

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

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.

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
27 ³ The asserted claims of '270 Patent allegedly cover the accused Alphatec Intradiscal Shim device. [Doc.
28 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.

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,
trans-psoas path, the three-bladed retractor assembly including:

3 a blade-holder assembly, and

4 a posterior-most retractor blade, a cephalad-most retractor blade, and a
5 caudal-most retractor blade that extend from the blade-holder assembly,
6 wherein the posterior-most, cephalad-most, and caudal-most retractor blades
7 are slideably advanced over the exterior of the outermost sequential dilator
8 while in a first position, wherein the blade-holder assembly is adjustable to
9 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,

10 wherein three-bladed retractor tool is configured to define the operative corridor
11 along the lateral, trans-psoas path to the lumbar spine in which a space extending
12 to the targeted spinal disc between the posterior-most, cephalad-most, and
13 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.

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

15 NuVasive alleges that the limitations of Claim 1 of the '832 patent read on
16 Alphatec's Battalion Lateral System. *See* Declaration of Jim A. Youseff, M.D., ¶¶ 171-
17 191, and Appendix C. [Doc. No. 37-45, at 70-74; Doc. No. 37-71, at 2-21.] Referencing
18 the Alphatec Battalion Lateral Lumbar Spacer System Thoracolumbar Surgical Technique
19 Guide and devices disclosed therein, [Doc. No. 1-38, at 2-30], NuVasive demonstrated that
20 the Battalion Lateral System: (1) forms an operative corridor to the patient's lumbar spine
21 through the psoas muscle; (2) uses an initial dilator with neuromonitoring to traverse the
22 psoas to the disc space; (3) introduces a K-wire (elongate inner element) through the initial
23 dilator into the disc space; (4) introduces a secondary sequential dilator over the initial
24 dilator [Id., at 7-9]; and (5) introduces a retractor, called the Squadron Retractor, over the
25 second dilator and moves it flush to the disc space [Id., at 11.] The Squadron Retractor is
26 a tool with a blade-holder assembly and three blades, center, right and left. [Id., at 15, 17,
27
28

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.