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Paper 43
Date: February 11, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.,
Petitioner,

v.

NUVASIVE, INC.,
Patent Owner.

Case IPR2013-00507
Patent 8,187,334 B2

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

SIU, *Administrative Patent Judge*.

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

I. BACKGROUND

Medtronic, Inc. ("Petitioner") filed a Petition (Paper 1) ("Pet.") seeking *inter partes* review of claims 1–5, 10, 11, and 14–28 of U.S. Patent No. 8,187,334 B2 (Ex. 1013, "the '334 patent") pursuant to 35 U.S.C. §§ 311–319. On February 13, 2014, the Board instituted an *inter partes* review of claims 1–5, 10, 11, and 14–28 (Paper 7) ("Dec. on Inst.").

Subsequent to institution, Nuvasive, Inc. ("Patent Owner") filed a Patent Owner Response (Paper 17) ("PO Resp."), and Petitioner filed a Reply (Paper 24) ("Pet. Reply"). Patent Owner also filed a Motion to Exclude Evidence. Paper 34. Petitioner filed an Opposition to Patent Owner's Motion to Exclude (Paper 37) ("Opp."), and Patent Owner filed a Reply (Paper 41) ("PO Reply"). An Oral Hearing was conducted on November 18, 2014, pursuant to Requests for Oral Argument filed by Petitioner (Paper 28) and Patent Owner (Paper 29). Patent Owner also filed a Motion for Observation on certain cross-examination testimony of Petitioner's declarant, Richard A. Hynes, M.D. (Paper 35, "Hynes Obs.") and a Motion for Observation on certain cross-examination testimony of Petitioner's declarant, Loic Josse (Paper 34, "Josse Obs."). Petitioner filed a Response to each of Patent Owner's Motions for Observation (Paper 39, "Hynes Obs. Resp."; Paper 40, "Josse Obs. Resp.").

The Board has 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. For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–5, 10, 11, 14–17, and 19–28 of the '334 patent are unpatentable, but has not shown by a preponderance of the evidence that claim 18 of the '334 patent is unpatentable.

A. The '334 Patent

The '334 patent describes a spinal fusion system, including a spinal fusion implant and an insertion instrument. Ex. 1013, 5:6–9. 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. In one embodiment, the spinal fusion implant has a width ranging between 9 and 18 mm and a length ranging between 25 and 44 mm. *Id.* at 5:17–19.

B. Illustrative Claim

Claim 1 is illustrative of the claimed subject matter of the '334 patent, and is reproduced 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, 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 halftimes 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.

C. Instituted Challenge

This *inter partes* review involves the following ground of unpatentability:

Reference(s)	**Basis**	**Claims challenged**
Frey[1] and Michelson[2]	§103	1–5, 10, 11, 14, 15, and 18–28

D. Claim Interpretation

The parties appear to agree on the interpretation of claim terms of the '334 patent. Having considered whether the construction set forth in the Decision to Institute should be changed in light of evidence introduced during trial, we are not persuaded any modification is necessary. Therefore, we maintain the constructions set forth in the Decision to Institute and determine that no other express constructions are necessary. *See* Dec. on Inst. 4-5.

[1] Frey, US 2002/0165550 A1, filed Nov. 7, 2001 (Ex. 1103).
[2] Michelson, US 5,860,973, issued Jan. 19, 1999 (Ex. 1105).

II. ANALYSIS

A. Frey and Michelson

We conclude that Petitioner has shown by a preponderance of the evidence that all of the limitations of claims 1–5, 10, 11, 14, 15, and 19–28 are taught or suggested by the combination of Frey and Michelson. Pet. 52–56. Claim 1 recites an implant that "has a longitudinal length greater than 40 mm" and that the longitudinal length (that is greater than 40 mm) is "at least two and a half times greater than the maximum lateral width." Claims 2–5, 10, 11, and 14–28 depend from claim 1.

Petitioner argues that "Frey provides that the length of the implant is 'sufficient to span the disc space'" and discloses "using the disclosed implant in lateral . . . approaches to the disc space." Pet. 53, 54 (citing Ex. 1003 ¶ 0130). Petitioner also argues that Michelson discloses "a spinal fusion implant – that is used in a lateral . . . fashion . . . that has a longitudinal length greater than 40 mm." Pet. 56 (citing Michelson 10:41–46). Hence, Petitioner argues that it would have been obvious to one of ordinary skill in the art, given Frey's laterally inserted spinal implant, to have provided that the laterally inserted spinal implant measures greater than 40 mm in length, as disclosed by Michelson.

Patent Owner argues that it would not have been obvious to combine the teachings of Frey and Michelson to achieve an implant with a length greater than 40 mm as disclosed by Michelson because "the proposed modification would render the resulting implant inoperable for Frey's intended purpose." PO Resp. 27 (citing Ex. 2020 ¶¶ 108, 109). Patent Owner further characterizes the "intended purpose" of Frey to be "to provide

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