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**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF CALIFORNIA**

SAMY ABDOU,

Plaintiff,

vs.

ALPHATEC SPINE, INC.,

Defendant.

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

**ORDER DENYING ALPHATEC  
SPINE, INC.'S MOTION FOR  
SUMMARY JUDGMENT**

[Docket No. 51]

Presently before the Court is Alphatec Spine, Inc.'s Motion for Summary Judgment. (Docket No. 51.) For the reasons stated below, the Motion is **DENIED**.

**BACKGROUND**

Plaintiff Samy Abdou, M.D., alleges that Defendant Alphatec Spine, Inc. willfully infringed U.S. Patent Nos. 7,951,153 ("the '153 patent") and 8,172,855 ("the '855 patent"), 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 spine consists of a vertebral column and a spinal cord. The vertebral column provides support for the body and protects the spinal cord. Posterior to the vertebral column is the spinal cord, and anterior to the vertebral column is the aorta and vena cava, the body's two major blood vessels. The vertebral column is made up of individual vertebral bones, which are separated by an intervertebral disc space. The

1 disc space permits movement between vertebral bones and absorbs shock from the load  
2 transmitted through the vertebral column. Many medical problems involving the spine  
3 result from a problem of the disc (e.g., herniation) or compression of surrounding  
4 nerves. Treatment of these issues include implanting devices between vertebrae in  
5 order to adjust, align, and maintain the spatial relationship between them.

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

17 A claim construction hearing was held on January 17, 2014. The Court declined  
18 to construe the ten sets of disputed claim terms found in the '153 and '855 patents,  
19 finding that they had a plain and ordinary meaning. (Docket No. 74.) Presently before  
20 the Court is Alphatec’s Motion for Summary Judgement. (Docket No. 51.)

## 21 **DISCUSSION**

22 Alphatec argues that because the Court has previously construed the claims as  
23 permitting the mounting of the devices outside of the body, the asserted claims are  
24 invalid for failure to meet the written description and enablement requirements of 35  
25 U.S.C. § 112(a).

26 Summary judgment is appropriate when “after opportunity for discovery and  
27 upon motion, there is no genuine dispute of material fact for trial and one party is  
28 entitled to judgment as a matter of law.” *Novartis Corp. v. Ben Venue Labs., Inc.*, 271

1 F.3d 1043, 1046 (Fed. Cir. 2001); FED. R. CIV. P. 56(c). All facts must be viewed in  
2 the light most favorable to the non-moving party, and all doubts must be resolved in  
3 the non-movant's favor. *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1345-46 (Fed.  
4 Cir. 2000).

5 "Under 35 U.S.C. § 282, a patent is presumed valid, and the one attacking  
6 validity has the burden of proving invalidity by clear and convincing evidence." *Atlas*  
7 *Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1573 (Fed. Cir. 1984).  
8 "Thus, a moving party seeking to invalidate a patent at summary judgment must submit  
9 such clear and convincing evidence of invalidity so that no reasonable jury could find  
10 otherwise." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001).

11 **A. WRITTEN DESCRIPTION**

12 "The specification shall contain a written description of the invention, and of the  
13 manner and process of making and using it." 35 U.S.C. § 112(a). "Specifically, the  
14 description must clearly allow persons of ordinary skill in the art to recognize that the  
15 inventor invented what is claimed. In other words, the test for sufficiency is whether  
16 the disclosure of the application relied upon reasonably conveys to those skilled in the  
17 art that the inventor had possession of the claimed subject matter as of the filing date."  
18 *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)  
19 (internal quotation marks, citation, and alteration omitted). "Put another way, one  
20 skilled in the art, reading the original disclosure, must immediately discern the  
21 limitation at issue in the claims." *Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d  
22 1320, 1323 (Fed. Cir. 2000).

23 The Court finds that Alphatec has failed to prove a lack of written description  
24 by clear and convincing evidence. As discussed in the Claim Construction Order, the  
25 "mount," "anchor device," "fixation member," and "first member" limitations of the  
26 claimed devices are mountable, positionable, or attachable both inside and outside of  
27 the body. (Docket No. 74, at 4.) The claim language is agnostic as to whether the  
28 point of attachment is inside or outside of the body. (*See, e.g.*, '153 patent, at 7:35-37

1 (“a first mount . . . mountable to a defined anatomical position relative to the target  
2 space”); *id.* at 8:31-33 (“a mount that is positionable at a defined anatomical  
3 relationship relative to the target space between the skeletal segments”); *id.* at 8:61-65  
4 (“anchor device having . . . a second region [that] attaches onto a surface with defined  
5 spatial relationship to the disc space”); ’855 patent, at 15:38-40 (“positioning an  
6 implant insertion assembly in proximity to the target location”); *id.* at 17:1-2  
7 (“positioning . . . a first member of a targeting apparatus in proximity to the first  
8 vertebral bone”).) In addition, the specifications indicate that no particular attachment  
9 location is required. (*See, e.g.*, ’153 patent, at 5:45-49 (“The coupler 110 of the device  
10 100 is then attached to an attachment point. It should be appreciated that the  
11 attachment point need not be the disc space itself. The coupler 110 can be attached  
12 directly to one of the vertebrae or to some other reference location.”); ’855 patent, at  
13 13:66-14:1 (“In other embodiments, one or more anchors may be placed into the inter-  
14 spinous ligament, lateral to the inter-spinous space, into the pedicles or any other  
15 suitable anchor point.”).)

16 This action is similar to *Gen-Probe Inc. v. Becton Dickinson & Co.*, 899 F. Supp.  
17 2d 971 (S.D. Cal. 2012). One of the patents at issue in *Gen-Probe* claimed a seal or  
18 seals on a collection vessel that are penetrated by a fluid transfer device. *Id.* at 976.  
19 The defendant moved for summary judgment of invalidity of the asserted claims of the  
20 patent, on the basis that the patent specification failed to convey that the inventors  
21 invented a penetrable cap without a filter because the specification only described a  
22 patent with a filter. *Id.* at 978-79. This Court denied summary judgment because: (1)  
23 the embodiments with a filter were preferred embodiments, (2) an embodiment in the  
24 Summary of the Invention could “fairly be interpreted” as a cap lacking a filter, and (3)  
25 “the entire Summary of the Invention section [was] a series of paragraphs that describe  
26 various embodiments of the invention.” *Id.* at 979-80. *Gen-Probe* is analogous to the  
27 present action in that the Court has found in the Claim Construction Order that the  
28 embodiments that describe the devices as attaching inside of the body are preferred

1 embodiments, and the patents claim devices that are mountable, positionable, or  
2 attachable both inside and outside of the body. As in *Gen-Probe*, “the Court cannot  
3 find that [Alphatec] has met it[s] burden to provide such clear and convincing evidence  
4 of invalidity that no reasonable jury could find otherwise.” *Id.* at 980 (internal  
5 quotation marks omitted).

6 Alphatec’s arguments to the contrary are not convincing. First, Alphatec argues  
7 that summary judgment should be granted because the patents at issue fail to provide  
8 any examples of the distal end of the mounting device attaching outside of the body.  
9 Alphatec is correct that “the lack of any disclosure of examples may be considered  
10 when determining whether the claimed invention is adequately described.” *Boston*  
11 *Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1364 (Fed. Cir. 2011).  
12 However, “examples are not always required to satisfy the written description  
13 requirement.” *Id.* Although relevant to the Court’s analysis, this factor is not  
14 determinative.

15 Second, Alphatec cites *TurboCare Division of Demag Delaval Turbomachinery*  
16 *Corp. v. General Electric Co.*, 264 F.3d 1111, 1119 (Fed. Cir. 2001), for the  
17 proposition that vague references in the patents referring to “other locations” cannot  
18 provide the requisite written description support. The patent at issue in *TurboCare*  
19 claimed a shaft seal used in fluid-driven devices such as steam turbines. *Id.* at 1113.  
20 On an appeal of the district court’s granting of summary judgment for failure to meet  
21 the written description requirement, the plaintiff argued that “one of ordinary skill in  
22 the art would recognize that the only viable location for mounting a spring ‘adjacent  
23 to said rings’ would be between the casing shoulders and the shoulders of the outer ring  
24 portion of the segment, and therefore that the claimed subject matter was inherent in  
25 the original disclosure.” *Id.* at 1119. However, the plaintiff conceded that the only  
26 support in the original disclosure for the location of a claimed spring was the language,  
27 “spring located . . . adjacent to said rings,” from one of the original, rejected claims.  
28 *Id.* The court upheld the district court’s granting of summary judgment, finding that

1 the “original disclosure [was] completely lacking in any description of an embodiment  
2 in which the spring is located between the casing shoulders and the inner surface of the  
3 outer ring portion of the ring segment.” *Id. TurboCare*, however, is distinguishable  
4 from the present action. In *TurboCare*, the plaintiff attempted to limit the mounting  
5 location for the spring to between the casing shoulders and the shoulders of the outer  
6 ring portion of the segment, when such a limitation was not present in the general  
7 language of the original claims. Here, in contrast, Abdou argues that the claimed  
8 devices are *not* limited to being mountable, positionable, or attachable only inside of  
9 the body, which is consistent with this Court’s finding that the patents at issue claim  
10 devices that are mountable, positionable, or attachable both inside and outside of the  
11 body.

12 Third, Alphatec cites *University of Rochester v. G.D. Searle & Co.*, 358 F.3d  
13 916, 923 (Fed. Cir. 2004), for the proposition that generalized language is inadequate  
14 for satisfying the written description requirement. There, the court stated that  
15 “generalized language may not suffice if it does not convey the detailed identity of an  
16 invention.” *Id.* at 923. By way of example, the court explained that “in the nineteenth  
17 century, use of the word ‘automobile’ would not have sufficed to describe a newly  
18 invented automobile; an inventor would need to describe what an automobile is, *viz.*,  
19 a chassis, an engine, seats, wheels of axles, etc.” *Id.* In addition, the court noted that  
20 “there [was] no language here, generalized or otherwise, that describe[d] compounds  
21 that achieve the claimed effect.” *Id.* Here, in contrast, the parties do not dispute a term  
22 that describes a generic object, but rather the point of attachment for the devices at  
23 issue. In other words, the patents at issue here sufficiently convey the identity of the  
24 invention.

25 Alphatec has failed to meet its burden to provide such clear and convincing  
26 evidence of invalidity that no reasonable jury would find otherwise. *Eli Lilly*, 251 F.3d  
27 at 962; *see also Atlas Powder*, 750 F.2d at 1573 (“Under 35 U.S.C. § 282, a patent is  
28 presumed valid, and the one attacking validity has the burden of proving invalidity by

1 clear and convincing evidence.”). Accordingly, Alphatec’s motion for summary  
2 judgment based on lack of written description is **DENIED**.

3 **B. ENABLEMENT**

4 “A patent’s specification must describe the invention and ‘the manner and  
5 process of making and using it, in such full, clear, concise, and exact terms as to enable  
6 any person skilled in the art to which it pertains . . . to make and use the same.’” *Wyeth*  
7 *& Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013) (quoting 35  
8 U.S.C. § 112(a)). “Claims are not enabled when, at the effective filing date of the  
9 patent, one of ordinary skill in the art could not practice their full scope without undue  
10 experimentation.” *Id.*

11 “The specification need not explicitly teach those in the art to make and use the  
12 invention; the requirement is satisfied if, given what they already know, the  
13 specification teaches those in the art enough that they can make and use the invention  
14 without ‘undue experimentation.’” *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314  
15 F.3d 1313, 1334 (Fed. Cir. 2003); *see also Hybritech Inc. v. Monoclonal Antibodies,*  
16 *Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) (“[A] patent need not teach, and preferably  
17 omits, what is well known in the art.”). Claims are enabled if “the trial and error  
18 required to practice the claimed invention [is not] unduly laborious or beyond the reach  
19 of one of ordinary skill in the art.” *Koito Mfg. Co., Ltd. v. Turn-Key-Tech, LLC*, 381  
20 F.3d 1142, 1155 (Fed. Cir. 2004).

21 When determining whether undue experimentation would be required, courts  
22 may consider: “(1) the quantity of experimentation necessary, (2) the amount of  
23 direction or guidance presented, (3) the presence or absence of working examples, (4)  
24 the nature of the invention, (5) the state of the prior art, (6) the relative skill of those  
25 in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the  
26 claims.” *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). These factors “are  
27 illustrative, not mandatory.” *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200,  
28 1213 (Fed. Cir. 1991). The Court will consider each of the *Wands* factors in turn.

1                   **1. Quantity of Experimentation Necessary**

2           Alphatec argues that attaching the distal end of the mounting device outside of  
3 the body would require a large amount of non-routine experimentation. According to  
4 Alphatec, if the distal end of the mounting device is not attached within the body, one  
5 of skill in the art would need to determine for each individual patient and surgery how  
6 to make the distal end of the curved member intersect the target space such that the  
7 target space can be accessed and the implant placed there without injuring the patient.  
8 (Foley Decl. ¶ 40.) Specifically, a physician would need to “(1) determine an  
9 appropriate mounting location in the operating room, (2) determine the precise spatial  
10 relationship between that location and the patient, (3) completely immobilize the  
11 patient in relation to the mounting location, so as to maintain the spacial relationship,  
12 (4) determine the appropriate geometry of the curved member based on the  
13 relationship, (5) plot a path that would be intersected by the curved member, (6)  
14 determine what critical anatomical structures were in the vicinity of the path and how  
15 to avoid them, and (7) reconfigure the components of the device based on the  
16 calculated spatial relationships and path.” (Mot. at 18.) In addition, Alphatec argues,  
17 it would be difficult to maintain a fixed relationship between the mounting device and  
18 the target space because patients move during surgery. (Foley Decl. ¶ 44.) Patient  
19 movement may be caused, for example, by the patient’s breathing, the impact of  
20 surgical tools on the patient, and the physician leaning against the patient. (*Id.*)

21           Abdou argues that any experimentation needed to make and use the claimed  
22 apparatuses and surgical techniques would be routine and trivial. First, Abdou submits  
23 evidence that proper patient positioning may greatly reduce involuntary patient  
24 movement. Patients may be secured to a surgical table using straps, surgical tape,  
25 bolsters, chest rolls, and other devices. (Moshirfar Decl. ¶ 23.)<sup>1</sup> Positioning patients  
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27           <sup>1</sup> Alphatec moves to strike the declaration of Ali Moshirfar, M.D., arguing that  
28 (1) it is conclusory, and (2) he did not have the requisite experience needed to be a  
person of ordinary skill in the art by the October 4, 2005 filing date of the '153 patent.  
(Docket No. 59-7.) First, Moshirfar’s Declaration is sufficiently supported by other



1 in this manner allows a surgeon to position other equipment relative to surgical points  
2 of interest, and to maintain this positioning as needed throughout the surgical  
3 procedure. (*Id.*) Second, Abdou submits evidence that by using commonly known  
4 imaging techniques, a surgeon may locate a surgical point of interest within the  
5 patient's body. (*Id.* ¶ 43.) Furthermore, while the precise anatomy of each patient  
6 varies, the location of anatomical structures is known and predictable. (*Id.* ¶ 48.)  
7 Third, Abdou submits evidence that a surgeon may position and maintain other  
8 equipment relative to the surgical point of interest. As discussed below, it is well  
9 known in the art how to anchor surgical devices outside of the patient's body in ways  
10 that maintain the spatial relationship between the patient and the surgical device. (*Id.*  
11 ¶ 24.) Fourth, Abdou submits evidence that a surgeon may determine how to make the  
12 distal end of the insertion device intersect the target location by using the known  
13 distance from the targeted surgical location to the guide arm's center of rotation. (*Id.*  
14 ¶ 43.)

15 Abdou submits sufficient evidence to create a genuine issue of fact as to whether  
16 attaching the distal end of the mounting device outside of the body would require a  
17 large amount of non-routine experimentation. Accordingly, this factor weighs against  
18 finding a lack of enablement.

## 19 2. The Amount of Direction or Guidance Presented

20 Abdou submits evidence that the patents at issue provide sufficient direction and  
21 guidance to practice the claimed invention by attaching the device outside of the  
22 patient's body. In regards to positioning the mounting device, the patents teach that  
23 a surgeon may determine how to make the distal end of the insertion device intersect  
24 the target location by using the known distance from the targeted surgical location to  
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26 evidence, including prior art. Second, Alphatec does not cite any authority for the  
27 proposition that in order to qualify as an expert witness, the expert witness must have  
28 had sufficient experience to qualify as a person of ordinary skill in the art at the time  
the patent was filed. Alphatec's motion to strike Moshirfar's Declaration is **DENIED**.  
In addition, Alphatec's evidentiary objections (Docket No. 59-7) are **OVERRULED**  
to the extent not inconsistent with this Order.

1 the guide arm's center of rotation. ('855 patent, at 2:54-57 ("Since the distance from  
2 the guide arm's center of rotation to the tip of the localizing needle is known, a guide  
3 arm of radius equal to that distance will necessarily form an arc that contains the needle  
4 point on its circumference.");<sup>2</sup> *see also id.* at 2:41-45, 7:30-38, 9:12-31, 9:42-44; '153  
5 patent, at 4:20-22 ("The radius of curvature of the curved portion 140 can vary. In one  
6 embodiment, the radius of curvature is approximately equal to the length of the straight  
7 portion 130.")) In addition, the patents teach how to use imaging techniques to  
8 properly position the devices. *See* '153 patent, at 5:65-6:2 ("[O]ne or more x-ray image  
9 can be taken of the target location and the target location localized using the x-ray  
10 images by iteratively moving the mount so that the insertion device provides a guide  
11 toward the target location."); '855 patent, at 3:38-41 ("[T]here is disclosed a  
12 minimally-invasive surgical procedure, comprising localizing a surgical point of  
13 interest using an x-ray to identify the point of interest; relating the point of interest to  
14 a delivery apparatus . . .").

15       Moreover, the law does not require the disclosure of "what is well known in the  
16 art." *Hybritech*, 802 F.2d at 1384. As explained below, methods for securely  
17 positioning a patient for spine surgery on surgical tables or frames, how to anchor  
18 surgical devices outside of the patient's body in ways that maintain the spatial  
19 relationship between the patient and the surgical device, and various imaging  
20 techniques were well known in the art at the time the patent was filed. Accordingly,  
21 a person of ordinary skill in the art ("POSITA") would need little direction or guidance  
22 to use the claimed inventions by anchoring them outside of the patient's body.  
23 (Moshirfar Decl. ¶ 44.)

24       In support of its argument that there is insufficient guidance presented in the  
25 patents regarding how the devices may attach outside of the body, Alphatec cites

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26       <sup>2</sup> Alphatec argues that where the localizing needle is taught in the patent, it is  
27 attached to screws and a platform that guide the needle into the target space. This  
28 Order cites to the descriptions of the localizing needle in the '855 patent only for the  
purpose of demonstrating that the patent teaches a method for determining the radius  
of a guide arm needed to form an arc with the target location on its circumference.

1 *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371 (Fed. Cir. 2007), *Genentech, Inc.*  
2 *v. Novo Nordisk A/S*, 108 F.3d 1361 (Fed. Cir. 1997), and *Automotive Technologies*  
3 *International, Inc. v. BMW of North America, Inc.*, 501 F.3d 1274 (Fed. Cir. 2007).

4 These cases, however, are inapposite.

5 First, in *Liebel-Flarsheim*, the court found that the claims of the patents at issue,  
6 which covered injectors both with and without a pressure jacket, were not enabled. The  
7 court based its decision, in part, on the fact that the specification failed to describe an  
8 injector without a pressure jacket, and all figures and discussion referred to pressure  
9 jackets. *Liebel-Flarsheim*, 481 F.3d at 1379. The specification, however, explicitly  
10 taught away from an injector without a pressure jacket. *Id.* The court found that  
11 “where the specification teaches against a purported aspect of an invention, such a  
12 teaching is itself evidence that at least a significant amount of experimentation would  
13 have been necessary to practice the claimed invention.” *Id.* (internal quotation marks  
14 omitted). Here, in contrast, the Court has not found that the patents at issue teach  
15 against attaching the device outside of the body.

16 Second, Alphatec cites *Genentech* for the proposition that “[t]ossing out the mere  
17 germ of an idea does not constitute enabling disclosure.” *Genentech*, 108 F.3d at 1366.  
18 The patent at issue in *Genentech* claimed a method for producing hGH by cleaving an  
19 hGH-contained conjugate protein. *Id.* at 1363, 1366. The court determined “whether  
20 the specification would have enabled a person having ordinary skill in the art at the  
21 time of filing to use cleavable fusion expression to make hGH without undue  
22 experimentation.” *Id.* at 1365. Although the specification did not describe how to  
23 make hGH using cleavable fusion expression, *Genentech* argued that “the knowledge  
24 of one skilled in the art was sufficient to provide all of the missing information and,  
25 more specifically, that the disclosure of a DNA encoding hGH, when combined with  
26 prior art cleavable fusion expression techniques applied to non-human proteins, would  
27 enable the practice of the claimed method.” *Id.* The court found the patent to be  
28 invalid. *Id.* Specifically, the court found that the patent contained “no disclosure of

1 any specific starting material or of any of the conditions under which a process can be  
2 carried out.” *Id.* at 1366. Rather, “[t]his specification provide[d] only a starting point,  
3 a direction for future research.” *Id.* The court noted, in fact, that “no one had been able  
4 to produce *any* human protein via cleavable fusion expression as of the application  
5 date.” *Id.* at 1367. The court concluded that “[w]here, as here, the claimed invention  
6 is the application of an unpredictable technology in the early stages of development,  
7 an enabling description in the specification must provide those skilled in the art with  
8 a specific and useful teaching.” *Id.* at 1367-68.

9 Here, in contrast, the claimed invention does not involve unpredictable  
10 technology in the early stages of development. Rather, as discussed below, Abdou  
11 submits evidence that the prior art included methods for securely positioning a patient  
12 for spine surgery on surgical tables or frames, anchoring surgical devices outside of the  
13 patient’s body in ways that maintain the spatial relationship between the patient and the  
14 surgical device, and using various imaging techniques. Unlike the patent in *Genentech*,  
15 the patents at issue here provide more than a starting point for future research.

16 Third, Alphatec cites *Automotive Technologies* in support of its argument that  
17 the patents at issue are not enabled because they contain lengthy explanations regarding  
18 how to practice the invention when the mounting device is attached inside the body,  
19 but not when it is attached outside of the body. The technology at issue in *Automotive*  
20 *Technologies* involved “crash sensing devices for deployment in an occupant  
21 protection apparatus, such as an airbag, during an impact or crash involving the side  
22 of a vehicle.” 501 F.3d at 1277-78. Specifically, the invention was “directed to a  
23 velocity-type sensor placed in a position within a vehicle in order to sense a side  
24 impact.” *Id.* at 1278. The court affirmed summary judgment of invalidity due to lack  
25 of enablement, basing its decision in part on the way the specification described  
26 mechanical side impact sensors in detail, but only briefly described electronic sensors.  
27 *Id.* at 1282. In addition, the court found that at the time the patent was filed, the  
28 plaintiff was not aware of any electronic sensors used to sense side impact crashes. *Id.*

1 at 1283. The court reasoned that “[g]iven that side impact sensing was a new field and  
2 that there were no electronic sensors in existence that would detect side impact crashes,  
3 it was especially important for the specification to discuss how an electronic sensor  
4 would operate to detect side impacts and to provide details of its construction.” *Id.* at  
5 1284. The court concluded that the “specification provide[d] ‘only a starting point, a  
6 direction for further research’ on using electronic sensors for sensing side impact  
7 crashes.” *Id.* (citing *Genentech*, 108 F.3d at 1366).

8 Here, in contrast, the claimed invention is not part of a new field of technology.  
9 Rather, as discussed below, Abdou submits evidence that the prior art included  
10 methods for securely positioning a patient for spine surgery on surgical tables or  
11 frames, anchoring surgical devices outside of the patient’s body in ways that maintain  
12 the spatial relationship between the patient and the surgical device, and using various  
13 imaging techniques. As stated above, the patents at issue here provide more than a  
14 starting point for future research.

15 Abdou submits sufficient evidence to create a genuine issue of fact as to whether  
16 the patents at issue provide sufficient direction and guidance to practice the claimed  
17 invention by attaching the device outside of the patient’s body. Accordingly, this  
18 factor weighs against finding a lack of enablement.

### 19 3. The Presence of Absence of Working Examples

20 The absence of working examples weighs against enablement. *Auto. Techs. Int’l*  
21 *v. BMW of N. Am., Inc.*, 378 F. Supp. 2d 780, 817 (E.D. Mich. 2005), *aff’d* 501 F.3d  
22 1274 (Fed. Cir. 2007). Here, the patents at issue contain no working examples in  
23 which the distal end of the mounting device attaches outside of the body. The absence  
24 of working examples supports finding a lack of enablement.

### 25 4. The Nature of the Invention

26 The ’153 patent claims a relatively simple mechanical device, while the ’855  
27 patent claims a method for using that mechanical device. (Moshirfar Decl. ¶ 45.) Even  
28 Alphatec’s expert witness, Kevin T. Foley, M.D., testifies that “the apparatus claims

1 recite a simple mechanical device.” (Foley Decl. ¶ 52.) Although Alphatec argues that  
2 the claimed device is complex because it is used in minimally invasive spine surgery  
3 which involves significant health risks, this goes toward the seventh factor, the  
4 predictability or unpredictability of the art. Accordingly, this factor weighs against  
5 finding lack of enablement.

## 6           **5. State of the Prior Art**

7           The relevant time frame for determining the state of the prior art is measured  
8 from October 5, 2004, which is the earliest date to which the earliest filed patent at  
9 issue claims priority. *See* U.S. Patent Application No. 60/616,100 (provisional  
10 application for the ’153 patent).

11           At that time, methods for securely positioning a patient for spine surgery on  
12 surgical tables or frames was well known in the art. A variety of positioning  
13 techniques existed, including placing the patient on his or her side, in the prone  
14 position, or on a surgical table or frame. (Moshirfar Decl. ¶ 23.) In addition, straps,  
15 wide tape, bolsters, chest rolls, sand bags, foot boards, buckled boots, and other  
16 supporting pads could be used to secure the patient to the surgical table or frame. (*Id.*)  
17 Numerous surgical reference guides describe such principles and techniques. (Pl.’s  
18 Resp. to Def.’s Statement of Uncontroverted Facts and Conclusions of Law., Exh. 4  
19 [ARTHUR H. WHITE, M.D. ET AL., LUMBER SPINE SURGERY: TECHNIQUES &  
20 COMPLICATIONS, 86-102 (E. Klein ed., C.V. Mosby Co. 1987)], Exh. 5 [ROBERT G.  
21 WATKINS, M.D. ET AL., SURGICAL APPROACHES TO THE SPINE, 167-68 (Springer-Verlag  
22 1983)].)

23           Moreover, how to anchor surgical devices outside of the patient’s body,  
24 including to the surgical table, in ways that maintain the spatial relationship between  
25 the patient and the surgical device was also well known in the art. For instance, U.S.  
26 Patent No. 3,221,743, issued to Richard Thompson, M.D. in 1965 and entitled “System  
27 and Apparatus for Positioning and Securing Surgical Implements,” claimed a surgical  
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1 retractor.<sup>3</sup> This patent claimed an “apparatus for positioning and supporting surgical  
2 accessories and implements in selected positions relative to an operating table and  
3 relative to the body of the patient supported upon the table.” (*Id.*, Exh. 6 [’743 patent,  
4 at 2:11-15].) U.S. Patent No. 8,137,284, filed on October 8, 2003 and entitled  
5 “Surgical Access System and Related Methods,” claimed various methods “of  
6 accessing a spinal target site.” (*Id.*, Exh. 7 [’284 patent, claims 1, 17].) This patent’s  
7 specification stated that “[a]ny number of suitable mounting units (not shown) may be  
8 employed to maintain the retraction assembly 10 in a fixed and rigid fashion relative  
9 to the patient. The mounting structure 20 may be coupled to any number of  
10 mechanisms for rigidly registering the mounting structure 20 in fixed relation to the  
11 operating site, such as through the use of an articulating arm mounted to the operating  
12 table.” (*Id.* at 8:6-12.) In addition, such principles and techniques were well known  
13 and used in the art before 2004, as described in various surgical reference guides.  
14 (Moshirfar Decl. ¶ 24; Pl.’s Resp. to Def.’s Statement of Uncontroverted Facts and  
15 Conclusions of Law, Exh. 4 [LUMBER SPINE SURGERY: TECHNIQUES &  
16 COMPLICATIONS at 375].) References cited on the face of the asserted patents, such as  
17 U.S. Patent No. 5,976,146 (*id.*, Exh. 11, at Fig. 121), disclose mounting surgical  
18 devices outside of the patient’s body in ways that maintain a spatial relationship to the  
19 surgical site.

20 Lastly, various imaging techniques, including x-ray, computed tomography, and  
21 fluoroscopy, have been practiced for decades. (Moshirfar Decl. ¶ 25.) These imaging  
22 techniques can be used during orthopedic surgery to identify, localize, and visualize  
23 bony and soft tissue structures. (*Id.*) Such principles and techniques were well known  
24 in the art long before 2004, and are described in various surgical reference guides. (*Id.*;

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26 <sup>3</sup> Alphatec argues that retractors do not qualify as prior art. According to  
27 Alphatec, retractors are inserted into the body after the surgeon has done significant  
28 surgical dissection to expose the anatomy, while the invention here consists of an  
insertion device that is pushed through tissue through a small incision. Although the  
function of the invention differs from the function of a retractor, this Order refers to  
retractors as prior art only for the purpose of establishing that a POSITA was familiar  
with how to anchor surgical devices outside of the patient’s body.

1 Pl.'s Resp. to Def.'s Statement of Uncontroverted Facts and Conclusions of Law, Exh.  
2 5 [SURGICAL APPROACHES TO THE SPINE, 101, 168].)

3 Accordingly, the state of the prior art weighs against finding a lack of  
4 enablement.

### 5 **6. Relative Skill of Those in the Art**

6 A POSITA includes surgeons with several years of experience in surgical  
7 procedures pertaining to the spine and with the corresponding instruments and tools,  
8 including minimally invasive procedures, instruments, and tools. (Moshirfar Decl. ¶¶  
9 22, 47; Buccigross Decl., Exh. 8, at 16.) A surgeon learns early in his or her training  
10 how to securely position a patient for spine surgery on various surgical tables or  
11 frames, anchor surgical devices outside of the patient's body, and use various imaging  
12 techniques such as x-ray, computed tomography, and fluoroscopy. (Moshirfar Decl.  
13 ¶¶ 23, 24, 25.) Accordingly, the Court finds that a POSITA at the respective  
14 application dates would have been trained and effective in proper patient positioning,  
15 locating surgical points of interest within the body using various imaging techniques,  
16 and positioning and maintaining surgical devices relative to the identified surgical  
17 points of interest. This factor weighs against finding a lack of enablement.

### 18 **7. Predictability or Unpredictability of the Art**

19 The "scope of enablement varies inversely with the degree of predictability  
20 involved." *Application of Angstadt*, 537 F.2d 498, 502 (C.C.P.A. 1976). Here, the  
21 pertinent art is minimally invasive surgical procedures pertaining to the spine.  
22 Minimally invasive spine surgery is difficult and risky. (Foley Decl. ¶ 52.) The  
23 surgeon must distally manipulate small tools. (*Id.*) Moreover, the art is not entirely  
24 predictable because the surgeon cannot directly visualize all of the body parts that he  
25 or she must avoid damaging. (*Id.*) Accordingly, this factor supports finding lack of  
26 enablement.

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1                   **8.     The Breadth of the Claims**

2           The scope of enablement varies inversely with the breadth of the claims. *Auto.*  
3 *Techs.*, 378 F. Supp. 2d at 818-19. The claims of the '153 and '855 patents are fairly  
4 broad. The '153 patent discloses a curved insertion device for delivering an orthopedic  
5 device to a target location using a mount that is positionable at locations inside or  
6 outside of the body that have a spatial relationship to the surgical target. (Moshirfar  
7 Decl. ¶ 49.) The '855 patent covers methods for delivering an orthopedic device onto  
8 a target location by identifying the target location with an imaging method, positioning  
9 a mount in proximity to the target location, and using a curved insertion in conjunction  
10 with the mount to access the target location. (*Id.*)

11           The patents encompass mounting points both inside and outside of the patient's  
12 body. (*Id.*) However, the mounting point is not unconstrained; it must have a spatial  
13 relationship to the target that allows for use of the device. (*Id.*) Accordingly, this  
14 factor weighs slightly towards finding a lack of enablement.

15                   **9.     Conclusion**

16           The absence of working examples, unpredictability of the art, and breadth of the  
17 claims weigh in favor of finding a lack of enablement. However, the quantity of  
18 experimentation needed, the amount of direction and guidance presented, nature of the  
19 invention, state of the prior art, and relative skill of those in the art weigh against  
20 finding a lack of enablement. Alphatec has failed to meet its burden to provide such  
21 clear and convincing evidence of invalidity that no reasonable jury would find  
22 otherwise. *Eli Lilly*, 251 F.3d at 962; *see also Atlas Powder*, 750 F.2d at 1573 (“Under  
23 35 U.S.C. § 282, a patent is presumed valid, and the one attacking validity has the  
24 burden of proving invalidity by clear and convincing evidence.”). Accordingly,  
25 Alphatec’s motion for summary judgment based on lack of enablement is **DENIED**.

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**CONCLUSION**

For the reasons stated above, the Motion for Summary Judgment is **DENIED**.  
**IT IS SO ORDERED.**

DATED: June 27, 2014

  
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HON. ROGER T. BENITEZ  
United States District Judge