United States District Court,
M.D. Florida, Ft. Myers Division.

ARTHREX, INC,
Plaintiff.
v.
DEPUY MITEK, INC,
Defendant.

No. 2:04-cv-328-FtM-99DNF

Oct. 16, 2006.

Gabriella Coman, Philip G. Hampton, Salvatore P. Tamburo, Stephen A. Soffen, Dickstein Shapiro Morin & Oshinsky LLP, Washington, DC, William F. Jung, Jung & Sisco, P.A., Tampa, FL, for Plaintiff.

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REPORT AND RECOMMENDATION

DOUGLAS N. FRAZIER**, United States Magistrate Judge.**

TO THE UNITED STATES DISTRICT COURT

This cause came on for consideration on Defendant, DePuy Mitek, Inc.'s ("Mitek") Claim Construction Memorandum (Doc. 140), Plaintiff, Arthrex, Inc. ("Arthrex") Opening Brief on Claim Construction (Doc. 141), Mitek's Response to Arthrex's Opening Brief on Claim Construction (Doc. 142), Arthrex's Opposition to DePuy Mitek's Claim Construction Memorandum (Doc. 143), the parties' Joint Claim Construction Statement (Doc. 147), Mitek's Memorandum on Undisclosed Cases relied on by Arthrex at the *Markman* Hearing (Doc. 148), and Arthrex's Response to DePuy Mitek's Memorandum on Undisclosed Cases Relied on by Arthrex at the *Markman* Hearing (Doc. 150). On May 25, 2006, the Honorable John E. Steele, United States District Judge entered an Order (Doc. 135) which referred the *Markman* hearing to this Court for the issuance of a Report and Recommendation. A *Markman* hearing was held on June 30, 2006.

I. Background

Arthrex is suing Mitek for patent infringement concerning two patents, U.S. Patent No. 6,733,529 ('529) and U.S. Patent No. 6,974,477 ('477) which are the fifth and sixth in a series of patents based upon a patent which was granted in 1999. (Doc. 140, p. 1, Doc. 141, p. 1) According to Arthrex, all six of these patents relate back to a provisional application, U.S. Provisional Application Serial No. 60/037,610 ('610) which was filed on February 12, 1997. (Doc. 141, p. 1).

These patents all involve "[a] surgical method for loading grafts into a joint"of the knee to reconstruct the anterior cruciate ligament ("ACL"). (Exhibit 1 to Doc. 141, p. 1). The ACL is the piece of tissue that connects the femur (thigh bone) to the tibia (shin bone). When the ACL is torn, the entire ACL is removed and replaced with a substitute ligament (from a hamstring of the patient or a cadaver) that attaches to the femur and to the tibia. (Doc. 140, p. 6-7).

Arthrex claims that the history of this lawsuit dates back to 1999, when Innovasive Devices, Inc. ("Innovasive") a predecessor to Mitek began promoting the SlingShot method. (Doc. 141, p. 1). This SlingShot method was allegedly a copy of Arthex's TransFix technique, and Arthrex sued Innovasive for patent infringement. (Doc. 141, p. 1-2). Innovasive agreed to discontinue promoting the SlingShot method and system. (Doc. 141, p. 2). Mitek Surgical Products acquired Innovasive and attempted to circumvent Arthex's patent by making a modification to the SlingShot. (Doc. 141, p. 2). Arthrex amended its claim on a pending continuation application, and after receiving another patent, sent a cease and desist letter to Mitek. According to Arthrex, Mitek promised to discontinue its promotion of the SlingShot T-Loop system in return for a one-year license. (Doc. 141, p. 2). Arthrex agreed. At the expiration of the one-year license Mitek Surgical Products successor, DePuy Mitek, Inc. reneged on its promise and introduced a new version of the SlingShot method. (Doc. 141, p. 2-3). Arthrex again amended its pending continuation application (the '529 Patent) to encompass Mike's purported new design. (Doc. 141, p. 3). During the present lawsuit, Arthrex filed another pending continuation application, the ' 477 to attempt to establish a clear infringement in this case. (Doc. 141, p. 3). Arthrex sent a cease and desist letter to Mitek. The '529 and '477 Patents are nearly identical with the only difference being in the language of the "positioning step." (Doc. 141, p. 4).

II. Legal Framework for Claims Construction FN1

FN1. The law of the Court of Appeals for the Federal Circuit on patent issues is binding on lower federal courts. Colt Defense LLC v. Bushmaster Firearms, Inc., 2006 WL 300407, * 6 (D.Me.2006), and Midwest Industries, Inc. v. Karavan Trailers, Inc. 175 F.3d 1356, 1358-59 (Fed.Cir.1999).

The court and not the jury has the responsibility to construe or interpret disputed terms in patent claims. Markman v. Westview Instruments, Inc., 517 U.S. 370, 390-91 (1996). "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 Corporation, 415 F.3d 1303, 1312 (Fed.Cir.2005), *citing,* Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1115 (Fed.Cir.2004). The words of the claim are generally given their ordinary and customary meaning. Phillips v. AWH Corporation, 415 F.3d at 1312. "We have made clear, moreover, that the ordinary and customary meaning of a claim term 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 1313. How a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin a claim interpretation. *Id*. Inventors typically are persons skilled in the field of inventing and the language in the patents is addressed to others who are also skilled in the pertinent field or art. *Id*. A person of ordinary skill in the field is deemed to read the terms in the claim in the context of the entire patent including the specification. *Id*. "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id* at 1314. Then general dictionaries may be helpful. *Id*. When the terms of the claim are not readily apparent and have a particular meaning in a field or art, then the Court must look to the intrinsic evidence of the words of the claims

themselves, the remainder of the specification, the prosecution history, and then look to the extrinsic evidence of the scientific principles, the meaning of technical terms, and the state of the art. *Id*.

A. Claim Language and Specification (Intrinsic Evidence)

The claim itself provides substantial guidance in determining the meaning of the language. Phillips v. AWH Corporation, 415 F.3d at 1314. A court should look to the context of the term. *Id*. A court should also review the other claims of the patent to determine the meaning of the language in the claim. *Id*. Claims must also be read in view of the specification. *Id* at 1315-16. A specification may provide a special definition for a claim term that differs from its general meaning, and in such cases the "inventor's lexicography governs." *Id*. at 1316. The language in the specification, however does not " 'import limitations from the specification into the claims.' " Varco, L.P. v. Pason Systems USA Corp., 436 F.3d 1368, 1373 (Fed.Cir.2006), (quoting CollegeNet, Inc. v. ApplyYourself, Inc., 418 F.3d 1225, 1231 (Fed.Cir.2005)). Claims may not be broader in scope than the invention that is set forth in the specification. *On* Demand Machine Corp. v. Ingram Industries, Inc., 442 F.3d 1331, 1340 (Fed .Cir.2006). It is necessary to consider the specification as a whole and to read all of the portions of the written description so that the patent as a whole is internally consistent. Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc., 429 F.3d 1364, 1373 (Fed.Cir.2005).

It is generally impermissible to limit a claim to a preferred embodiment or to any inferences drawn from the description of the preferred embodiment. Bell Atlantic Network Services, Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1273 (Fed.Cir.2001). Even if the specification describes a very specific embodiment, the claims are not confined to the embodiment described. LizardTech, Inc. v. Earth Resource Mapping, Inc., 433 F.3d 1373, 1377 (Fed.Cir.2006). "In particular, we have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." *Id,* (citing Gemstar-TV Guide v. Int'l Trade Comm'n, 383 F.3d 1352, 1366 (Fed.Cir.2004)), *See also,* Kapusta v. Gale Corp., 155 Fed.Appx. 518 (Fed.Cir.2005). "To avoid importing limitations from the specification into the claims, it is important to keep in mind that the purposes of the specification are to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so." Phillips v. AWH Corporation, 415 F.3d at 1323. Although the task to determine if the preferred embodiment is the outer limit of the claim or merely an example of the invention may be difficult, the Federal Circuit has found that "attempting to resolve that problem in the context of the particular patent is likely to capture the scope of the actual invention more accurately than either strictly limiting the scope of the claims to the embodiments disclosed in the specification or divorcing the claim language from the specification." *Id*.

B. Prosecution History (Intrinsic Evidence)

The prosecution history which is the compete record of the proceedings before the Patent and Trademark Office is considered part of the "intrinsic evidence" for claim construction purposes. Phillips v. A WH Corporation, 415 F.3d at 1317. The prosecution history shows how the inventor and the Patent and Trademark Office understood the patent. *Id*. The prosecution history is generally less useful than the specification because it is the ongoing negotiations of the applicant and the Patent and Trademark Office and lacks the clarity of the specification. *Id*. "Disclaimers based on disavowing actions or statements during prosecution, however, must be both clear and unmistakable." Sorensen v. International Trade Commission, 427 F.3d 1375, 1379-80 (Fed.Cir.2005), (citing Omega Eng'g. Inc. v. Raytek Corp., 334 F.3d 1314, 1326 (Fed.Cir.2003)). Further, it is the applicant and not the examiner who must " 'give up or disclaim subject matter' " that would otherwise be included within the scope of the claim. Sorensen, 427 F.3d at 1380, (quoting Innova/Pure Water, Inc., 381 F.3d at 1124). The statement of an examiner alone will not

necessarily limit a claim. Bell Atlantic Network Services, Inc. v. Covad Comm'c'ns Group, Inc. 262 F.3d 1258, 1273 (Fed.Cir.2001).

C. Dictionaries, Treatises (Extrinsic)

Extrinsic evidence is less significant and less reliable than intrinsic evidence. Phillips v. AWH Corporation, 415 F.3d at 1317, 1318. Dictionaries and treatises, especially technical dictionaries, may be helpful especially technical dictionaries may help the court with technical terms. Id. at 1318.

D. Expert Testimony (Extrinsic)

Expert testimony may be useful to the court to provide background on the technology, on how the invention works, and to ensure that the court's understanding of the technical aspects of the patent are consistent with a person of ordinary skill in the art. Phillips v.. AWH Corporation, 415 F.3d at 1318. A court should ignore conclusory, unsupported assertions by experts, and any expert testimony that is at odds with the terms of the claim itself, the prosecution history, or the written record of the patent. *Id*.

III. Claim Construction of Disputed Terms

A. '529 Patent ***Claim Language*** **(Exhibit 2 to Doc. 141)**

1. A method of anterior cruciate reconstruction surgery of the knee, comprising the steps of:

forming a[sic] opening in a femur, the opening having an entrance facing a joint of the knee;

forming a transverse hole in the femur extending completely across the femur, the transverse hole extending through a first sidewall of the opening on a first side of the femur, intersecting the opening, and extending through an opposite sidewall of the opening on an opposite side of the femur;

positioning a flexible strand in the knee such that the flexible strand extends from outside of the knee, through the transverse hole and into the opening in the femur through the first sidewall of the opening, out through the entrance of the opening and through a tunnel in the tibia, and, after forming a loop outside of the tibial tunnel, extending back into the tibial tunnel and into the opening through the entrance of the opening, and out of the knee through the transverse hole in the opposite sidewall of the opening;

looping a graft over the loop of the strand extending outside of the tibial tunnel;

pulling the loop of the graft through the tibial tunnel and into the opening; and

securing the graft in the opening by advancing an implant transversely into the opening and under the graft.

2. The method of claim 1, wherein the strand is used as a guide for advancing the implant transversely into the opening and under the graft.

3. The method of claim 1, wherein the implant has a threaded back end, the method further comprising the step of securing the implant in the knee by engaging a wall of the transverse hole with the threaded back end of the implant.

B. '477 Claim Language (Exhibit 1 to Doc. 141)

1. A method of anterior cruciate reconstruction surgery of the knee, comprising the steps of:

forming an opening in a femur, the opening having an entrance facing a joint of the knee;

forming a transverse hole in the femur extending completely across the femur, the transverse hole extending through a first sidewall of the opening on a first side of the femur, intersecting the opening, and extending through an opposite sidewall of the opening on an opposite side of the femur;

positioning a flexible strand in the knee such that the flexible strand extends from outside of the knee, through the transverse hole and into the opening in the femur through the first sidewall of the opening, out through the entrance of the opening and through a tunnel in the tibia, and, after forming a loop outside of the tibial tunnel, extending back into the tibial tunnel and into the opening through the entrance of the opening, and into the transverse hole in the opposite sidewall of the opening;

looping a graft over the loop of the strand extending outside of the tibial tunnel;

pulling the loop of the graft through the tibial tunnel and into the opening; and

securing the graft in the opening by advancing an implant transversely into the opening and under the graft.

2. The method of claim 1, wherein the strand is used as a guide for advancing the implant transversely into the opening and under the graft.

3. The method of claim 1, wherein the implant has a threaded back end, the method further comprising the step of securing the implant in the knee by engaging a wall of the transverse hole with the threaded back end of the implant.

The language of the claims in the '529 and '477 Patents are identical with the exception of the last clause in the section beginning "positioning a flexible strand." The last clause in the '427 Patent does not have the words "and out of the knee through."

C. Disputed Claim Language FN2

FN2. The language in the table is from the Joint Claim Construction Statement (Doc. 147).

The following is a chart of the language of the claim in Patent '477 FN3, Arthrex's claim construction, and then Mitek's claim construction.

FN3. Since the language in the '529 and '477 patents are identical with the exception of the "positioning" clause, the Court will use the language in the '477 patent to illustrate claim construction differences. The claim construction arguments are nearly identical for both patents. Any difference will be noted by the Court.

Claim Language '477 Patent	Arthrex Claim Construction (Doc. 141)	Mitek's Claim

		Construction (Exh. 19, Doc. 140)
A method of anterior cruciate reconstruction surgery of the knee, comprising the steps of:	A method of reconstructing the anterior cruciate ligament of the knee, the method comprising the steps of:	Undisputed
forming an opening in a femur, the opening having an entrance facing a joint of the knee;	forming an opening (e.g. a tunnel or a socket) in a femur, the opening having an entrance that faces a joint of the knee.	"opening" means "closed-end socket"
forming a transverse hole in the femur extending completely across the femur, the transverse hole extending through a first sidewall of the opening on a first side of the femur, intersecting the opening, and extending through an opposite sidewall of the opening on an opposite side of the femur;	forming a transverse tunnel that extends completely across the femur, where the transverse tunnel extends through a first sidewall of the opening on a first side of the femur, intersects the opening, and extends through an opposite sidewall of the opening on an opposite side of the femur.	Undisputed
positioning a flexible strand in the knee such that the flexible strand extends from outside of the knee, through the transverse hole and into the opening in the femur through the first sidewall of the opening, out through the entrance of the opening and through a tunnel in the tibia, and, after forming a loop outside of the tibial tunnel, extending back into the tibial tunnel and into the opening through the entrance of the opening, and [FN4] into the transverse hole in the opposite sidewall of the opening;	positioning a flexible strand in the knee such that the flexible strand extends from outside of the knee, through the transverse tunnel on one side of the knee and into the opening in the femur. The flexible strand then extends out through the entrance of the opening and through and out of a tibial tunnel. The flexible strand then extends back into and through the tibial tunnel and into the opening, and into the transverse tunnel on the opposite sidewall of the opening. A loop exists where the flexible strand is at its furthest point outside the tibial tunnel.	The flexible strand is positioned all the way through the transverse hole and then a loop of the strand is formed by pulling the strand outside the tibial tunnel.

FN4. The '529 Patent's claim language differs in the positioning claim in that it concludes that clause with the following: "out of the knee through the transverse hole in the opposite sidewall of the opening."

looping a graft over the loop of the strand extending outside of the tibial tunnel; [FN5]	looping a graft over the portion of the flexible strand that extends outside of the tibial tunnel	Undisputed

FN5. In the Joint Claim Construction Statement (Doc. 147), the parties added the language at the end of the clause "and into the opening." This language does not appear in the '477 Patent.

pulling the loop of the graft through the tibial tunnel and into the opening;	pulling the loop of the graft through the tibial tunnel and into the opening in the	"pulling" means pulling the flexible

	femur.	strand.
securing the graft in the opening by advancing an implant transversely into the opening and under the graft.	securing the graft in the opening by advancing an implant transverse to and into the opening and under the graft.	"securing the graft in the opening by advancing" means "to make the graft fast by impacting."
The method of claim 1, wherein the strand is used as a guide for advancing the implant transversely into the opening and under the graft.	The method of claim 1, wherein the flexible strand is used to guide the implant into the opening and under the graft.	Undisputed except for the term opening as set forth above.
The method of claim 1, wherein the implant has a threaded back end, the method further comprising the step of securing the implant in the knee by engaging a wall of the transverse hole with the threaded back end of the implant.	The method of claim 1, further comprising the step of securing the implant, which has a threaded back end, in the knee by contacting a wall of the transverse tunnel with the threaded back end of the implant.	"end" means "the extreme or last part lengthwise."

D. "Opening"

Mitek argues that the term "opening" should be limited to a "closed-end socket" in both the '477 and the '529 Patents. Mitek asserts that the patents describe and illustrate only closed-end sockets in the first clause which includes "forming an opening in a femur, the opening having an entrance facing a joint of the knee." Mitek cites to Claim 1 where it refers to "a tunnel in the tibia" and argues when Arthrex needed to use the term "tunnel" it did so elsewhere in the patents. Mitek also indicated that the term "opening" is not mentioned in the specification to refer to the longitudinal femoral hole. A court may look to other terminology in the specification which describes the same term as used in the claim if the exact term is not found in the specification. Network Commerce, Inc. v. Microsoft Corp., 422 F .3d 1353, 1361 (Fed.Cir.2005) (when the term in the claim "download component" was not found in the specification, the court relied on the term "download file" in the specification which appeared to have the same function and description as the term "download component" had in the claim). Mitek asserts that the drawings all show a closed-end socket, and the Abstract refers to a longitudinal socket. (Doc. 140, Exh. 1, Abstract).

Mitek indicates that during the prosecution of the related U.S. Patent No. 5,918,604 ('604), the Patent Office rejected certain claims over prior art because the claims were not limited to a "blind hole or partial hole". (See, Doc. 140, Exh. 18, and Exh. 7, page 3). Arthrex amended these claims and specifically used the word "socket." (Doc. 140, Exh. 8, pgs.2-3). Mitek argues that Arthrex distinguished its invention from prior inventions by having a socket form in the bone rather than a tunnel or hole. (See, Doc. 140, Exh. 8, p. 5).

Arthex argues that the specification allows for either a femoral socket or a femoral tunnel. It cites to the language in the Summary of the Invention which states "[a]ccording to the present invention, forming the socket is preferred to forming a tunnel through the lateral femoral cortex." (Doc. 140, Exh. 1, 2: 42-44). Further, another part of the specification discusses "femoral tunnels" when describing the openings in the femur. (Doc. 140, Exh. 1, 3:30). In the Detailed Description of the Preferred Embodiments, a "femoral tunnel" is used to describe where the wire forms a loop. (Doc. 140, Exh. 1, 4:24-27). In this same section, the term "femoral tunnel" is used to state that the tendons must fit snugly within it, however later in the sentence the term "femoral socket" is also used. (Doc. 140, Exh. 1, 6:22-25).

Arthrex adds that it is improper to import a limitation to a claim from the language of the specification citing Ethicon Endo-Surgery, Inc., 93 F.3d 1572, 1578 (Fed.Cir.1996). Arthrex asserts that it used specific language in the claim regarding the "transverse hole" that extends across the femur so that the flexible strand may be inserted, but did not use this type of limiting language when describing the opening in the femur, so that either a femoral socket or a femoral tunnel could be used. Arthex indicates that the claim has no limiting language as to the type of "opening."

From the prosecutorial history, Arthex asserts that the provisional patent '610, had the language in claim 1 of "forming a hole in a bone", and then in claim 4, stated the hole in claim 1 "is closed at one end." (Doc. 143, Exh. 1, p. 12). Claim 4 would be meaningless, Arthex argues, if the hole in claim 1 was only a closed end hole. Arthrex argues that one claim cannot vitiate the meaning of another, and therefore, hole or opening in the '477 patent is not limited to being a socket, citing Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d. 898, 910 (Fed.Cir.2004). Arthex also argues that it never limited the term "opening" in the '604 patent to a socket.

To determine how a person of ordinary skill in the art would construe the term "opening," the Court will begin by reviewing the language of the claim itself, and the specification. The term "opening" is used in the claim as follows: "forming an opening in a femur, the opening having an entrance facing a joint of the knee." (Doc. 140, Exh. 1, 6:34-36). The claim language does not limit the meaning of the term "opening." Upon review of the specification, the term "opening" is not used. In the Summary of Invention, the term "femoral socket" is used repeatedly to describe the longitudinal hole in the femur. (Doc. 140, Exh. 1, 2:41, 43, 45, 48, 50, 63, 64, 3:2). However, the term "femoral tunnel" is also used, although less frequently, to describe the opening in the femur. (Doc. 140, Exh. 1, 3:30, 4:24-27). In one clause of the Summary of the Invention, the following language is used: "[a]ccording to the present invention, forming the socket is preferred to forming a tunnel through the lateral femoral cortex. Advantageously, the diameters of the tibial tunnel and femoral socket are made just large enough to accommodate the graft in a snug fit." (Doc. 140, Exh. 1, 2:42-44).

Case law cautions that claims may not be broader than the scope of the invention that is set forth in the specification, yet the language of the specification may not import limitations on the claims. *See,* Varco, L.P. v. Pason Systems USA Corp., 436 F.3d at 1373, and *On* Demand Machine Corp. v. Ingram Industries, Inc., 442 F.3d at 1340. The patent as a whole must be consistent. Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc., 429 F.3d at 1373. Reviewing the patent as a whole, it is clear that the preferred method is to have the "opening in the femur" be a femoral socket. The term "opening" is not used in the specification. However, the term "femoral socket," which is used to describe the opening in the femur, is used repeatedly throughout the specification. Even though "femoral socket" is used more frequently, the term "femoral tunnel" is also used in the specification to describe the "opening in the femur." In the Summary of the Invention, the patents provide that the preferred method is a femoral socket, however, a femoral tunnel is not specifically disavowed. The description of the invention contemplates the use of a femoral socket, but it also anticipates the use of a femoral tunnel by some and cautions that a femoral socket is the better practice. The purpose of the specification is to "teach and enable those of skill in the art" to use the invention and to provide the best method of using the invention. Phillips v. AWH Corporation, 415 F.3d at 1323. Even though the preferred embodiment uses a femoral socket, a claim is not limited to a preferred embodiment. *See,* Bell Atlantic Network Services, Inc. v. Covad Comm'c'ns Group, Inc., 262 F.3d at 1273.

The prosecution history is less useful for the term "opening" than the specification because it lacks the clarity of the specification. *See,* Phillips v. AWH Corporation, 415 F.3d at 1317. The provisional patent ' 610

does not use the term "opening ." Rather, it does contain the clause that the "hole is closed at one end," however this modifies the term in claim 1 which states that the procedure is "forming a hole in a bone." (See, Doc. 143, Exh. 1, p. 12). If "forming a hole in a bone" meant a closed end socket, then the language "hole is closed at one end" would be superfluous. After the provisional patent '610, the later patents went through many amendments and modifications before the '529 and '477 patents were granted. Likewise, in the '604 patent which was cited by Mitek, the term "opening" does not appear. Mitek also cites to the prosecution of the '604 patent which modified the language in the patent based upon comments of the Patent Examiner. (See, Doc. 140, Exh. 7, p. 3). The comments of the Patent Examiner regarding the term "socket" are not clear in that he states, "[s]ince the 'socket' (a blind hole or a partial hole through the bone) is not claimed in these claims, they therefore reads [sic] on any strand that has been intersected and passing though a hole through the bone." (Doc. 140, Exh. 7, p. 3). The Court finds no support in limiting the term "opening" from these comments. Mitek also cites to a deposition of the inventor, Dr. Jeffery Whelan in support of its position, however, the subjective intent of the inventor is not appropriate to construe terms in the claim. Superior Fireplace Co. v. Majestic Products Co., 270 F.3d 1358, 1375 (Fed.Cir.2001).

Relying mainly on the claim language itself, and the specification, the Court determines that "a person of ordinary skill in the art" would construe the "ordinary and customary meaning" of the term "opening" as being either a femoral socket or a femoral tunnel. Both femoral socket and femoral tunnel are mentioned in the specification for the '529 and '477 patents, and even though the femoral socket is the preferred embodiment, the femoral tunnel is also an option for the procedure.

E. "Positioning"

Mitek argues that the "positioning" clause requires a two-step process, first the flexible strand is pulled though the entire transverse tunnel in the femur, and then a loop of the strand is formed outside of the tibial tunnel by pulling the flexible strand using a tool, such as a tunnel hook. Mitek cites to the Abstract in the '477 patent which includes the following language: "A flexible strand is drawn with the pin through the bone. A looped portion of the strand is diverted so as to protrude out of the entrance to the longitudinal socket. The ends of the strand remaining accessible on either side of the bone." (Doc. 140, Exh. 1, Abstract). Mitek cites to the Summary of Invention arguing it refers to the two-step process as follows: "Next, a flexible strand, preferably a wire formed of nitinol, is attached to the guide pin and pulled through the femur. Equal lengths of the strand protrude from the medial and lateral sides of the femoral shaft, and are secured to prevent accidental pull-out. The tunnel hook is withdrawn, the strand being captured in the slot of the hook." (Doc. 140, Exh. 1, 2:57-62). Mitek claims that the two-step procedure is not just the preferred embodiment, but characterizes the overall invention, citing to Detailed Description of the Preferred Embodiments which states that the "method of the present invention is described with reference to FIGS 10 through 16." (Doc. 140, Exh. 4:62-63). Later in the Detailed Description of the Preferred Embodiments, the following language appears, the flexible wire "is hooked onto hook 18 on the proximal end of drill pin. By pulling on the drill pin, the graft-passing wire is drawn through the femur until it is positioned with equal lengths at either end protruding from the medial and lateral sides of the femoral shaft. Hemostats 74 are clipped onto the ends of the wire to prevent them from being pulled into the transverse femoral tunnel as shown in FIG 14." (Doc. 140, Exh. 1, 5:51-58). Mitek argues that no other procedure is mentioned to position the flexible wire. Mitek asserts that the Patent Examiner allowed the '529 patent because of the method steps of positioning the flexible strand through the transverse hole, into the opening and then forming a loop through the tibial tunnel. (Doc. 140, Exh. 14, p. 2).

Arthex argues that the flexible strand extends from the outside of the knee, through the transverse tunnel,

into the femoral socket through a first sidewall of the femoral socket, out of the entrance to the femoral socket, down through the tibial tunnel, out of the tibial, back up through the tibial tunnel, into the femoral socket, and into the transverse tunnel on the opposite sidewall of the femoral socket. Arthrex argues that the patents are not limited to Mitek's asserted two-step procedure.

The Court will begin its analysis by reviewed the language of the claim and the specification. The positioning clause contains the following procedure:

positioning a flexible strand in the knee such that the flexible strand extends from outside of the knee, through the transverse hole and into the opening in the femur through the first sidewall of the opening, out through the entrance of the opening and through a tunnel in the tibia, and, after forming a loop outside of the tibial tunnel, extending back into the tibial tunnel and into the opening through the entrance of the opening, and into the transverse hole in the opposite sidewall of the opening.

(Doc. 140, Exh. 1, 6:42-50). The language in the Summary of the Invention, is as follows when describing the flexible strand in the femur:

Next, a flexible strand, preferably a wire formed of nitinol, is attached to the guide pin and pulled through the femur. Equal lengths of the strand protrude from the medial and lateral sides of the femoral shaft and are secured to prevent accidental pull-out. The tunnel hook is withdrawn, the strand being captured in the slot of the hook. The hook is retracted completely, through the femoral socket and out of the tibial tunnel, such that a loop of the flexible strand protrudes from the entrance to the tunnel.

(Doc. 140, Exh. 1, 2:57-62).

The Detailed Description of the Preferred Embodiments provides the

nitinol graft-passing wire 30 is hooked onto hook 18 on the proximal end of drill pin 12. By pulling on the drill pin, the graft-passing wire is drawn through the femur until it is positioned with equal lengths at either end protruding from the medial and lateral sides of the femoral shaft. Hemostats 74 are clipped onto the ends of the wire to prevent them from being pulled into the transverse femoral tunnel 70 as shown in FIG 14.

Referring to FIGS 13 and 14, once the graft-passing wire has been drawn through the femur, tunnel hook 2 is retracted from femoral socket 60 and tibial tunnel 56, pulling graft-passing wire 30 with it to form a loop that protrudes from the entrance of the tibial tunnel.

The preferred embodiment in the patents is limited to the two-step procedure raised by Mitek. From the Summary of the Invention and the Detailed Description of the Preferred Embodiments, the preferred method is to insert the flexible strand through the transverse tunnel in the femur, through a hook on the proximal end of a drill pin, and then through the remaining transverse tunnel. Next, the hook pulls the flexible strand through and out of the tibial tunnel. However, the claim language itself is not limited to this process. A court may not limit a claim to the preferred embodiment or make an inferences from the description of the preferred embodiment. Bell Atlantic Network Services, Inc. v. Covad Comm'c'ns Group, Inc., 262 F.3d at 1273. The claims are not limited to an embodiment even if the embodiment is very specific. LizardTech, Inc. v. Earth Resource Mapping, Inc., 433 F.3d at 1377. In this case, the claim language is not limited to the preferred embodiment or the language in the Summary of the Invention. Rather, the actual claim language

allows for the flexible strand to extend from the outside of the knee, through the transverse hole, into the opening in the femur, through the first sidewall of the opening, out through the entrance of the opening, through a tunnel in the tibia, making a loop outside of the tibia, back through the tunnel in the tibia, into the opening, and into the transverse hole in the opposite sidewall. The prosecution history is not useful regarding construing the "positioning" clause in that Mitek cites to statements by the Patent Examiner, however his statements alone cannot limit a claim. Bell Atlantic Network Services, Inc. v. Covad Comm'c'ns Group, Inc., 262 F.3d at 1273.FN6

FN6. The Court did not rely on the dictionary definitions as asserted by Mitek in that the Court relied on intrinsic evidence to make its determinations.

Relying on the claim language itself, and the specification, the Court determines that "a person of ordinary skill in the art" would construe the "ordinary and customary meaning" of the "positioning" clause not to be limited to the two-step method asserted by Mitek. Rather, to the meaning as set forth by Arthex which is the following: "positioning a flexible strand in the knee such that the flexible strand extends from outside of the knee, through the transverse tunnel on one side of the knee and into the opening in the femur. The flexible strand then extends out through the entrance of the opening and through and out of a tibial tunnel. The flexible strand then extends back into and through the tibial tunnel and into the opening, and into the transverse tunnel on the opposite sidewall of the opening. A loop exists where the flexible strand is at its furthest point outside the tibial tunnel." FN7

FN7. Although the language in the '529 patent differs slightly from the '477 patent, the claim construction by the Court applies equally to both patents.

F. "Pulling"

Mitek construes the term "pulling" to mean pulling the flexible strand which extends outside of the femoral transverse tunnel. Mitek argues that in the Summary of the Invention, the method used for pulling the graft into the femoral socket is by "pulling evenly on the medial and lateral ends of the strand." (Doc. 140, Exh. 1, 3:3-4). Mitek also cites to the Detailed Description of the Preferred Embodiments which states that the graft is retracted through the femoral socket "by pulling evenly on the medial and lateral ends of the graft-passing wire." (Doc. 140, Exh. 1, 6:2-3). Mitek argues that the inventor only contemplated one method of graft-loading, and the claim should be limited to that method. Mitek also asserts that in the Summary of the Invention, the inventor claimed this technique of graft-loading eliminated sutures. (Doc. 140, Exh. 1, 2:33-34). Mitek argues that since Arthex distinguished suture in-line graft-loading techniques (the prior art) from its transverse-wire technique, it cannot now assert that the claim broadly encompasses in-line graft-loading techniques.

Arthrex asserts that the patents disclose the preferred embodiment of how the graft is raised through the tibial tunnel. The preferred embodiment procedure is by pulling the ends of the flexible wire. However, the claim is not limited to the preferred embodiment. Arthex argues that a person with ordinary skill in the art would know that the graft could be pulled through the tibial tunnel and into the femoral socket by the preferred method discussed in the Detailed Description of the Preferred Embodiments or any other method, including the method in prior patents known as the "in-line" technique of pulling the graft. Arthrex also argues that a "flexible strand" is a type of suture, which is used in the '477 patent to load the graft into the

knee. Further, the '477 patent eliminates sutures as graft fixation devices not graft-loading devices.

The language in the claim is general in that it uses the term "pulling" in the following clause: "pulling the loop of the graft through the tibial tunnel and into the opening." (Doc. 140, Exh. 1, 6:53-54). This language is not limited to pulling the ends of the flexible strand that are protruding from the femur. The Summary of the Invention as well as the Detailed Description of the Preferred Embodiments does describe the method of pulling on the ends of the flexible strand that protrude from the femur to raise the graft into the knee. The issue is whether the outer limit of the claim is the method of pulling the flexible strand at both ends to raise the graft. It is impermissible to limit a claim to specification or the preferred embodiment, even if it is a single embodiment. Bell Atlantic Network Services, Inc. v. Covad Comm'c'ns Group, Inc., 262 F.3d at 1273, LizardTech, Inc. v. Earth Resource Mapping, Inc., 433 F.3d at 1377, Phillips v. AWH Corporation, 415 F.3d at 1323. The claim in this case is not limited by the specification nor by the preferred embodiment. A person of ordinary skill in the field would understand that the graft must be raised through the tibial tunnel and into the femur by some method, and the preferred method is by pulling on the flexible strand that is protruding from the femur, however any method of raising the graft would comply with the claim. The argument by Mitek that the Summary of the Invention shows that the graft-pulling technique eliminates sutures is without merit. The method articulated eliminates sutures as graft-fixing devices, not graft-pulling devices. (Doc. 140, Exh. 1, 2:33-34).

Relying on the claim language itself, and the specification and preferred embodiment, the Court determines that "a person of ordinary skill in the art" would construe the "ordinary and customary meaning" of the term "pulling" to mean pulling the loop of the graft through the tibial tunnel and into the opening in the femur.

G. "Securing"

Mitek argues that "securing by advancing" should be construed as "to make fast by impacting." Mitek asserts that the patents warn against securing the graft by rotating a screw-in type implant because the graft could become wrapped around the implant. Mitek cites to the Background of the Invention portion of the patent. (Doc. 140, Exh. 1, 1:60-62). Mitek also cites to the language in the patents which includes the implant is "driven into the femur" and later "the implant easily can be impact driven into the repair site," and a "mallet is used to drive the implant into the femur." (Doc. 140, Exh. 1, 3:5-6, 7-8, 6:11-12). Mitek argues that the patents do not propose any other method of securing the graft other than impaction.

Arthrex argues that the transverse implant can be advanced by impaction into the bone, however the claim is not limited to this suggested manner of advancing. Arthrex asserts that there is nothing in the claim language or the specification to limit how the "advancing" is to occur.

In the System for Loading Tendons into the Knee, the patent provides that "[a] threaded portion of the implant screws into the bone as the implant is advanced with rotation into the repair site. The technique is disadvantageous, however, because the graft can become wrapped around the implant as it is rotated. An improved bone implant is the subject of the U.S. Pat. No. 5,895,425." (Doc. 140, Exh. 1, 1:58-64). In the Summary of the Invention, the patent provides that the "implant is placed over the wire and driven into the femur. The implant preferably is formed with back-biting threads. Accordingly, the implant easily can be impact driven into the repair site, and yet can be removed if necessary by rotation." (Doc. 140, Exh. 1, 3:5-9). In the Detailed Description of the Preferred Embodiments, the patent provides for the implant being "driven by impaction into bone, and then, if necessary can be subsequently removed by screw rotation as discussed below." (Doc. 140, Exh. 14:59-61). Later in the Detailed Description of the Preferred

Embodiments, the patent provides that "a mallet is used to drive the implant into the femur." (Doc. 140, Exh. 1, 6:11-12).

The specific claim language does leave open the method of "advancing an implant transversely into the opening." (Doc. 140, Exh. 1, 6:55-56). However, considering the specification as a whole and in conjunction with the claim language, the terms "securing the graft by advancing an implant transversely" should be construed as by impaction and not by securing the graft by rotating a screw-in type implant. In the System for Loading Tendons Into the Knee, the language disavows the use of the screw-in type implant as possibly causing the graft to become wrapped around the implant when rotated. (Doc. 140, Exh. 1, 1:62-63). Relying on the language of the claim and the language in the specification, the Court determines that a "person of ordinary skill in the art" would construe the "ordinary and customary meaning" of the terms "securing the graft into the opening by advancing an implant transversely into the opening and under the graft," to mean to secure the graft by impacting and not by rotating a screw-in type implant.

H. "End"

Mitek argues that the term "end" in the following clause in claim 1, "threaded back end" should be construed to mean the extreme or last part lengthwise. Mitek argues that the patent does not cover implants that have a head at the end. Mitek cites to the language in the Preferred Embodiments that the "[i]mplant 40 has a threaded proximal end and a threaded distal ends." (Doc. 140, Exh. 14:51). Arthrex argues that there is no support for Mitek's request to limit the implant to those that do not have a head at the end, and that this patent is directed to a method of ACL surgery and not to a specific type of implant used in that method.

In the Summary of the Invention, the patent provides that the "implant preferably is formed with back-biting threads. Accordingly, the implant easily can be impact driven into the repair site, and yet can be removed if necessary by rotation." (Doc. 140, Exh. 1, 3:6-9). The Preferred Embodiments provides that the implant "can be driving by impaction into bone, and then, if necessary can be subsequently removed by screw rotation as discussed below." (Doc. 140, Exh. 1, 4:60-62). The Court finds no language in the claim or the specification which limits the type of screw end. Relying on the language of the claim and the language in the specification, the Court determines that a "person of ordinary skill in the art" would construe the "ordinary and customary meaning" of the terms "threaded back end," to mean either a screw with or without a head that has a threaded back part.

IV. Conclusion

The Court respectfully recommends that the terms in Patent Nos. '477 and '529 be construed as follows:

1) In favor of Arthrex as to the term "opening" to mean forming an opening either a socket or a tunnel in the femur.

2) In favor of Arthrex as to the term "positioning" to mean positioning a flexible strand in the knee such that the flexible strand extends from outside of the knee, through the transverse tunnel on one side of the knee and into the opening in the femur. The flexible strand then extends out through the entrance of the opening and through and out of a tibial tunnel. The flexible strand then extends back into and through the tibial tunnel and into the opening, and into the transverse tunnel on the opposite sidewall of the opening. A loop exists where the flexible strand is at its furthest point outside the tibial tunnel.

3) In favor of Arthrex as to the term "pulling" to mean pulling the loop of the graft through the tibial tunnel

and into the opening in the femur.

4) In favor of Arthrex as to the term "end" to mean either a screw with or without a head that has a threaded pack part.

5) In favor of Mitek as to the term "securing" to mean to secure the graft by impacting and not by rotating a screw-in type implant.

Failure to file written objections to the proposed findings and recommendations contained in this report within ten (10) days from the date of its filing shall bar an aggrieved party from attacking the factual findings on appeal.

Respectfully recommended in Chambers in Ft. Myers, Florida this *16th* day of October, 2006.

M.D.Fla.,2006.
Arthrex, Inc. v. Depuy Mitek, Inc.

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