UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

NUVASIVE, INC., Plaintiff, v. ALPHATEC HOLDINGS, INC., Defendant.	Case No.: 3:18-CV-347-CAB-MDD **ORDER DENYING MOTION FOR PRELIMINARY INJUNCTION** [Doc. No. 37]

On February 13, 2018, Plaintiff NuVasive, Inc., filed a complaint alleging patent infringement against Defendants Alphatec Holdings, Inc., and Alphatec Spine, Inc., (jointly "Alphatec"). [Doc. No. 1.] The complaint asserts infringement of six patents: U.S. Patent No. 7,819,801; U.S. Patent No. 8,335,780; U.S. Patent No. 8,439,832; U.S. Patent No. 9,833,227; U.S. Patent No. 8,735,270; and U.S. Patent No. 8,361,156.[1] The '801, '780, '832, '227 and '270 patents are directed toward systems and methods for accessing a targeted disc space through a lateral, trans-psoas path ("the Access Platform patents"). The '156 patent describes a spinal implant that is introduced into the disc space of a patient's spine from a lateral approach ("the Implant patent"). [Doc. No. 38, at 8-9.][2]

On April 5, 2018, NuVasive filed a motion for preliminary injunction. [Doc. No. 37; Doc. No. 38 (sealed version).] NuVasive seeks to enjoin sales and use of the accused

[1] The complaint also asserted infringement of two design patents, but the Court granted Alphatec's motion to dismiss those claims with prejudice. [Doc. No. 45.]

[2] Document numbers and page references are to those assigned by CM/ECF for the docket entry.

Battalion™ Lateral System, which includes the Squadron™ Lateral Retractor, and the Battalion™ Lateral Spacer, during the pendency of the litigation. The parties filed a joint request on April 12, 2018, to extend the briefing schedule to allow for discovery. [Doc. No. 39.] Alphatec filed its opposition on May 17, 2018. [Doc. No. 49, Doc. No. 53 (sealed version).] NuVasive filed a reply on June 14, 2018. [Doc. No. 77, Doc. No. 79 (sealed version).] A hearing on the motion was held on June 21, 2018. [Doc. No. 87.] For the reasons set forth on the record at the hearing and as discussed below, the motion is DENIED.

I. Background

NuVasive is a medical device company with over $1 billion in annual revenues. In 2003, NuVasive launched a minimally-invasive, lateral access surgical procedure for spinal surgery, known as XLIF. The patented procedures and tools utilized in XLIF surgery, including the MaXcess® retractor and CoRoent® XLIF implants, allow for a lateral approach to a patient's targeted spinal disc space through the psoas muscle and for the delivery of a large, oversized implant for spinal fusion. [Doc. No. 38, at 6-7.] For over a decade, NuVasive has developed, patented and marketed the XLIF procedure and components. This product line now accounts for conservatively $250-300 million of NuVasive's annual revenue. [Id., at 8.]

In approximately July 2014, Alphatec began developing a competing lateral access surgical procedure that became known as its Battalion Lateral System. On April 5, 2016, Alphatec submitted the accused components and procedure for FDA approval, which it received on September 8, 2016. On February 14, 2017, Alphatec made its first sale and public surgical use of the accused components. [Doc. No. 79-4, at 7.] In April 2017, Alphatec launched a limited release of the Battalion Lateral System. Alphatec made a full launch in October 2017. [Doc. No. 1, ¶ 43.] NuVasive now seeks to enjoin Alphatec from making, using, selling, offering to sell, or importing into the United States the components of Alphatec's Battalion Lateral System, specifically the Squadron Lateral Retractor,

Dilators, K-Wire, Intradiscal Shim and Shim Inserter Tool, 4th Blade and Light Cable/Light Source Connector; and Alphatec's Battalion Lateral Spacer.

II. Legal Standard

The grant or denial of a preliminary injunction under 35 U.S.C. § 283 is within the sound discretion of the district court. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). "A preliminary injunction is an extraordinary remedy never awarded as a matter of right." *Winter v. Natural Resources Defense Council*, 555 U.S. 7, 24 (2008). "A plaintiff seeking a preliminary injunction must establish that [it] is likely to succeed on the merits, that [it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction is in the public interest." *Id*. at 20. The district court must weigh and measure each factor against the other factors and against the form and magnitude of the relief requested. "[A] movant cannot be granted a preliminary injunction unless it establishes *both* of the first two factors, *i.e.* likelihood of success on the merits and irreparable harm." *Amazon.com*, 239 F.3d at 1350.

III. Likelihood Of Success On The Merits

To demonstrate a likelihood of success on the merits, the movant must show that it will likely prove infringement of one or more claims of the asserted patents and that at least one of the same allegedly infringed claims will also likely withstand the validity challenges presented by the accused infringer. *See Amazon.com*, 239 F.3d at 1350-51 (holding that if the non-movant raises a substantial question concerning either infringement or validity that the patentee cannot prove "lacks substantial merit," the preliminary injunction should not issue). Thus, in considering NuVasive's motion, the Court must assess infringement claims made by NuVasive as well as any invalidity arguments made by Alphatec.

A. Infringement

The burden lies with the patentee to establish that the accused product infringes by a preponderance of the evidence. An infringement analysis involves two steps. First, the claim scope must be determined. Second, the properly construed claim is compared with

the accused devices to determine whether all the claim limitations are present either literally or by a substantial equivalent. *Amazon.com*, 239 F.3d at 1351.

NuVasive asserts the Access Platform patents against Alphatec's Battalion Lateral System and the Implant patent against the Battalion Lateral Spacer. A demonstration of the likelihood of a finding of infringement as to an asserted independent claim of any of the following patents could support NuVasive's request to enjoin the sale of the Battalion Lateral System: the '801 Patent (System Claim 1); the '780 Patent (System Claim 21); the '832 Patent (System Claim 1 or Method Claim 12); and the '227 Patent (Method Claims 1 or 16).[3] In response to the Court's request that NuVasive select the claim it considers best demonstrates its burden on infringement and validity [Doc. No. 86], NuVasive elected to proceed at argument on Claim 1 of the'832 patent and Claim 1 of the '156 patent.

Claim 1 of the '832 Patent

The '832 Patent is for a Surgical Access System and Related Methods. [Doc No. 1-8, at 2-34.] It is directed at a system for establishing an operative corridor to the spine through the psoas muscle. Claim 1 claims:

> 1. A system for forming an operating corridor to a lumbar spine, comprising:
> a distraction assembly to create a tissue distraction corridor in a lateral, trans-psoas path to a lumbar spine, wherein said distraction assembly includes an elongate inner element and a plurality of dilators, the plurality of dilators being configured to sequentially advance along the lateral, trans-psoas path to the lumber spine, the elongate inner element being positionable in a lumen of an initial dilator of the plurality of dilators, wherein at least one instrument from the group consisting of said elongate inner element and said dilators includes a stimulation electrode that outputs electrical stimulation for nerve monitoring when the at least one instrument is positioned in the psoas muscle;

[3] The asserted claims of '270 Patent allegedly cover the accused Alphatec Intradiscal Shim device. [Doc. No. 1-12, at 32, Col. 14:30-61.] A finding of a likelihood of infringement of the asserted claims would not support the request to enjoin sales or use of the whole Battalion Lateral System or the Squadron Retractor, just that component.

> a three-bladed retractor tool slidable over an exterior of an outermost sequential dilator of the dilator system toward the targeted spinal disc along the lateral, trans-psoas path, the three-bladed retractor assembly including:
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> a blade-holder assembly, and
>
> a posterior-most retractor blade, a cephalad-most retractor blade, and a caudal-most retractor blade that extend from the blade-holder assembly, wherein the posterior-most, cephalad-most, and caudal-most retractor blades are slideably advanced over the exterior of the outermost sequential dilator while in a first position, wherein the blade-holder assembly is adjustable to move the posterior-most, cephalad-most, and caudal-most retractor blades to a second position in which the cephalad-most and caudal-most retractor blades are spaced apart from the posterior-most retractor blade to define an operative corridor,
>
> wherein three-bladed retractor tool is configured to define the operative corridor along the lateral, trans-psoas path to the lumber spine in which a space extending to the targeted spinal disc between the posterior-most, cephalad-most, and caudal-most refractor blades is dimensioned so as to pass an implant through the operative corridor along the lateral, trans-psoas path to the lumbar spine.

[Doc. No. 1-8, at 31-32, Col. 14:31- Col. 15:3.]

NuVasive alleges that the limitations of Claim 1 of the '832 patent read on Alphatec's Battalion Lateral System. *See* Declaration of Jim A. Youseff, M.D., ¶¶ 171-191, and Appendix C. [Doc. No. 37-45, at 70-74; Doc. No. 37-71, at 2-21.] Referencing the Alphatec Battalion Lateral Lumbar Spacer System Thoracolumbar Surgical Technique Guide and devices disclosed therein, [Doc. No. 1-38, at 2-30], NuVasive demonstrated that the Battalion Lateral System: (1) forms an operative corridor to the patient's lumbar spine through the psoas muscle; (2) uses an initial dilator with neuromonitoring to traverse the psoas to the disc space; (3) introduces a K-wire (elongate inner element) through the initial dilator into the disc space; (4) introduces a secondary sequential dilator over the initial dilator [Id., at 7-9]; and (5) introduces a retractor, called the Squadron Retractor, over the second dilator and moves it flush to the disc space [Id., at 11.] The Squadron Retractor is a tool with a blade-holder assembly and three blades, center, right and left. [Id., at 15, 17,

30.] The right and left blades can be moved cranially and caudally to open access to the disc space to introduce the implant. [Id., at 16-17, 21, 25.]

In response, Alphatec contends that NuVasive cannot demonstrate that the accused system infringes Claim 1 of the '832 patent because the Battalion Lateral System does not meet the limitation of "a distraction assembly" that includes an elongate inner element and plurality of dilators. [Doc. No. 53, at 13.] Alphatec's expert, Dr. Barton Sachs, opines that "assembly" in this claim should be construed as pre-assembled components that allow the parts to be introduced simultaneously. *See* Declaration of Barton L. Sachs, M.D., ¶¶ 122-125. [Doc. No. 49-5, at 45-46.] Dr. Sachs points out that in connection with the reexamination of the '801 patent, NuVasive's expert Dr. Youssef distinguished prior art by defining the "handle assembly" of that invention as pre-assembled components that introduce the parts of the assembly simultaneously. [Doc. No. 49-5, ¶ 124.]

The Court is not persuaded, at least for the purposes of the instant motion, that the limitation of a distraction assembly in the '832 patent must be construed as a "pre-assembled" set of components for simultaneous introduction. The distraction assembly is a collection of components, including the elongate inner element and a plurality of dilators. The claim language states that the plurality of dilators included in the assembly are sequentially advanced along the trans-psoas path, indicating they are introduced in sequence not simultaneously. [Doc. No. 1-8, Col. 14:35-38.] Neither the claim language nor the specification support a construction that this assembly of components is preassembled to be introduced into the patient simultaneously.

Alphatec asserted no other challenge to NuVasive's infringement analysis of Claim 1 of the '832 patent. Thus, for purposes of this motion, the Court finds that NuVasive has demonstrated a likelihood of success with regard to its allegation that the Battalion Lateral System and Squadron Retractor infringe Claim 1 of the '832 Patent.

Claim 1 of the '156 Patent

According to the abstract, the '156 Patent is a "system and method for spinal fusion comprising a spinal fusion implant of non-bone construction releasably coupled to an

insertion instrument dimensioned to introduce the spinal fusion implant into any of a variety of spinal target sites. [Doc. No. 1-14, at 2.] Claim 1 claims:

> 1. A spinal fusion implant of non-bone construction positionable within an interbody space between a first vertebra and a second vertebra, said implant comprising:
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> an upper surface including anti-migration elements to contact said first vertebra when said implant is positioned within the interbody space, a lower surface including anti-migration elements to contact said second vertebra when said implant is positioned within the interbody space, a distal wall, a proximal wall, a first sidewall, and a second sidewall generally opposite from the first side wall, wherein said distal wall, proximal wall, first sidewall and second sidewall comprise a radiolucent material;
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> wherein said implant has a longitudinal length extending from a proximal end of said proximal wall to a distal end of said distal wall, said implant has a maximum lateral width extending from said first sidewall to said second sidewall along a medial plane that is generally perpendicular to said longitudinal length, and said longitudinal length is greater than said maximum lateral width;
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> at least a first fusion aperture extending through said upper surface and lower surface and configured to permit bond growth between the first vertebra and the second vertebra when said implant is positioned within the interbody space, said first fusion aperture having: a longitudinal aperture length extending generally parallel to the longitudinal length of said implant, and a lateral aperture width extending between said first sidewall and said second sidewall, wherein the longitudinal aperture length is greater than the lateral aperture width; and
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> at least first and second radiopaque markers oriented generally parallel to a height of the implant, wherein said first radiopaque marker extends into said first sidewall at a position proximate to said medial plane, and said second radiopaque marker extends into said second sidewall at a position proximate to said medial plane.

[Doc. No. 1-14, at 30, Col. 12:32-67.]

NuVasive alleges that the limitations of claim 1 read on the Battalion Lateral Spacer. [Doc. No. 38, at 16-17]. *See* Youseff Declaration ¶¶ 317-334, and Appendix F. [Doc. No. 37-45, at 103-108; Doc. No. 37-74, at 2-24.] The Battalion Lateral Spacer is a spinal fusion implant made of non-bone material with anti-migration ridges on both sides of the implant.

[Doc. No. 1-39, at 2.] It is manufactured from a radiolucent material, poly-ether-ether–ketone ("PEEK"). [Doc. No. 1-38, at 29.] It has a distal wall generally opposite a proximal wall and a first sidewall generally opposite a second sidewall. The longitudinal length from proximal wall to the distal wall is greater than the maximum lateral width from the first sidewall to the second sidewall. [Doc No. 1-39, at 2.] It has a first fusion aperture extending through the upper and lower surface, having a longitudinal length extending generally parallel to the longitudinal length of the implant and a width extending between the first and second sidewall, the length of the aperture being greater than the width. [Id.] The Battalion Lateral Spacer has radiopaque markers extending into the first and second sidewalls at a position proximate to the medial plane (i.e., near the middle of the implant). [Doc. No. 37-47, at 8.]

Alphatec did not challenge Dr. Youseff's infringement analysis of Claim 1 of the '156 patent in its opposition brief. [Doc. No. 53, at 15.] Consequently, for purposes of this motion, the Court finds that NuVasive has demonstrated a likelihood of success with regard to its allegation the Battalion Lateral Spacer infringes this claim.

B. Validity

Having established a likelihood of success on the merits with regard to infringement of Claim 1 of the '832 patent and Claim 1 of the '156 patent, NuVasive must also demonstrate that those claims are likely to withstand the validity challenges presented by Alphatec. *Amazon.com*, 239 F.3d at 1350-51. In the context of a motion for preliminary injunction, the patentee must present a clear case supporting the validity of the patent in suit. *Id.* at 1359 ("for example by showing that the patent in suit had successfully withstood previous validity challenges in other proceedings").

In resisting a preliminary injunction, "one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial." *Id.* "Validity challenges during preliminary injunction proceedings can be successful, that is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment at trial." *Id.* at 1358.

'832 Patent

The '832 patent is a continuation of U.S. Patent 7,691,057. [Doc.No.1-8, at 1.] The '057 Patent was the subject of an *inter partes* reexamination ("IPR"), and in its Final Decision on Appeal, the Patent Trial and Appeal Board ("PTAB") found method claims 17-22 and 24-27 unpatentable over certain prior art. [Doc. No. 49-5, at 121, ¶ 423; Doc. No. 49-63, at 7.] While an appeal of the PTAB's final decision was pending before the Federal Circuit, NuVasive and the third party that brought the IPR reached a settlement. As a result, the PTAB's determination of invalidity was neither affirmed nor reversed.

Alphatec's expert, Dr. Sachs, submitted an analysis demonstrating the similarities between claim 1 of the '832 patent and the claims of the '057 patent that were found to be obvious (claims 17, 18 and 27) by the PTAB. [Doc. No. 49-5, at 122-24, ¶ 427.] In light of the PTAB finding of obviousness of the method claims of the '057 and those claims' similarity to claim 1 of the '832 patent, a continuation of the '057 patent, Alphatec has raised substantial question of invalidity as to claim 1 of the '832 patent.

NuVasive offers no specific response to the challenge to the validity of the '832 patent. [Doc. No. 79, at 13-14.] NuVasive's general arguments that all Alphatec's invalidity arguments are based on hindsight and do not discuss the objective indicia of non-obviousness[4] are insufficient to present a clear case supporting validity, as is NuVasive's burden here. Consequently, for purposes of this motion, the Court finds that NuVasive has not demonstrated a likelihood of success with regard to Alphatec's challenge to the validity of claim 1 of the '832 patent.

[4] NuVasive relies upon *Plantronics, Inc. v. Aliph, Inc.* 724 F.3d 1343 (Fed. Cir. 2013), to support its assertion that for Alphatec's validity challenge to be sufficient it required a discussion of indicia of non-obviousness. However a preliminary injunction was not at issue in *Plantronics* and the case offers no support for NuVasive's contention that such an analysis by the party contesting validity is required to oppose a motion for preliminary injunction.

'156 Patent

With regard to the '156 patent, Alphatec has raised a substantial question as to the validity of claim 1. The '156 patent was the subject of an IPR proceeding and in its Final Written Decision, the PTAB concluded claim 1, among others, was unpatentable, finding it obvious in light of certain prior art references. The Federal Circuit vacated the decision and remanded because the PTAB failed to articulate the motivation to combine the prior art references to place the radiopaque markers on the medial plane (i.e., near the middle of the insert). *In re NuVasive, Inc*, 842 F.3d 1376, 1384-85 (Fed. Cir. 2016). [Also Doc. No. 49-5, at 168, ¶¶ 625-629; Doc No. 49-69.] On remand the PTAB was directed to make additional findings and explanations regarding the motivation to combine. *In re NuVasive, Inc*, 842 F.3d at 1385. The parties to the IPR settled before the PTAB reached a determination on remand leaving the matter unresolved. [Doc. No. 49-5 at 168, ¶629.] Thus, the challenge raised by Alphatec to the validity of claim 1 of the'156 patent remains a substantial question.

With its opposition, Alphatec included an analysis by Dr. Sacks of the obviousness of claim 1 of the '156 patent, including his explanation of the motivation for one of skill in the art to combine the references. [Doc. No. 49-5, at 159-165, 168, ¶¶ 578-597, 625-629.] In response NuVasive must present a clear case supporting the validity of the patent in suit. *Amazon.com*, 239 F.3d at 1359. It does not.

NuVasive offers no specific response to the challenge to the validity of the '156 patent. [Doc. No. 79, at 13-14.] To oppose a preliminary injunction Alphatec does not need to make out a case of actual invalidity, only vulnerability. *Id*. NuVasive's contention that "Alphatec has not demonstrated likelihood that they will prove invalidity by clear and convincing evidence," improperly shifts the burden to Alphatec in the context of this motion. For purposes of this motion, the Court finds that NuVasive has not demonstrated a likelihood of success with regard to Alphatec's challenge to the validity of claim 1 of the '156 patent.

Assignor Estoppel

NuVasive's foremost contention regarding Alphatec's challenges to the validity of the Access Platform patents, including the '832 patent, is that Alphatec should be barred by the doctrine of assignor estoppel from contesting validity.[5] Assignor estoppel is an equitable remedy that prohibits an assignor of a patent, or one in privity with an assignor, from attacking the validity of that patent when he is sued for infringement by the assignee. *MAG Aerospace Indus. v. B/E Aerospace*, 816 F.3d 1374, 1379-80 (Fed. Cir. 2016). As an equitable doctrine, the application of assignor estoppel is within the sound discretion of the trial court. *Checkpoint Sys., Inc. v. All-Tag Sec. S.A.*, 412 F.3d 1331, 1337 (Fed. Cir. 2005).

NuVasive contends Alphatec is in privity with Patrick Miles, an inventor of the Access Platform patents. Whether Alphatec is in privity and should be bound by the doctrine of assignor estoppel depends on the equities dictated by the relationship between the inventor and the company in light of the act of infringement. *Shamrock Tech., Inc. v. Med. Sterilization, Inc.*, 903 F.2d 789, 793-94 (Fed. Cir. 1990).

To determine whether a finding of privity is appropriate, the Court considers a number of factors identified in *Shamrock Technologies:* (1) the assignor's leadership role at the employer; (2) the assignor's ownership stake in the defendant company; (3) whether the defendant company changed course from manufacturing non-infringing goods to infringing activity after the inventor was hired; (4) the assignor's role in the infringing activities; (5) whether the inventor was hired to start the infringing operations; (6) whether the decision to manufacture the infringing products was made partly by the inventor; (7) whether the defendant company began manufacturing the accused product shortly after hiring the assignor; and (8) whether the inventor was in charge of the infringing operation. *MAG Aerospace Indus.*, 816 F.3d at 1380.

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[5] The doctrine of assignor estoppel does not apply to the '156 patent.

Mr. Miles has 25 years of industry experience, and was a "central figure" in NuVasive's history. [Doc No. 1-43, at 2.] Just prior to joining Alphatec, he was NuVasive's Vice Chairman responsible for strategic plans for the future of spine surgery and supporting technical development. [Doc. No. 1-3, at 7.] A named inventor on all the asserted Access Patents, Mr. Miles assigned all his right, title and interest in those patents to NuVasive.

On October 2, 2017, Mr. Miles joined Alphatec as Executive Chairman and on March 8, 2018, he assumed the role of Chief Executive Officer. [Doc No. 1-43 at 2.] It is undisputed that Mr. Miles holds a leadership role at Alphatec and was recruited to further define and implement Alphatec's strategic initiatives, expand relationships with surgeon customers and lead new technology development. [Id.] His leadership position supports a finding of privity, but it is not dispositive. *See e.g., HWB, Inc. v. Braner, Inc*., 869 F.Supp. 579, 581-82 (N.D. Ill. 1994) ("the relevant knowledge and assistance of which the defendant company avails itself is knowledge and assistance associated with the manufacture of the infringing product").

Alphatec had embarked on the development and marketing of the accused systems and devices long before Mr. Miles joined the company. Mr. Miles was not brought on board to initiate the allegedly infringing activity, but rather for his expertise to promote and increase Alphatec's share in the spine surgery market. [Doc. No. 38, at 19.] On or about December 27, 2017, Mr. Miles closed on the purchase of Alphatec common stock directly and through his company, MOM, LLC, resulting in his ownership of approximately 11.6% of Alphatec's common stock. [Doc Nos. 1-3 at 6; 1-42 at 6, 8; 1-43 at 3.] Mr. Miles' investment reflects his commitment to Alphatec's initiative to compete in the spinal surgery market, but does not demonstrate effective control over Alphatec's operations. The timing of his investment and his percentage of interest does not demonstrate that he financially enabled the alleged development of the accused system as suggested by NuVasive. *See Mentor Graphics Corp. v. Quickturn Design Sys*., 150 F.3d 1374, 1379

(Fed. Cir. 1998) (Meta, the assignor, sold all its stock Mentor, the party found in privity, to obtain the capital so Meta could manufacture the accused devices.)

The remaining factors in a privity analysis focus on the role that assignor had at the defendant company in the decision to engage in the manufacture of the accused device. *MAG Aerospace Indus*., 816 F.3d at 1380 (change course to infringing activity after inventor was hired; role in the infringing activities; hired to start infringing operations; decision to manufacture infringing products made in part by inventor; began manufacturing shortly after hiring inventor; and inventor in charge of the infringing operation). Mr. Miles was not affiliated with Alphatec when these decisions were made.

Alphatec began research and development of the Battalion Lateral System in 2014. [Doc. No. 1, at ¶ 58; Doc. No. 1-30, at 3.] In 2016, Alphatec sought and received FDA clearance for the accused system. [Doc. No. 37-9, at 6.] The Alphatec Surgical Guide [Doc No. 1-38, at 2-30] that provided the basis for many of NuVasive's infringement contentions, was published January 5, 2017. [Id., at 30.] On February 14, 2017, Alphatec made its first sale and public surgical use of the accused components. [Doc. No. 79-4, at 7.] In April of 2017, Alphatec launched a limited release of the Battalion Lateral System. Alphatec made a full launch in October of 2017. [Doc. No. 1, ¶ 43.] Mr. Miles joined Alphatec on October 2, 2017. By the time he became an officer at Alphatec, the company was already deeply committed to, manufacturing and promoting the accused system.

Based on the evidence presently before the Court, the Court finds that Mr. Miles' role at Alphatec is to promote the sale and any future development of the accused system. Alphatec however had embarked on its competing technology, and it was fully developed well before it sought any of Mr. Miles' expertise. Mr. Miles' status at Alphatec, and the expertise he brings in sales and marketing, does not compel a finding of assignor estoppel based on privity. Accordingly, for purposes of the motion for preliminary injunction, NuVasive has not demonstrated a likelihood of success with regard to its position that the doctrine of assignor estoppel bars Alphatec from asserting invalidity defenses against the Access Platform patents.

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In sum, for the purposes of the instant motion NuVasive has sufficiently established a likelihood of success on its claims for infringement of Claim 1 of the '832 patent and Claim 1 of the '156 patent. However, NuVasive has not demonstrated a clear case that those claims are likely to withstand the validity challenges presented by Alphatec. As a result, NuVasive has not met its burden to establish a likelihood of success on the merits. For this reason alone, NuVasive's motion fails.

IV. Irreparable Harm

Even if NuVasive had established a likelihood of success on the merits, its motion would still fail because it has not established irreparable harm. A patentee must make a clear showing that it is at risk of irreparable harm, which entails showing a likelihood of substantial and immediate irreparable injury. *Apple, Inc. v. Samsung Electronics Co, Ltd., Inc.*, 678 F.3d 1314, 1325 (Fed. Cir. 2012). There is no presumption of irreparable harm in patent infringement cases. *Robert Bosch LLC v. Pylon Mfg. Corp*., 659 F.3d 1142, 1149 (Fed. Cir. 2011) ("eBay jettisoned the presumption of irreparable harm as it applies to determining the appropriateness of injunctive relief.") "An injunction will not be issued simply to prevent the possibility of some remote future injury." *Winter*, 555 U.S. at 22 (citing 11A C. Wright, A. Miller, & M. Kane, Federal Practice and Procedure § 2948.1, p. 154-55 (2d ed. 1995)). Issuing an injunction based only on a possibility of irreparable harm is inconsistent with the characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief. *Id.* at 22.

Potential lost sales alone is not sufficient to manifest irreparable harm. *Abbott Labs v. Andrez Pharm, Inc*., 452 F.3d 1331, 1348 (Fed. Cir. 2006) ("acceptance of that position [loss of sales alone] would require a finding of irreparable harm to every manufacturer/patentee regardless of circumstances"). On the other hand, evidence showing that no amount of monetary damages could address the harm caused by the alleged infringement tends to support a finding of irreparable harm. *Metalcraft of Mayville, Inc. v.*

The Toro Com., 848 F.3d 1358, 1368 (Fed. Cir. 2017). Price erosion, loss of goodwill, damage to reputation and loss of business opportunities are all valid grounds for finding irreparable harm. *Celsis in Vitro, Inc. v. Celezdirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012).

NuVasive argues that Alphatec's offering of its competing product line is causing an immediate and irretrievable defection of long-time NuVasive customers and a decline in NuVasive's market share. Nuvasive also contends that competition from Alphatec will likely result in price erosion, loss of goodwill and loss of business opportunities. To support these contentions, NuVasive provided the Declaration of Matthew Link, Executive Vice President of Strategy, Technology and Corporate Development for NuVasive. [Doc. No. 38-2.]

As of April 5, 2018, when his declaration was filed, Mr. Link states that starting in or about October 2017, NuVasive became aware that Alphatec was targeting NuVasive's long-time customers with the intent to convert them irretrievably to Alphatec's competing lateral surgical offerings.[6] [Id., at 30-31, ¶ 52 (identifying 14 surgeons with customer relationships to NuVasive contacted by Alphatec representatives).] Mr. Link identifies seven surgeons persuaded to try Alphatec's products, and three of those seven he characterizes as having been converted to Alphatec's lateral portfolio. [Id., at 31-36, ¶¶ 53-61.]

On June 14, 2018, Mr. Link filed a supplemental declaration in conjunction with NuVasive's reply brief.[7] [Doc. No. 79-3.] In that declaration, Mr. Link states that in the

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[6] NuVasive must establish irreparable harm arising from sales of the accused products. Link's reference to "lateral surgical offerings" is insufficient as "lateral surgical offerings" could include products that are not accused of infringing the patents. Moreover, the evidence indicates that the majority of actual sales of alleged infringing products were of implants that allegedly infringe the '156 Patent as opposed to the Access Platform patents.

[7] Alphatec's Motion to Exclude New Evidence Submitted on Reply [Doc. No. 84], with regard to Mr. Link's Declaration, for improperly providing new evidence in reply, is overruled. The Court finds the portions of the declaration updating NuVasive's information regarding the impact of the presence of Alphatec's lateral surgical system in the market relevant and appropriate.

ten weeks since he made his first declaration, he can identify seven more NuVasive customers who have been targeted by Alphatec to switch to Alphatec's product line. [Id., at 7-8, ¶ 9.] As of June 14, 2018, Mr. Link contends that from the original fourteen surgeons he identified and the seven additional surgeons identified in his supplement declaration, he has information that eleven surgeons have tried Alphatec products. [Id. at 9-13, ¶¶ 10-21.] Mr. Link's supplemental declaration contends that six of those elevens surgeons have been "converted," probably irretrievably to Alphatec's product line.

In an interrogatory response dated June 11, 2018, [Doc. No. 79-4, at 3-6], Alphatec acknowledges that since April, 2017 to that date, it offered its products to 99 surgeons, 74 of whom NuVasive identifies as its customers. Alphatec also acknowledges that it sold an Alphatec product to 39 of those customers NuVasive identifies as its customers.[8] [Id.] Although this supports NuVasive's contention that NuVasive has lost some sales to Alphatec, it is not convincing that customers are being wholly and irretrievable converted to Alphatec's products.

Alphatec, through the declaration of Kelli Howell, Executive Vice President of Clinical Strategies at Alphatec Spine, [Doc. No. 49-1], represents that a number of surgeons using NuVasive's XLIF products investigated and/or tried Alphatec's products but then continued to use NuVasive's products. [Id., at 6, ¶ 23.] Although NuVasive disagrees with her statement, the revenue figures provided by Alphatec for sales of the accused components from April 2017 to June 2018 corroborate her assessment. Specifically, Alphatec's June 11, 2018 interrogatory responses show sales of the accused components of just over $1.9 million since April of 2017, with approximately 80% of those sales

[8] The materials provided to the Court represent that Alphatec has contacted existing NuVasive customers, but not what percentage of NuVasive's overall customer base those contacts represent. The significance of offers to 74 customers and sales to 39 of them is difficult to evaluate without knowing the percentage of NuVasive's total customers that represents. The dollar value of those sales which the Court does have however does not support a conclusion this "inroad" into NuVasive's customer base has been substantial and irreparable.

attributable to Battalion Lateral implants. [Doc. No. 79-4, at 10-11.] During that time period, sales of $358,475 were attributable to the Battalion Lateral System components. Of those sales, 25% were to non-NuVasive customers, meaning the estimated total revenue generated by sales of the Battalion Lateral System components to NuVasive customers over an eight month period (based on the October full launch of the product line) is only $268,856.

Compared to NuVasive's representation that its competing XLIF system accounts for $250-$300 million in annual revenue [Doc. No. 38, at 8], Alphatec's total revenue reported in its interrogatory response since the introduction of is Battalion line has been less than three-quarters of one percent of NuVasive's annual sales in this market. Although the magnitude (or lack thereof) of the harm will not determine whether it is irreparable, it does strongly suggest that the rate of conversion is not nearly as severe as NuVasive contends. Nor do these numbers support NuVasive's contention that Alphatec's entry into the market is substantially eroding its market share. *See Cordis Corp. v. Boston Scientific Corp.*, 99 Fed. Appx. 928, 934 (Fed. Cir. 2004) (relevant market effects may factor into the balance of hardships). These numbers simply do not demonstrate a substantial, ongoing and irretrievable move by NuVasive's customers to Alphatec's lateral surgical system, despite NuVasive's dire characterizations. [Doc No. 79 at 16, fn.17 ("Alphatec's high ratio of NuVasive customers (and targeted customers) after less than one year fully on the market and the rate of conversion underscores the immediacy of the harm.")]

NuVasive has not demonstrated that Alphatec's entry into the market has resulted in significant market share loss, any price erosion, or loss of goodwill. Mr. Link asserts these are possibilities in the future but provides no support that Alphatec is undercutting NuVasive in the market, that there has been a reduction in prices to compete, or that NuVasive's reputation as an industry leader and innovator has been diminished. "An injunction will not be issued simply to prevent the possibility of some remote future injury." *Winter*, 555 U.S. at 22.

NuVasive is clearly distressed by Alphatec's entry into the market, particularly since a number of NuVasive's former employees elected to join Alphatec.[9] Alphatec is calling upon surgeons, including NuVasive's customers, to promote its new product line causing some lost sales for NuVasive. The actual impact of Alphatec's efforts in the market however do not support NuVasive's contention that the defendant is causing substantial and irreparable injury that cannot be compensated by money damages. Accordingly, NuVasive has not met its burden to make a clear showing of a likelihood of substantial and immediate irreparable injury meriting injunctive relief.

V. Conclusion

"[A] movant cannot be granted a preliminary injunction unless it establishes *both* of the first two factors, *i.e.* likelihood of success on the merits and irreparable harm." *Amazon.com*, 239 F.3d at 1350. NuVasive has not met its burden to establish either of these two necessary factors.

The remaining factors to do change the analysis. The balance of equities may arguably lean in NuVasive's favor given the employment of former NuVasive personnel by Alphatec promote its competitive position in the market. But there is also an interest in allowing individuals to move in a competitive market and use their skills so long as they are not constrained by contractual obligations. Additionally, NuVasive's large market share as compared with the market share of Alphatec can be considered in the balance of equities. *Bell & Howell Document Mgt. Prod. Co. v. Altek Sys*. 132 F.3d 701, 708 (Fed. Cir. 1997). NuVasive is the dominant player in this market with established customer relationships, and the information before the Court a year after Alphatec's entrance into the market shows it has not made a substantial or sustained impact.

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[9] NuVasive contends that Alphatec is "continuously and systematically looting" or "poaching" NuVasive key employees. [Doc. No. 37-1, at 10, 28.] That characterization is refuted. For example, Ms. Howell, one of those alleged poached employees, states that she did not have an offer from Alphatec when she elected to leave NuVasive. [Doc No. 49-1, at 3, ¶ 10.]

There has been no showing that the public interest will be benefitted or burdened as a result of either a grant or denial of the requested injunction. Therefore the Court finds these remaining factors do not overcome NuVasive's insufficient showing of likelihood of success on the merits and irreparable harm. The motion for preliminary injunction is **DENIED**.

It is **SO ORDERED**.

Dated: July 10, 2018

Hon. Cathy Ann Bencivengo
United States District Judge