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Paper 48
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 IPR2013-00508
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. 1115, "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 21) ("PO Resp."), and Petitioner filed a Reply (Paper 28) ("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 41) ("Opp."), and Patent Owner filed a Reply (Paper 46) ("PO Reply"). An Oral Hearing was conducted on November 18, 2014, pursuant to Requests for Oral Argument filed by Petitioner (Paper 32) and Patent Owner (Paper 33). Patent Owner also filed a Motion for Observation on certain cross-examination testimony of Petitioner's declarant, Richard A. Hynes, M.D. (Paper 38, "Hynes Obs.") and a 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 45, "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. 1115, 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 grounds of unpatentability:

Reference(s)	**Basis**	**Claims challenged**
Baccelli,[1] Michelson,[2] and SVS[3]	§103	1–5, 10, 11, and 14–28
Baccelli, Michelson, and Telamon[4]	§103	1–5, 10, 11, and 14–28

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,

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[1] Baccelli, US 2003/0028249 A1, filed Feb. 6, 2003 (Ex. 1104).
[2] Michelson, US 5,860,973, issued Jan. 19, 1999 (Ex. 1105).
[3] Synthes Vertebral Spacer – PR Brochure, Synthes Spine 2002 ("SVS", Ex. 1106).
[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").

we maintain the constructions set forth in the Decision to Institute and determine that no other express constructions are necessary. *See* Dec. on Inst. 5-6.

II. ANALYSIS

A. Baccelli, Michelson, and One of SVS or Telamon (Claims 1–5, 10, 11, and 14–28)

We conclude that Petitioner has shown by a preponderance of the evidence that all of the limitations of claims 1–5, 10, 11, 14–17, and 19–28 are taught or suggested by the combination of Bacelli, Michelson, and one of SVS or Telamon. Pet. 14–60. 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 "the SVS-PR [implant] has a longitudinal length at least two and half times greater than the maximum lateral width," that "the Telamon [implant] has a 10 mm width, and may have a length of 26 mm [which provides an implant with a longitudinal length at least two and a half times greater than the maximum lateral width]," and that "a skilled artisan . . . inclined to provide an implant for lateral insertion . . . would have been taught by Michelson to make the length of the implant 40 mm or greater" at least in order "to provide more stable support for the vertebra" and because doing so "represents nothing more than an application-specific

dimensional optimization in accordance with the prior art." Pet. 18, 20, 21, 42–44 (citing Ex. 1101 ¶72).

Patent Owner argues that Michelson fails to disclose or suggest an implant with a longitudinal length at least two and a half times greater than the maximum lateral width, "discloses no reason to size an implant to be greater than 40 mm and also narrow," "never suggests that a narrow, 40mm implant would be beneficial or even acceptable," and "did not recognize the benefits of the claimed dimensions." PO Resp. 42–43 (citing Ex. 2020, 24, 117–120). In addition, according to Patent Owner, Michelson discloses "oversized" implants and "discloses no implant that is both long (over 40 mm) and narrow (length at least 2.5 times width)." PO Resp. 43–44 (citing Ex. 1101 ¶ 150; Ex. 2020 ¶¶ 94, 117–119). In addition, Patent Owner's Declarant, Dr. Barton Yuan, testifies that "the '334 patent presents novel dimensions and length-to-width proportions for implants that are greater than 40mm in length that had not been contemplated before . . . ." Ex. 2020 ¶ 47.

However, we credit the testimony of Petitioner's Declarant (Dr. Richard A. Hynes) that Michelson discloses a spinal implant with a length that is greater than 40mm and at least 2.5 times the width. For example, Dr. Hynes testifies that Michelson discloses spinal implants that measure greater than 40mm in length (e.g., 44mm) that is at least 2.5 times the width of the implant (e.g., the width measuring 17mm, which is less than 44mm/2.5 = 17.6mm). Ex. 1157 ¶ 12 (citing Ex. 1118).

In addition, Michelson expressly discloses an implant "with 42 mm being the preferred length" and a width that "approximates the depth of the vertebrae," that measures "in the range of 24 mm to 32 mm," with "the

preferred width being 26 mm." Ex. 1105, 10:40–41, 10:44–47. In other words, Michelson discloses that an implant with a preferred width of 26 mm (or between 24 mm and 32 mm) would approximate the depth of the vertebrae. In one embodiment of Michelson, one implant "has a narrower width such that more than one spinal fusion implant . . . may be combined . . . for insertion within the disc space." *Id.* at 10:52–54. For example, if the total width of at least two spinal fusion implants measures 26 mm (i.e., the depth of the vertebrae), then each implant would measure 26 mm/2 implants = 13 mm, which, when multiplied by a factor of 2.5, would be less than the length of the implant (e.g., preferably 42 mm).

Thus, it would have been obvious to one of ordinary skill in the art to have provided an implant with a length of greater than 40 mm (e.g., 42 mm) and at least 2.5 times the width, as recited in claim 1.

Patent Owner argues that "[i]f the size of the SVS-PR PLIF implant were increased according to the dimensions disclosed by Michelson, the . . . width would be increased from 8 mm . . . to between 24 to 32 mm" and that "if the size of the Telamon PLIF implant were increased according to these dimensions disclosed by Michelson, the . . . width would be increased from 10 mm . . . to between 24 to 32 mm." PO Resp. 31. However, Patent Owner does not explain sufficiently why one of ordinary skill in the art would have increased the width of either the SVS or Telamon implant to 24–32 mm based on Michelson. On the contrary, as argued by Petitioner[5] and

[5] Petitioner argues that "as best exemplified in Figure 18, Michelson discloses long and narrow implants used for lumbar fusion. *See* Ex. 1157 ¶ 28. One of ordinary skill in the art would have understood that the implant 1000 disclosed a width in the range of 12 mm to 16 mm, or smaller, than implant 900, which is described as having a width "in the range of 24 mm to

as previously discussed, Michelson discloses an implant with a length greater than 40 mm and a width such that the total combined width of at least two of such implants would approximate the depth of the vertebrae of approximately 26 mm. Hence, Michelson discloses at least one example in which the width of an implant would be 13 mm with a length of 42 mm. Michelson further discloses that the implant(s) should "be small enough so as to fit into the same limited spinal width." Ex. 1105, 2:51–52. If the width of an implant was increased to 24–32 mm, as suggested by Patent Owner, then the total combined width of the combination of more than one implant as disclosed in Michelson would be 48–64 mm, which would exceed the approximate size of the intervertebral space of 26 mm, also as disclosed by Michelson. As Patent Owner points out, one of ordinary skill in the art would not have considered expanding the size of spinal implants beyond the confines of the intervertebral space because doing so may "compromise[e] the spinal cord, or nerve roots residing in the canal, potentially resulting in paralysis." PO Resp. 37.

Patent Owner argues that it would not have been obvious to one of ordinary skill in the art to have combined the teachings of either SVS or Telamon with Michelson because the implants of SVS or Telamon are both implants "designed with the intended purpose of use in PLIF procedures" but the implants of Michelson are "laterally inserted implants [as opposed to PLIF implants]" such that combining the teachings of either SVS or Telamon with that of Michelson (which, according to Patent Owner,

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32 mm." *See* Ex. 1105, 10:41–44; Ex. 1157 ¶ 28; *see also* Ex. 1148, 14:9–14 (disclosing tube, larger than implant, used to create space for implant "with 20 mm being the preferred outer diameter [of the tube]. . . ."); *id*. at 10:30–34."

discloses lateral implantation with an implant greater than 40 mm in length) "would fully eliminate SVS-PR's and Telamon's specifically intended insertion path and usage, rendering it inoperable for its intended purpose as a PLIF implant." PO Resp. 32–33, 35–37 (citing Ex. 2020 ¶¶ 82–83, 85, 87–88, 113–114).

SVS discloses that "[t]he Vertebral Spacer is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture)." Ex. 1106, 1. Hence, the "intended purpose" of the implant of SVS is to replace components within vertebrae. Telamon discloses a process of inserting an implant into an intervertebral space to achieve "decompression of the neural elements" and "satisfactory immobilization of the grafted interspace." Ex. 1108, 9. Hence, the "intended purpose" of the implant of Telamon is to achieve immobilization of the grafted interspace (and/or decompression of neural elements). We disagree with Patent Owner that Michelson, which discloses an implant that "engage[s] more of the adjacent vertebrae," (Ex. 1105, 3:49–50) would have "fully eliminated" the purpose of the SVS or Telamon implants of replacing collapsed, damaged, or unstable intervertebral components or immobilizing the interspace. Instead, the intended purpose of Michelson (a spinal fusion implant) appears to be the same as the intended purpose of either of SVS or Telamon, i.e., to achieve immobilization of the grafted interspace, for example. We are not persuaded by Patent Owner's argument.

Patent Owner argues that "using a 41 mm implant in a PLIF procedure would be extremely dangerous to the patient, risking paralysis or death" due to "the location of blood vessels and the spinal cord" and that "no

responsible surgeon would insert a 41 mm implant [of Michelson] in the PLIF approach intended by Telamon . . . and SVS." PO Resp. 38, 40 (citing Ex. 2020, 114–116). Hence, Patent Owner contends that "Michelson . . . specifically teaches away from inserting a posterior implant large enough to extend out of the disc space." PO Resp. 38–39 (citing Ex. 1105, 2:7–12). As previously described, the Petitioner argues that SVS and Telamon both disclose spinal implants and that "a skilled artisan . . . inclined to provide an implant for lateral insertion . . . would have been taught by Michelson to make the length of the implant 40 mm or greater" at least in order "to provide more stable support for the vertebra" and because doing so "represents nothing more than an application-specific dimensional optimization in accordance with the prior art." Pet. 18, 20, 21, 42–44 (citing Ex. 1101 ¶ 72). Hence, even assuming to be true Patent Owner's contention that "no responsible surgeon would insert a 41 mm implant in the PLIF approach," we are not persuaded by Patent Owner's argument because one of ordinary skill in the art, based on Michelson, would have inserted the "41 mm implant" laterally and not posteriorly. PO Resp. 38, 40 (citing Ex. 2020, 114–116).

In any event, Petitioner submits evidence supporting the contention that the insertion of implants measuring over 40 mm in length via a posterior approach is practiced safely in the art and, therefore, we are not persuaded by Patent Owner that "no responsible surgeon would insert" an implant measuring greater than 40 mm in length posteriorly. For example, Petitioner explains that Tohmeh (US Patent No. 8,623,088 B1 – Ex. 1131) discloses a spinal implant measuring up to 45 mm in length and "approaches a patient's spine posteriorly." Pet. Reply 5 (citing Ex. 1131, 5:32–35); Ex. 1131, 4:3.

Tohmeh does not disclose that such a practice would be "extremely dangerous to the patient, risking paralysis or death." In addition, as Petitioner explains, Patent Owner's Declarant (Dr. Yuan) testifies that a spinal implant measuring greater than 40 mm in length would fit within the circumference of the intervertebral space. Pet. Reply 5 (citing Ex. 1173, 244–245).

Claim 1 recites an implant including a radiopaque marker at least partially positioned in the central region of the implant (i.e., portions of the first and second sidewalls positioned generally centrally between the proximal and distal walls). Claim 16 further recites a radiopaque marker positioned in the central region. Petitioner argues that Baccelli discloses "a third radiopaque marker that is at least partially positioned in said central region." Pet. 22 (citing Ex. 1104, ¶ 41). Baccelli discloses "spikes" that are disposed "about the sagittal midplane" and is "made of a material that is opaque to X-rays." Ex. 1104 ¶¶ 41, 50–51.

Patent Owner argues that "it is not obvious to add the spikes 24 of Baccelli to the PLIF implants of SVS-PR and Telamon because such spikes are unsuitable for PLIF procedures" and that "Baccelli's elongated metal fixation spikes . . . could not be safely inserted in a PLIF procedure . . . because the vertebrae cannot be distract[ed] to the same degree as in an anterior procedure and the spikes would prevent or cause undesirable damage during impaction." PO Resp. 47, 55 (citing Ex. 2020 ¶ 125). Patent Owner's Declarant (Dr. Yuan) testifies that he is of the belief that "the vertebrae cannot be distracted . . . from a posterior approach due to a number of anatomic structures" and that, based on this alleged inability to distract the vertebrae in a posterior approach, "the protruding metal spikes 24 [of

Baccelli] would substantially impair posterior insertion" of an implant. Ex. 2020 ¶ 125. Dr. Yuan, however, does not provide sufficient evidence supporting the contention that the vertebrae "cannot be distracted . . . from a posterior approach." In fact, Dr. Yuan also testifies that during insertion of a spinal implant via a posterior lateral approach, the surgeon may "distract [the vertebrae] probably a couple of millimeters." Ex. 1173, 45. Dr. Yuan does not testify that distracting the vertebrae by "a couple of millimeters" would be insufficient when using "protruding metal spikes."

Patent Owner argues that it would not have been obvious to one of ordinary skill in the art to have combined the teachings of the cited references because various implants "include[] no radiopaque markers in the central region." PO Resp. 46. We are not persuaded by Patent Owner's argument because the question is whether it would have been obvious to one of ordinary skill in the art to combine the cited references and not whether any specific implants on the market contain a radiopaque marker in a central region or not.

Patent Owner argues that "Baccelli . . . describes no reason why radiopaque markers should be added to a PLIF implant [purportedly of SVS or Telamon] in any particular location, let alone in the central region of such PLIF implants" and that Petitioner's Declarant (Dr. Hynes) "never explains why one would add a pair of markers to the central region for such PLIF implants, and certainly does not cite any evidence supporting what he proposes was 'common sense' in 2004 or ever." PO Resp. 48–50 (citing Ex. 1101 ¶ 100; Ex. 2020 ¶¶ 124, 126). We are not persuaded by Patent Owner's argument because, as Petitioner explains, Baccelli discloses radiopaque markers in the central region of a spinal implant.

Patent Owner argues that it would not have been obvious to one of ordinary skill in the art "to add a pair of radiopaque markers to the central region" of an implant because, according to Patent Owner, to do so "would add no meaningful 'additional information' . . . and would increase the likelihood of confusing surgeons." PO Resp. 51 (citing Ex. 2020 ¶¶ 124, 126; Ex. 2013, 163:23 – 164:25). We credit the testimony of Patent Owner's Declarant (Dr. Yuan) that one of ordinary skill in the art would have understood that an implant that "includes two radiopaque markers in the central region [would provide] . . . better align[ment of] the implant" and "also allows a surgeon to see in an anterior-to-posterior x-ray view whether the implant is askew and the degree to which the implant is askew." Ex. 2020 ¶ 64. Given the relative level of skill in the art, we agree with Dr. Yuan that the use of markers to improve x-ray visualization of the alignment of implants, for example, would have been well within the purview of one of ordinary skill in the art at the time of the invention. Hence, we are not persuaded by Patent Owner's contention that "a pair of radiopaque markers to the central region" of an implant would "add no meaningful 'additional information.'"

Also, we are not persuaded by Patent Owner's argument that it would not have been obvious to one of ordinary skill in the art to use a radiopaque marker in the central region of an implant because doing so would confuse surgeons (or those of ordinary skill in the art). Patent Owner's Declarant (Dr. Yuan) testifies that one "complication with using markers . . . is that the implant can have too many of them." Ex. 2020 ¶ 45. Dr. Yuan, however, does not assert or provide sufficient evidence that the specific use of a radiopaque marker in the central region would by "too many" as to result in

confusion or whether such alleged resulting confusion (if any) would be excessive or prohibitive. PO Resp. 54 (citing Ex. 2020 ¶ 45).

Dr. Yuan also testifies that the use of a radiopaque marker in the central region of an implant "could cause problems, including possibly providing confusing imaging information to the surgeon." PO Resp. 54 (citing Ex. 2020 ¶ 124). Dr. Yuan, however, provides insufficient evidence in support of this contention. For example, Dr. Yuan does not provide persuasive evidence supporting the contention that "problems" would arise in the use of a radiopaque marker in the central region of an implant, the nature and extent of any potential "problems," or how any such problems would "confuse" one of ordinary skill in the art and to what extent. Indeed, as previously discussed, Baccelli discloses radiopaque markers in the central region of an implant and does not disclose that one of ordinary skill in the art is confused by such an arrangement.

Patent Owner further argues that Petitioner's Declarant (Dr. Hynes) testifies that it would not have been obvious to one of ordinary skill in the art to have incorporated a radiopaque marker in the central region of an implant because doing so would be "a possible source of confusion." PO Resp. Br. 54 (citing Ex. 2013, 163:23–164:19). However, Dr. Hynes merely testifies that using "the wrong marker" in "the wrong place" may "create[] confusion sometimes." Ex. 2013, 164:11, 12–13. Neither Patent Owner, nor Dr. Hynes, asserts, or demonstrates sufficiently to overcome Petitioner's contrary showing, that the general use of a radiopaque marker in the central region of an implant, as required by the claimed invention, would be using "the wrong marker" that is in "the wrong place." On the contrary, Baccelli discloses the use of such a marker in the central region of an implant, thus

suggesting to one of ordinary skill in the art that such a marker would not have been "wrong" and that the central region would not have been a "wrong place" for such a marker. We are not persuaded by Patent Owner's arguments.

Claim 18 depends from claim 1 and further recites that the maximum lateral width of the implant is approximately 18 mm. Petitioner argues that Michelson discloses an implant "having a maximum lateral width in the range of 14 to 26 mm." Pet. 32 (citing Ex. 1105, 7:26–30). Patent Owner, however, points out that, "Michelson discloses no implant that is longer than 40 mm *and* has a width of 18mm." PO Resp. 57 (citing Ex. 2020 ¶¶ 94, 119). Instead, even assuming that the cited implant of Michelson has a maximum width of 18 mm, as argued by Petitioner, Michelson discloses that the implant measures 12–30 mm in length, which is less than 40 mm, in contrast to the requirement of claim 18 of an implant length that is greater than 40 mm. Nor does Petitioner articulate reasoning with some rational underpinning to support the conclusion that it would have been obvious to one of ordinary skill in the art to have modified Michelson's implant to have a length greater than 40 mm.

Petitioner also asserts Michelson incorporates by reference U.S. Patent No. 5,772,661 (Ex. 1046, "Michelson '661") and U.S. Patent No. 5,484,437 (Ex. 1048, "Michelson '437") and argues that "Michelson '661" discloses an implant with a maximum width of 18 mm. *See* Pet. 32. Michelson '661 discloses an implant with a width "in the range of 10 mm to 30 mm." Ex. 1148, 10:31. Even assuming that Michelson '661 discloses an implant with a maximum width of 18 mm (as within the range of 10 mm to 30 mm), Michelson '661 discloses that the length of the implant is "less than

the known transverse width W (side to side) of the vertebrae T7 and T8." Ex. 1148, 10:21–23. Petitioner does not assert or demonstrate sufficiently that the "known transverse width W (side to side) of the vertebrae T7 and T8" (corresponding to the length of the implant) is greater than 40 mm, as required by claim 18. Nor does Petitioner articulate reasoning with some rational underpinning to support the conclusion that it would have been obvious to one of ordinary skill in the art to have modified the cited implant to have a length greater than 40 mm.

Petitioner also cites U.S. Patent No. 5,484,437 (Ex. 1150, "Michelson '437") as disclosing an implant with a maximum width of 18 mm. *See* Pet. 32–33. Even assuming that Michelson '437 discloses an implant with a maximum width of 18 mm, Petitioner does not assert or demonstrate sufficiently that Michelson '437 also discloses that the implant with a maximum width of 18 mm measures greater than 40 mm in length, as required by claim 18. Nor does Petitioner articulate reasoning with some rational underpinning to support the conclusion that it would have been obvious to one of ordinary skill in the art to have modified the cited implant to have a length greater than 40 mm.

B. Secondary Considerations

Patent Owner argues that "detailed testimony establishes a nexus between NuVasive's CoRoent XL implants and the invention of the '334 patent, and proves the commercial success of the product after NuVasive pioneered the market for lateral, trans-psoas interbody fusion surgeries with the CoRoent XL implant." PO Resp. 59 (citing Ex. 2020, 53–63; Ex. 2030, 7–10, App. A, Section III.D).

We recognize that evidence of secondary considerations must always be considered en route to the determination of obviousness, but its existence alone does not control the conclusion of obviousness. *Richardson-Vicks v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997). The weight given to evidence of secondary considerations is dependent upon whether there is a nexus between the merits of the claimed invention and the evidence offered. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1539 (Fed. Cir. 1983).

Even assuming that NuVasive's CoRoent XL implant experienced "commercial success," as Patent Owner asserts, Patent Owner has not demonstrated sufficiently that there is a nexus between the merits of the *claimed* invention and the evidence offered. For example, Patent Owner argues that NuVasive "pioneered the market for lateral, trans-psoas interbody fusion surgeries," (PO Resp. 59) but fails to demonstrate sufficiently that any of the disputed claims recite "lateral, trans-psoas interbody fusion surgeries." We are not persuaded by Patent Owner's arguments.

C. Motion to Exclude

In its Motion to Exclude, Patent Owner seeks to exclude the Declaration of Loic Josse (Ex. 1116, "Josse Declaration"). We did not rely on the Josse Declaration in this decision. Therefore, Patent Owner's motion to exclude is dismissed as moot.

D. Motion for Observation

Patent Owner's observations are directed to the cross-examination testimony of Richard A. Hynes, M.D. (Ex. 38), who was cross-examined after Petitioner filed its Reply. We have considered Patent Owner's

observations and Petitioner's responses in rendering our decision, and have accorded the testimony the appropriate weight as explained above. *See* Obs. 1–9.

Patent Owner also submits observations to the cross-examination testimony of Loic Josse (Ex. 39). As previously discussed, we did not rely on the Josse Declaration in this decision. Therefore, we have not considered Patent Owner's observations directed to the cross-examination testimony of Loic Josse.

ORDER

Petitioner has demonstrated, by a preponderance of the evidence, that claims 1–5, 10, 11, 14–17, and 19–28 are unpatentable over Baccelli, Michelson, and any one of SVS or Telamon under 35 U.S.C. § 103(a). Petitioner has not demonstrated, by a preponderance of the evidence, that claim 18 is unpatentable over Baccelli, Michelson, and any one of SVS or Telamon under 35 U.S.C. § 103(a).

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–5, 10, 11, 14–17, and 19–28 of the '334 patent have been shown to be unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude is *dismissed*.

This is a final decision. Parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2013-00508
Patent 8,187,334 B2

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