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Paper 7
Date: February 13, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.
Petitioner

v.

NUVASIVE, INC.
Patent Owner

Case IPR2013-00507
U.S. Patent No. 8,187,334 B2

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

SIU, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. BACKGROUND

A. Background

Medtronic, Inc. ("Petitioner") filed a petition requesting an *inter partes* review of claims 1-5, 10, 11, and 14-28 of U.S. Patent No. 8,187,334 B2 ("the '334 patent," Ex. 1013) pursuant to 35 U.S.C. §§ 311-319. Paper 1 ("Pet."). NuVasive, Inc. ("Patent Owner") filed a preliminary response ("Prelim. Resp."). Paper 6. We have jurisdiction under 35 U.S.C. § 314. The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which provides:

> THRESHOLD – The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

We determine based on the record that Petitioner has shown, under 35 U.S.C. § 314(a), that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims.

Petitioner relies on the following prior art:

US 2002/0165550 A1 (Frey)	Nov. 7, 2002	Ex. 1003
US 2003/0028249 A1 (Baccelli)	Feb. 6, 2003	Ex. 1004
US 5,860,973 (Michelson)	Jan. 19, 1999	Ex. 1005
US 2003/0100950 A1 (Moret)	May 29, 2003	Ex. 1006
US 2003/0139813 A1 (Messerli)	Jul. 24, 2003	Ex. 1007

Petitioner contends that the challenged claims are unpatentable under 35 U.S.C § 103(a) based on the following specific grounds (Pet. 3):

Reference(s)	Basis	Claims challenged
Frey	§ 102(b)	1-3, 10, 14, 15, and 19-28
Frey and Baccelli	§ 103(a)	1-5, 10, 11, 14-17, and 19-28
Frey and Messerli	§ 103(a)	1-3, 10, 14, 15, and 19-28
Frey and Michelson	§ 103(a)	1-5, 10, 11, 14, 15, and 18-28
Frey and Moret	§ 103(a)	1-3, 10, 14, 15, and 19-28

B. The '334 patent

The '334 patent describes a spinal fusion system, including a spinal fusion implant and an insertion instrument. Ex. 1013, col. 5, ll. 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 col. 5, ll. 10-15 and 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 col. 5, ll. 17-19.

Claim 1 of the '334 patent 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:
>
> 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.

According to Petitioner, the ’334 patent is the subject of co-pending district court litigation, *Warsaw Orthopedic, Inc. v. NuVasive, Inc*., originally filed in the Northern District of Indiana, Case No. 3:12-cv-00438-JD-CAN, on August 17, 2012, and transferred to the Southern District of California on November 8, 2012, as Case No. 3:12-cv-02738-CAB-MDD. *See* Pet. 1. Petitioner has filed a second petition seeking *inter partes* review of the ’334 patent (IPR2013-00508) and two additional petitions seeking *inter partes* review of related U.S. Patent No. 8,361,156 B2 (IPR2013-00504 and IPR2013-00506).

C. Claim Interpretation

Consistent with the statute and the legislative history of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, 329 (2011) ("AIA"), the Patent Trial and Appeal Board ("Board") interprets claim terms by applying the broadest reasonable construction in the context of the Specification in which the claims reside. 37 C.F.R. § 42.100(b); *see* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012.)

Under the broadest reasonable interpretation standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). In this regard, however, we are careful not to read a particular embodiment appearing in the written description into the claim if the claim language is broader than the embodiment. *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993).

Petitioner provides a construction for each of "distal wall / proximal wall" (claim 1), "releasably mate" (claim 3), "longitudinal length" (claim 11), "extend generally perpendicular to said longitudinal length" (claim 11), "elongate body" (claims 14 and 17), "generally rectangular and generally oblong in shape" (claim 23), "lateral width of the distal end of said distal wall / a lateral width of said proximal end of said proximal wall" (claim 24), and "oriented generally parallel to a height of the implant" (claim 17 recites an elongate body oriented generally perpendicular to said longitudinal length and entirely through a height of said

proximal wall). Pet. 4-7. Patent Owner does not provide a construction for any of these terms.

Petitioner's proposed constructions for the above-mentioned claim terms appear to take into account the plain meaning of the terms and their usage in the specification. We, therefore, adopt Petitioner's proposed constructions for the above-mentioned claim terms for purposes of this decision.

II. ANALYSIS

A. Cited References

a. Overview of Frey

Frey discloses a spinal implant that "has a length sufficient to span the disc space from the distal portion . . . to the proximal portion." Ex. 1003 ¶ [0130]. The implant has grooves to increase frictional resistance between adjacent vertebrae (*id*. at ¶ [0153]) and may be inserted "from a postero-lateral or uni-lateral approach into the disc space" or can be inserted via "other approaches to the disc space, such as lateral, anterior or antero-lateral approaches." *Id*. at ¶ [0150].

b. Overview of Baccelli

Baccelli discloses an intervertebral implant. Ex. 1004 ¶ [0001]. The implant has a front wall (*id*. at ¶ [0036], Fig. 8 – element 4b) that contains an orifice (*id*. at ¶ [0039], Fig. 8 – element 18) into which a threaded endpiece is connected for placing the implant into position between vertebrae. *Id*. at ¶¶ [0044] – [0045].

The implant is made of a material that is transparent to X-rays, such as PEEK. *Id*. at ¶ [0050]. One or more markers that are opaque to X-rays may be

used to identify the position and/or the presence of the implant when X-rays are taken. *Id*. The radiopaque (i.e., a material that is opaque to X-rays) markers may be positioned within the anterior (i.e., proximal) wall and/or the posterior (i.e., distal) wall of the implant. *Id*. at Figs. 1-4, 8, and 9.

The implant may further include spikes positioned symmetrically about the sagittal midplane and extending in the frontal midplane in a vertical axis. *Id*. at ¶ [0041], Figs. 1-5, 8, and 9. The spikes may be made of a radiopaque material. *Id*. at ¶ [0051].

c. Overview of Michelson

Michelson discloses a translateral spinal fusion implant. Ex. 1005, col.5, ll. 44-45. In one embodiment, the implant has "a length in the range of 32 mm to 50 mm, with 42 mm being the preferred length." *Id.* at col.10, ll. 46-47. The implant may also have "a maximum diameter in the range of 14-26 mm, with the preferred diameter being 20 mm." *Id.* at col. 7, ll. 28-30.

d. Overview of Messerli

Messerli discloses a spinal implant that "range[s] from about 26 to about 32 mm in length, and [has] a width from about 9 to 11 mm." Ex. 1007 ¶ [0055].

e. Overview of Moret

Moret discloses an intervertebral implant that contains a marker of high density metal that permits the implant to be "observed and assessed during the operation by means of an image intensifier." Ex. 1006 ¶ [0026].

B. Anticipation by Frey

Petitioner asserts that claims 1-3, 10, 14, 15, and 19-28 are anticipated by Frey. Pet. 3. Claim 1 recites that the implant has a longitudinal length greater than 40 mm. Petitioner argues that Frey discloses an implant that is "sufficient to span the disc space." Pet. 20 (citing Ex. 1003 ¶ 0130). Petitioner also argues that the average width of the body of a vertebrae is greater than 40 mm at L3, L4, and L5. Pet. 20 (citing S. H. Zhou, et al., *Geometrical Dimensions of the Lower Lumbar Vertebrae – Analysis of Data from Digitised CT Images*, 9 EUR SPINE J. 242-248 (2000), "Zhou," Ex. 1012).

As Patent Owner explains, however, Petitioner does not demonstrate sufficiently that Frey discloses an implant that has a longitudinal length greater than 40 mm, as required by claim 1, either expressly or inherently. In addition, even assuming that Zhou discloses average widths of vertebrae as being greater than 40 mm, as Petitioner contends, Petitioner has not demonstrated persuasively that the width of a disc space of Frey is also greater than 40 mm. In other words, Petitioner does not show adequately that Zhou discloses that disc spaces (as opposed to vertebral bodies) are larger than 40 mm. Nor does Petitioner provide sufficient evidence to show that the implant of Frey spans the entire dimension of a disc space that measures greater than 40 mm in length. Indeed, Frey appears to disclose that the implant does not span the entire width of the vertebral body and does not disclose the measurement of the portion(s) of the body of the vertebrae that the implant does not span (much less the length of the portion of the vertebra body that the implant does span). *See e.g.*, Ex. 1003, Fig. 47.

C. Obviousness over Frey and any one of Baccelli, Messerli, or Moret

Petitioner asserts that claims 1-3, 10, 14, 15, and 19-28 are obvious over Frey and any one of Messerli or Moret, and that claims 1-5, 10, 11, 14-17, and 19-28 are obvious over Frey and Baccelli. Pet. 3. Petitioner does not demonstrate that any of Baccelli, Messerli, or Moret make up for the deficiency noted above with respect to Frey by disclosing an implant that has a longitudinal length greater than 40 mm, as required by claim 1.

D. Obviousness over Frey and Michelson

Petitioner asserts that claims 1-5, 10, 11, 14, 15, and 18-28 are obvious over Frey and Michelson. Pet. 3. In support of this asserted ground of unpatentability, Petitioner provides explanations as to how each claim limitation is disclosed or suggested by Frey and Michelson and, based on the current record, articulates sufficient reasoning with a rational underpinning to justify support for the conclusion of obviousness. *See* Pet. 52-58. Upon consideration of Petitioner's analysis and supporting evidence, and taking into account Patent Owner's preliminary response, we determine that Petitioner's contentions have merit. On this record, we conclude that Petitioner has demonstrated that there is a reasonable likelihood that it would prevail with respect to obviousness of claims 1-5, 10, 11, 14, 15, and 18-28 over Frey and Michelson.

Claim 1 recites that the 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." As Petitioner explains, "Michelson discloses a spinal fusion implant . . . that has a longitudinal length greater than 40 mm." Pet. 56. Patent Owner argues that it would not have been obvious to one of ordinary skill in the art

to have combined the teachings of Michelson with that of Frey because, according to Patent Owner, such a combination would have rendered the Frey implant "inoperable for its intended purpose" and "would require 'a change in the basic principle under which the [Frey] construction was designed to operate.'" Prelim. Resp. 14, 17 (citations omitted).

In particular, Patent Owner argues that "modifying Frey's implant . . . to be greater than 40 mm [as disclosed by Michelson] would fully eliminate Frey's most preferred insertion path, thereby rendering it inoperable for Frey's intended purpose." Prelim. Resp. 15. Patent Owner contends that such a modification "would reconstruct [Frey's] implant so that its leading end would impinge upon the anterior wall of the disc annulus well before the trailing end reaches the disc space, thereby requiring unsafe damage/impingement upon the transverse process, the superior articular process, the spinal canal, and other portions of the spine." Prelim. Resp. 15-16.

Frey does not disclose specific dimensions of the body of the vertebrae or disc space. Therefore, the measurement of the disc space or vertebral body in Frey is not known and, therefore, without additional evidence it is not known whether the distance from the posterior to anterior edges of the disc space in Frey is less than, equal to, or greater than 40 mm, for example. Patent Owner does not provide evidence sufficient to show that using an implant that is greater than 40 mm in length would, in fact, result in "unsafe damage/impingement upon the transverse process, the superior articular process, the spinal canal, and other portions of the spine," the distance between the point of insertion of the implant and the anterior aspect of the disc not being disclosed in Frey.

Even assuming that the distance between the point of insertion of the implant and the anterior aspect of the disc space was disclosed by Frey as being

less than 40 mm, Patent Owner provides insufficient evidence to demonstrate that, with respect to the level of ordinary skill in the art, maneuvering the implant to prevent damage or impingement to the transverse process, superior articular process, spinal canal or other portions of the spine would have been uniquely challenging or difficult. *See Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007) (citing *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007)). Indeed, Michelson discloses an implant with a length that is greater than 40 mm and does not disclose that inserting such an implant results in the alleged damage or impingement. Hence, Michelson demonstrates that it would have been obvious to one of ordinary skill in the art to have inserted an implant measuring greater than 40 mm in length without unsafe damage or impingement upon the transverse process, the superior articular process, the spinal canal, or other portions of the spine.

Patent Owner argues that Michelson discloses inserting an implant into an intervertebral space laterally, but that Frey discloses inserting an implant into an intervertebral space posteriorly, and that inserting the implant of Frey into an intervertebral space laterally (instead of posteriorly) would produce a "result [that] is entirely contrary to Frey's principle purpose of providing a solution for a 'posterior lateral approach to the disc space . . .'." Prelim. Resp. 18. However, as noted previously, Frey explicitly discloses inserting an implant into an intervertebral space using "other approaches . . . such as lateral . . . ." Ex. 1003, ¶ [0150]. Patent Owner does not explain adequately how an approach of inserting an implant that is explicitly disclosed by Frey is contrary to the intended purpose (or principle of operation) of Frey.

Even assuming that it would have been impossible for one of ordinary skill in the art to have inserted an implant measuring greater than 40 mm in length into

an intervertebral space via a posterior approach without resultant damage or impingement, as Patent Owner contends, Frey alternatively discloses inserting an implant into an intervertebral space via a lateral approach, the same orientation of insertion of an implant described by Michelson. Patent Owner appears to agree that one of ordinary skill in the art would have understood that it was obvious to insert safely a spinal implant with a length greater than 40 mm using a lateral approach. Hence, contrary to Patent Owner's contention, Frey would not be rendered "inoperable" even under Patent Owner's hypothesized scenario because Frey could still be "operable" to insert the spinal implant measuring greater than 40 mm in length via a lateral approach (an approach explicitly disclosed by both Frey and Michelson).

With respect to claim 21, Petitioner explains that the upper and lower surfaces of the implant disclosed by Frey are generally parallel. Pet. 29 (citing Ex. Frey, Fig. 62). Patent Owner argues that "the upper and lower surfaces of Frey's implant . . . are not generally parallel." Prelim. Resp. 20. Claim 21, which depends from claim 1, recites that the "upper and lower surfaces are generally parallel to one another." Patent Owner argues that Petitioner asserts that the upper and lower surfaces of the Frey implant "are generally parallel to [each other]" but also argues separately, with respect to claim 22 which depends from claim 1, that the upper and lower surfaces are "generally angled relative to one another." Prelim. Resp. 19-21.

On this record, we are not persuaded that the upper and lower surfaces are oriented relative to one another in such a way that one of ordinary skill in the art would have considered the surfaces not to be "generally" parallel to one another, as recited in claim 21, and "generally" angled relative to one another, as recited in claim 22. For example, we agree with Petitioner that one of ordinary skill in the

art would have understood that the upper and lower surfaces are "generally" parallel to each other at least because the general overall relative positions of the upper and lower surfaces are oriented in approximately the same direction in at least one aspect.

Patent Owner points out that the upper and lower surfaces of the implant of Frey, when considered from the rear aspect of the implant, appears to be generally parallel to each other but that the upper and lower surfaces of the implant of Frey, when considered from the side aspect of the implant appears to be generally angled relative to each other. Prelim. Resp. 19-21. Patent Owner does not demonstrate sufficiently that claim 21 requires the upper and lower surfaces of the implant to be generally parallel in all aspects.

Claim 21 recites that the upper and lower surfaces of the implant are "generally" parallel to each other and does not require that the upper and lower surfaces of the implant are strictly parallel to each other in every aspect. Similarly, claim 22 recites that the upper and lower surfaces of the implant are "generally" angled relative to one another and does not require that the upper and lower surfaces of the implant are angled relative to each other in every aspect. Indeed, both claims 21 and 22 recite that the upper and lower surfaces are "generally" oriented relative to one another in a particular manner. Thus, an upper surface that is generally parallel in at least some aspects to a lower surface meets the claim 21 limitation. Moreover, an upper and lower surface that are generally angled relative to one another in at least some aspect meets the claim 22 limitation. Thus, we disagree with Patent Owner's argument that Petitioner's reliance on a single embodiment showing both generally parallel and generally angled surfaces is improper.

III. CONCLUSION

For the foregoing reasons, we determine that the information presented in the Petition establishes that there is a reasonable likelihood that Petitioner would prevail with respect to claims 1-5, 10, 11, 14, 15, and 18-28 under 35 U.S.C. § 103(a) as obvious over Frey and Michelson.

The information presented in the petition does not, however, establish that there is a reasonable likelihood that Petitioner would prevail with respect to claims 1-3, 10, 14, 15, and 19-28 under 35 U.S.C. § 102(b) as anticipated by Frey; claims 1-5, 10, 11, 14-17, and 19-28 under 35 U.S.C. § 103(a) as obvious over Frey and Baccelli; and claims 1-3, 10, 14, 15, and 19-28 under 35 U.S.C. § 103(a) as obvious over Frey and any one of Messerli or Moret.

IV. ORDER

For the reasons given, it is

ORDERED that the petition is granted as to claims 1-5, 10, 11, 14, 15, and 18-28 under 35 U.S.C. § 103(a) as obvious over Frey and Michelson.

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the ’334 patent is hereby instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

FURTHER ORDERED that an initial conference call with the Board is scheduled for Thursday, February 27, 2014 at 3PM. The parties are directed to the Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,765-66 (Aug. 14, 2012), for guidance in preparing for the initial conference call, and should be

prepared to discuss any proposed changes to the Scheduling Order entered herewith and any motions the parties anticipate filing during the trial.

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