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6 UNITED STATES DISTRICT COURT
7 SOUTHERN DISTRICT OF CALIFORNIA

8 NUVASIVE, INC.,

9 Plaintiff,

10 v.

11 ALPHATEC HOLDINGS, INC.,

12 Defendant.

Case No.: 3:18-CV-347-CAB-MDD

**ORDER DENYING MOTION FOR
PRELIMINARY INJUNCTION**

[Doc. No. 37]

13
14 On February 13, 2018, Plaintiff NuVasive, Inc., filed a complaint alleging patent
15 infringement against Defendants Alphatec Holdings, Inc., and Alphatec Spine, Inc.,
16 (jointly “Alphatec”). [Doc. No. 1.] The complaint asserts infringement of six patents: U.S.
17 Patent No. 7,819,801; U.S. Patent No. 8,335,780; U.S. Patent No. 8,439,832; U.S. Patent
18 No. 9,833,227; U.S. Patent No. 8,735,270; and U.S. Patent No. 8,361,156.¹ The ‘801, ’780,
19 ‘832, ‘227 and ‘270 patents are directed toward systems and methods for accessing a
20 targeted disc space through a lateral, trans-psoas path (“the Access Platform patents”). The
21 ‘156 patent describes a spinal implant that is introduced into the disc space of a patient’s
22 spine from a lateral approach (“the Implant patent”). [Doc. No. 38, at 8-9.]²

23 On April 5, 2018, NuVasive filed a motion for preliminary injunction. [Doc. No. 37;
24 Doc. No. 38 (sealed version).] NuVasive seeks to enjoin sales and use of the accused
25

26
27 ¹ The complaint also asserted infringement of two design patents, but the Court granted Alphatec’s motion
28 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.

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

9 **I. Background**

10 NuVasive is a medical device company with over \$1 billion in annual revenues. In
11 2003, NuVasive launched a minimally-invasive, lateral access surgical procedure for spinal
12 surgery, known as XLIF. The patented procedures and tools utilized in XLIF surgery,
13 including the MaXcess® retractor and CoRoent® XLIF implants, allow for a lateral
14 approach to a patient's targeted spinal disc space through the psoas muscle and for the
15 delivery of a large, oversized implant for spinal fusion. [Doc. No. 38, at 6-7.] For over a
16 decade, NuVasive has developed, patented and marketed the XLIF procedure and
17 components. This product line now accounts for conservatively \$250-300 million of
18 NuVasive's annual revenue. [Id., at 8.]

19 In approximately July 2014, Alphatec began developing a competing lateral access
20 surgical procedure that became known as its Battalion Lateral System. On April 5, 2016,
21 Alphatec submitted the accused components and procedure for FDA approval, which it
22 received on September 8, 2016. On February 14, 2017, Alphatec made its first sale and
23 public surgical use of the accused components. [Doc. No. 79-4, at 7.] In April 2017,
24 Alphatec launched a limited release of the Battalion Lateral System. Alphatec made a full
25 launch in October 2017. [Doc. No. 1, ¶ 43.] NuVasive now seeks to enjoin Alphatec from
26 making, using, selling, offering to sell, or importing into the United States the components
27 of Alphatec's Battalion Lateral System, specifically the Squadron Lateral Retractor,
28

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

3 **II. Legal Standard**

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

16 **III. Likelihood Of Success On The Merits**

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

25 **A. Infringement**

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

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

3 NuVasive asserts the Access Platform patents against Alphatec's Battalion Lateral
4 System and the Implant patent against the Battalion Lateral Spacer. A demonstration of
5 the likelihood of a finding of infringement as to an asserted independent claim of any of
6 the following patents could support NuVasive's request to enjoin the sale of the Battalion
7 Lateral System: the '801 Patent (System Claim 1); the '780 Patent (System Claim 21); the
8 '832 Patent (System Claim 1 or Method Claim 12); and the '227 Patent (Method Claims 1
9 or 16).³ In response to the Court's request that NuVasive select the claim it considers best
10 demonstrates its burden on infringement and validity [Doc. No. 86], NuVasive elected to
11 proceed at argument on Claim 1 of the '832 patent and Claim 1 of the '156 patent.

12 ***Claim 1 of the '832 Patent***

13 The '832 Patent is for a Surgical Access System and Related Methods. [Doc No. 1-
14 8, at 2-34.] It is directed at a system for establishing an operative corridor to the spine
15 through the psoas muscle. Claim 1 claims:

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

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

1 a three-bladed retractor tool slidable over an exterior of an outermost sequential
2 dilator of the dilator system toward the targeted spinal disc along the lateral,
3 trans-psoas path, the three-bladed retractor assembly including:

4 a blade-holder assembly, and

5 a posterior-most retractor blade, a cephalad-most retractor blade, and a
6 caudal-most retractor blade that extend from the blade-holder assembly,
7 wherein the posterior-most, cephalad-most, and caudal-most retractor blades
8 are slideably advanced over the exterior of the outermost sequential dilator
9 while in a first position, wherein the blade-holder assembly is adjustable to
10 move the posterior-most, cephalad-most, and caudal-most retractor blades to
11 a second position in which the cephalad-most and caudal-most retractor
12 blades are spaced apart from the posterior-most retractor blade to define an
13 operative corridor,

14 wherein three-bladed retractor tool is configured to define the operative corridor
15 along the lateral, trans-psoas path to the lumbar spine in which a space extending
16 to the targeted spinal disc between the posterior-most, cephalad-most, and
17 caudal-most refractor blades is dimensioned so as to pass an implant through the
18 operative corridor along the lateral, trans-psoas path to the lumbar spine.

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

20 NuVasive alleges that the limitations of Claim 1 of the '832 patent read on
21 Alphatec's Battalion Lateral System. *See* Declaration of Jim A. Youseff, M.D., ¶¶ 171-
22 191, and Appendix C. [Doc. No. 37-45, at 70-74; Doc. No. 37-71, at 2-21.] Referencing
23 the Alphatec Battalion Lateral Lumbar Spacer System Thoracolumbar Surgical Technique
24 Guide and devices disclosed therein, [Doc. No. 1-38, at 2-30], NuVasive demonstrated that
25 the Battalion Lateral System: (1) forms an operative corridor to the patient's lumbar spine
26 through the psoas muscle; (2) uses an initial dilator with neuromonitoring to traverse the
27 psoas to the disc space; (3) introduces a K-wire (elongate inner element) through the initial
28 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,

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

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

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

22 Alphatec asserted no other challenge to NuVasive’s infringement analysis of Claim
23 1 of the ‘832 patent. Thus, for purposes of this motion, the Court finds that NuVasive has
24 demonstrated a likelihood of success with regard to its allegation that the Battalion Lateral
25 System and Squadron Retractor infringe Claim 1 of the ‘832 Patent.

26 ***Claim 1 of the ‘156 Patent***

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

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

3 1. A spinal fusion implant of non-bone construction positionable within an
4 interbody space between a first vertebra and a second vertebra, said implant
5 comprising:

6 an upper surface including anti-migration elements to contact said first vertebra
7 when said implant is positioned within the interbody space, a lower surface
8 including anti-migration elements to contact said second vertebra when said
9 implant is positioned within the interbody space, a distal wall, a proximal wall, a
10 first sidewall, and a second sidewall generally opposite from the first side wall,
11 wherein said distal wall, proximal wall, first sidewall and second sidewall
12 comprise a radiolucent material;

13 wherein said implant has a longitudinal length extending from a proximal end of
14 said proximal wall to a distal end of said distal wall, said implant has a maximum
15 lateral width extending from said first sidewall to said second sidewall along a
16 medial plane that is generally perpendicular to said longitudinal length, and said
17 longitudinal length is greater than said maximum lateral width;

18 at least a first fusion aperture extending through said upper surface and lower
19 surface and configured to permit bond growth between the first vertebra and the
20 second vertebra when said implant is positioned within the interbody space, said
21 first fusion aperture having: a longitudinal aperture length extending generally
22 parallel to the longitudinal length of said implant, and a lateral aperture width
23 extending between said first sidewall and said second sidewall, wherein the
24 longitudinal aperture length is greater than the lateral aperture width; and

25 at least first and second radiopaque markers oriented generally parallel to a height
26 of the implant, wherein said first radiopaque marker extends into said first
27 sidewall at a position proximate to said medial plane, and said second radiopaque
28 marker extends into said second sidewall at a position proximate to said medial
29 plane.

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

30 NuVasive alleges that the limitations of claim 1 read on the Battalion Lateral Spacer.
31 [Doc. No. 38, at 16-17]. *See* Youseff Declaration ¶¶ 317-334, and Appendix F. [Doc. No.
32 37-45, at 103-108; Doc. No. 37-74, at 2-24.] The Battalion Lateral Spacer is a spinal fusion
33 implant made of non-bone material with anti-migration ridges on both sides of the implant.

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

12 Alphatec did not challenge Dr. Youseff’s infringement analysis of Claim 1 of the
13 ‘156 patent in its opposition brief. [Doc. No. 53, at 15.] Consequently, for purposes of
14 this motion, the Court finds that NuVasive has demonstrated a likelihood of success with
15 regard to its allegation the Battalion Lateral Spacer infringes this claim.

16 **B. Validity**

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

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

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

7 On October 2, 2017, Mr. Miles joined Alphatec as Executive Chairman and on
8 March 8, 2018, he assumed the role of Chief Executive Officer. [Doc No. 1-43 at 2.] It is
9 undisputed that Mr. Miles holds a leadership role at Alphatec and was recruited to further
10 define and implement Alphatec’s strategic initiatives, expand relationships with surgeon
11 customers and lead new technology development. [Id.] His leadership position supports a
12 finding of privity, but it is not dispositive. *See e.g., HWB, Inc. v. Braner, Inc.*, 869 F.Supp.
13 579, 581-82 (N.D. Ill. 1994) (“the relevant knowledge and assistance of which the
14 defendant company avails itself is knowledge and assistance associated with the
15 manufacture of the infringing product”).

16 Alphatec had embarked on the development and marketing of the accused systems
17 and devices long before Mr. Miles joined the company. Mr. Miles was not brought on
18 board to initiate the allegedly infringing activity, but rather for his expertise to promote and
19 increase Alphatec’s share in the spine surgery market. [Doc. No. 38, at 19.] On or about
20 December 27, 2017, Mr. Miles closed on the purchase of Alphatec common stock directly
21 and through his company, MOM, LLC, resulting in his ownership of approximately 11.6%
22 of Alphatec’s common stock. [Doc Nos. 1-3 at 6; 1-42 at 6, 8; 1-43 at 3.] Mr. Miles’
23 investment reflects his commitment to Alphatec’s initiative to compete in the spinal
24 surgery market, but does not demonstrate effective control over Alphatec’s operations. The
25 timing of his investment and his percentage of interest does not demonstrate that he
26 financially enabled the alleged development of the accused system as suggested by
27 NuVasive. *See Mentor Graphics Corp. v. Quickturn Design Sys.*, 150 F.3d 1374, 1379
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1 (Fed. Cir. 1998) (Meta, the assignor, sold all its stock Mentor, the party found in privity,
2 to obtain the capital so Meta could manufacture the accused devices.)

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

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

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

1 ***

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

8 **IV. Irreparable Harm**

9 Even if NuVasive had established a likelihood of success on the merits, its motion
10 would still fail because it has not established irreparable harm. A patentee must make a
11 clear showing that it is at risk of irreparable harm, which entails showing a likelihood of
12 substantial and immediate irreparable injury. *Apple, Inc. v. Samsung Electronics Co, Ltd.,*
13 *Inc.*, 678 F.3d 1314, 1325 (Fed. Cir. 2012). There is no presumption of irreparable harm
14 in patent infringement cases. *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1149
15 (Fed. Cir. 2011) (“eBay jettisoned the presumption of irreparable harm as it applies to
16 determining the appropriateness of injunctive relief.”) “An injunction will not be issued
17 simply to prevent the possibility of some remote future injury.” *Winter*, 555 U.S. at 22
18 (citing 11A C. Wright, A. Miller, & M. Kane, Federal Practice and Procedure § 2948.1, p.
19 154-55 (2d ed. 1995)). Issuing an injunction based only on a possibility of irreparable harm
20 is inconsistent with the characterization of injunctive relief as an extraordinary remedy that
21 may only be awarded upon a clear showing that the plaintiff is entitled to such relief. *Id.*
22 at 22.

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

1 *The Toro Com.*, 848 F.3d 1358, 1368 (Fed. Cir. 2017). Price erosion, loss of goodwill,
2 damage to reputation and loss of business opportunities are all valid grounds for finding
3 irreparable harm. *Celsis in Vitro, Inc. v. Celedirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir.
4 2012).

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

12 As of April 5, 2018, when his declaration was filed, Mr. Link states that starting in
13 or about October 2017, NuVasive became aware that Alphatec was targeting NuVasive’s
14 long-time customers with the intent to convert them irretrievably to Alphatec’s competing
15 lateral surgical offerings.⁶ [Id., at 30-31, ¶ 52 (identifying 14 surgeons with customer
16 relationships to NuVasive contacted by Alphatec representatives).] Mr. Link identifies
17 seven surgeons persuaded to try Alphatec’s products, and three of those seven he
18 characterizes as having been converted to Alphatec’s lateral portfolio. [Id., at 31-36, ¶¶
19 53-61.]

20 On June 14, 2018, Mr. Link filed a supplemental declaration in conjunction with
21 NuVasive’s reply brief.⁷ [Doc. No. 79-3.] In that declaration, Mr. Link states that in the
22

23
24 ⁶ NuVasive must establish irreparable harm arising from sales of the accused products. Link’s reference
25 to “lateral surgical offerings” is insufficient as “lateral surgical offerings” could include products that are
26 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.

27 ⁷ Alphatec’s Motion to Exclude New Evidence Submitted on Reply [Doc. No. 84], with regard to Mr.
28 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.

1 ten weeks since he made his first declaration, he can identify seven more NuVasive
2 customers who have been targeted by Alphatec to switch to Alphatec’s product line. [Id.,
3 at 7-8, ¶ 9.] As of June 14, 2018, Mr. Link contends that from the original fourteen
4 surgeons he identified and the seven additional surgeons identified in his supplement
5 declaration, he has information that eleven surgeons have tried Alphatec products. [Id. at
6 9-13, ¶¶ 10-21.] Mr. Link’s supplemental declaration contends that six of those eleven
7 surgeons have been “converted,” probably irretrievably to Alphatec’s product line.

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

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

24
25
26 ⁸ The materials provided to the Court represent that Alphatec has contacted existing NuVasive customers,
27 but not what percentage of NuVasive’s overall customer base those contacts represent. The significance
28 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.

1 attributable to Battalion Lateral implants. [Doc. No. 79-4, at 10-11.] During that time
2 period, sales of \$358,475 were attributable to the Battalion Lateral System components.
3 Of those sales, 25% were to non-NuVasive customers, meaning the estimated total revenue
4 generated by sales of the Battalion Lateral System components to NuVasive customers
5 over an eight month period (based on the October full launch of the product line) is only
6 \$268,856.

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

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

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

9 **V. Conclusion**

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


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

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27 ⁹ NuVasive contends that Alphatec is “continuously and systematically looting” or “poaching” NuVasive
28 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.]

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

6 It is **SO ORDERED.**

7 Dated: July 10, 2018

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10 Hon. Cathy Ann Bencivengo
11 United States District Judge
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