IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

K2M, INC., Plaintiff, v. ORTHOPEDIATRICS CORP. and ORTHOPEDIATRICS US DISTRIBUTION CORP.,

Defendants.

Civil Action No. 17-61-GMS

ORDER CONSTRUING THE TERMS OF U.S. PATENT NOS. 9,532,816 and 9,655,664

After having considered the submissions of the parties and hearing oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent Nos. 9,532,816 (the "'816 Patent") and 9,655,664 (the "'664 Patent"):¹

 The phrase "grasping members configured to grasp a portion of a bone anchor therebetween" as used in Claim 16 of the '816 Patent and Claims 8, 12, and 17 of the '644 Patent is construed pursuant to 35 U.S.C. § 112, ¶ 6. The claimed function is: "grasping a portion of a bone anchor." The corresponding structure is: "grasping members 64, 66; grasping elements 80, 82; and rod contact member 20."²

¹ The '816 Patent and the '664 Patent share the same specification. All citations to the specification in this order will be made to the '816 Patent.

² Defendants OrthoPediatrics Corp. and OrthoPediatrics US Distribution Corp. argue that this claim should be construed pursuant to § 112, \P 6 with the function being "grasping a portion of a bone anchor" and the corresponding structure being "grasping members 64, 66; grasping elements 80, 82; and rod contact member 20." (D.I. 43 at 11.) Plaintiff K2M, Inc. urges the court to adopt the claim's plain and ordinary meaning. (D.I. 44 at 5-6.) If the court determines that a means-plus-function construction is required, Plaintiff agrees with Defendants' claimed function, but disputes Defendants' inclusion of the rod contact member as a part of the corresponding structure.

There is a presumption that a term falls outside § 112, ¶ 6 where the claim does not employ the word "means." Williamson v. Citrix Online, LLC, 792 F.3d 1339, 1349 (Fed. Cir. 2015). This presumption may be overcome when the claim fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function. Id.

The claim language states in relevant part that: "a housing defining a longitudinal axis, the housing including first and second grasping members configured to grasp a portion of a bone anchor therebetween, the first and second grasping members defining a plane." '816 Patent, Claim 16; '664 Patent, Claim 8, 12, 17 (emphasis added). Defendants argue that "members" does not provide sufficient structure and that this word, like the words "mechanism" or "element," is a generic placeholder that has no specific structural meaning to a person of ordinary skill in the art. (D.I. 48 at 12); see also Williamson, 792 F.3d at 1350 ("Generic terms such as 'mechanism,' 'element,' 'device,' and other nonce words that reflect nothing more than verbal constructs may be used in a claim in a manner that is tantamount to using the word 'means' because they 'typically do not connote sufficiently definite structure' and therefore may invoke § 112, para. 6."); M.P.E.P. § 2181. On the other hand, Plaintiff contends that "one of skill in the art would understand the claim language, as explained and supported by this intrinsic evidence, as defining sufficient structure." (D.I. 44 at 7) (citing *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1023-24 (Fed. Cir. 2006)). The court disagrees with Plaintiff.

Plaintiff's argument and citation to *DePuy Spine* conflates the standard used in *Williamson* to determine the applicability of § 112, ¶ 6 with the standard used to determine whether the specification points to sufficient corresponding structure after the determination that a claim is subject to § 112, ¶ 6. The court agrees with Defendants that Plaintiff incorrectly assumes that just because a claim term has a related structure in the specification then that means that the disputed term has a definitive meaning in the art for a structure that performs the claimed function. (D.I. 48 at 9.) Such a standard would render every claim without the word "means" either outside the purview of § 112, ¶ 6 or indefinite. Defendants have articulated the correct standard which is whether, in the absence of the word "means," a person of ordinary skill in the art would understand "grasping members" to have a sufficiently definite meaning as the name for a structure that performs the function of "grasping a bone anchor." *See* (D.I. 43 at 11.) The court finds that "grasping members" does not have such meaning.

As noted above, Defendants argue "members" is a quintessential example of a generic word used to replace the word "means." *See Williamson*, 792 F.3d at 1350. Additionally, Defendants' expert, Ottie Pendleton, supported Defendants' assertion that the claim limitations including the phrase "grasping members" would not be understood by a person of ordinary skill in the art as having a sufficiently definite meaning to connote structure. (D.I. 48, Ex. H at ¶ 11.) In his declaration, Mr. Pendleton explained: "the claim term 'grasping members' as recited in the claims of the '816 and '664 Patents, does not convey a special meaning to a person of ordinary skill in the art" and that he is "not aware of any known definitions for the term 'grasping members' in the field of medical devices relating to spinal surgery." (*Id.* at ¶ 11-12.)

Plaintiff, on the other hand, argues that "the Federal Circuit has previously determined that the term 'member' does not trigger the application of 35 U.S.C. § 112, ¶ 6" and cites to Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308 (Fed. Cir. 1999) in support. (D.I. 46 at 5.) Plaintiff is correct that the Federal Circuit has held that in some instances the term "member," when coupled with modifiers or accompanied by dependent claims that add more structural context, may not trigger the application of § 112, ¶ 6. This, however, is not one of those instances. Even if the claim language imparted some structure to "grasping members" by describing that grasping member is configured, or shaped, in a way that allows it to grasp a portion of a bone anchor therebetween, "the recitation of some structure in a means-plus-function element does not preclude the applicability of § 112 (6)." Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1536 (Fed. Cir. 1991). The inclusion of modifiers "first and second" or "grasping" also does not convey sufficiently definite structure, material, or acts for achieving the specified function to bring the claim element out of the purview of § 112, ¶ 6. Williamson, 792 F.3d at 1347. Indeed, the claim language here neither provides a list of structure underlying the grasping means nor does it provide a detailed recitation of the structure for performing the function of grasping a bone anchor. Cf. Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 1317-19 (Fed. Cir. 1999) (holding that although the claim elements "eyeglass hanger member" and "eyeglass contacting member" include a function, these claim elements do not invoke 35 U.S.C. 112, sixth paragraph because the claims themselves contain sufficient structural limitations for performing these functions). Under these circumstances, the court finds that Defendants have successfully rebutted the presumption that 35 U.S.C. §112 ¶ 6 does not apply.

2. The phrase "**extending through the housing**" as used in Claim 16 of the '816 Patent and Claims 8, 12, and 17 of the '664 Patent is construed as "extending through the fixed portion of the of the rod reducing device that defines the body through passage."³

The court finds that the rod contact member's movement is necessary for the grasping members and grasping elements to perform the claimed function of "grasping a portion of the bone anchor." First, at the *Markman* hearing, the parties both agreed that the grasping members and grasping elements could not perform the act of grasping without the rod contact member. *Markman* Hr'g 32:21-24 ("Without the rod contact member shown in blue on Slide 40, there would be nothing to push the arms together. They would just dangle."); *Markman* Hr'g 17: 7-12. (Q: "How does the invention grasp? How does this device that we are looking at, Figure 5, grasp the anchor if not but for 20 being screwed down on top?" A: "In this embodiment, it's the rod contact member, Your Honor, that when it comes down it will bring these grasping arms together.").

Plaintiff's construction also ignores the additional context of the specification that explains the features of the device, like the rod contact member, that actually allows the invention to perform the claimed grasping function. Indeed, Figures 1, 2, 4, and 5 illustrate that the rod contact member's movement is required for the grasping members to grasp by "forc[ing] the opposing grasping members 64, 66 inward toward one another to the end that the opposing first and second screw grasping elements 80, 82 will be forced inward to make grasping contact with complimentary configured bone screw head." '816 Patent, col. 6, ll. 38-40; *Id.*, Figures 1-2, 4-5. In addition, the specification makes clear to the court that rod contact member's action of forcing the grasping members towards each other leads the grasping members and the grasping elements to grasp a portion of the bone anchor. Consequently, there is a clear link between the rod contact member and the grasping function. Therefore, the court finds that grasping members 64 and 66, grasping elements 80 and 82 and the rod contact member 20 are the corresponding structures necessary to perform the claimed function of "grasping a portion of the bone anchor."

³ Plaintiff argues that the instant claim phrase should be given its plain and ordinary meaning. (D.I. 84 at 7.) Alternatively, Plaintiff suggests that the claim phrase means "extending entirely through the housing." (D.I. 44 at 9.) Defendants assert that the claim phrase means "extending through the entire length of the rigid casing of the rod

Next, the court must identify the claimed function. *Williamson*, 792 F.3d at 1351; *see also Lockheed Martin Corp. v. Space Systems/Loral, Inc.*, 324 F.3d 1308, 1318 (Fed. Cir. 2003) ("The first step in analyzing a claim written in means-plus-function form is to identify the claimed function."). Then, the court must determine the corresponding structure disclosed in the specification. *Williamson*, 792 F.3d at 1351-52.

Here, the parties agree that the function is "grasping a portion of a bone anchor." (D.I. 84 at 6.) The crux of the remaining disagreement is whether the specification describes the rod contact member, in addition to the grasping members and grasping elements, as necessary to perform the function of "grasping a portion of a bone anchor." (*Id.*) "A structure disclosed in the specification qualifies as a 'corresponding structure' if the specification or the prosecution history 'clearly links or associates that structure to the function recited in the claim." *Noah Sys., Inc. v. Intuit Inc.*, 675 F.3d 1302, 1311 (Fed. Cir. 2012) (quoting *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed. Cir. 1997)). The structure identified in the written description must be necessary to perform the claimed function. *Micro Chem., Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1258 (Fed. Cir. 1999) ("§ 112, ¶ 6 requires both identification of the structure in the written description necessary to perform that function.").

Plaintiff argues that Defendants find no support in the intrinsic or extrinsic record for the addition of the rod contact member as a corresponding structure. (D.I. 44 at 8.) In contrast, Defendants contend that without the rod contact member, the grasping members and grasping elements would not be able to perform the function of grasping a portion of a bone anchor. *Markman* Hr'g 32:21-24. The court agrees with Defendants.

reducing device." (D.I. 43 at 16.) The court construes the claim as "extending through the fixed portion of the rod reducing device that defines the body through passage."

Plaintiff and Defendants disagree on the construction of the term "housing." Plaintiff contends that "housing," like the rest of the claim phrase, should be given its plain and ordinary meaning. (D.I. 84 at 2.) Defendants, however, argue that "housing" means "rigid casing," as derived from a dictionary definition of the term. (D.I. 43 at 17) ("Housing' is defined by the Oxford English Dictionary as a 'rigid case or cover that encloses and protects . . . any [] mechanism or piece of apparatus.""). Plaintiff argues that Defendants' construction is confusing because it defines housing in a way that is not supported by the Patents' specification. (D.I. 44 at 10.)

It is well settled that the claim language and the specification are the best tools to aid in the construction of a claim. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The claim language reads in relevant part: "A rod reducing device comprising: . . . a rotatable member extending through the housing along the longitudinal axis." '816 Patent, Claim 16; '664 Patent, Claim 8, 12, 17. While the specification does not use the word "housing," both Plaintiff and Defendants agree that "housing" refers to the part of the invention labeled as the Fork Assembly body. *Markman* Hr'g 76:5-7 ("We appear to be in agreement with respect to the housing, and that that is referring to the same piece on the figures"); *Markman* Hr'g 70:4-5 ("The only portion that this rotatable member extends the entire length of is this rigid portion of the fork assembly"). The specification explains that "the fork assembly body 42 defines a body through passage 44 that is sized and complimentary configured to permit passage of the elongated threaded screw shaft 16 of the screw jack mechanism 12." '816 Patent, col. 5, ll. 7-11; (D.I. 44 at 9). When the invention is in use, the rotatable member passes through a "body through passage" that is created by an opening in the Fork Assembly body. *Markman* Hr'g 73:1-5; *see also* (D.I. 43 at 17.) Therefore, the court finds that "housing" should be construed as "the fixed portion of the rod reducing device that defines the body through passage."

Next, the parties disagree on whether and where to insert the words "entire" or "entirely." Plaintiff proposes its alternate construction of "extending entirely through the housing," but offers no explanation for its inclusion of the word "entirely." (D.I. 44 at 9.) In contrast, Defendants contend that "extending through" means "extending through the entire length of." (D.I. 43 at 16.) Because the '816 Patent indicates that the threaded screw shaft passes "through" the body through passage, Defendants' proposed construction reflects the dictionary definition of "through" as "indicat[ing] movement into at one side or point and out at another and especially opposite of." (D.I. 43 at 16); *Through, Webster's New Explorer Encyclopedia* (2006). The court finds Defendants' argument unpersuasive.

At the *Markman* hearing Defendants stated that their construction was premised upon their belief that the jury would understand "housing" to include not only the fork assembly, but also the elongated grasping members. *Markman* Hr'g 65:1-22. Defendants' argument is rendered moot by the court's finding as to the meaning of "housing." Further, both parties improperly assume that "through" necessarily means in one end and completely out the other end. The specification's descriptions and illustrations demonstrate that that is an incorrect assumption.

The inclusion of the term "entirely" or "entire" would exclude the preferred embodiments and would be read out portions of the specification. Figure 3B shows a cross-sectional view of the device in its fully activated configuration after the rotational member has passed through the fork assembly body. '816 Patent, col. 3, ll. 27-28. Contrary to both parties' arguments, Figure 3B does not show that the rotatable member's threaded screw shaft passes "entirely through" or "through the entire length" of the housing. '816 Patent, FIG 3B. Instead, the threaded shaft of the rotatable member is shown to still be within the lower portion of the body through passage of the fork assembly member after the device is fully deployed. *Id.* The specification notes that there is a portion of the body through passage that is "provided with complimentary threads to the threads of the elongated threaded screw shaft" serves to "hold the threaded shaft 16 in its place and so provide a position securing effect that can be released at will by the user." '816 Patent, col. 5, ll. 14-17. A construction that would suggest that the screw shaft passes *entirely* through or through the *entire length* of the housing would not accord with the claim language or the specification. Therefore, the court rejects both Plaintiff's and Defendants' constructions, and construes the entire claim phrase to mean, "extending through the fixed portion of the rod reducing device that defines the body through passage."

3. The term "translatable" as used in Claim 16 of the '816 Patent and Claims 8, 12, and 17 of the '664 Patent is construed as "capable of downward motion along the longitudinal axis."⁴

The claim language states that "a rod contact member positioned at a distal end of the rotatable member, the rod contact member *translatable* along the longitudinal axis in response to the rotation of the rotatable member about the longitudinal axis." '816 Patent, Claim 16 (emphasis added). Plaintiff, in support of its argument for a plain and ordinary meaning construction, submitted a declaration of its expert Troy D. Drewry. (D.I. 47.) Mr. Drewry explained that:

In my opinion, a person of ordinary skill in the art would readily understand the term 'translatable' within the context of the 816 and 664 patents as having a plain and ordinary meaning, and would not require any additional construction. The plain and ordinary meaning as understood by one of ordinary skill in the art would be consistent with K2M's alternate proposal of 'movable,' which in the context of the 816 and 664 patents is described and expressly used in the asserted claims as being moveable along 'the longitudinal axis.'

(*Id.* at ¶ 7.)

Plaintiff also claims that its alternate construction is supported by the specifications' description of the rod contact member's "downward" motion along the length of the device and, therefore, "translatable" would be understood to encapsulate that specific type of movement. (D.I. 43 at 10); '816 Patent, col. 6, ll. 29-42

Alternatively, Defendants argue that construing "translatable" as "moveable" would ignore the inference that the two different terms used in the Patents have two different meanings. (D.I. 43 at 15.) Instead, Defendants claim that "translatable" specifically describes the rod contact member's "elevator type movement, where everything moves along parallel paths." *Markman* Hr'g 56:12-13. Defendants propose that the court adopt the dictionary definition of "translation" meaning "capable of motion in which all the points in the object follow parallel paths." (D.I. 48 at 15); *Markman* Hr'g 56:18-25.

First, the court declines to consider Defendants' extrinsic evidence. "In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996). The court finds that this is one of those circumstances.

As counsel for Plaintiff aptly stated, "this is not an extremely complicated construction. . . OrthoPediatrics is trying to make this very complicated." *Markman* Hr'g 60:8-10. The result of the rotatable member's rotational movement, like the movement of any screw-like object, is to "force[] downward" or "pass[] downward" both the rotatable member and the attached rod contact member. *Id.*, col. 6, ll. 29-42. The downward movement, or as Defendants appropriately describe as "elevator type movement," activates the invention and causes the rod contact member to pull the grasping members inward and grasp a portion of the bone anchor. *Id.* Given the claim language and the specification's description of the rod contact member's motion, the court finds that construing the term as "moveable" would be too broad. Thus, the court finds that the construction of "capable of downward motion along the longitudinal axis" provides a more accurate description of the claim term's meaning within the context of the claim language and specification of the Patents.

⁴ Plaintiff's argument is twofold. First, Plaintiff argues that "translatable" needs no construction because its meaning would be understood by a person of ordinary skill in the art. (D.I. 44 at 10.) Second, Plaintiff argues that if the court finds that the claim requires construction, the court should adopt its alternate construction of "moveable." (D.I. 84 at 2.) Defendants contend that the disputed claim term means "capable of motion in which all the points in the object follow parallel paths." (*Id.*) The court finds that "translatable" means "capable of downward motion along the longitudinal axis."

4. The phrase "grasping members defining a plane" as used in Claim 16 of the '816 Patent and Claims 1, 8, 12, 17 of the '664 Patent is construed as "a plane defined by any three non-collinear points on the grasping members, where two of the points are on one grasping member and the other point is on the other grasping member."⁵

The '816 Patent

5. The phrase "grasping feature engageable with a portion of a bone anchor" as used in Claim 18 of the '816 Patent is construed pursuant to 35 U.S.C. § 112, ¶ 6. The claimed function is "engaging with a portion of a bone anchor." The corresponding structure is "grasping elements 80, 82."⁶

The '664 Patent

6. The phrase "first and second elongated grasping members" as used in Claim 1 of the '664 Patent is construed pursuant to 35 U.S.C. § 112, ¶ 6. The claimed

⁵ The parties have agreed on the construction of this term. (D.I. 84 at 4.)

⁶ The parties dispute whether this claim is subject to § 112, ¶ 6. (D.I. 84 at 8.) Like the claim limitation above, *supra* note 1, this claim limitation does not employ the word "means." Again, there is a presumption that § 112, ¶ 6 does not apply. Defendants' expert, Mr. Pendleton, provided that "grasping feature," like "grasping members," "does not convey a special meaning to a person of ordinary skill in the art." (D.I. 47, Ex. H at ¶ 13-14.) Plaintiff presented no expert testimony of their own to contradict Defendants'. In addition, "feature," like "members," is a word that is used simply to replace the word "means." See Williamson, 792 F.3d at 1350. Thus, for reasons similar to the court's reasoning supra note 1, the court finds that Defendants have successfully rebutted the presumption that § 112, ¶ 6 does not apply.

The parties agree on the corresponding structure as "grasping elements 80, 82." (D.I. 84 at 8.) The parties' main point of contention is whether to include the word "with" in the claimed function. (*Id.*) When determining the function of a means-plus-function claim, the court first looks to the claim language. *Lockheed Martin Corp.*, 324 F.3d at 1319. Claim 18 states in relevant part: "The rod reducing device of claim 16, wherein respective distal ends of the first and second grasping members include at least one grasping feature engageable *with* a portion of a bone anchor." '816 Patent, Claim 18 (emphasis added). Defendants offered no evidence or argument to support their removal of the word "with" from the claimed function that Plaintiff adapted straight from the claim language itself. Likewise, the court sees no reason to exclude "with." Thus, the court finds that the function is "engaging with a portion of a bone anchor."

function is "grasping a portion of a bone anchor." The corresponding structure is "grasping members 64, 66, grasping elements 80, 82; and rod contact member 20."⁷

7. The phrase "screw grasping element" as used in Claim 1 of the '664 Patent is construed pursuant to 35 U.S.C. § 112, ¶ 6. The claimed function is "grasping a screw." The corresponding structure is "grasping elements 80, 82."⁸

⁸ Plaintiff argues that the term "screw grasping element" is readily understood by a person of ordinary skill in the art and does not require construction. (D.I. 44 at 16.) Defendants argue that the claim language should be construed pursuant to § 112, ¶ 6 with the function being "grasping a screw" and the corresponding structure being "grasping elements 80, 82." (D.I. 84 at 5.) Plaintiff proposes that if the court adopts the means-plus-function construction as suggested by Defendants, Plaintiff agrees with Defendants' corresponding structure, but construes the claimed function as "grasping a portion of a bone anchor." (*Id.*)

The claim phrase at issue is: "a body including first and second elongated grasping members extending therefrom, each of the first and second elongated grasping members having a *screw grasping element*." '664 Patent, Claim 1 (emphasis added). Here, the court finds that "screw grasping element," like "grasping members" *supra* note 1 and 7 and "grasping feature" *supra* note 6, recites a function without sufficiently identifying the structure and, thus, the claim language is subject to § 112, \P 6.

⁷ Plaintiff and Defendants disagree on whether this claim should be construed as a means-plus-function claim. The court's reasoning mirrors that of "grasping members," *supra* note 1. Despite the use of modifiers, "grasping members" is set forth by the function it performs as opposed to the specific structure, material, or acts that perform the function. The court finds similarly for "first and second elongated grasping members." Thus, § 112, ¶ 6 is applicable.

The parties agree that the claimed function is "grasping a portion of a bone anchor." (D.I. 84 at 9.) The parties disagree on the corresponding structure. Plaintiff argues that the only corresponding structure is "grasping members 64, 66." (D.I. 44 at 13.) Defendants contend that the corresponding structure includes "grasping members 64, 66; grasping elements 80, 82; and rod contact member 20." (D.I. 48 at 8.) The court agrees with Defendants.

[&]quot;Structure disclosed in the specification qualifies as 'corresponding structure' if the intrinsic evidence clearly links or associates that structure to the function recited in the claim." *Williamson*, 792 F.3d at 1352; *supra* n.1. Plaintiff argues that the grasping elements and the rod contact member are claimed elsewhere and their inclusion in the structure of the instant claim would make the rest of the claim language redundant and superfluous. (D.I. 44 at 15.) Regardless of the effect on the rest of the claim language, the standard for determining corresponding structure of a means-plus-function claim is that the structure must be adequate to perform the claimed function. *Williamson*, 792 F.3d at 1351-52. As discussed *supra* note 1, the necessary structure for performing the grasping function includes grasping members 64 and 66, grasping elements 80 and 82 and the rod contact member. Thus, the court adopts Defendants' means-plus-function construction.

The parties agree on the corresponding structure as "grasping elements 80, 82," but disagree on the claimed function. (D.I. 84 at 5.) Defendants argue that the function is "grasping a screw." (*Id.*) Plaintiff, on the other hand, argues that Defendants' function attempts to limit the claim in such a way that is not supported by the intrinsic evidence. (D.I. 44 at 16.) As previously noted *supra* note 1, the court employs ordinary rules of claim construction to determine the function of a means-plus-function claim limitation. *Lockheed Martin Corp.*, 324 F.3d at 1319. The claim language in this case ends the inquiry; the function of the "screw grasping element" is simply "grasping a screw." Therefore, the court adopts Defendants' means-plus-function construction.

UNITED STATES DISTRICT JUNGE

Dated: May_3, 2018