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

ARTHRODESIS TECHNOLOGY LLC.,	)
Plaintiff,	)
v.	) C.A. No. 21-11 (MN)
WRIGHT MEDICAL TECHNOLOGY,	)
Defendant.	)

#### **MEMORANDUM ORDER**

At Wilmington, this 26th day of August 2022:

IT IS HEREBY ORDERED that the claim terms of U.S. Patent No. 6,579,293 ("the '293 patent") with agreed-upon constructions are construed as follows (see D.I. 64 at 2):

- 1. The preambles of claims 1, 6, and 11 are limiting;
- 2. "ankle arthrodesis" is "a surgical procedure to fuse ankle bones." (Claims 1, 6, and 11);
- 3. "tibio-calcaneal arthrodesis" means "fusion of the tibia and calcaneal bones through a surgical procedure." (Claim 1);
- 4. "a sealed package" is "an unopened package." (Claims 3 and 7);
- 5. "said screw is packaged in a manner suited for a surgical implant and labeled in a manner which indicates that it is a medical device intended for ankle arthrodesis" means "said screw is packaged in a manner suited for a surgical implant and the package is labeled in a manner which indicates that the screw is a medical device intended to establish ankle arthrodesis." (Claim 6).

The Court heard arguments for the disputed terms on July 8, 2022. (D.I. 105). As announced in a teleconference held on July 12, 2022 (D.I. 106), IT IS HEREBY ORDERED that the disputed claim terms of the '293 Patent are construed as follows:

- 1. "being properly sized and suited for surgical insertion" means "sized to allow and otherwise appropriate for surgical insertion in a patient." (Claims 1 and 6);
- 2. "so that the tip enters a tibial bone to establish" means "insertion of the tip into a tibial bone establishes." (Claim 1);
- 3. "an oblique hole passing through the shaft" means "a hole positioned at a slanted angle allowing the screw to pass through the shaft." (Claim 1);
- 4. "allows the screw to establish compression of the tibial bone against the calcaneal bone when the screw is rotated" (claim 1) and "establish compression of the tibial bone against the calcaneal bone when the screw is rotated" (claim 6) means "the rotation of the screw causes contact between and compression of the tibial bone against the calcaneal bone";
- 5. "wherein said angle is within a range of about 30 to about 50 degrees" is not indefinite. (Claim 2);
- 6. "in a region proximate to the base," "proximal," and "proximate to the base" all include "proximal" or "proximate," which means "near." (Claims 4, 5, 8, and 9);
- 7. "a jig base component which will be positioned adjacent to a bottom surface of a patient's heel during a surgical operation" is not indefinite and means "a jig base component which will be positioned sufficiently close to a bottom surface of a patient's heel to allow for adjoinment during surgery." (Claim 11);
- 8. "a jig arm component which will be positioned roughly parallel to a patient's tibia bone during a surgical operation" means "a jig arm component sufficiently parallel to a patient's tibia bone to allow for drilling and proper alignment with screws." (Claim 11);
- 9. "means for engaging the vertical rod in a manner which: (i) allows controlled alignment of. . .; (ii) allows controlled rotation of . . .; and (iii) allows controlled alignment of . . ." means "a rotatable shaft having external threads at an upper end, a sleeve having a set of alignment fins at an upper end, and a knurled surface or shaped flattened head, wherein the rotatable shaft is rotatable within the sleeve and equivalents thereof." (Claim 11).

The parties briefed the issues (D.I. 91) and submitted an appendix containing intrinsic and extrinsic evidence. (D.I. 92). The Court carefully reviewed all submissions in connection with

the parties' contentions regarding the disputed claim terms, heard oral argument (*see* D.I. 105) and applied the following legal standards in reaching its decision.

## I. <u>LEGAL STANDARDS</u>

#### A. Claim Construction

"[T]he ultimate question of the proper construction of the patent [is] a question of law," although subsidiary fact-finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015). "[T]he words of a claim are generally given their ordinary and customary meaning [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (internal citations and quotation marks omitted). Although "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Id.* at 1314. "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted).

The patent specification "is always highly relevant to the claim construction analysis . . . [as] it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. "Even when the specification describes only a single embodiment, [however,] the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom* 

Servs., Inc. v. Stryker Corp., 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotation marks omitted) (quoting Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004)).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence, . . . consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id*.

In some cases, courts "will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. Expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Phillips*, 415 F.3d at 1318. Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, although extrinsic evidence "may be useful to the court," it is "less reliable" than intrinsic evidence, and its consideration "is unlikely

to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc.* v. *Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

#### **B.** Indefiniteness

"The primary purpose of the definiteness requirement is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, *e.g.* competitors of the patent owner, can determine whether or not they infringe." *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779-80 (Fed. Cir. 2002) (citing *Warner-Jenkinson Co. v. Hilton-Davis Chem. Co.*, 520 U.S. 17, 28-29 (1997)). Put another way, "[a] patent holder should know what he owns, and the public should know what he does not." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 731 (2002).

A patent claim is indefinite if, "viewed in light of the specification and prosecution history, [it fails to] inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). A claim may be indefinite if the patent does not convey with reasonable certainty how to measure a claimed feature. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015). But "[i]f such an understanding of how to measure the claimed [feature] was within the scope of knowledge possessed by one of ordinary skill in the art, there is no requirement for the specification to identify a particular measurement technique." *Ethicon Endo–Surgery, Inc. v. Covidien, Inc.*, 796 F.3d 1312, 1319 (Fed. Cir. 2015).

Like claim construction, definiteness is a question of law, but the Court must sometimes render factual findings based on extrinsic evidence to resolve the ultimate issue of definiteness. *See, e.g., Sonix Tech. Co. v. Publications Int'l, Ltd.*, 844 F.3d 1370, 1376 (Fed. Cir. 2017); *see also Teva*, 135 S. Ct. at 842-43. "Any fact critical to a holding on indefiniteness . . . must be proven by the challenger by clear and convincing evidence." *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1366 (Fed. Cir. 2003); *see also Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1338 (Fed. Cir. 2008).

### II. THE COURT'S RULING

The Court's ruling regarding the disputed claim terms of the '293 patent were announced during a teleconference on July 12, 2022 as follows:

At issue we have nine disputed terms in one patent, U.S. Patent No. 6,579,293. I am prepared to rule on each of the disputes. I will not be issuing a written opinion, but I will issue an order stating my rulings. I want to emphasize before I announce my decisions that although I am not issuing a written opinion, we have followed a full and thorough process before making the decisions I am about to state. I have reviewed the patent. I have also reviewed the portions of the prosecution history, the expert declarations, dictionary definitions and the other references submitted. There was full briefing on each of the disputed terms and we had argument last week. All of that has been carefully considered.

As to my rulings, I am not going to read into the record my understanding of claim construction law. I have a legal standard section that I have included in earlier opinions, including somewhat recently in *CAO Lighting, Inc. v. General Electric Co.*, C.A. No. 20-681 (MN). I incorporate that law and adopt it into my ruling today and will also set it out in the order that I issue.

The first disputed term is "being properly sized and suited for surgical insertion" in claims 1 and 6. Plaintiff proposes the construction "sized to allow for surgical insertion in a patient." Defendant proposes: "properly sized and labelled only for" surgical insertion. Here, although Plaintiff ignores the words "suited for" in its proposal, I think that Plaintiff's proposal is more correct and more consistent with the claim language.

Defendant argues that the specification and the prosecution history support its construction. In the specification, Defendant points to a reference to labelling and to the statement "this invention claims a screw with certain traits . . . which 'is packaged in a manner suited for a surgical implant and labelled in a manner which indicates that it is a medical device intended for ankle arthrodesis." [1] Although the quoted portion addresses labeling, f it does not make clear that suited for means labeling. To the contrary the packaging referenced must be both suited for and labelled. In any event, the claims at issue (claims 1 and 6) refer to various components being sized and suited for surgical insertion, [2] not the packaging.

During prosecution, the applicant also focused on labelling, stating that "the sole and explicitly limited used for the current invention is to enable a certain type of ankle repair, known as ankle arthrodesis . . ."[3] and noting that the Medical Devices Act, a federal statute, requires labelling of items to be inserted into a patient during surgery. The applicant then argued that "a device that is going to be inserted into a patient, during surgery, must – absolutely must – be accompanied by labelling information which discloses what the device is," and added a few sentences later that "a surgical rod as covered by the claims, which is designed for ankle implantation, must – absolutely must – be sold in a package which indicates that the rod is to be used for an ankle repair." [4] Again, the language references the packaging requirement, rather than the components of the device as claimed.

Accordingly, I will construe the first term to mean "sized to allow and otherwise appropriate for surgical insertion in a patient." And to be clear that I am not construing this term to require labeling of the parts of the device claimed.

The second disputed term is "so that the tip enters a tibial bone to establish," which is present in claim 1. Plaintiff proposes that the term be construed "so the tip of the rod enters the tibial bone to allow

<sup>(&#</sup>x27;293 patent, 9:1-5; *see also* cl. 6 ("said screw is packaged in a manner suited for a surgical implant and labelled in a manner...). In this order, all citations to a patent are to the '293 patent).

<sup>&</sup>lt;sup>2</sup> (Cl. 1a ("rod being properly sized and suited"); cl. 1b ("screw being properly sized and suited"); cl. 6 ("threaded tip region being properly sized and suited")).

<sup>&</sup>lt;sup>3</sup> (D.I. 92, Ex. S at 2).

<sup>&</sup>lt;sup>4</sup> (*Id*).

for compression" and Defendant would have this term read "so that insertion of the tip into a tibial bone is sufficient to establish."

First, some context. In claim 1, the limitation containing this phrase reads: "at least one tibio-calcaneal rod having a tip, a shaft, and a base, said rod being properly sized and suited for surgical insertion through a calcaneal bone so that the tip enters a tibial bone to establish tibio-calcaneal arthrodesis."<sup>[5]</sup>

Here, I think that Defendant's construction better aligns with the language of the claim and the intrinsic evidence. As I just noted, the claim language states that the "tip enters a tibial bone to establish tibio-calcaneal arthrodesis." [6] Establish means "to cause or bring into being" and the specification uses that word in various contexts consistent with that ordinary meaning. [8] The parties agreed that tibio-calcaneal arthrodesis means "fusion of the tibia and calcaneal bones through a surgical procedure." Thus, the ordinary meaning of the term is that the tip enters the bone during the surgical procedure to cause the fusion claimed.

This is supported by the specification, which explains that immobilizing the ankle joint requires "inserting one or more rigid rods or pins . . . into one or more bones in the ankle, and in the 'hindfoot' portion of the foot . . . The medical term for this type of permanent bone fixation is 'arthrodesis.'"<sup>[9]</sup> Elsewhere, the specification explains that if the vertical rod is used by itself to immobilize the ankle joint, the fixation is called "tibio-calcaneal arthrodesis."<sup>[10]</sup>

Thus, Plaintiff's proposal "allow for compression" is inconsistent with the plain meaning of the claim term and inconsistent with the

<sup>&</sup>lt;sup>5</sup> (11:35–39).

<sup>&</sup>lt;sup>6</sup> (11:38–39).

<sup>&</sup>lt;sup>7</sup> (See D.I. 105 (Tr.) at 28-29).

<sup>(7:25-26 (&</sup>quot;This will help establish compression . . ."); 2:45–49 (the anterior tip . . . of the horizontal pin is slightly lower than the posterior tip . . . This establishes an obtuse angle between the rod and the pin[.]"); 8:52–55 ("The layers can be sealed to each other by means of a peripheral seal, to establish a watertight and airtight enclosure that maintains sterility of the components inside the sealed envelope.")).

<sup>&</sup>lt;sup>9</sup> (1:13–20).

<sup>&</sup>lt;sup>10</sup> (2:33–34).

specification, both of which require more than compression.<sup>[11]</sup> They require establishing arthrodesis. I will adopt Defendant's construction and construe the term to mean "insertion of the tip into a tibial bone establishes." I don't think we need to include sufficient in there – that seems redundant.

The fifth term in the briefs is "wherein said angle is within a range of about 30 to about 50 degrees" in claim 2. There is some asserted relevance of this term to arguments made about the third briefed term, [12] so I will address it before I get to the third. Plaintiff proposes the construction "wherein the angle of the oblique hole is within a range of about 30 to about 50 degrees." Defendant argues that this term is indefinite because claim 1 (on which claim 2 depends) includes two "angles," and it is not possible to tell which of these is referred to in claim 2.

The two angles in claim 1 are: "said screw being properly sized and suited for surgical insertion *at an angle* through a calcaneal bone ..."<sup>[13]</sup> and "wherein the oblique hole passes through the shaft of the rod *at an angle* with respect to the shaft."<sup>[14]</sup> The question is whether the patent informs, with reasonable certainty, which of these angles is being referred to by claim 2.

Plaintiff argues that "said angle" clearly refers to the angle of the oblique hole, as the specification states that "[f]or most patients, the preferred angle between rod and screw will usually fall within a range of about 30 to 50 degrees . . . Accordingly, vertical rods can be provided with oblique holes at various angles, ranging from about 30 degrees to about 50 degrees, and a surgeon can choose a vertical rod having an optimal angle for a particular patient." [15] Defendant denies that the specification provides clarity, as, in Defendant's view, the specification refers to both an angle of a screw and an

The specification does allow for additional steps (*see*, *e.g.*, 5:42–46) which describe affixing a rod with screws, but these steps are referred to as important for "caus[ing] the fixation of the two bones to be more secure and less subject to problems." *See* 7:26–30.

Defendant believes term five is indefinite. Plaintiff contends that term five, which is present in claim two, is not indefinite because it refers to the angle of the oblique hole in claim one, which is the subject of the third disputed term. Plaintiff's definiteness argument relies in part on claim differentiation.

<sup>13 (11:44–49 (</sup>emphasis added)).

<sup>14 (11:50–51 (</sup>emphasis added)).

<sup>&</sup>lt;sup>15</sup> (6:31–46).

angle of an oblique hole that passes through the shaft of the rod as being within 30 to 50 degrees.

During the argument, we had some colloquy about whether the measurement aspect of claim 2, *i.e.* that the angle is "measured between the tip of the rod and the tip of the screw" added clarity. I don't know that we reached a definitive answer. But I do know that for a claim to be held invalid for indefiniteness, there must be clear and convincing evidence.<sup>[16]</sup> And at this time, I find that Defendant has not met its burden to show that this term is indefinite. Should there still be a disagreement regarding this term in the future, Defendant may raise the issue as appropriate after full fact and expert discovery.

Now, back to the third term, which is "an oblique hole passing through the shaft" in claim 1. Plaintiff proposes that the "oblique hole passing through the shaft" means "a hole positioned at a slanted angle allowing the screw to pass through the shaft." Defendant proposes that that means "a hole passing through the shaft at an angle of between 30 to 50 degrees."

Here, I agree with Plaintiff. The specification describes the "oblique" hole as having a "slanted angle" or being a "slanted hole" in different places. [17] And this description is consistent with the ordinary meaning of "oblique." [18] Defendant's proposal is based on an embodiment describing a "preferred angle... within a range of about 30 to about 50 degrees." That reference to a preference is insufficient to require reading that angle in an embodiment into the claim. Accordingly, I adopt Plaintiff's construction.

The next dispute involves two similar terms relating to compression: "allows the screw to establish compression of the tibial bone against the calcaneal bone when the screw is rotated" in claim 1 and "establish compression of the tibial bone against the calcaneal bone when the screw is rotated" in claim 6. Plaintiff proposes that the first term means "allows rotation of the screw to pull the tibial bone toward the calcaneal bone" and the latter means "pull the tibial bone toward the calcaneal bone as the screw is rotated." Defendant proposes that both terms mean "causes compression of the tibial

See Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 912 n. 10 (invalidity defenses must be proved by "clear and convincing evidence") (citing *Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. 91, 95 (2011)).

<sup>17 (3:45–54; 4:6–8; 5:49–57; 6:24–26).</sup> 

<sup>(</sup>See D.I. 92, Exs. A, D, F, G, H (dictionary definitions of 'oblique.')).

bone in the direction of and in contact with the calcaneal bone as a result of the rotation of the screw."

Notwithstanding all the words in Defendant's proposal, the crux of this dispute is whether the claim requires causing contact and compression between the tibial bone and the calcaneal bone or simply pulling the tibial bone toward the calcaneal bone. Here, I think that the claims require more than pulling the bones some undetermined amount toward each other.

First, that more than "pulling" is required seems clear from the language of the claims themselves, which requires "compression of the tibial bone against the calcaneal bone."<sup>[19]</sup> It is also supported by the specification. At column 10, lines 40-48, it states:

substantial pressure preferably should be placed on the horizontal base 232 of the jig 230, to press the calcaneal bone firmly against the lower end of the tibial bone. Compression of the two bones against each other during the drilling step will help align the holes in the calcaneal and tibial bones properly, . . . .

Similarly, at column 7, lines 63-67, it states that if a particular screw design is used, "the screw will cause the lower end of the tibial bone to be pulled farther toward (and therefore compressed harder against) the upper surface of the calcaneal bone." These disclosures contemplate the tibial and calcaneal bone being pressed against each other.

Plaintiff contends that the specification permits the invention to be used on patients who have a talus bone, pointing to column 2, line 57 through column 3, line 12 and Figure 2.<sup>[20]</sup> Plaintiff argues that if a patient has a talus bone, the tibial and calcaneal bones will not be in contact. That may be so, but when that is the case, the patentee knew how to say that. For example, at column 4, lines 10-13, the

When an object is "compressed against" another object, the two objects are in contact. Indeed, Plaintiff itself submitted dictionary definitions that support this view and cut against its interpretation. For example, Random House-Webster's College Dictionary defines "compress" as "to press or squeeze together; force into less space" and Merriam-Webster defines compress as "to press or squeeze together." (D.I. 92, Exs. I, J).

Contrary to Plaintiff's argument, the specification explains that "FIG. 2 is a side view of the rod-and-screw assembly of this invention, showing vertical rod and oblique screw inside the major bones of an ankle joint. In this drawing, the posterior portion of the talus bone has been degraded, *and no longer separates the tibia from the calcaneum*." (4:25–30 (emphasis added)).

specification refers to compression of the lower end of the tibia bone against the talus and/or calcaneum. In the claims, Plaintiff did not refer to the talus.

So I will construe these terms to mean "the rotation of the screw causes contact between and compression of the tibial bone against the calcaneal bone."

Next we have some related terms: "in a region proximate to the base," "proximal," and "proximate to the base," which are in claims 4, 5, 8 and 9. Each term uses some form of the word "proximate" to describe the location of a screw's external threads relative to the base of the screw. Plaintiff's position has changed a bit. In its opening brief, Plaintiff asserted that the term did not need to be construed, but proposed "sufficiently close to the base to allow for the base to be secured but still separate" to the extent that a construction were needed. In its reply brief, Plaintiff argued that "the Court should either conclude that there is no need to define this term or should adopt the plain and ordinary meaning of 'proximate,' which is 'near.'" Defendant on the other hand proposed "close to the base and spaced apart from the threaded tip region."

Defendant primarily relies on Figure 4, a depiction of a screw with external threads that are close to the base and separated from a threaded tip region. It argues that Figure 4 supports its construction because all of the claims that include the disputed terms have screws with both external threads and a threaded tip region. Here, I think that Defendant is improperly reading an embodiment into the That is particularly inappropriate here, where the specification states that "threads can cover all or most of the entire surface of the oblique screw."[21] I think that "near" accurately depicts the claim as written and discussed in the specification, and I will construe "proximate" or "proximal" in these terms to mean "near."

Next, we have the seventh and eighth briefed terms. The parties argued these together and I will address them together. Term seven is "a jig base component which will be positioned adjacent to a bottom surface of a patient's heel during a surgical operation." Term eight is "a jig arm component which will be positioned roughly parallel to a patient's tibia bone during a surgical operation." Both terms are in claim 11, which covers an apparatus. Defendant contends that these terms are indefinite because they are

<sup>21</sup> (7:21-24).

method steps in an apparatus claim. Plaintiff disagrees and proposes constructions. [22]

Here, I agree with Plaintiff that neither of these terms is indefinite. I do not think that these claims are like those in IPXL Holdings, L.L.C. v. Amazon.com, Inc. [23] Functional language describing components of claims does not inject a method step into a system or apparatus claim when it represents capabilities of the component. [24] I think that is what we have here. The terms at issue do not require user action, but rather are addressing what the apparatus is configured to do. In claiming a system with "a jig base component which will be positioned adjacent to a bottom surface of a patient's heel during a surgical operation," the claim covers what the jig base component is configured to do, and not what a user must do. For term eight, similarly, a "jig arm component which will be positioned roughly parallel to a patient's tibia bone during a surgical operation" does not command user action, but instead describes the term's structure by reference to something that it is configured to do. Read together, these terms describe the structure of the claimed alignment jig – the alignment jig must have a jig base that is positioned to be adjacent to a patient's heel while the jig arm is parallel to a patient's tibia bone, and vice versa.

Accordingly, I find that Defendant has not demonstrated by clear and convincing evidence that the disputed terms are indefinite, and as Defendant did not really dispute Plaintiff's proposed constructions for terms seven and eight, I will adopt those proposals.

The final term is in element (d) of claim 11. The parties agree that the "means for engaging the vertical rod" is a means-plus-function element. The dispute centers on what structure is disclosed in the specification. Plaintiff proposed "a rotatable shaft having external threads at an upper end, a sleeve having a set of alignment fins at an upper end, and a knurled surface or shaped flattened head to allow for gripping and rotating of the shaft during operation, wherein the

Plaintiff proposes that term seven be construed as "a jig base component which will be positioned sufficiently close to a bottom surface of a patient's heel to allow for adjoinment during surgery." (D.I. 91 at 55). For term eight, Plaintiff proposed "a jig arm component sufficiently parallel to a patient's tibia bone to allow for drilling and proper alignment with screws." (*Id.* at 68).

<sup>&</sup>lt;sup>23</sup> 430 F.3d 1377 (Fed. Cir. 2005).

See, e.g., MasterMine Software, Inc. v. Microsoft Corp, 874 F.3d 1307, 1315 (Fed. Cir. 2017); Microprocessor Enhancement Corp. v. Texas Instruments Inc., 520 F.3d 1367 (Fed. Cir. 2008).

rotatable shaft is rotatable within the sleeve." Defendant proposed "a rod coupling bolt comprising a rotatable shaft having external threads at an upper end, a sleeve having a set of alignment fins at an upper end, and a knurled surface or shaped flattened head to allow for gripping and rotating of the shaft during operation to loosen or tighten the external threads with respect to accommodating threads within the vertical rod sufficient to disengage the alignment fins from accommodating slots inside a shaft of the vertical rod, wherein the rotatable shaft is rotatable within the sleeve, wherein the rod coupling bolt:"

Here, I agree with Plaintiff. Defendant's proposal adds functional language that is not necessary in describing the structure. [26] I will construe this term to mean "a rotatable shaft having external threads at an upper end, a sleeve having a set of alignment fins at an upper end, and a knurled surface or shaped flattened head, wherein the rotatable shaft is rotatable within the sleeve and equivalents thereof."

The Honorable Maryellen Noreika

United States District Judge

During the argument, when the Court pointed out that the objection to some purportedly functional language in Defendant's was inconsistent with Plaintiff's proposal to include "to allow for gripping and rotation of the shaft during operation," Plaintiff dropped the language from its proposal. (D.I. 105 at 74:23–75:10).

Defendant's proposal also includes "rod coupling bolt" in the construction. I do not include these as the limitation already includes the term "rod coupling component."