. at 248. In order to avert a summary judgment motion, the non-moving party cannot rely on speculation or conclusory allegations, but rather must cite to the record. Fed. R. Civ. P. 56(c). In ruling on a motion for summary judgment, the court considers the evidence in the light most favorable to the non-moving party. Anderson, 477 U.S. at 256. "Summary judgment is appropriate in a patent case, as in other cases, when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." Nike Inc. v. Wolverine World Wide, Inc., 43 F.3d 644, 646 (Fed. Cir. 1994).

Therefore, "[s]ummary judgment is appropriate when it is apparent that only one conclusion as to infringement could be reached by a reasonable jury." Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1323 (Fed. Cir. 2001). "Summary judgment of noninfringement is appropriate where the patent owner's proof is deficient in meeting an essential part of the legal standard for infringement, since such failure will render all other facts immaterial." Id.

The patent holder bears the burden of proving infringement by a preponderance of the evidence. SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1123 (Fed. Cir. 1985). Evaluating a claim of infringement involves a two-part inquiry. Bayer v. Elan Pharmaceutical Research Corp., 212 F.3d 1241, 1247 (Fed. Cir. 2000). First, the claims are construed so as to define the scope of the asserted claims. Id. Second, "the claims, as construed, are compared to the accused device." Id.

Regarding the second step, an accused device can infringe the asserted claims of a patent either literally or under "the doctrine of equivalents." Id. Literal infringement requires the patentee to prove that "the accused device contains each limitation of the asserted claim(s)." Id. If the accused device does not meet every limitation, "infringement may still occur under the doctrine of equivalents if there is not a substantial difference between the limitations of the claim and the accused [device]." Id. at 1250.

Under this framework, infringement of a Section 112(f) claim "requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent to the corresponding structure in the specification." Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Intern., Inc., 389 F.3d 1370, 1378 (Fed. Cir. 2004) (citing Odetics, Inc. v. Storage Tech. Corp., 185 F.3d 1259, 1267 (Fed. Cir. 1999)). The inquiry for

equivalence under Section 112(f) examines whether "the assertedly equivalent structure performs the claimed function in substantially the same way to achieve substantially the same result as the corresponding structure described in the specification." Id. (citing Odetics, 185 F.3d at 1267).

III. ANALYSIS

Transcend has moved for summary judgment of non-infringement. At issue is whether Transcend's CyPass Micro-Stent or Applier infringes any of the asserted claims in the patents-in-suit. Transcend argues that there is no genuine issue of material fact that its device does not infringe because the undisputed evidence shows that (1) the CyPass Micro-Stent creates an artificial drainage site and, therefore, does not drain aqueous humor to the naturally occurring uveal-scleral outflow pathway as is required by the patents-in-suit; (2) unlike the device claimed in the patents-in-suit, the CyPass Micro-Stent bypasses the ciliary body; and (3) the CyPass Applier does not satisfy the functional or structural components of the deployment mechanism disclosed in the patents-in-suit. I address each argument in turn.

A. The CyPass Micro-Stent

Transcend first asserts that the CyPass Micro-Stent is not configured for placement into the naturally existing uveal scleral outflow pathway because it creates an artificial drainage site in the eye when implanted. Transcend urges that the undisputed evidence demonstrates that the CyPass Micro-Stent separates the sclera from the ciliary body causing aqueous humor to collect in lakes and a tented space surrounding the stent. According to Transcend, the tented space and lakes are "artificial drainage sites" because they do not naturally occur in the eye and are only produced by anatomical changes caused by implantation of the CyPass Micro-Stent. As such, Transcend argues that the CyPass Micro-Stent does not satisfy the uveal scleral outflow pathway

limitation of the asserted claims because that term was explicitly construed to exclude an "artificial drainage site."

Glaukos counters that there is a genuine issue of material fact as to whether the CyPass Micro-Stent satisfies the uveal scleral outflow claim requirement. In support, Glaukos relies on Dr. Katz's opinion that enlarging the supraciliary-suprachoroidal space does not render the naturally occurring supraciliary-suprachoroidal space an "artificial" drainage site. (Pl.'s Mem. Ex. 2, Katz Opening Report pp. 38-45.) Glaukos further notes that both of its experts, Dr. Katz and Dr. Richard Lewis, have opined that the CyPass Micro-Stent is placed in the naturally occurring supraciliary-suprachoroidal space. (Id. at pp. 26-29; Pl.'s Mem. Ex. 13, Lewis Report ¶ 30.)

The term "uveal scleral outflow pathway" was construed to include the supraciliary-suprachoroidal space. As such, I find that the testimony of Dr. Katz and Dr. Lewis creates a genuine issue of material fact as to whether the CyPass-Micro-Stent drains fluid to an artificial drainage site or the uveal-scleral outflow pathway.

Transcend's second non-infringement argument is based on the fact that the term uveal scleral outflow pathway as used in the patents-in-suit was construed to mean the path by which fluid flows from the anterior chamber and through the ciliary body en route to the supraciliary/suprachoroidal space. Transcend urges that the undisputed evidence demonstrates that, unlike the uveal scleral outflow pathway limitation, the CyPass Micro-Stent bypasses the ciliary body. Transcend asserts that its device in fact derives its name from the fact that it bypasses the ciliary body as it is an abbreviation of "Ciliary ByPass." (Pl.'s Mem. Ex. 15.)

In support, Transcend notes that its expert Dr. Joseph Caprioli testified that the CyPass Micro-Stent bypasses the ciliary body. (Def.'s Opp. Ex. A, Caprioli Dep. p. 71.) It is telling that

Glaukos own expert, Dr. Lewis, agreed that the CyPass Micro-Stent bypasses the ciliary body. (Pl.'s Mem. Ex. 14, Lewis Dep. p. 49.) Dr. Lewis' testimony on this issue is as follows:

> Q. You've seen OCT photographs of the CyPass fully implanted; correct?
>
> A. Yes.
>
> Q. And when it's fully implanted, is it your understanding that neither the distal end nor the proximal end is contained within the ciliary body?
>
> A. It is suprachoroidal or supraciliary.
>
> Q. Correct. So the answer to my question is: Neither the distal end or the proximal end is contained within the ciliary body; correct?
>
> A. Yes.
>
> Q. All right. Have you ever seen an OCT picture of an implanted CyPass where the stent was actually – in its final resting place – in the ciliary body?
>
> A. I have not.

(Id. at 49:10-25.) Dr. Lewis further testified:

> Q. . . . [W]hether you call it supraciliary or suprachoroidal, the intent of the CyPass is to place the stent into a space above the ciliary body or ciliary muscle and below the sclera?
>
> A. I agree.
>
> Q. And in all of the OCT pictures that you've ever seen, that's what they reflect as its final resting place?
>
> A. That's the desired resting place.

(Id. at 50:16-24.)

In light of this testimony, Transcend urges that the undisputed evidence demonstrates that the CyPass Micro-Stent, unlike the stent disclosed in the patents-in-suit, bypasses the ciliary body as neither end of the CyPass Micro-Stent is contained within the ciliary body.

Glaukos counters that the CyPass Micro-Stent permits fluid to flow from one location in the eye to another location, just like the implants disclosed in the patents-in-suit. In support, Glaukos points to the Summary of Invention section of the patents-in-suit which states "Glaucoma surgical morbidity would greatly decrease if one were to bypass the focal resistance to outflow of aqueous only at the point of resistance." (See Pl.'s Mem. Ex. 1, Patent '782 4:24-27.)

I find that the general statement in the Summary of Invention section does express views regarding the best practices for treatment of glaucoma. This statement, however, does not describe the invention. More fundamentally, even if this statement did expressly require that the claimed device bypass the ciliary body, such a statement would be inconsistent with the term as construed. The statement relied upon by Glaukos cannot overcome the claim construction or alter the fact that Glaukos' own expert admitted that the CyPass bypasses the ciliary body.

In sum, no reasonable fact finder could find that the CyPass Micro-Stent satisfies the ciliary body limitation recited in the properly construed claims. Having found that the ciliary body claim limitation is absent from the CyPass Micro-Stent, there is no literal infringement as a matter of law. See Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1247 (Fed. Cir. 2000) ("If any claim limitation is absent from the accused device, there is no literal infringement as a matter of law").

The patents-in-suit set forth the ocular implant and delivery device as a single claim. (See, e.g., Pl.'s Mem. Ex. 1, Patent '782 claim 1). As such, having found that the CyPass Micro-Stent does not contain the ciliary body limitation of Glaukos' ocular implant, the parties' infringement positions regarding the CyPass Applier are of no moment as the accused device must contain every limitation of a claim in order to infringe that claim. That said, for the reasons

briefly set forth below, I do agree with Glaukos that there are material facts in dispute regarding the respective delivery devices.

B. <u>The CyPass Applier</u>

Glaukos contends that Transcend's CyPass Applier infringes the deployment mechanism limitation in the patents-in-suit. Transcend has moved for summary judgment on the grounds that, unlike the deployment mechanism recited in the patents-in-suit, the CyPass Applier does not include a push-pull type plunger or its equivalent and the components of the CyPass Applier do not operate via relative movement.

Transcend contends that the undisputed evidence demonstrates that the CyPass Applier does not involve a push-pull plunger. Relying on pictures and diagrams of both devices, Transcend contends that Glaukos' push-pull plunger is a simple device and the CyPass Applier, in stark contrast, is a "complicated structure." Transcend further urges that the "complex, structural linkage" of the CyPass Applier's components are unlike any "portion of the simple 'push-pull' plunger." (Pl.'s Mem. pp. 20-21; Ex. 2, Katz Opening Report pp. 59-61; Ex. 1, Patent '782 Fig. 31.)

Glaukos counters that there is a genuine issue of material fact as to whether the CyPass Applier's structure is equivalent to the push-pull plunger. Glaukos' expert Dr. Katz examined the CyPass Applier structure and found it to be substantially similar to the push-pull plunger. (Pl.'s Mem. Ex. 2, Katz Opening Report p. 67.)

I agree with Glaukos that Dr. Katz's testimony is sufficient to create a genuine issue of material fact as to whether the CyPass Applier is equivalent to the push-pull type plunger depicted in the patents-in-suit. Transcend's arguments regarding the reliability and correctness of

Dr. Katz's opinions on this issue require factual determinations which are not appropriate at the summary judgment stage.

Transcend also urges that the undisputed evidence shows that the CyPass Applier does not perform the deployment mechanism's claimed function because the CyPass Applier's components remain fixed during implantation and, therefore, do not operate via relative movement during implantation. Transcend asserts that the functional language of the deployment mechanism as construed requires "relative movement" between the deployment mechanism and the "elongated member" to deliver the stent to its implantation location.

According to Transcend, during surgery, the surgeon's hand pushes the entire CyPass Applier forward to the eye and the CyPass Applier's components remain fixed relative to each other while the CyPass Micro-Stent is positioned at its implantation location. Transcend maintains that relative movement only occurs after the stent is in position and the guidewire is withdrawn to release the stent from the CyPass Applier. Transcend argues that this is inconsistent with the patent-in-suits because Glaukos' deployment mechanism's function as construed requires relative movement to position the stent in place.

Glaukos counters that Transcend misreads the claimed function of the deployment mechanism. According to Glaukos, when read in context of the entire claim, Glaukos' deployment mechanism's function requires relative movement to release the stent from the elongated member. Glaukos notes that Figure 31 shows that the stent already extends out past the end of the plunger before it is advanced and, therefore, no relative movement is required to advance the stent to its implantation location in the eye. (See Pl.'s Mem. Ex. 1, Patent '782 Fig. 31.)

Based on this reading, Glaukos urges that deployment is the release of the implant from the elongated member rather than positioning at the implantation location. Relatedly, Glaukos notes that Dr. Katz opined that the CyPass Applier's spring and stopper tube move relative to the guidewire to release the stent and that Dr. Lewis offered a similar opinion. (Pl.'s Mem. Ex. 2, Katz Opening Report pp. 66-8; Ex. 13, Lewis Report ¶¶ 43-5.)

Given the conflicting evidence regarding the functionality of the deployment mechanism and the CyPass Applier, there is a genuine issue of material fact as to whether the CyPass Applier performs the claimed function. However, this conclusion does not alter the fact that Transcend is entitled to summary judgment because the undisputed evidence demonstrates that Transcend's CyPass Micro-Stent does not satisfy the uvealscleral outflow path claim limitation of the patents-in-suit.

An appropriate order follows.