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Paper 58
Date: July 8, 2020

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.

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*.

JUDGMENT
Final Written Decision
Determining No Challenged Claim Unpatentable
Denying Patent Owner's Motion to Exclude
35 U.S.C. § 318(a)

I. INTRODUCTION

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

A. Background and Summary

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. Pursuant to 35 U.S.C. § 314, we instituted an *inter partes* review of the '334 patent. Paper 17 ("Dec. to Inst."). In particular, we instituted review of claim 16 on all presented challenges. Dec. to Inst. 2, 26, 33, 35.

After institution, Patent Owner filed a Response (Paper 27, "PO Resp."), to which Petitioner filed a Reply (Paper 35, "Pet. Reply"). Patent Owner thereafter filed a Sur-Reply (Paper 41, "PO Sur-reply").

Patent Owner also filed a motion to exclude (Paper 39, "Mot."), and Petitioner filed an Opposition to Patent Owner's Motion to Exclude (Paper 45, "Opp."), to which Patent Owner filed a Reply (Paper 49, "Mot. Reply"). In an Order (Paper 38), we authorized Patent Owner to file a Supplemental Sur-Reply, which was filed (Paper 42) and Petitioner to file a Supplemental Sur-Sur-Reply, which was also filed (Paper 43). An oral hearing in this proceeding was held on April 3, 2020; a transcript of the hearing is included in the record (Paper 55, "Tr."). *See also* Exs. 1066, 2062 (parties' errata sheets for the transcript).

For the reasons that follow, we determine that Petitioner has not shown by a preponderance of the evidence that claim 16 of the '334 patent is unpatentable. We also deny Patent Owner's Motion to Exclude.

B. Real Parties in Interest

Petitioner states that "Alphatec Holdings, Inc. and Alphatec Spine, Inc. are the real-parties-in-interest for purposes of this proceeding." Pet. 70. "In accordance with 37 C.F.R. § 42.8(b)(1), Patent Owner identifies NuVasive, Inc. as the real party-in-interest." Paper 4, 2.

C. Related Matters

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.) and *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, Case No. 3:12-cv-002738-CAB-MDD (S.D. Cal.). Pet. 70; Paper 4, 2. The parties also indicate that the '334 patent is the subject of 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 dependent claims (2–5, 10, 11, 14, 15, and 19–28) are invalid"). A related patent, U.S. Patent No. 8,361,156 B2, is challenged in IPR2019-00362. Pet. 70; Paper 4, 2.

D. 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, codes (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.

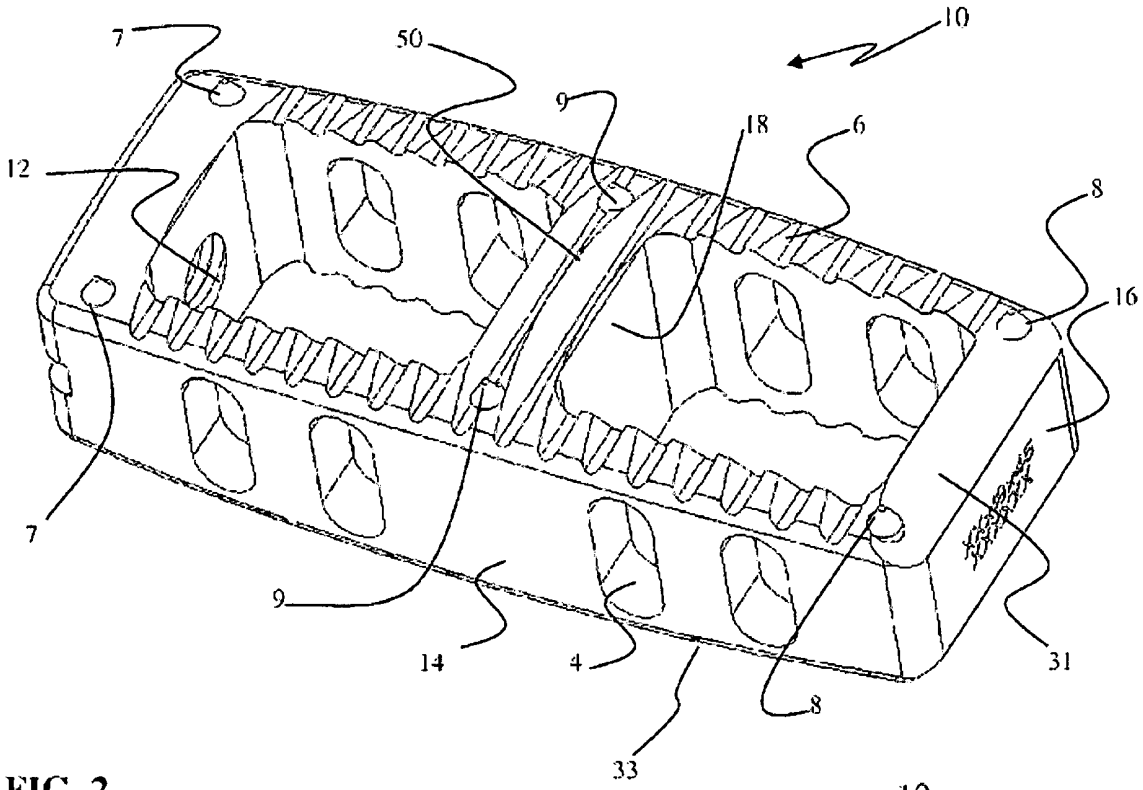

FIG. 2 10

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.

E. Sole Challenged Claim

The '334 patent has 28 claims, 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

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