Paper 17 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 IPR2019-00546 Patent 8,187,334 B2

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

JUNG, 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 claim 16 of U.S. Patent No. 8,187,334 B2 (Ex. 1001, "the '334 patent"). NuVasive Inc. ("Patent Owner") filed a Preliminary Response (Paper 10, "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 the only challenged claim, claim 16. Thus, we institute an *inter partes* review of claim 16 of the '334 patent on all presented challenges.

II. BACKGROUND

A. Related Proceedings

The parties indicate that the '334 patent has been asserted in *NuVasive, Inc. v. Alphatec Holdings, Inc.*, Case No. 3:18-cv-00347-CAB-MDD (S.D. Cal.). Pet. 70; Paper 4, 2. The parties also indicate that the '334 patent is the subject of Case IPR2019-00361. Pet. 70; Paper 4, 2.

Patent Owner additionally notes that the '334 patent was previously challenged in Cases IPR2013-00507 and IPR2013-00508. Paper 4, 2 (citing *In re NuVasive, Inc.*, 841 F.3d 966 (Fed. Cir. 2016)); *see also* Pet. 1 (stating that "the Federal Circuit affirmed the Board's finding in IPR2013-00507 (Ex. 1004) that sole independent claim 1 of the '334 patent and eighteen



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dependent claims (2–5, 10, 11, 14, 15, and 19–28) are invalid"). The parties also state that a related patent is challenged in Case IPR2019-00362. Pet. 70; Paper 4, 2.

B. The '334 Patent (Ex. 1001)

The '334 patent issued May 29, 2012, from an application filed 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], [45], [60], [63], 1:7–13.

The '334 patent particularly 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 1:18–21. Figure 2 of the '334 patent is reproduced below.

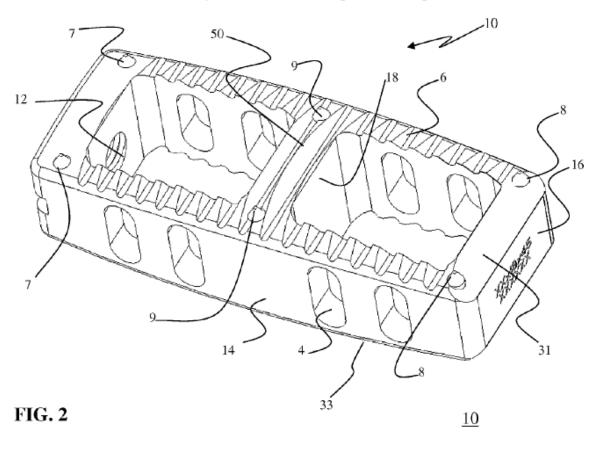




Figure 2 shows a perspective view of a lumbar fusion implant. *Id.* at 3:36. The spinal fusion implant is introduced into the disc space via a lateral approach to the spine or via a posterior, anterior, antero-lateral, or postero-lateral approach, and is made from a radiolucent material, such as PEEK (poly-ether-ether-ketone). *Id.* at 5:10–15, 5:29–33.

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. 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 pairs of 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. Sole Challenged Claim

The '334 patent has 28 claims and its claim 18 was found patentable and claims 1–5, 10, 11, 14, 15, and 19–28 were cancelled in IPR2013-00507. Ex. 1001, 34. Petitioner challenges claim 16, which depends from cancelled claim 1. Claims 1 and 16 are 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, said distal wall, proximal wall, first sidewall, and second sidewall comprising a radiolucent material;

wherein said implant has a longitudinal length greater than 40 mm extending from a proximal end of said proximal wall to a distal end of said distal wall;

wherein a central region of said implant includes portions of the first and second sidewalls positioned generally centrally between the proximal wall and the distal wall, at least a portion of the central region defining a maximum lateral width of said implant extending from said first sidewall to said second sidewall, wherein said longitudinal length is at least two and half times 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 three radiopaque markers; wherein a first of the at least three radiopaque markers is at least partially positioned in said distal wall, a second of said at least three radiopaque markers is at least partially positioned in said proximal wall, and a third of said at least three radiopaque markers is at least partially positioned in said central region.

16. The spinal fusion implant of claim 1, further comprising a fourth radiopaque marker situated within said



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