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Paper 18
Entered: July 9, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALPHATEC HOLDINGS, INC. and ALPHATEC SPINE, INC.,
Petitioner,

v.

NUVASIVE, INC.,
Patent Owner.

Case IPR2019-00362
Patent 8,361,156 B2

Before DENISE M. POTHIER, HYUN J. JUNG, and SHEILA F. McSHANE, *Administrative Patent Judges.*

POTHIER, *Administrative Patent Judge.*

DECISION TO INSTITUTE
35 U.S.C. § 314

I. INTRODUCTION

Alphatec Holdings, Inc. and Alphatec Spine, Inc. (collectively, "Petitioner") filed a Petition (Paper 2, "Pet.") requesting institution of an *inter partes* review of claims 1–3, 5, 9, 10, 12–21, 23, 24, and 27 of U.S. Patent No. 8,361,156 B2 (Ex. 1001, "the '156 patent"). NuVasive Inc. ("Patent Owner") filed a Preliminary Response (Paper 11, "Prelim. Resp."). Under 35 U.S.C. § 314, an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

Upon consideration of the Petition and Preliminary Response and for the reasons explained below, we determine that Petitioner has shown that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. We institute an *inter partes* review of all challenged claims on all presented challenges and, thus, institute an *inter partes* review of claims 1–3, 5, 9, 10, 12–21, 23, 24, and 27 of the '156 patent.

II. BACKGROUND

A. Related Proceedings

The parties indicate that the '156 patent has been asserted in *NuVasive, Inc. v. Alphatec Holdings, Inc.*, Case No. 3:18-cv-00347-CAB-MDD (S.D. Cal.) and *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, Case No. 3:12-cv-002738-CAB-MDD (S.D. Cal.). Pet. 76–77; Paper 4, 2. Petitioner indicates the latter litigation was settled on July 27, 2016. Pet. 77.

The parties additionally note that the '156 patent was previously challenged in Cases IPR2013-00504, IPR2013-00506, and IPR2014-00487.

Pet. 16, 21; Paper 4, 2 (citing *In re NuVasive, Inc.*, 842 F.3d 1376 (Fed. Cir. 2016)).

The parties also state that a related patent, U.S. Patent 8,187,334, is challenged in Cases IPR2019-00361 and IPR2019-00546. Pet. 77; Paper 4, 2 (further citing Cases IPR2013-00507 and IPR2013-00508 and *In re NuVasive, Inc.*, 841 F.3d 966 (Fed. Cir. 2016)); Paper 7, 2.

B. The '156 Patent (Ex. 1001)

The '156 patent issued January 29, 2013, from an application filed April 6, 2012, which is a continuation of an application filed on April 5, 2012, which is a continuation of an application filed on April 4, 2011, which is a continuation of an application filed on March 29, 2005, and claims priority to a provisional application filed on March 29, 2004. Ex. 1001, (22), (60), (63), 1:6–15.

The '156 patent relates to "a system and method for spinal fusion comprising a spinal fusion implant of non-bone construction . . . to introduce the spinal fusion implant into any of a variety of spinal target sites." *Id.* at 1:21–25. Figure 2 of the '156 patent is reproduced below.

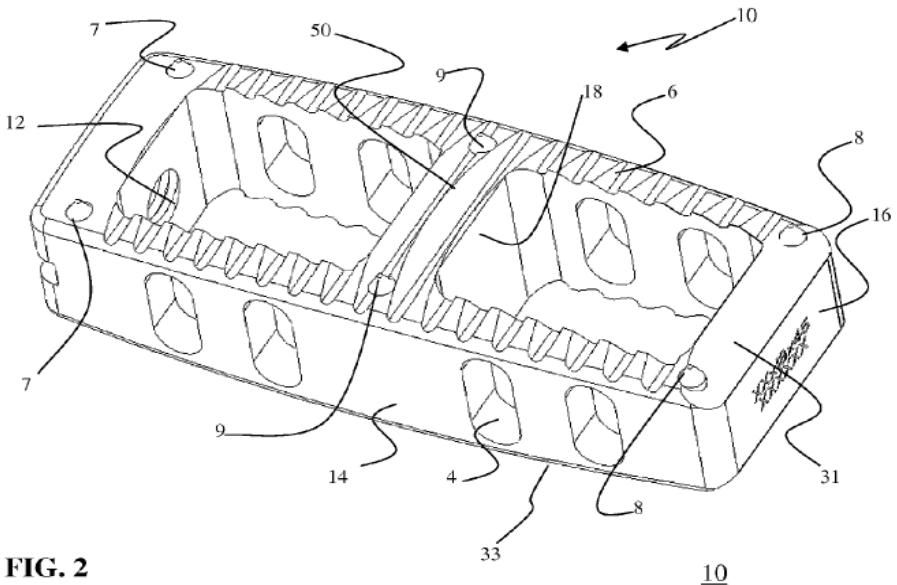

FIG. 2 10

The above Figure 2 shows a perspective view of a lumbar fusion implant. *Id.* at 3:36. The spinal fusion implant is introduced into a lumbar disc space through a lateral, a posterior, an anterior, an antero-lateral, or a postero-lateral approach to the spine. *Id.* at 5:29–35. The implant is made from a radiolucent material, such as poly-ether-ether-ketone (PEEK). *Id.* at 5:10–15.

Common attributes of the various embodiments of spinal fusion implant 10 includes top surface 31, bottom surface 33, lateral sides 14, proximal side 22, and distal side 16. *Id.* at 6:6–9, Figs. 2–3. By way of example, spinal fusion implant 10 may have "a width ranging between 9 and 18 mm, a height ranging between 8 and 16 mm, and a length ranging between 25 and 45 mm." *Id.* at 5:15–19.

Spinal fusion implant 10 also preferably includes anti-migration features, such as ridges 6 and spike elements 7–9, designed to increase friction between spinal fusion implant 10 and adjacent contacting surfaces of vertebral bodies. *Id.* at 6:21–32, Figs. 2–3. Spike elements 7–9 are preferably made from materials having radiopaque characteristics. *Id.* at 6:35–38.

Spinal fusion implant 10 has fusion apertures 2, separated by medial support 50, extending through top surface 31 and bottom surface 33. *Id.* at 6:57–59, Figs. 2–3. "[F]usion apertures 2 function primarily as an avenue for bony fusion between adjacent vertebrae." *Id.* at 6:59–61.

C. Illustrative Claim

The '156 patent has 27 claims. Ex. 1001, 12:32–14:43. Petitioner challenges claims 1–3, 5, 9, 10, 12–21, 23, 24, and 27. Claim 1 is the only independent claim and is reproduced below.

> 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:
>
> 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 sidewall, wherein said distal wall, proximal wall, first sidewall, and second sidewall comprise a radiolucent material;
>
> 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;
>
> at least a first fusion aperture extending through said upper surface and lower surface and configured to permit bone 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 to said second sidewall, wherein the longitudinal aperture length is greater than the lateral aperture width; and
>
> *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*.

Ex. 1001, 12:32–67 (emphases added).

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