UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

SAMY ABDOU,

Plaintiff,

VS.

ALPHATEC SPINE, INC.,

Defendant.

CASE NO. 12-CV-1804 BEN (RBB)

# ORDER GRANTING MOTIONS FOR SUMMARY JUDGMENT

[Docket Nos. 84, 89]

Alphatec Spine, Inc. has filed two motions for summary judgment. (Docket Nos. 84, 89.) The first asserts that Plaintiff Samy Abdou, M.D. is not entitled to provisional rights for infringement of U.S. Patent Nos. 7,951,153 ("the '153 patent") and 8,172,855 ("the '855 patent") for a period between when the applications for the patents were published and the patents were issued. (Docket No. 89.) The second asserts that certain claims of the '153 and '855 patents are indefinite. (Docket No. 84.) As explained more fully below, Abdou is not entitled to provisional rights, *i.e.* pre-issuance royalties, because the claims of the published patent application are not substantially identical to the claims of the issued patents and certain claims of the '153 and '855 patents are indefinite under a new indefiniteness standard because the claims terms are not reasonably certain. Alphatec's motions for summary judgment are **GRANTED**.

///

#### BACKGROUND

Abdou alleges that Alphatec willfully infringed the '153 and '855 patents, both of which are entitled, "Devices and Methods for Inter-Vertebral Orthopedic Device Placement." The patents at issue are directed toward the treatment of diseases of the spine.

The '153 and '855 patents teach and claim devices and methods to target, access, and perform surgical work in the intervertebral space with minimal tissue dissection. The '153 patent discloses devices by which a surgeon may access the intervertebral space by using a curved or arced portal that allows for placement of a sizeable implant. The curved portal contains an internal bore which extends from the proximal opening (nearest the surgeon) toward the distal end (at the disc space). An orthopedic implant is advanced through the bore and into the targeted disc space. The '855 patent discloses methods for targeting and accessing a targeted location within the spinal column, including between vertebrae, and for delivering an orthopedic implant into a target location, using devices similar to those described in the '153 patent.

Abdou identifies a person of ordinary skill in the art to include a surgeon with several years of experience in surgical procedures pertaining to the spine and the corresponding instruments and tools, including minimally invasive procedures, instruments, and tools.

#### DISCUSSION

"Summary judgment is appropriate if 'the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Augme Techs., Inc. v. Yahoo!, Inc., 755 F.3d 1326, 1329 (Fed. Cir. 2014) (quoting Fed. R. Civ. P. 56(a)). "At the summary judgment stage, [the court must] credit all of the nonmovant's evidence and draw all justifiable inferences in its favor." Id. (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986)).

///

///

-2-

12cv1804

1 2

3 4 5

6 7

8 9

11

10

12 13

14

15 16

17

18

19 20

21

22 23

24

25

26

27

### I. Provisional Rights

Generally, a patentee can only recover for infringement occurring after a patent is issued, but under 35 U.S.C. § 154(d) a patentee can "obtain a reasonable royalty" for infringement occurring between publication of the patent *application* and issuance of the patent. However, these provisional rights, also referred to as pre-issuance royalties, are only available "if: (1) the issued patent claims are *substantially identical* to the claims in the published application; and (2) [defendant] had *actual notice* of the published patent application." *Stephens v. Tech Int'l, Inc.*, 393 F.3d 1269, 1275 (Fed. Cir. 2004) (emphasis added) (citing 35 U.S.C. § 154(d)(1)-(2)) As explained below, the claims of the published patent applications and the issued patents are not substantially identical.

## A. Substantially Identical

"The right . . . to obtain a reasonable royalty shall not be available . . . unless the invention as claimed in the patent is *substantially identical* to the invention as claimed in the published patent application." 35 U.S.C. § 154(d)(2). The Federal Circuit has not interpreted "substantially identical" in § 154(d), however, it has interpreted it in the reissue statute, 35 U.S.C. § 252. This requirement precludes damages for infringement prior to issuance of the patent unless the claims "are 'without substantive change." *Laitram Corp. v. NEC Corp.*, 163 F.3d 1342, 1346 (Fed. Cir. 1998) (quoting *Seattle Box Co. v. Indus. Crating & Packing*, 731 F.2d 818, 827-28 (Fed. Cir. 1984)). The claims need not be verbatim or use the same words, but "the scope of the claims must be the same." *Bloom Eng'g Co. v. N. Am. Mfg. Co.*, 129 F.3d 1247, 1250 (Fed. Cir. 1997); *see also Laitram Corp.*, 163 F.3d at 1346 ("we must discern whether the scope of the claims are identical, not merely whether different works are used."). A claim

In addition to using the same terminology, § 154(d)'s legislative history indicates the substantially identical analysis under § 252 applies to provisional rights. H.R. Rep. No. 105-39, at 62 (1997) ("That standard, [substantially identical in 35 U.S.C. § 252], has been adopted here for provisional rights."). The legislative history also notes the addition of "substantially" before "identical" in § 252 to conform § 252's statutory language to its decisional law.

may be amended to clarify "or make[] it more definite" without substantively changing the claim, but only if the change does not "affect[] its scope." *Bloom* at 1250; *see also Seattle Box*, 731 F.2d at 828 (finding a change that was "not a matter of mere clarification of language to make specific what was always implicit or inherent" was no without substantive change).

#### 1. '153 Patent

Both the prosecution history and the claim language indicate that the claims of U.S. 2006/0111728 ("published application '728") and the issued claims of the '153 patent are not substantially identical. The claims changed substantively, both through amendment of the claims and through the addition of entirely new claims not disclosed in the published application.

The Court will not recite the entire five-year history of amendments that eventually resulted in issuance of the '153 patent, but the Court notes that claims were cancelled, amended, and newly added to overcome numerous rejections based on prior art. Although there is no per se rule that "a rejected claim that became allowable when amended is not substantively changed by the amendment," the number of changes and reasons for the changes indicate the claims are not substantially identical. *Laitram Corp.*, 163 F.3d at 1348.

A comparison of the claim language between the published application and issued patent also reflects the substantive nature of the changes that occurred through prosecution. Alphatec's briefing includes a comparison table reflecting the significant changes made to issued claims 1 and 6 that have an analog in the published application and the substance of new issued claims 8, 12, 20, and 21 that were not in the '728 published application. (Def.'s Mot. for Partial Summ. J. Re Pl.'s Damages ("Def.'s Damages Mot." 5-11.) For example, compare published claim 11 and issued claim 6.

///

27 ///

28 ///

25

26

27

28

[Original Claim 11]. An instrument for implanting an implant device into a space between skeletal segments, comprising:

an insertion device having a delivery shaft, wherein the insertion device can be

pivotably mounted in a predetermined spatial relationship relative to the space between the skeletal segments, the insertion device pivoting to a delivery orientation such that the delivery shaft provides a pathway for the delivery of an orthopedic device into the space between the skeletal segments.

[Issued Claim 6]. An instrument for implanting an orthopedic implant device into a target space between skeletal segments, comprising:

an insertion device having a delivery shaft, wherein the insertion device can be pivotably mounted in a predetermined spatial relationship relative to the space between the skeletal segments, the insertion device pivoting to a delivery orientation such that the delivery shaft provides a pathway for the delivery of an orthopedic device into the space between the skeletal segments, straight member and a curved elongate body extending from the straight member, wherein the curved elongate body has a proximal end attached to the straight member and wherein the curved elongate body contains an arcuate internal bore extending along a first axis from a proximal opening at a proximal region of the curved elongated body to a distal opening at a distal region of the curved elongated body and wherein at least a portion of the internal bore extends along the first axis from the proximal opening toward the distal opening in a curved trajectory, and wherein the internal bore, the proximal opening, and the distal opening are sized to permit advancement of the orthopedic implant therethrough;

a mount that is positionable at a defined anatomical relationship relative to the target space between the skeletal segments, wherein the mount attaches to the straight member of the insertion device at a proximal end of the insertion device and, when attached to the insertion device, the mount limits movement of the insertion device relative to the skeletal segments; and

an orthopedic implant that is adapted to implant into the target space, wherein the implant is sized to be advanced through the arcuate internal bore and into the target space.

- 5 -

12cv1804

US 2006/0111728 (Pub. May 25, 2006)

Although it may be hypothetically possible to have claim language altered this extensively through a lengthy prosecution that includes changes to overcome prior art without changing the claim substantively, that is not the case here.

Because Abdou focused its argument on issued claim 6 to show the claims were substantially identical, the Court addresses it first. As illustrated above, substantial changes were made to the language of published claim 11 to end up with issued claim 6, but Abdou argues the differences are not as stark if published claim 11 and its dependent claims, published claims 12 and 14, are also considered. There is support for this approach to the analysis. *See Bloom Eng'g Co.*, 129 F.3d at 1250 (restating original dependent claims in independent form does not constitute a substantive change because "a dependent claim incorporates by reference all of the limitations of the claim from which it depends"). Abdou provides the following table to illustrate his point:

'153 Patent as Issued (Ex. 2)

6. An instrument for implanting an
orthopedic implant into a target space
between skeletal segments, comprising:
an insertion device having a straight
member and a curved elongate body
extending from the straight member,
wherein the curved elongate body has a
proximal end attached to the straight
member and wherein the curved elongate
body contains an arcuate internal bore
extending along a first axis from a
proximal opening at a proximal region of
the curved elongated body to a distal
opening at a distal region of the curved
elongated body and wherein at least a

portion of the internal bore extends along the first axis from the proximal opening toward the distal opening in a curved trajectory, and wherein the internal bore, the proximal opening, and the distal opening are sized to permit advancement of the orthopedic implant therethrough;

12. An instrument as in claim 11, further comprising an mount for positioning the insertion device in the predetermined spatial relationship relative to the space between the skeletal segments, the mount comprising a post having a distal end removably positioned adjacent the space, and a proximal end pivotably attached to the insertion device.

a mount that is positionable at a defined anatomical relationship relative to the target space between the skeletal segments, wherein the mount attaches to the straight member of the insertion device at a proximal end of the insertion device and, when attached to the insertion device, the mount limits movement of the insertion device, the relative to the skeletal segments; and

14. An instrument as in claim 11, wherein the insertion device includes a **straight portion and a curved portion**, wherein the straight portion extends outwardly from the proximal end of the mount, and wherein the curved portion extends from an outward tip of the straight portion toward the distal end of the mount, the guide shaft being positioned in the curved portion.

an orthopedic implant that is adapted to implant into the target space, wherein the implant is sized to be advanced through the arcuate internal bore and into the target space.

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

The highlighted terms are the terms Abdou argues are equivalent disclosures despite the change in the language of the claims.

Issued claim 6 is substantively different from published claim 11 even when its dependent claims are considered. Among other changes, the issued claim includes an arcuate internal bore used to advance the orthopedic implant into the target space. The issued claim also indicates the internal bore, proximal opening, and distal opening are "sized to permit advancement of the orthopedic implant therethrough" and the "implant is sized to be advanced through the arcuate internal bore and into the target space."

Relying on the chart above, Abdou argues the "arcuate internal bore" in issued claim 6 is disclosed as a "delivery shaft" in published claim 11. As the Court noted during oral argument, the arcuate internal bore described in issued claim 6 is something the implant goes through. This is evident from the requirements that the internal bore be "sized to permit advancement of the orthopedic implant therethrough" and correspondingly that the "implant is sized to be advanced through the arcuate internal bore." There is only one reference in published claim 11 and its dependent claims that suggests the guide shaft is something an implant could go inside. Published claim 15 adds a plunger "positionable inside the guide shaft." Although this description might suggest the "guide shaft" is something an implant could go inside, that is substantively different from an internal bore "sized to permit advancement of the orthopedic implant therethrough." Additionally, issued claim 6 also describes the arcuate internal bore "extending along a first axis from a proximal opening at the proximal region of the curved elongated body to a distal opening at a distal region of the curved elongated body" where the proximal opening and distal opening are, like the internal bore "sized to permit advancement of the orthopedic implant therethrough." There is no similar description in published claim 11 or its dependent claims.

There are similar substantive differences in the descriptions of the mount. Abdou highlights language describing the mount being positioned relative to the space between the skeletal segments, but published dependent claim 12 describes "the mount

comprising a post having a distal end removably positioned adjacent to the space" while issued claim 6 does not describe the mount further. Instead, it describes where the mount attaches to the insertion device, "the straight member." Issued claim 6 also provides more description of the mount, indicating the "mount limits movement of the insertion device relative to the skeletal segments."

Published claim 11 and its dependent claims also lack any description of the orthopedic implant while issued claim 6 describes it as "adapted to implant into the target space, wherein the implant is sized to be advanced through the arcuate internal bore and into the target space."

The other issued claim that has a predecessor in the published application, issued claim 1, is similarly not substantially identical to published claim 1 for some of the same reasons noted above, but there are also additional substantive changes. The description in issued claim 1 of the arcuate plunger's conical distal end and positioning of it within the arcuate internal bore such that the proximal end and conical distal end protrude out of the proximal and distal ends is not present in published claim 1. These are not changes to clarify "language to make specific what was always implicit or inherent." *Seattle Box*, 731 F.2d at 828. These are substantive changes. *See Laitram Corp.*, 163 F.3d at 1348 (finding changing "alpha-numeric characters" to "type quality alpha-numeric characters" constituted a substantive change because the original claim covered any quality of character while the amended claim covered only type quality characters).

Additionally, as Alphatec notes, four asserted independent claims are new—issued claims 8, 12, 20, and 21. These claims were added during prosecution and a review of these claims and the published claims indicates they are not substantially identical.

Because the claims of the published application and the issued claims are not substantially identical, Abdou is not entitled to provisional rights under § 154(d) as to the '153 patent.

2 3 4

10 11 12

13

9

14 15 16

17 18

19 20 21

23 24

26 27

28

25

22

As to the '855 patent, the Court finds the claims of U.S. 2006/0149278 ("published application '278") and the claims of the issued patent are not substantially identical. Like the '153 patent, the '855 patent has a lengthy history with many changes to overcome prior art. However, as to the '855 patent, none of the claims of the published application ever issued and the asserted independent claims at issue in this case, claims 6 and 28, were added less than a year before the patent issued.

It seems this should be the end of the inquiry. A potential infringer should not be required to pay pre-issuance royalties for infringement of claims that were not in the published application and only added shortly before the patent issued. The requirement to show substantial identity of the claims serves to ensure a minimal level of fairness. A potential infringer is not on the hook for infringement when there was nothing yet to infringe. Allowing access to pre-issuance royalties in such a case has great potential to discourage innovation. How could an inventor, with any confidence, create something new when what is already claimed is being cancelled and substantively amended? Section 154(d) is essentially an exception to the general rule that a patentee is precluded from obtaining damages for infringement until the patent actually issues. This exception should not be exploited when the published claims never issue.

A bright-line rule denying provisional rights when none of the claims of the published application issue is appealing, but because the cases addressing substantial identity focus on the substance of the claims, Laitram, 163 F.3d at 1346, the Court addresses some of the substantive differences.

Abdou only specifically addresses issued claim 6 of the '855 patent. He argues that it is substantially identical to published claim 25. These claims do have two things in common. Both note the use of imaging, an x-ray in published claim 25 and an "imaging technique" in issued claim 6. The Court notes this commonality is itself a substantive change from a specific type of imaging to the broader "imaging technique" that also encompasses other types of imaging. Published claim 25 and issued claim 6

also both result in an implant ending up in a location, "localized point of interest" in published claim 25 and "the target location" in issued claim 6. This is where the similarity ends. Published claim 25 describes "using an inserter device that pivots about a central axis such that the inserter device travels along a curveilinear path." In contrast, issued claim 6 describes use of an invention assembly with an "elongated curvilinear body and an internal bore" where the bore "extends from a proximal opening to a distal opening along a curvilinear trajectory, and wherein the internal bore is sized to permit advancement of the implant through the internal bore." Claim 6 also describes use of a fixation member that "limits movement of the implant insertion member relative to the target location." No similar descriptions exist in published claim 25. There is little identity between the two other than an implant ending up in a location. How the implant gets to the location and what is used to get it there are substantively different. The Court cannot find these claims are without substantive change.

Because the claims of the published application and the issued claims are not substantively identical, Abdou is not entitled to provisional rights under § 154(d) as to the '855 patent.

#### II. Indefiniteness

# A. Legal Standard

Indefiniteness is a question of law. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 723 F.3d 1363, 1368 (Fed. Cir. 2013). "[D]etermination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1376 (Fed. Cir. 2001) *abrogated on other grounds by Nautilus v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2130 n.9 (2014). Indefiniteness is a challenge to the validity of the patent that must be established by clear and convincing evidence. *Nautilus*, 134 S. Ct. at 2230, n.10 (citing *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S. Ct. 2238, 2242 (2011) for the clear-and-convincing standard applicable to challenges to invalidity and

declining to alter this standard).

Under 35 U.S.C. § 112 ¶ 2, "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." "A lack of definiteness renders invalid 'the patent or any claim in suit." *Nautilus*, 134 S. Ct. at 2125 (citing 35 U.S.C. § 282, ¶ 2(3)). Until recently, a claim was indefinite "only when it [was] not amendable to construction or insolubly ambiguous." *Id.* at 2127. The Supreme Court rejected this standard as too imprecise. *Id.* at 2130.

Under the new standard, "a patent is invalid for indefiniteness if its claims, read in light of the specification . . . , and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Id.* at 2124 (emphasis added). In rejecting the prior standard, the court found it insufficient "that a court [could] ascribe *some* meaning to a patent's claims." *Id.* at 2130. Reasonable certainty is something more precise than insolubly ambiguous, but short of absolute precision. *Id.* at 2129-30. In describing the new standard the court "mandates clarity." *Id.* at 2129.

The Supreme Court noted the "delicate balance" to the indefiniteness analysis. *Id.* at 2128. In summarizing this balance post-*Nautilus*, the Federal Circuit explained that "[t]he definiteness standard 'must allow for a modicum of uncertainty' to provide incentives for innovation, but must also require 'clear notice of what is claimed, thereby appris[ing] the public of what is still open to them." *Interval Licensing LLC v. AOL*, 766 F.3d 1364, 1370 (Fed. Cir. 2014) (emphasis added) (quoting *Nautilus*, 134 S. Ct. at 2128-29).

24 | /// 25 | ///

26 ///

27 ///

28 ///

The Supreme Court did not apply the new standard in *Nautilus*.<sup>2</sup> However, the Federal Circuit has applied it and provided guidance on the level of precision required. *Interval*, 766 F.3d at 1369-71. "Although absolute precision or mathematical precision is not required, it is not enough as some of the language in . . . prior cases may have suggested, to identify 'some standard for measuring the scope of the phrase." *Id.* at 1370-71 (quoting party's brief and earlier authority, *Datamize*, *LLC v. Plumtree Software*, *Inc.*, 417 F.3d 1342, 1351 (Fed. Cir. 2005)). "The claims, when read in light of the specification and the prosecution history, must provide *objective boundaries* for those of skill in the art." *Id.* at 1371 (emphasis added) (relying on *Nautilus*, 134 S. Ct. at 2130 & n.8). In noting the necessity for objective boundaries, the Federal Circuit relied on *Halliburton Energy Servs.*, *Inc. v. M-I LLC* and that court's finding that "[e]ven if a claim term's definition can be reduced to words, the claim is still indefinite if a person of ordinary skill in the art cannot translate the definition into *meaningfully precise* claim scope." *Id.* (emphasis added) (relying on *Halliburton*, 14 F.3d 1244, 1251 (Fed. Cir. 2008)).

Other parts of the indefiniteness inquiry remain the same. Indefiniteness is still "evaluated from the perspective of someone skilled in the relevant art at the time the patent was filed." *Nautilus*, 134 S. Ct. at 2128. Claims must also still "be read in light of the patent's specification and prosecution history." *Id.* at 2128.

#### B. Indefinite Claims

Alphatec argues that independent claims 1, 6, 8, 12, and 21 of the '153 patent and independent claims 6 and 28 of the '855 patent are indefinite. In the '153 patent, Alphatec identifies the following terms as indefinite: "defined anatomical position;" "defined anatomical relationship;" and "defined spatial relationship." In the '855

- 13 -

<sup>&</sup>lt;sup>2</sup>The court declined to apply the new "reasonable certainty" standard to the claim language at issue in *Nautilus*, "mounted . . . in spaced relationship with each other." *Nautilus*, 134 S. Ct. at 2131. The language describes the location of two electrodes on a cylinder held in the user's hand. *Id.* at 2127. In concluding the language was not indefinite, the reversed Federal Circuit decision had concluded the spaced relationship could not be greater than the width of a user's hand. *Id.* at 2127.

patent, Alphatec identifies the following terms as indefinite: "attaches on to a first surface" and "in proximity to the first vertebral bone."

The question here is whether the absence of identified boundaries in terms of proximity, distance, or location renders the claims indefinite under a new and more rigorous standard imposed by the Supreme Court? The Court finds that it does.

The parties have submitted expert declarations that reach different conclusions concerning whether the claims are indefinite. However, as explained below, even if the Court accepts, as put forth by Abdou's expert, that the apparatus must be fully within an operating room, accepts that the relationship terms are limited by the necessity to accurately target the surgical site, and accepts that mounting or anchoring must limit movement of the insertion device, the claims are still indefinite because they lack "objective boundaries for those of skill in the art." *Interval*, 766 F.3d 1371.

In context, the terms at issue are as follows:

- "a first mount comprising an elongate body having a distal end mountable at a defined anatomical position relative to the target space"
- "a mount that is positionable at a *defined anatomical relationship* relative to the target space between the skeletal segments"
- "at least one anchor device having a first region that attaches with the proximal end of the insertion device at the proximal end of the insertion device and a second region attaches onto a surface with defined spatial relationship to the disc space"
- "A method for delivery of an orthopedic implant onto a target location within a spinal column of a subject, comprising . . . a fixation member, having a first segment that attaches onto a proximal segment of the implant insertion member and a second segment that attaches onto a first surface"
- A method to target and access a spinal segment of a subject, comprising: identifying a target location within the spinal segment, wherein the target location is *in proximity* to a first vertebral bone; positioning at least a first

member of a targeting apparatus in proximity to the first vertebral bone" 3

Generally, each of the relationship terms purports to describe the connection between two parts of the invention, *i.e.* the mount or first mount and target space and the anchor device and disc space. Similarly, "in proximity" describes the distance between the target location apparatus and the first vertebral bone. Finally, "attaches onto a first surface" describes what the second segment of the fixation member attaches to.

Alphatec argues these terms do not sufficiently limit the relationships or provide any parameters for defining what the relationship, position, or proximity is. Abdou argues the claims themselves limit the relationships to those that result in accurately targeting the surgical site and positioning the mount or anchor device to limit movement of the insertion device. Additionally, Abdou argues a person of skill in the art would know the apparatus is limited to an operating room.

There is no question that the relationship terms lack any quantitative parameters or a range of distance between the mount or anchor and a target or disc space. Likewise, neither "in proximity" nor any other language in the specification otherwise defines what the proximity would be in any specific way and "first surface" is not further described in anyway that would define what or where the surface should be.

Additionally, as Abdou persuasively argued during claim construction and this Court explained in its claim construction order, the claims are not limited to inside the patient's body. However, the Court agrees these relationships are limited by the necessity that the surgical site be accurately targeted and that the mount, anchor device, or fixation member be positioned to limit movement. The Court is also willing to accept, for purposes of this analysis that the entirety of the apparatus must be in an operating room.

///

<sup>&</sup>lt;sup>3</sup>These terms appear in additional claims with slight variation in the surrounding language.

These limitations "ascribe[s] *some* meaning to [the] patent's claims." *Nautilus*, 134 S. Ct. at 2130 (finding "*some* meaning" insufficient). But, that is not enough. *Id.* The new standard mandates, at a minimum, clarity. *Id.* at 2129. The limitation of accurately targeting the surgical site provides some guidance, but because nothing in the claims or specification tells a person of ordinary skill in the art what the anatomical position, anatomical relationship, spacial relationship, or proximity should be to accurately target the surgical site, it is not sufficient under the new standard. The accurate targeting of the surgical site and positioning the mount, anchor, or fixation member to limit movement provide "some standard for measuring the scope of the phrase[s]," but something more, short of absolute or mathematical precision, is required. *Interval*, 766 F.3d at 1370-71 (rejecting prior authority finding some standard sufficient).

The lack of guidance provided by these terms is illustrated by reading the claim without it. Claim 6 of the '153 patent could say, "a mount that is positionable [] relative to the target space between the skeletal segments." Removing "at a defined anatomical relationship" does not change the guidance as to the scope of the claim. With or without it, the claim only conveys there is some relationship between the mount and the target space. The same is true of the other claims at issue. The terms, "defined anatomical position;" "defined anatomical relationship;" and "defined spatial relationship" add little to the claim because they provide no guidance to a person of skill in the art about what the relationship or position is. The "in proximity to" language is more necessary to the claim because of the way it is phrased, but it still does not state with reasonable certainty what that proximity is. Absolute precision is not necessary, but some objective boundaries are required. *Interval*, 766 F.3d at 1351, 1370.

///

<sup>&</sup>lt;sup>4</sup>The inclusion of "defined" may serve to disclose that the relationship must be defined at some point, but what the relationship should be is not disclosed.

Similarly, as to the "first surface," it must be something that allows for accurate targeting of the surgical site and limits movement. But otherwise, the "first surface" the second segment of the fixation member attaches onto could be anything in the operating room; a large number of options. Abdou claims it is not this open-ended, but does not explain how the limitations of accurately targeting the surgical site and limiting movement would allow for use of one operating room fixture to the exclusion of another. There is no other indication what that first surface might be, leaving a person of skill in the art to engage in trial and error with each surface accessible in an operating room. This is not reasonably certain.

These claims all have some meaning and are not insolubly ambiguous, but they do fall short of the new, more rigorous reasonable certainty standard for indefiniteness. *Nautilus*, 134 S. Ct. at 2124. The lack of clarity in these claims leaves the next inventor in the "zone of uncertainty," not knowing what is claimed and what is still open. *Id.* at 2129 (explaining the need for precision and clear notice of what is claimed to avoid a "zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement of claims"); *see also Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002) ("A patent holder should know what he owns, and the public should know what he does not.").

#### **CONCLUSION**

IT IS SO ORDERED.

DATED: November \_\_\_\_\_, 2014

HON. ROGER T. BENITEZ United States District Judge