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Paper No. 47
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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MEDTRONIC, INC.,
Petitioner,

v.

NUVASIVE, INC.,
Patent Owner.

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Case IPR2013-00506
Patent 8,361,156 B2

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Before SALLY C. MEDLEY, LORA M. GREEN, and STEPHEN C. SIU, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
*35 U.S.C. § 318(a) and 37 C.F.R. § 42.73*

## I. INTRODUCTION

### *A. Background*

Petitioner, Medtronic, Inc. ("Medtronic"), filed a Petition requesting *inter partes* review of claims 1–14, 19, 20, and 23–27 ("the challenged claims") of U.S. Patent No. 8,361,156 B2 ("the '156 patent"). Paper 1 ("Pet."). Patent Owner, NuVasive, Inc. ("NuVasive"), filed a Patent Owner

Preliminary Response. Paper 8. We determined that the information presented in the Petition and the Preliminary response demonstrated that there was a reasonable likelihood that Petitioner would prevail in challenging claims 1–14, 19, 20, and 23–27 as unpatentable under 35 U.S.C. § 103(a). Pursuant to 35 U.S.C. § 314, the Board instituted trial on February 13, 2014 , as to the challenged claims of the '156 patent. Paper 9 ("Institution Decision"; "Dec. Inst.").

Patent Owner filed a Response (Paper 21, "PO Resp."), but did not file a motion to amend. Petitioner subsequently filed a Reply. Paper 28 ("Reply"). An oral hearing was held on November 18, 2014. The transcript of the hearing has been entered into the record. Paper 46. Patent Owner also filed a Corrected Motion for Observation on certain cross-examination testimony of Petitioner's declarant, Richard A. Hynes, M.D. (Paper 38, "Hynes Obs.") and a Corrected Motion for Observation on certain cross-examination testimony of Petitioner's declarant, Loic Josse (Paper 39, "Josse Obs."). Petitioner filed a Response to each of Patent Owner's Motions for Observation (Paper 44, "Hynes Obs. Resp."; Paper 43, "Josse Obs. Resp.").

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. Based on the record before us, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 1–14, 19, 20, and 23–27 of the '156 patent are unpatentable.

*B. Related Proceedings*

Medtronic filed concurrently another petition for an *inter partes* review of the '156 patent, IPR2013-00504, in which we declined to institute *inter partes* review. IPR2013-00504, Paper 8. Petitioner subsequently filed

another petition for an *inter partes* review, IPR2014-00487, in which we also declined to institute *inter partes* review. IPR2014-00487, Paper 8.

Medtronic indicates further that it is a named counterclaim-defendant in the district court action titled *Warsaw Orthopedic, Inc. v. NuVasive Inc.*, Case No: 3:12-cv-02738-CAB-MDD (S.D. Cal.), which also involves the '156 patent. Pet. 1.

*C. The '156 Patent (Ex. 1115)*

The '156 patent issued on January 29, 2013, with Matthew Curran and Mark Peterson as the listed co-inventors. The '156 patent is drawn to a spinal implant, and methods of spinal fusion using the implant. Ex. 1115, 1:20–24. A spinal fusion procedure generally involves removing some or all of a diseased spinal disc, and inserting an intervertebral implant into the disc space. *Id.* at 1:30–33. 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, depending on the size of the implant. *Id.* at 5:29–35. As taught by the '156 patent, the implant is made from a material "having suitable radiolucent characteristics," such as PEEK (poly-ether-ether-ketone). *Id*. at 5:10–15.

The '156 patent teaches further that the implant "may be provided in any number of suitable shapes and sizes depending on the particular surgical procedure or need," and that it "may be dimensioned for use in the cervical and/or lumbar spine." *Id.* at 2:12–16. Thus, before a spinal fusion procedure is performed, "the clinician must first designate the appropriate implant size." *Id.* at 11:10–12.

*D. Illustrative Claim*

Petitioner challenges claims 1–14, 19, 20, and 23–27 of the '156 patent. Claims 1, 5, and 9 read as follows:

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.

5. The spinal fusion implant of claim 1, further including at least one receiving aperture position at said proximal wall wherein said longitudinal length is greater than 40 mm.

9. The spinal fusion implant of claim 1, wherein said maximum lateral width of said implant is approximately 18 mm.

*E. Instituted Challenges*

| **Claims** | **Basis** | **References** |
|---|---|---|
| 1–4, 7, 8, 10–14, 19, 20, 23, 24, 26, and 27 | § 103(a) | SVS[1] and Baccelli[2] |
| 5, 6, and 9 | § 103(a) | SVS, Baccelli, and Michelson[3] |
| 25 | § 103(a) | SVS, Baccelli, and Telamon[4] |
| 1–4, 7, 10–14, 19, 20, and 23–27 | § 103(a) | Telamon and Baccelli |
| 5, 6, 8, and 9 | § 103(a) | Telamon, Baccelli, and Michelson |

## II. ANALYSIS

*A. Claim Construction*

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the

[1] Synthes Vertebral Spacer – PR Brochure, Synthes Spine 2002 ("SVS", Ex. 1106).
[2] Baccelli, US 2003/0028249 A1, filed February 6, 2003 (Ex. 1104).
[3] Michelson, US 5,860,973, issued January 19, 1999 (Ex. 1105).
[4] Medtronic Sofamor Danek, Telamon, Verte-Stack PEEK Vertebral Body Spacer, ©2003 Medtronic Sofamor Danek USA, Inc (Ex. 1107); and Telamon, Posterior Impacted Devices, ©2003 Medtronic Sofamor Danek USA, Inc. (Ex. 1108) (collectively, "Telamon").

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