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Paper No. 47
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.,
Petitioner,

v.

NUVASIVE, INC.,
Patent Owner.

Case IPR2013-00506
Patent 8,361,156 B2

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").

specification of the patent in which they appear. 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). Claim terms also 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). If an inventor acts as his or her own lexicographer, the definition must be set forth in the specification with reasonable clarity, deliberateness, and precision. *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998).

In the Institution Decision, we "interpret[ed] the claim language consistently with its plain and ordinary meaning, when read in view of the Specification." *See, e.g.*, Dec. Inst. 6. The parties appear to agree on the interpretation of the claim terms, and we see no reason to depart from our interpretation in the Institution Decision.

B. Patentability

1. Principles of Law

To prevail on its challenges to the patentability of claims, Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art;

(2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). The level of ordinary skill in the art usually is evidenced by the references themselves. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978).

Prior art references must be "considered together with the knowledge of one of ordinary skill in the pertinent art." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (quoting *In re Samour*, 571 F.2d 559, 562 (CCPA 1978)). Moreover, "it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." *In re Preda*, 401 F.2d 825, 826 (CCPA 1968). That is because an obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418; *see In re Translogic Tech., Inc.*, 504 F.3d. 1249, 1259 (Fed. Cir. 2007).

2. Obviousness of Claim 1 under 35 U.S.C. § 103(a) Over One of SVS or Telamin, Combined with Baccelli

Petitioner contends that the combination of one of SVS or Telamon with Baccelli renders obvious independent claim 1. Pet. 14–16; 38–39. Petitioner sets forth claim charts demonstrating where each element of the claim is taught by the reference (*Id.* at 16–18; 39–42), and relies, initially, on the Declaration of Dr. Hynes (Ex. 1101). Patent Owner disagrees with Petitioner's assertions (PO Resp. 32–47), and relies on the Declaration of

Dr. Hansen A. Yuan (Ex. 2020) as evidence that the asserted combination does not render obvious the challenged claims.

a. SVS (Ex. 1106)

SVS discloses a vertebral spacer (or spinal implant) made of a radiolucent polymer that allows fusion to occur through the implant. In one embodiment, the implant measures 22 mm depth by 8 mm width and includes two radiopaque marker pins. Ex. 1106, 1–2.

b. Telamon (Ex. 1107)

Telamon discloses a radiolucent spinal implant measuring 22-26 mm length by 10 mm width. Ex. 1107, p. 2. The implant further includes radiographic markers. *Id.*

c. Baccelli (Ex. 1104)

Baccelli discloses an intervertebral implant. Ex. 1104 ¶ 1. The implant has a front wall (*id.* ¶ 6, Fig. 8 – element 4b) that contains an orifice (*id.* ¶ 39, Fig. 8, element 18) into which a threaded endpiece is connected for placing the implant into position between vertebrae. *Id.* ¶¶ 44–45.

The implant is made of a material that is transparent to X-rays, such as PEEK. *Id.* ¶ 50. 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 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, 9.

The implant may further include spikes positioned symmetrically about the sagittal midplane and extending in the frontal midplane in a

vertical axis. *Id.* ¶ 41, Figs. 1–5, 8, 9. The spikes may be made of a radiopaque material (i.e., a material that is opaque to X-rays). *Id.* ¶ 51.

d. Analysis

Petitioner asserts that SVS and Telamon disclose almost all the limitations of independent claim 1. Pet. 14–15, 38. The SVS and Telamon implants have radiopaque markers in their distal and proximal walls. *Id* at 15, 38. Petitioner asserts that Baccelli also teaches the use of radiopaque markers, wherein the "at least first and second radiopaque markers . . . extend into a first sidewall and a second sidewall at positions proximate to a medial plane of the implant." *Id.* at 15, 39.

According to Petitioner, it would have been obvious to the ordinary artisan at the time of invention to include the radiopaque markers of Baccelli in the implants of SVS or Telamon in order to provide additional information regarding the location and/or orientation of the implant, both during surgery and after implantation. *Id.* at 15, 39 (citing Ex. 1101 ¶ 68). Petitioner contends further that such a combination is "nothing more than an application of known prior art elements to improve a similar device in the same way." *Id.* at 15, 39.

Patent Owner contends that neither Telamon nor SVS disclose an interbody fusion implant "with radiopaque markers in the medial plane." PO Resp. 33. Patent Owner contends further that the implant designed by Dr. Hynes, the Saber implant, does not include radiopaque markers in the medial plane. *Id.* (citing Ex. 2011; Ex. 2020 ¶ 95). Rather, the markers are only at the proximal and distal ends. *Id.* at 33–34. Thus, Patent Owner contends, "it is plainly apparent that the implant designers for each of Medtronic, Synthes, and DePuy Spine all considered radiopaque markers to

be inappropriate or at least unnecessary in the medial plane for PLIF [posterior lumbar interbody fusion] implants." *Id.* at 34 (citing Ex. 2020 ¶¶ 45, 98–99, and 102). 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.

Patent Owner contends further that none of the references relied upon by Petitioner provide a reason to add a pair of radiopaque markers to the medial plane of a PLIF implant, such as those of Telamon and SVS. *Id.* at 36 (citing Ex. 2020 ¶¶ 89, 98, 99). Patent Owner argues that the reason articulated by Petitioner's expert, Dr. Hynes, of providing additional information "is simply a vague explanation with no rational underpinning." *Id.* at 37 (citing Ex. 1101 ¶ 68). In particular, Patent Owner contends that Dr. Hynes "does not provide a rational explanation for what 'additional information' and certainly does not cite any evidence that what he proposes was 'common sense' in 2004 or ever." *Id.* at 37–38. Patent Owner argues that any information provided by adding markers to the medial plane would be at best redundant, or at worst, a possible source of confusion. *Id*. at 38. Dr. Hynes, Patent Owner contends, engaged in impermissible hindsight to combine Bacelli with SVS and Telamon to arrive at an implant having radiopaque markers at the medial plane. *Id*. at 38–40.

Patent Owner contends that the ordinary artisan would not have added markers to the medial plane "because doing so would add no meaningful 'additional information' beyond that already provided by the existing markers and would increase the likelihood of causing confusion." *Id.* at 49

(citing Ex. 2020 ¶¶ 98–99). Patent Owner cites their expert, Dr. Yuan, in arguing that the "conventional and proper position for radiopaque markers in PLIF implants is at the proximal and distal ends," as they allow the surgeon to determine the location and orientation of the PLIF implant in PLIF implantation procedures. *Id.* at 40–41 (citing Ex. 2020 ¶¶ 45, 98, 99). Thus, having markers as the proximal and distal walls provides all the information necessary for both during and after the surgery. *Id.* at 42.

Moreover, according to Patent Owner, Petitioner's expert, Dr. Hynes, testified that markers in the wrong place may actually create confusion. *Id.* at 43 (citing Ex. 2013, 163:23–164:25). "Every excess marker increases the risk of confusing one marker for another," and, thus, "designers are very purposeful about the number and location of markers added to fusion implants." *Id.* at 44 (citing Ex. 2020, ¶¶ 45–46, 98, 99).

We do not find Patent Owner's arguments persuasive. As Petitioner notes (Reply 11), Baccelli teaches the use of radiopaque markers in the central regions of an implant. *See* Ex. 1104 ¶¶ 41, 51; Figs. 1–5, 8, 9. We also agree with Petitioner that the addition of markers along the medial plan would not confuse a surgeon of ordinary skill in the art, and "vastly underestimates the ordinary skill of surgeons in this field." Reply 11 (citing Ex. 1104, FIG. 2; Ex. 1129).

In that regard, 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 ¶ 60. 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.

We note that Dr. Yuan testified that one "complication with using markers . . . is that the implant can have too many of them" (Ex. 2020 ¶ 45), and testified also that the use of a radiopaque marker in the central region of an implant "could cause problems, including confusing the surgeon" (Ex. 2020 ¶ 98). 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 a surgeon 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.

As to Patent Owner's argument that Petitioner's Declarant, Dr. Hynes), testified 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 may cause confusion, Dr. Hynes merely testifies that using "the wrong marker" in "the wrong place" may "create[] confusion sometimes." Ex. 2013, 164:11, 12–13. As already noted, however, 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.

Hence, we are not persuaded by Patent Owner's contention that the addition of pair of radiopaque markers to the medial region of an implant would not add any meaningful information and would cause confusion.

Patent Owner contends further that neither Telamon nor SVS disclose an interbody fusion implant with elongate metal fixation spikes, such as those taught by Baccelli, and that the Saber implant designed by Dr. Hynes also did not incorporate such spikes. PO Resp. 34. According to Patent Owner, such spikes "would hinder or interfere with the intended PLIF usage of those implants." *Id*. That is, Patent Owner argues, as the Medtronic, Synthese, and DePuy Spine did not incorporate such spikes, it is "plainly apparent" that the designers "considered such metal fixation spikes to be inappropriate for the PLIF implant." *Id.* at 35. Thus, Patent Owner argues, the ordinary artisan would not have included the metal spikes of Baccelli on the implants of SVS or Telamon. *Id.* at 46.

Petitioner responds that the disclosure of Baccelli was not relied upon for the disclosure of spikes, but for locating radiopaque markers along the medial plane. Reply 12. We agree with Petitioner that the ordinary artisan would understand from the disclosure of Baccelli that radiopaque markers could be also located at the medial plane of the implant. "The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references

would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981) (citations omitted).

3. Obviousness of Claims 5 and 9 under 35 U.S.C. § 103(a) Over One of SVS or Telamin, Combined with Baccelli and Michelson

a. Michelson

The disclosures of SVS, Telamon, and Baccelli are discussed above as to the challenge of claim 1. Michelson discloses a translateral spinal fusion implant. Ex. 1105, 5:44-45. 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 10:46-47. The implant may also have "a maximum diameter in the range of 14-26 mm, with the preferred diameter being 20 mm." *Id.* at 7:28-30.

b. Claims 5 and 9

Petitioner contends that the combination of SVS or Telamon with Baccelli and Michelson renders obvious claims 5 and 9. Pet. 21–24, 27–29, 45–49, 52–53. Petitioner sets forth a claim chart demonstrating where each element of the claims is taught by the reference (*id.* at 25–26, 29, 49–50, 53), and relies, initially, on the Declaration of Dr. Hynes (Ex. 1101). Patent Owner disagrees with Petitioner's assertions (PO Resp. 47–59), and relies on the Declaration of Dr. Yuan. (Ex. 2020) as evidence that the asserted combination does not render obvious the challenged claims.

Specifically, as to the limitation of claim 5 that the longitudinal length is greater than 40 mm, Petitioner relies on Michelson for its disclosure of a spinal fusion implant that may have a longitudinal length greater than 40 mm. Pet. 22, 47. According to Petitioner, it would have been obvious to the ordinary artisan to include a longitudinal length greater than 40 mm to the

SVS or Telamon implant, as the implant would span the disc space and provide for more stable support. *Id.* at 22, 47 (Ex. 1101 ¶ 81). Petitioner contends that increasing the length of the SVS or Telamon implant would involve nothing more than routine optimization, requiring only the "exercise of ordinary skill and common sense to apply an identified, predictable solution to a known design need." *Id.* at 24, 49.

Claim 9 adds the limitation that the maximum lateral width of the implant is approximately 18 mm. Petitioner relies on Michelson's teaching of an implant having a width in the range of 14 to 26 mm, as disclosing an embodiment of a lumbar spinal fusion implant having a width of 18 mm. *Id.* at 27,52 . According to Petitioner, the ordinary artisan would have modified the implant of SVS or Telamon to have a maximum width of approximately 18 mm, as Michelson teaches that a greater surface area of contact of the implant with the adjacent vertebra allows for greater stability. *Id.* at 27–28, 52 (citing Ex. 1105, 7:11–20).

Patent Owner contends that the SVS and Telamon "disclose PLIF implants designed with the intended purpose of use in PLIF procedures." PO resp. 47 (citing Ex. 2020, ¶¶ 79, 80, 84, 85). Although Petitioner relies on Michelson to meet the limitation of the implant being lengthened to exceed 40 mm in length, Patent Owner asserts that "Michelson discloses length in excess of 40 mm only for laterally inserted implants." *Id.* Petitioner asserts that modifying the implant of either SVS or Telamon to be greater than 40 mm would eliminate SVS and Telamon's "specifically intended insertion path and usage," making the SVS and Telamon implants inoperable for their intended use in PLIF procedures. *Id.* at 51 (citing Ex. 2020 ¶¶ 105, 106). That is, Patent Owner argues, the increased length would

make the implant of SVS and Telamon unsafe for a posterior insertion path. *Id.* at 51–55. Patent Owner asserts that Petitioner's approach that "require[s] a wholesale abandonment of the *primary reference's* intended PLIF purpose so as to achieve an entirely different use and operation." *Id.* at 53. Patent Owner contends that "[t]he fact that Dr. Hynes proposes modifying the SVS-PR and Telamon implants in a way that would cause them to be unsafe in PLIF procedures is evidence that Dr. Hynes is simply reading the claim language and then improperly inventing combinations using the benefit of hindsight." *Id.* at 56.

Petitioner responds that the claims are drawn to an apparatus, that is, a spinal implant, and are not method claims. Reply 1. Moreover, Petitioner notes that the Specification of the '156 patent states that the implants may be introduced through a variety of approaches. *Id.* (citing Ex. 1115, 5:31–34). Petitioner asserts further that Patent Owner's expert, Dr. Yuan, testifies that he had inserted implants suitable for a PLIF or ALIF approach using a lateral or oblique approach. *Id.* (citing Ex. 2020 ¶ 51).

Petitioner responds further that both Dr. Hynes and Dr. Yuan acknowledge that "a longer implant increases stability and provides more structural support to the adjacent vertebrae." Reply 4 (citing Ex. 1157 ¶¶ 7, 24; Ex. 2020 ¶ 41). Moreover, Petitioner argues, longer implants have been inserted using a posterior approach, and Dr. Yuan in fact "admitted that the disc space can accommodate such implants, much like the ones he himself inserted." *Id.* at 5 (citing Ex. 1173, 62, 121–122, 245). Dr. Yuan also testified that the Telamon implant, "as a vertebral body spacer, could be put in laterally, at an angle, or anteriorly," and that the SVS implant "could be inserted laterally, at an angle, or anteriorally." *Id.* at 7 (citing Ex. 1173, 62,

121–122). Dr. Yuan testified also that "an implant over 40 mm could be inserted posterior laterally (at an angle) from the back and fit in the disc space." *Id.* at 10 (citing Ex. 1173, 233–234). According to Petitioner, Dr. Hynes agrees, and has done such surgeries. *Id.* (citing Ex. 1157 ¶ 5).

After considering the parties respective positions and evidence, we do not find Patent Owner's contentions persuasive 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," and, thus, "permits greater stability" (Ex. 1105, 3:49–51) 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.

As to the argument that inserting a longer implant, such as an implant that is approximately 40 mm in length, posteriorly, would have been dangerous, 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 (PO Resp. 53–54) 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 uses a "posterior approach." Reply 5 (citing Ex. 1131, 4:3, 5:32–35). Tohmeh does not disclose that such a practice would be "extremely dangerous to the patient, risking paralysis or death" (PO resp. 53). In addition, as Petitioner explains, Dr. Yuan testified that a spinal implant measuring greater than 40 mm in length would fit within the circumference of the intervertebral space. Reply 5 (citing Ex. 1173, 244–245).

Moreover, even assuming to be true Patent Owner's contention that a responsible surgeon would not 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, not posteriorly. Patent Owner presents no evidence that maneuvering the implant to prevent damage to the annulus on the anterior aspect of the disc would have been uniquely challenging or difficult for one of ordinary skill in the art. *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 damage to the annulus on the anterior aspect of the disc. Ex. 1105, 10:41–46. Hence, Michelson demonstrates that it would have been obvious to one of ordinary skill in the art to have inserted an implant

measuring at least 40 mm in length without damage to the annulus on the anterior aspect of the disc.

As to claim 9, Patent Owner contends again that the intended purpose of the SVS and Telamon implants is PLIF implantation, whereas Michelson teaches a width of 18mm only for laterally inserted implants. PO Resp. 57. According to Patent Owner. "[w]idening the SVS-PR and Telamon PLIF implants to be 18 mm would render them inoperable for their intended purpose of PLIF implantation." *Id.* at 58 (citing Ex. 2020 ¶¶ 109-113). Patent Owner argues that modifying the SVS or Telamon implant would make the implant too wide to be safely inserted posteriorly in a PLIF procedure. *Id.*

Petitioner responds that "it is undisputed that one of ordinary skill in the art would have been motivated to adjust the dimensional footprints of SVS-PR and Telamon, including their respective widths, to provide a more stable implant that better supports its adjacent vertebrae." Reply 6. We conclude that Petitioner has the better position for the same reasons set forth with respect to claim 5. That is, the claim is drawn to an apparatus, and not a method of insertion. It would have well within the level of skill of the ordinary surgeon to determine the appropriate size of the implant. *See*, *e.g.*, Ex. 1115, 11:10–12 (noting that before a spinal fusion procedure is performed, "the clinician must first designate the appropriate implant size."). Moreover, Michelson specifically teaches an implant having a width of 18mm, and one of ordinary skill in the art, based on Michelson, would have understand that the "18 mm implant" could be laterally, rather than posteriorly.

4. Claims 2–4, 6–8, 10–14, 19, 20, and 23–27

Patent Owner presents no additional argument as to dependent claims 2–4, 6–8, 10–14, 19, 20, and 23–27. PO Resp. 46. Upon review of those claims, as well as the contentions and evidence relied upon by Petitioner, we determine that the preponderance of the evidence of record demonstrates that those claims are rendered also unpatentable over the challenges as based on SVS or Telamon.

5. Secondary Considerations

Before we can determine that the obviousness determinations above render the challenged claims unpatentable, we must consider the evidence of obviousness anew in light of any evidence of secondary considerations of nonobviousness presented by Patent Owner. *See Graham*, 383 U.S. at 17–18 ("Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy."); *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012) ("This objective evidence must be 'considered as part of all the evidence, not just when the decision maker remains in doubt after reviewing the art.'") (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983)).

"Evidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention and the commercial success." *Ormco Corp. v. Align Tech. Inc.*, 463 F.3d 1299, 1311–12 (Fed. Cir. 2006). "For objective evidence to be accorded

substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention." *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995). In order to establish a proper nexus, the patent owner must offer proof that the sales were a direct result of the unique characteristics of the claimed invention—as opposed to other economic and commercial factors unrelated to the quality of the patented subject matter. *See Microsoft v. Proxyconn, Inc.*, Case IPR2012-00026, slip op. at 4 (PTAB Mar. 8, 2013) (Paper 32).

Patent Owner contends that the evidence of commercial success demonstrates the non-obviousness of the claimed implants. PO Resp. 59. According to Patent Owner, "the detailed testimony establishes a nexus between NuVasive's CoRoent XL implants and the invention of the '156 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." *Id.* (citing Ex. 2020 ¶¶53-63; Ex. 2030 ¶¶ 7-10 and App. A). Patent Owner asserts further that the fact that Petitioner never practiced the lateral lumbar implants depicted in Michelson '973, and did not introduce its Clydesdale implants until the success of Patent Owner's CoRoent XL, "is telling of [Patent Owner's] commercial success and pioneering efforts." *Id.* (citing Ex. 2030 ¶¶ 7, 9 and App. A at 8).

First, we note that Patent Owner did not even attempt to establish any nexus between the claimed implant and any purported commercial success in its response, but merely cited to the Declaration of Patrick Miles (Ex. 2030) and the Declaration of Dr. Yuan (Ex. 2020), which improperly incorporates such arguments by reference from those Declarations into the Patent Owner response. *See* 37 C.F.R. § 42.6(a)(3) ("Arguments must not

be incorporated by reference from one document into another document."); *see also* Rules of Practice for Trials Before The Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions; Final Rule, 77 Fed. Reg. 48,612, 48,617 (Aug. 14, 2012) (prohibition against incorporation by reference is to eliminate abuses that arise from incorporation).

Moreover, Dr. Yuan merely opines that it is his opinion that the CoRoent XL implant embodies the claims of the '156 patent. Ex. 2020 ¶ 53. And although Mr. Miles states that "NuVasive's CoRoent XL implants have enjoyed commercial success" (Ex. 2030 ¶ 9), neither the Declaration, nor Appendix A, explains why that success is due to the characteristics of the claimed invention, rather than to XLIF[5] system as a whole, or to marketing of the implant (*See, e.g.*, Ex. 2030, Appendix A (DLIF marketing plan)). And 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." Thus, Patent Owner's evidence of secondary considerations is entitled to little weight.

[5] According to Mr. Miles, the XLIF (eXtreme Lateral Interbody Fusion) system and procedure include the CoRoent XL implant. Ex. 2030 ¶ 3.

6. Conclusion

After considering Petitioner's and Patent Owner's positions, as well as their supporting evidence, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–4, 7, 8, 10–14, 19, 20, 23, 24, 26, and 27 are rendered obvious under 35 U.S.C. § 103(a) by the combination of SVS and Baccelli; claims 5, 6, and 9 are rendered obvious under 35 U.S.C. § 103(a) by the combination of SVS, Baccelli, and Michelson; claim 25 is rendered obvious under 35 U.S.C. § 103(a) by the combination of SVS, Baccelli, and Telamon; claims 1–4, 7, 10–14, 19, 20, and 23–27 are rendered obvious under 35 U.S.C. § 103(a) by the combination of Telamon and Baccelli; and claims 5, 6, 8, and 9 are rendered obvious under 35 U.S.C. § 103(a) by the combination of Telamon, Baccelli, and Michelson.

C. Patent Owner's Motion to Exclude (Paper 34)

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. 2037), who was cross-examined after Petitioner filed its Reply. Paper 38. We have considered Patent Owner's observations and Petitioner's responses in rendering our decision, and have accorded the testimony the appropriate weight.

Patent Owner also submits observations to the cross-examination testimony of Loic Josse. Paper 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.

III. CONCLUSION

Petitioner has shown by a preponderance of the evidence that claims 1–14, 19, 20, and 23–27 are unpatentable under 35 U.S.C. § 103(a).

IV. ORDER

Accordingly, it is hereby:

ORDERED that Petitioner has shown by a preponderance of the evidence that claims 1–14, 19, 20, and 23–27 of the '156 patent are unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude is *dismissed* as moot; and

FURTHER ORDERED that, because this is a final written 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.

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