

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.

IPR2019-00362
Patent 8,361,156 B2

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

POTHIER, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background and Summary

Alphatec Holdings, Inc. and Alphatec Spine, Inc. (collectively, “Petitioner”) filed a Petition (Paper 2, “Pet.”) requesting *inter partes* review of claims 1–3, 5, 9, 10, 12–21, 23, 24, and 27 (“the challenged claims”) 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.”). Pursuant to 35 U.S.C. § 314, we granted the request and instituted *inter partes* review on July 9, 2019, as to the challenged claims on all grounds. Paper 18 (“Dec. Inst.”).

Following institution, Patent Owner filed a Response (Paper 27, “PO Resp.”), Petitioner filed a Reply (Paper 34, “Reply”), and Patent Owner filed a Sur-Reply (Paper 40, “Sur-reply”). Patent Owner objected to evidence submitted by Petitioner in its Petition and future filings (Papers 23, 35). With prior authorization (Paper 37), Patent Owner submitted a Supplemental Sur-Reply (Paper 41, “Supp. Sur-reply”) related to the its objections and Petitioner submitted a Supplemental Sur-sur-reply (Paper 42, “Supp. Sur-sur-reply”). Patent Owner also filed a Motion to Exclude (Paper 38, “Mot. Excl.”), Petitioner filed an Opposition to the Motion to Exclude (Paper 44, “Opp.”), and Patent Owner filed a Reply to support the Motion to Exclude (Paper 48, “Mot. Reply”).

A hearing was held on April 3, 2020, and a transcript of the hearing has been made part of the record. Paper 54; Ex. 1066.

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

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For the reasons discussed below, we conclude that Petitioner has not shown by a preponderance of the evidence that the challenged claims of the '156 patent are unpatentable. We also deny Patent Owner's Motion to Exclude.

B. Related Matters

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-02738-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 also 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 panel denied institution in IPR2013-00504 and IPR2014-00487. IPR2013-00504, Paper 8 (PTAB February 13, 2014); IPR2014-00487, Paper 8 (PTAB September 11, 2014). In IPR2013-00506, the Board determined that claims 1–14, 19, 20, and 23–27 of the '156 patent were unpatentable. IPR2013-00506, Paper 47, 24 (PTAB February 11, 2015). The Federal Circuit vacated the decision in IPR2013-00506 and remanded for additional findings and explanation. *In re NuVasive*, 842 F.3d 1376, 1384 (Fed. Cir. 2016). On remand, the parties indicated that they had entered into a settlement agreement, and the panel granted a joint motion to terminate the proceeding. IPR2013-00506, Paper 57 (PTAB May 9, 2017).

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.

C. 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, codes (22), (45), (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.

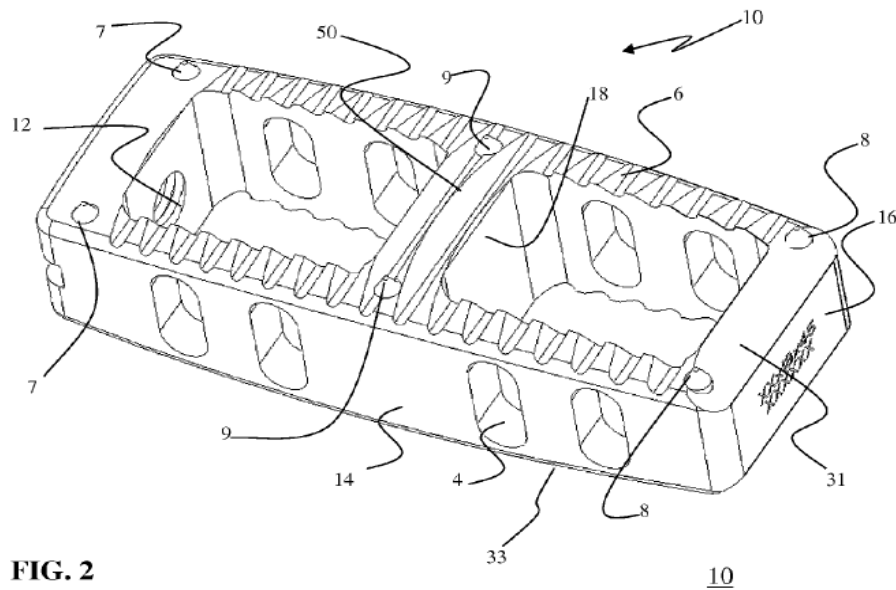


FIG. 2

Figure 2, above, 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 include 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 for lumbar fusion 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; *see id.* at 2:17–21.

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 that are “observable under X-ray and fluoroscopy[,] such that a surgeon may track the progress of the implant 10 during implantation and/or the placement of the implant 10 after implantation.” *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.

D. 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:

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