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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.
Requester and Appellant

v.

NUVASIVE, INC.
Patent Owner and Respondent

Appeal 2016-008303
Reexamination Control 95/001,888
Patent 7,691,057 B2
Technology Center 3900

Before DANIEL S. SONG, RAE LYNN P. GUEST, and
BRETT C. MARTIN, *Administrative Patent Judges*.

GUEST, *Administrative Patent Judge*.

FINAL DECISION ON APPEAL UNDER 37 C.F.R. § 41.77(f)

In a Decision on Appeal mailed July 1, 2014 (hereinafter “Decision”),
the Board entered the following new grounds of rejection:

claims 17, 18, and 24 as rendered obvious by Branch in view of
Kossmann, and Koros (Ground 1; RAN 2);

claims 19–22 as rendered obvious by Branch in view of Kossmann,
Koros, and Kelleher (Ground 2; RAN 2);

claim 25 as rendered obvious by Branch in view of Kossmann, Koros, and Michelson (Ground 3; RAN 2);

claim 26 as rendered obvious by Branch in view of Kossmann, Koros, and Tsou (Ground 4; RAN 2); and

claim 27 as rendered obvious by Branch in view of Kossmann, Koros, Tsou, and Kelleher (Ground 5, RAN 2).

In response to the Decision, Patent Owner, NuVasive, Inc.¹ (hereinafter “Patent Owner”) filed a Request to Reopen Prosecution on September 4, 2014 (hereinafter “Request”).

On January 23, 2015, the Board ordered that the Patent Owner’s Request be remanded to the Examiner under 37 C.F.R. § 41.77(d) for consideration of Patent Owner’s proposed amendments to independent claim 17 by adding the step of performing a particular neuromonitoring method during the step of creating a distraction corridor along a lateral trans-psoas path (step (a)) and Patent Owner’s proposed amendment to claim 19, which originally recited performing neuromonitoring “during at least one of steps (a), (c), and (d),” to recite additional neuromonitoring during either steps (c) or (d), to be consistent with the amendment to claim 17.² The Examiner was also asked to consider Patent Owner’s new evidence in the form of a Declaration of Dr. Frank Phillips (hereinafter “Phillips Decl.”) and a Declaration of Mr. Patrick Miles (hereinafter “Miles Decl.”), both dated

¹ See Patent Owner Respondent Brief 1 (filed February 19, 2013) (hereinafter “PO Res. Br.”).

² We denied Patent Owner’s request for reconsideration of proposed amendments to claims 23, 28, and 29, which were not subject to reexamination.

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September 2, 2014, and Patent Owner's new arguments and evidence regarding the patentability of claim 17 and the claims that depend therefrom, as amended, in light of evidence of secondary considerations of non-obviousness of the subject claims submitted therewith.

The Examiner submitted a Determination under 37 C.F.R. § 41.77(d) on May 4, 2015 (hereinafter "Determination").

The Examiner determined that "the response of Patent Owner under 37 C.F.R. 41.77(b)(1) **overcomes** the [Decisions'] new grounds of rejection." Determination 11. The Examiner considers the application of the teachings of Keller to the amendment to claim 17 and is persuaded that claim 17, as amended, is patentable over the teachings of Branch, Kossmann and Kelleher. Determination 13–14.

According to the Examiner,

While it is clear that Kelleher teaches neuromonitoring during a spinal procedure, Kelleher very clearly does not teach neuromonitoring during a lateral, trans-psoas spinal procedure. Kelleher teaches neuromonitoring during a variety of spinal procedures, such as stimulating the cauda equine and a pedicle screw test application (see col. 11, lines 5-20 of Kelleher), but does not teach or suggest using neuromonitoring during a lateral, trans-psoas approach.

Determination 13–14. The Examiner also finds Patent Owner admits that "Kelleher discloses using stimulated EMG neuromonitoring techniques in spinal access applications and the concept has been known for years prior to the patent under reexamination." Determination 12. The Examiner further finds that Patent Owner admits that "all of the applied references, including Kelleher, are within the field of spinal surgery." Determination 13.

Nonetheless, the Examiner reasons that “in order to form the basis for a tenable combination, Kelleher must provide some suggestion or teaching to apply the taught neuromonitoring during a lateral trans-psoas spinal procedure. Kelleher does not.” Determination 14 (citing *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007) for the proposition that “there must be some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art”). The Examiner is further persuaded by Dr. Phillips’ testimony regarding the lack of teaching in Kelleher as to the specific neural network that comes into play with a lateral, trans-psoas approach and the special considerations the skilled artisan would have made regarding these nerves in that approach. *Id.* at 13–14 (citing Phillips Decl. ¶¶ 34, 60–63).

The Examiner further considered the Patent Owner’s evidence of secondary considerations, namely long-felt need, initial skepticism, praise and recognition, improved patient outcomes, commercial success, and copying by competitors, presented via the testimony of Dr. Phillips and Dr. Miles and found this evidence persuasive of non-obviousness. *Id.* at 14–15.

In response to the Examiner’s Determination, Patent Owner filed Comments under 37 C.F.R. § 41.77(e) agreeing with the Examiner’s Determination and identifying additional “ongoing related USPTO proceedings,” including the issuing of a reexamination certificate in Reexamination Control No. 95/001,202, regarding U.S. Patent 7,207,949, and that “Final Written Decisions were issued on April 3, 2015 in *inter*

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partes review case nos. IPR2014-00034, IPR2014-00073, IPR2014-00074, IPR2014-00075, IPR2014-00081, and IPR2014-00087.” Comments 1–2.

Third Party Requester, Globus Medical, Inc. (“Requester”)³ did not file any Comments under 37 C.F.R. §§ 41.77(c) or 41.77(e). We reconsider this matter and issue this Final Decision in accordance with 37 C.F.R. § 41.77(f).

For the reasons discussed in detail below, we disagree with Examiner’s Determination, do not find that Patent Owner’s amendments overcome the teachings of the prior art, and do not find Patent Owner’s evidence of secondary considerations persuasive. Accordingly, we maintain that claims 17–22 and 24–27 are not patentable over the teachings of Branch, Kossmann, Koros, Kelleher, Michelson, and Tsou.

DISCUSSION

Claim 17 is the sole independent claim on appeal and was not amended during reexamination. Claim 17 was not amended when considered during the Decision. Claim 17 as amended in the Patent Owner’s Request reads as follows (with underlining showing language added in the Request):

1. A method of accessing a surgical target site within a spine, comprising the steps of:
 - (a) creating a distraction corridor along a lateral, trans-psoas path to a targeted lumbar spinal disc in a lumbar spine using a distraction assembly comprising at least two dilators that are sequentially inserted along the lateral, trans-psoas path

³ See Requester’s Appeal Brief 1–2 (filed January 16, 2013) (hereinafter “Req. App. Br.”).

to the targeted lumbar spinal disc, and performing neuromonitoring during at least a portion of the time the distraction assembly is used in creating the distraction corridor along the lateral, trans-psoas path, wherein the neuromonitoring comprises causing the emission of a plurality of electrical stimulation signals from a stimulation electrode provided on a distal portion of at least one component of the distraction assembly and monitoring for resulting electromyographic (EMG) activity after the emission of each stimulation signal, and wherein the component of the distraction assembly is coupled to a control unit of a neuromonitoring system that is capable of displaying to a user an indication of at least one of proximity and direction of a nerve to the stimulation electrode provided on the component of the distraction assembly based on the monitored resulting electromyographic (EMG) activity;

(b) slidably advancing a plurality of retractor blades of a retraction assembly along an outermost dilator of the at least two dilators of the distraction assembly, the retraction assembly comprising a handle assembly coupled to the plurality of retractor blades such that the retractor blades extend generally perpendicularly relative to arm portions of the handle assembly, each of said plurality of retractor blades having a generally concave inner face and a generally convex exterior face, said handle assembly being capable of moving said plurality of retractor blades from a closed position to an open position, said closed position being characterized by said plurality of retractor blades being positioned to about one another and form a closed perimeter, said open position characterized by said plurality of retractor blades being positioned generally away from one another and forming an open perimeter;

(c) simultaneously introducing said plurality of retractor blades over the outermost dilator of said distraction assembly along the lateral, trans-psoas path to the targeted lumbar spinal disc while in said closed position;

(d) actuating said handle assembly to move said plurality of retractor blades to the open position so that the plurality of

retractor blades create an operative corridor along the lateral, trans-psoas path to the targeted lumbar spinal disc;

(e) releasably engaging a fixation element with at least one of the plurality of retractor blades so that a distal portion of the fixation element extends distally from the at least one retractor blade and penetrates into a lateral aspect of the lumbar spine, wherein the fixation element secures the at least one retractor blade to the lumbar spine;

(f) inserting an implant through the operative corridor created by the plurality of retractor blades along the lateral, trans-psoas path to the targeted lumbar spinal disc.

Request 2–3.

Claim Interpretation

Although we did not expressly construe the phrase “lateral, trans-psoas path to the targeted lumbar spinal disc” in our prior decision, we do so now, in view of the Patent Owner’s contentions discussed below and found persuasive in the Examiner’s Determination.

Patent Owner’s argument are substantially based on the fact that a “lateral, trans-psoas path to the targeted lumbar spinal disc” necessarily constitutes a path in which “the lumbar plexus[, which] forms a network of nerves within the psoas muscle that surgeons considered a no man’s land and simply avoided.” *See* Request 18–19 (citing Phillips Decl. 34).

Patent Owner argues that the invention described in the ’057 patent, for the first time, allowed surgeons to “safely and reproducibly traverse the psoas” and “avoid the nerve roots in the psoas muscle.” Request 22–23.

We acknowledge again the ’057 patent’s disclosure that its teachings allow safe and reproducible avoidance of nerves along a lateral, trans-psoas

path in a fashion that avoids the bony posterior elements of the spinal column. '057 patent, col. 12, ll. 41–52. Claim 17, however, does not require the “trans-psoas path” to pass through any particular portion of the psoas muscle, nor does the claim require any particular degree or extent of passage through the psoas. In particular, claim 17 does not require the “trans-psoas path” to go through the lumbar plexus. In fact, the '057 patent, is directed to using neuromonitoring to *avoid* the lumbar plexus entirely. '057 patent, col. 12, ll. 41–43 (“provides the ability to actively negotiate around or past such nerves”); *see also* Request 9–10: (“NuVasive’s XLIF invention provided for the first time a safe and reproducible way for spine surgeons to approach the lumbar spine from a lateral approach and safely traverse the psoas muscle by using nerve monitoring techniques *to avoid nerve structures that reside within the psoas muscle* and are critical to human bodily functions.”) (emphasis added); Youssef Decl. ¶ 9 (“the lateral, trans-psoas surgical approach avoids nerves in the psoas muscle, and thus contributes to the safe and reproducible nature of the NuVasive lateral solution that it provides to spinal surgeons.”).

The '057 patent does not expressly define “trans-psoas path.” At best the '057 patent states that a “so-called trans-psoas approach” is “a lateral or far lateral access path.” '057 patent, col. 2, ll. 31–35. Accordingly, we conclude that the broadest reasonable interpretation, consistent with the '057 patent specification, of “trans-psoas path,” encompasses a path that passes through any portion of the psoas muscle, regardless of the degree or extent of the passage. *See* Youssef Decl. ¶ 8 (testifying that “‘trans-psoas’ is a term well known within the spinal surgery community, and means going through

the psoas muscle” and distinguishing only a path in which a surgeon “retracts the entire psoas muscle”).

As to the “lateral” approach of the trans-psoas path required by claim 17, the ’057 patent refers to a “lateral or far lateral access path (so-called trans-psoas approach) to the lumbar spine” (’057 patent, col. 2, ll. 31–35), but the ’057 patent does not expressly define “lateral.” Regarding the accepted meaning of the term, Patent Owner’s expert, Dr. Youssef, testified that “laterally” means “(from the side).” Youssef Decl. ¶ 7; *see also* Phillips Decl. ¶ 16.

Accordingly, we conclude that the broadest reasonable construction, consistent with the specification of the ’057 patent, of “lateral, trans-psoas path to the targeted lumbar spinal disc,” encompasses a path, to the lumbar spinal disc, which passes through any portion of the psoas muscle, regardless of the portion, and which is to the lateral side of the body, to any significant degree, as compared to an anterior puncture.

It is in light of this construction that we examine Patent Owner’s arguments and evidence.

Claim 17 in view of Branch, Kossmann, Koros, and Kelleher

Patent Owner does not argue that the language added to claim 17 regarding the specific neuromonitoring steps is patentable over the neuromonitoring device described in Kelleher. To the contrary, Patent Owner admits that “stimulated EMG neuromonitoring techniques were known in the surgery arts long before the XLIF technique and ’057 inventions came about (indeed, decades earlier).” Request 11. Rather,

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Patent Owner argues that “Kelleher generally disclosing stimulated EMG neuromonitoring techniques in spinal access applications, simply did not suggest to one of skill in the art to apply those techniques in traversing the psoas muscle.” Request 12.

We disagree with the Examiner that “in order to form the basis for a tenable combination, Kelleher must provide some suggestion or teaching to apply the taught neuromonitoring during a lateral trans-psoas spinal procedure.” Determination 14. In *KSR*, the Supreme Court set aside any “rigid” application of the teaching, suggestion, motivation (“TSM”) test, advising that: “any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *KSR*, 550 U.S. at 420. The Supreme Court clarified that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does,” but that “the analysis need not seek out precise teachings [in the prior art] directed to the specific subject matter of the challenged claim.” *Id.* at 418.

In the original Decision we determined that:

“[B]ecause each reference [namely, Branch and Kossmann] teaches the desirability [sic] of avoiding nerves for patient safety and Kelleher’s neuromonitoring would achieve this, it would have been obvious to look to a reference such as Kelleher, which similarly discloses a minimally-invasive spinal surgical system.” Req. Reb. Br. 11-12. One of ordinary skill in the art would have recognized the benefit of using a neuromonitoring system as taught by Kelleher for the purpose taught by Kelleher, namely “to inform the operator that a surgical tool or probe is approaching a nerve.” *See* Request 37. To do so would have been no more than the predictable use of a

known neuromonitoring system according to its established function of detecting nerves during spinal surgery. *See KSR*, 550 U.S. at 417 (The question to be asked is “whether the improvement is more than the predictable use of prior art elements according to their established functions.”).

Decision 15–16. Our reasoning has not changed regarding the application of *Kelleher* to proposed claim 17, as amended. *Kelleher* is not relied upon as evidence that a trans-psoas path was known in the surgical arts; *Kossmann* is relied on for that teaching. It is of no moment that the nerves sought to be avoided in *Kossmann* are the iliohypogastric and ilioinguinal nerves,⁴ these are still nerves that *Kossmann* teaches should be avoided in a lateral approach, which includes the approach taught by *Kossmann* that involves splitting the psoas muscle. *Kelleher* teaches the use of neuromonitoring techniques in the spinal surgery art to avoid contacting nerves and thus would be useful for avoiding the nerves taught with respect to the lateral trans-psoas path described by *Kossmann*.

Moreover, Patent Owner’s arguments that *Kossmann* only teaches traversing a “‘safe zone’ of the psoas muscle[], not a region where the important lumbar plexus structures typically reside” (Request 11, 16–17) is consistent with the teachings of the ’057 patent of avoiding the lumbar plexus nerve root and is encompassed by the scope of a “lateral, trans-psoas path,” as interpreted above. Indeed, the claims do not recite a step of

⁴ While we note that Patent Owner’s experts report that the iliohypogastric and ilioinguinal nerves are not present in the psoas muscle, they are both considered part of the lumbar plexus and thus consistent with Patent Owner’s expert testimony that the lumbar plexus was to be avoided in a trans-psoas approach. *See Phillips Decl., Exhibit E (Cunningham’s Textbook of Anatomy) 791–792 and Exhibit F (Gray’s Anatomy) 277–279.*

avoiding the lumbar plexus or any particular nerves, nor do the claims define any particular “lateral, trans-psoas path.” Thus, even if Kossmann’s lateral, trans-psoas path does not implicate the majority of the lumbar plexus nerves, Kossmann expressly teaches avoiding the iliohypogastric and ilioinguinal nerves in the lateral approach, including the lateral, trans-psoas approach, described therein. No additional nerves need be avoided for the prior art to suggest that the skilled artisan include a step of “performing neuromonitoring during at least a portion of the time the distraction assembly is used in creating the distraction corridor along the lateral, trans-psoas path.”

Unlike the Examiner, we are not persuaded by the unsupported testimony of Dr. Phillips. For example, Dr. Phillips contends, but does not explain why, the use of a system for Kelleher would have been suggested for “a postero-lateral approach where surgical instruments come in close proximity to the exiting lumbar nerve root” (because it was being used for this approach) but would not have been suggested for the trans-psoas approach described by Kossmann, even though it was known in the art at the time that “the psoas muscle contains a network of important lumbar plexus nerve structures running through it.” Phillips Decl. ¶¶ 61–63. Similarly, Dr. Phillips does not support with factual evidence nor explain why “to suggest that one of skill in the art would have understood that Kelleher has applicability to any situation where one would want to avoid nerves *is simply an overstatement* of what one of skill in the art would have understood the capability of nerve monitoring to have been at the time.” Phillips Decl. ¶ 62. To the contrary, on its face, Kelleher teaches the use of

neuromonitoring to avoid nerves during spinal procedures. Determination 13–14 (finding Kelleher teaches avoiding nerves “during a variety of spinal procedures”) (citing Kelleher at 11, ll. 5–20); Request 18 (“Kelleher discloses various new stimulated EMG neuromonitoring techniques, and is focused more on how stimulated EMG is performed as opposed to particular applications of the techniques. That said, there are certainly many applications of the techniques that would have been obvious at the time, and some of those are described in Kelleher and other NuVasive patents filed about that time.”). Dr. Phillips’ testimony, without explanation, is conclusory opinion evidence to which we ascribe little, if any, weight, particularly when Kelleher teaches neuromonitoring in spinal surgeries generally. *Rohm & Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed. Cir. 1997) (“Nothing in the rules or in our jurisprudence requires the fact finder to credit the unsupported assertions of an expert witness.”). Patent Owner has not explained why Kelleher would not have suggested the same neuromonitoring process for the same purpose, namely avoiding lumbar plexus nerves, despite the particular approach for which these nerves might be accessed.

Patent Owner’s arguments, in effect, improperly seek reconsideration of an already decided issue (*see e.g.*, Request 16–17), in which we already determined that Kossmann expressly teaches a lateral, trans-psoas approach for “some very athletic patients.” We decline to revise our position as to that determination on the present record. Decision 9–10.

Secondary Considerations of Non-obviousness

Patent Owner contends that objective evidence shows that the claimed process would not have been obvious to an ordinarily skilled artisan. Request 12–15. In particular, Patent Owner contends that its surgical procedure and system solved a long-felt need (*id.* at 21–23), overcame significant skepticism (*id.* at 23–24), elicited significant praise and recognition among practitioners in the art as being advantageous as compared to other lumbar surgical techniques (*id.* at 25–27), experienced significant commercial success and improved patient outcomes (*id.* at 27–30), and was copied by competitors (*id.* at 30).

Before we conclude whether the challenged claims would have been obvious, in addition to the teachings in the prior art, “[s]uch 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.” *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). Such objective indicia of nonobviousness must be considered “as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art.” *Eurand, Inc. v. Mylan Pharm. Inc. (In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.)*, 676 F.3d 1063, 1076–77 (Fed. Cir. 2012) (citation omitted).

Nexus

“For objective evidence to be accorded substantial weight, its proponent [Patent Owner] 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 particular, the objective indicia “must be tied to the

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novel elements of the claim at issue” and must ““be reasonably commensurate with the scope of the claims.”” *Institut Pasteur & Universite Pierre Et Marie Curie v. Focarino*, 738 F.3d 1337, 1347 (Fed. Cir. 2013) (quoting *Rambus Inc. v. Rea*, 731 F.3d 1248, 1257 (Fed. Cir. 2013)).

We are not persuaded that the evidence of secondary considerations is entitled to substantial weight, because Patent Owner has not established a sufficient nexus between the claimed subject matter and that evidence. We are also not persuaded that the evidence of secondary considerations is reasonably commensurate in scope with the claimed subject matter.

Patent Owner focuses on its “XLIF” (“eXtreme Lateral Interbody Fusion”) system in contending that the claimed process allowed surgeons to safely and reproducibly traverse the psoas muscle to access the lumbar spine. Request 22–23. Patent Owner, however, does not establish adequately what XLIF is and whether it is encompassed by the claim 17 of the ’057 patent. Patent Owner repeatedly refers to features of this technique with a high degree of generality, for example stating that it is “the first minimally invasive lateral transpsoas approach to the lumbar spine using nerve monitoring,” *id.* at 22, and quoting an article that describes features of XLIF used in conjunction with another Patent Owner product (EMG IOM, or NeuroVision®), *id.* at 23 (quoting Miles Decl., Attachment A (Uribe et al. “Electromyographic Monitoring and Its Anatomical Implications in Minimally Invasive Spine Surgery,” *Spine*, Vol. 35, No. 265, S368, S370 (2010))). We are unable to discern, from such general evidence, how Patent Owner is relating the features of XLIF to the claims appealed.

Patent Owner contends that Dr. Phillips— “a board certified orthopaedic surgeon—compared XLIF to independent claim 17 of the ’057 patent . . . [and] concluded that the XLIF procedure and systems embody at least the amended independent claim 17 of the ’057 patent.” *Id.* at 23.

We acknowledge that Dr. Phillips’s Declaration includes a chart appearing to map the features of claim 17 of the ’057 patent to the NuVasive XLIF system and procedure. *See* Phillips Decl. ¶ 46, Attachment P. Dr. Phillips cites to Attachment L, which he alternately contends describes the “XLIF system.” Phillips Decl. ¶ 22, Attachment P. As its title suggests, however, Attachment L appears to describe a MaXcess II Access System, with XLIF being one surgical technique performable with this system. Phillips Decl., Attachment L, at 1. To the extent XLIF is a “system,” it appears that such a system would not correspond to claim 17 of the ’057 patent. For example, the MaXcess II system includes several surgical devices, but does not include at least two sequentially inserted dilators with nerve monitoring capability as claimed. Phillips Decl., Attachment L, at 4. Rather, Dr. Phillips relies on disclosure of the MaXcess II Access system to show dilators and disclosure of the separate NeuroVision® System to show the recited components of the neuromonitoring step of claim 17. Phillips Decl., Attachment P, at 2–3 (citing Attachment L, at 6, 8). Another portion of Dr. Phillips’ supporting document details the catalog numbers of the components of the “XLIF System,” none of which includes dilators with nerve monitoring capability. Attachment L, at 2. In contrast, dilators are included in the “MaXcess II Access System,” *id.* at 24, and nerve monitoring

appears to be provided by a “NeuroVision JJB System” and disposable “NeuroVision JJB XLIF Module,” *id.* at 25.

It appears, from this evidence, that XLIF is a marketing term that is sometimes used to identify a surgical technique and other times used to identify groups of products. Indeed, there is evidence to suggest that the “XLIF technique” was not consistent over the relevant time period described by Patent Owner, but rather was improved both procedurally and technologically over time. Phillips Decl., Attachment B, at S370 (describing that in 2010 the XLIF system was in its third generation). Thus, when Patent Owner uses the shorthand term “XLIF” in its Request, without clarification, we are unable to associate Patent Owner’s objective evidence with particular products or features.⁵ Rather, Patent Owner leaves it to us to figure out, on a case-by-case basis, what it references by the term “XLIF.” Indeed, Patent Owner’s Request does not cite to Attachment P, or to paragraph 46 of Dr. Phillips’ Declaration as evidence of nexus between NuVasive’s XLIF procedure and the limitations in claim 17.⁶ Specifically,

⁵ For example, evidence submitted by Patent Owner states that XLIF is the invention of Dr. Luiz Pimenta in collaboration with NuVasive, Inc. *See e.g.*, Miles Decl., Attachment P; Miles Decl., Attachment K, at 2, last col.; Miles Decl., Attachment D, 3rd ¶. Yet, Luiz Pimenta is not listed as an identified inventor of the ’057 patent.

⁶ In fact, the Request erroneously cites to Attachment E as support for Dr. Phillips’ testimony. Request 23. Attachment E is an excerpt from Cunningham’s Textbook of Anatomy, which does not reference NuVasive’s XLIF system and procedure. The Request also cites to paragraphs 22–23 and 27 of the Phillips Declaration (*id.*), which describes “what spinal surgeons were typically doing at the time of the invention instead of a transpsoas approach” and which do not cite to any attachments in support of the statements made therein.

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Patent Owner makes no attempt to explain in its Request how this evidence establishes a nexus. Instead, it is an improper incorporation by reference of arguments from the Phillips Declaration into the Request. *See* 37 C.F.R. § 42.6(a)(3) (“Arguments must not be incorporated by reference from one document into another document.”); *DeSilva v. DiLeonardi*, 181 F.3d 865, 866–67 (7th Cir. 1999) (rejecting “adoption by reference” as a self-help increase in the length of the brief and a pointless imposition on the court’s time as it requires the judges to play archeologist with the record.).

Moreover, Patent Owner acknowledges, the XLIF procedure “approaches the spine with sequential dilators orthogonal to the disc space in a true lateral position.” Request 23 (quoting Miles Decl., Attachment A (Uribe et al. “Electromyographic Monitoring and Its Anatomical Implications in Minimally Invasive Spine Surgery,” *Spine*, Vol. 35, No. 265, S368, S370 (2010))). Indeed, evidence advanced by Patent Owner explains that the XLIF procedure uses “a 90° off-midline or direct lateral approach,” and advises that it is “imperative that the approach be directly lateral to the operative level.” Miles Decl., Attachment F (Rodgers et al., “Experience and Early Results with a Minimally Invasive Technique for Anterior Column Support Through eXtreme Lateral Interbody Fusion (XLIF®),” *US Musculoskeletal Review: Orthopaedic Surgery Spine* (2007)).

Patent Owner distinguishes the XLIF procedure from the purportedly unpreferred lateral trans-psoas approach taught in the Kossmann reference which allegedly traverses the psoas muscle via a “safe zone.” Request 11. Similarly, Patent Owner distinguishes the XLIF procedure from the lateral trans-psoas approach developed by Dr. Obenchain in the late 1980s and

early 1990s, which was known to present only “relatively low nerve risk.” Request 13–14 (citing Phillips Decl. ¶¶ 45–47 (asserting that traversing the psoas according to teachings of Obenchain reference was done only “out of necessity” and that the psoas “would have only been incidentally traversed at its most anterior fibers”) and Attachment D (Obenchain Decl. ¶¶ 7, 13–15).

Yet, as explained above, claim 17 of the ’057 patent is not limited to the particular approach used in the XLIF procedure, but instead encompasses any psoas-traversing approach that is lateral to the midline to any significant degree. Even if we were to find a correspondence between XLIF and the claims, a critical part of what makes the XLIF procedure unique in the art and on which Patent Owner primarily relies is not a requirement of the claims. Claim 17 of the ’057 patent is not limited to XLIF’s approach, and instead encompasses other lateral trans-psoas approaches to the lumbar spine, including approaches that Patent Owner acknowledges were known to present relatively minimal risk of nerve damage, and for which Patent Owner has advanced no persuasive evidence of non-obviousness. Thus, the XLIF procedure further is not reasonably commensurate to the scope of the claims and is not probative to establishing the non-obviousness of the claimed invention over the other documented prior art approaches that are also within the scope of the claims.

Accordingly, Patent Owner’s evidence does not establish a nexus between its objective indicia and the novel elements of the claims, and such objective evidence is entitled to little weight.

Long-felt Need

“Evidence that an invention satisfied a long-felt and unmet need that existed on the patent’s filing date is a secondary consideration of nonobviousness.” *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1332 (Fed. Cir. 2009). To show a long-felt need, Patent Owner must introduce evidence to show when such a need first arose and how long this need was felt, and must introduce evidence to show that this need was met by the patented invention. *Id.* “[L]ong-felt need is analyzed as of the date of an articulated identified problem and evidence of efforts to solve that problem.” *Tex. Instruments, Inc. v. U.S. Int’l Trade Comm’n*, 988 F.2d 1165, 1178 (Fed. Cir. 1993).

Patent Owner contends that, prior to the ’057 patent, surgeons preferred to perform lumbar spinal interbody fusion surgery by approaching the spine from anterior (from the front of the patient) and posterior (from the back of the patient) directions, rather than a lateral direction (from the side of the patient) through the psoas muscle. Request 12–13. According to Dr. Phillips, the psoas muscle includes nerve roots that control important bodily functions and dangerous nerve damage can occur by traversing the psoas muscle. *Id.* at 14 (citing Phillips Decl. ¶¶ 18–20). Patent Owner argues that the locations of these nerves are unpredictable. Request 21–22.

Patent Owner acknowledges, however, that other approaches conventionally used at the time also had severe drawbacks. Request 13. According to Dr. Phillips, an anterior approach risks injuring the aorta and vena cava, among other issues, and a posterior approach requires removal of significant bone structure to access spinal disc space. *Id.* (citing Phillips Decl. ¶¶ 39–43). Patent Owner argues that, despite the drawbacks of

anterior and posterior approaches, they were still preferred to lateral approaches, illustrating the severity of surgeons' concerns regarding a transpsoas approach. Request 12–13, 22. Patent Owner further argues that, despite this knowledge, surgeons at the time, including Dr. Phillips and Dr. Obenchain, never considered using nerve monitoring to safely and reproducibly create a lateral transpsoas approach to the lumbar spine. *Id.* at 14. Patent Owner also cites to what it characterizes as experimental attempts to lateral approaches that failed to gain widespread adoption. *Id.* at 13–15, 22. According to Patent Owner, except for the incidental traversal of the psoas muscle described in Kossmann (and a similar procedure by Obenchain), these attempts either retracted the psoas muscle or did not mention it at all. *Id.*

Although Patent Owner has introduced evidence to show that each of the possible approaches has disadvantages and risks of patient injury, Patent Owner's evidence does not show that there was a long-felt but unmet need for a safe, reproducible lateral trans-psoas approach to the spine. Rather, at most, it shows that surgeons weighed the risks of each approach and opted for anterior and posterior approaches. Patent Owner's evidence is not sufficient to show a long-felt need.

The existence of alternative approaches to the lumbar spine supports a finding that the need for a suitable approach to the lumbar spine had been solved. *See Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004) (“[T]he mere passage of time without the claimed invention is not evidence of nonobviousness.”) (citation omitted). That those alternative approaches may have presented their own difficulties does

not persuade us that there was a long-felt but unmet need for the lateral trans-psoas pathway, absent evidence that widespread efforts by ordinarily skilled artisans had failed in that trans-psoas approach. *See In re Allen*, 324 F.2d 993, 997 (CCPA 1963) (An allegation of a long-felt but unsolved problem in the art “is not evidence of unobviousness unless it is shown . . . that the widespread efforts of skilled workers having knowledge of the prior art had failed to find a solution to the problem.”). Though the evidence shows concern in the art for the lateral, trans-psoas approach, Kossmann (and Obenchain) demonstrate success despite such concern, and Patent Owner concedes that even those efforts were not widespread in the art, but instead involved no more than “a small handful of patients.” Request 22. Had there been a strong and long-felt need in the art at the time of the invention, efforts would have been focused on improving the lateral trans-psoas approach. Instead, other approaches were routinely adopted. *Id.*

Even assuming Patent Owner’s evidence shows a long-felt need, Patent Owner has not shown that such a need was met by the invention of the ’057 patent. To show that such a need was met, Patent Owner relies on its XLIF procedure, which uses nerve monitoring to safely traverse the “main body of the psoas muscle” in an extreme lateral approach. Request 14 (citing Phillips Decl., Attachment D (Obenchain Decl. ¶¶ 14-15) (distinguishing XLIF’s traversing the “main body of the psoas muscle” from Obenchain’s own prior art traversing the psoas muscle via an “extreme medial” portion of the psoas muscle)) and 22-23. As explained above, Patent Owner’s evidence does not establish a nexus between XLIF (or an extreme lateral approach) and the claims, which require no such extreme

approach. Thus, Patent Owner's arguments are not probative to whether or not claim 17, as amended to include neuromonitoring, is non-obvious, but rather addresses the obviousness of issues already determined in our prior Decision.

Accordingly, we are not persuaded by Patent Owner's evidence of long-felt need or its product's satisfaction of such a need.

Skepticism Followed by Praise and Recognition

Skepticism that a patented device would work, followed by widespread acceptance and praise, can evince non-obviousness of an invention. *See Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1367–68 (Fed. Cir. 2012).

Patent Owner presents evidence that skilled artisans were initially skeptical of using XLIF in a trans-psoas approach, fearing it would result in neurological injury to the patient. Request 23 (citing Phillips Decl. ¶¶ 28–33 and Miles Decl. ¶¶ 12–15). Much of this evidence consists of personal recollections of Dr. Phillips, including his recollections of conversations he had with surgeons (including those working for Petitioner) in the 2003–2006 time frame as well as his review of deposition transcripts in related litigation. Request 23–24 (citing Phillips Decl. ¶¶ 28–30). Patent Owner also cites Dr. Obenchain, who testifies that he would have been skeptical at that time of “safely passing through the main body of the psoas muscle” or taking “a pure lateral approach.” *Id.* at 24 (citing Phillips Decl., Attachment D (Obenchain Decl. ¶¶ 14–15, 21)).

The objectivity of this evidence is questionable, as both Dr. Phillips and Dr. Obenchain are paid consultants to Patent Owner and are testifying

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long after the fact. *See* Ex. 2020 ¶¶ 1, 5; Tr. 143:6–23. *See also InTouch Techs., Inc. v. VGO Communications, Inc.*, 751 F.3d 1327, 1347, 1352 (Fed. Cir. 2014) (“The district court must consider evidence showing objective indicia of nonobviousness, which constitutes *independent evidence* of nonobviousness” (internal quotation marks omitted, emphasis added) in order to “guard against . . . hindsight bias.”); *Geo. M. Martin Co. v. Alliance Machine Sys. Int’l, LLC*, 618 F.3d 1294, 1305 (Fed. Cir. 2010) (discounting “self-serving statements by Martin’s president”).

Even if fully credited, however, Patent Owner’s evidence is not persuasive to show a nexus between XLIF and the claims, as explained above. The evidence relied upon by the Patent Owner is probative only to the issue of whether the extreme lateral, trans-psoas path of NuVasive’s XLIF system would have been safe and reproducible. Even according to Patent Owner’s experts, the less extreme lateral, trans-psoas path taught by Kossmann was recognized as relatively safe.

As to eventual acceptance and praise, Patent Owner introduces evidence, including the recollection of Mr. Miles, an executive of Patent Owner, that one-by-one, surgeons stopped doubting XLIF and began to adopt it. Request 25–27 (citing Miles Decl. ¶¶ 14–15). Additionally, Patent Owner introduces articles stating that XLIF and NeuroVision® are safe and reproducible and that nerve-sensing is an important part of that. Request 25–27. Much (but not all) of this evidence was funded by Patent Owner and/or was written by paid consultants of NuVasive, Inc., namely L.M. Pimenta, W.B. Rodgers, and A.G. Tohmeh. *See, e.g.*, Phillips Decl., Attachment B, at 2 (NuVasive funded special Spine edition); Phillips Decl.,

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Attachment I (Park, et al., “The Relationship of Intrapsoas Nerves During a Transpsoas Approach to the Lumbar Spine,” J. Spinal Disord. Tech., Vol. 23, No. 4, 223 (June 2010)), at 228; Phillips Decl., Attachment H (Tohmeh et al., “Dynamically evoked, discrete-threshold electromyography in the extreme lateral interbody fusion approach,” J. Neurosurg: Spine (December 17, 2010)), at 6; Miles Decl., Attachment C (SOLAS News, Issue 10 (April 2010)), at 8; Miles Decl., Attachment S (The Better Way Back Book (2010)), at 5. As the Federal Circuit has stated, “objective indicia of nonobviousness serve a particularly important role in a case, like this one, where there is a battle of scientific experts regarding the obviousness of the invention [because they] provide an *unbiased* indication regarding the credibility of that evidence.” *Kinetic Concepts*, 688 F.3d at 1370–71 (emphasis added). Here, Patent Owner’s evidence is less persuasive as an indication of the perceptions of independent, unbiased, surgeons because it was funded, at least in part, by Patent Owner.

Patent Owner also points to several examples of “improved patient outcomes,” including testimonials from doctors and patients that XLIF resulted in decreased risks and complications. Request 27–28. However, this evidence discusses the benefits of XLIF generally and substantially only in comparison to “open-spine surgery,” i.e., the midline anterior or posterior approach. The disadvantages of these approaches were known at the time of the invention. The benefits to a patient of a less invasive lateral approach over a more invasive open-spine surgery are not surprising or unexpected. At the time of the invention, the benefits to a less invasive lateral approach were known in the art. *See* Kossmann, at 293; Phillips Decl., Attachment D

(Obenchain Decl. ¶¶ 14, 18 (describing an anterolateral approach medial to the psoas muscle or through a very medial portion of the psoas muscle and a posterolateral approach as “preferred” over a posterior or anterior approach)), and Attachment K (McAfee et al., “Minimally Invasive Anterior Retroperitoneal Approach to the Lumbar Spine,” *Spine*, Vol. 23, No. 65 (1998), at 1483); Phillips Decl., Attachment J (U.S. Patent 4,545,374 to Jacobson), at col. 2, ll. 16–62. *See also* U.S. Patents 5,195,541 and 5,313,962 to Obenchain (describing lateral approaches to the lumbar spine). Thus, better patient outcomes from a minimally invasive approach over an open-spine approach are not unexpected or surprising, as argued by Patent Owner.

Further, Patent Owner directs us to no testimonials that discuss the use of nerve monitoring to traverse the psoas muscle or any other features of the claims. We note only one statement mentioning “strict adherence to surgical technique including neuromonitoring” (Miles Decl., Attachment G (Malham et al., “Clinical Outcome and Fusion Rates after the First 30 Extreme Lateral Interbody Fusions,” *Sci. World J.*, Vol. 2012, Article ID 246989 (2012)), at 5⁷).

In any case, as explained above, Patent Owner has not shown a nexus between XLIF and the claims.

Commercial Success

⁷ Even this reference identifies L. Pimenta, a paid consultant and shareholder for NuVasive, Inc., as an “Academic Editor,” drawing into question the independent nature of these statements. *See* Miles Decl., Attachment G, at 1.

Patent Owner argues that NuVasive has grown from the garage of Dr. James Marino in 1999 to “the third largest spine company in the U.S. and the fourth largest globally, employing more than 1300 people.” Request 28 (citing Miles Decl. ¶¶ 7, 9, 12, 25, 28). According to Patent Owner, its “meteoric growth” has been “a direct result of its XLIF procedure and systems and the claimed technology.” *Id.* at 29 (citing Miles Decl. ¶¶ 24–29). In support, Patent Owner and Dr. Miles rely on reports of market research from financial analysts crediting its success, at least in part, to XLIF. *Id.* at 29–30; Miles Decl., Attachment U, at 289 (“The majority of NuVasive’s revenue is directly related to the XLIF procedure and its related devices”); Miles Decl., Attachment AC, at 1, 3 (J.P. Morgan report attributing success to Maximum Access Surgery (MAS) platform, XLIF, NeuroVision®, and heavy salesforce investment); Miles Decl., Attachment W, at 12 (Canaccord Genuity report attributing success to the “critical component” NeuroVision® and MaXcess retractor system); Miles Decl., Attachment AD, at 3 (Caris & Co. report stating, *inter alia*, that “Despite the obvious advantages of the lateral approach, it requires that the surgeon avoid the nerve roots on the spine, which wasn’t practical until NUVA launched its Inter-operative Nerve monitoring system (NVJJB/M5).”).

“A prima facie case of nexus is made when the patentee shows both that there is commercial success, and that the product that is commercially successful is the invention disclosed and claimed in the patent.” *Crocs, Inc. v. U.S. Int’l Trade Comm’n*, 598 F.3d 1294, 1310–11 (Fed. Cir. 2010). As explained above, Patent Owner has not shown a correspondence between

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XLIF (or, for that matter, NueroVision, MaXcess retractor system, and the MAS platform) and the claims.

Moreover, Patent Owner has not been consistent in its attribution of commercial success. In this matter, Patent Owner argues that “[t]he novel combination found in NuVasive’s neuromonitoring enabled distraction/retraction system as claimed in the ’057 patent has resulted in XLIF and NuVasive being commercially successful.” Request 28. Yet, much of Patent Owner’s evidence attributes commercial success to being the first system that allowed for a lateral spinal approach that could be reproduced safely. Request 29 (quoting Miles Decl., Attachment AD, at 3–4 (“XLIF..., unlike more traditional methods, access to the spinal area to be fused is done through a lateral (i.e., the side)—as opposed to posterior (i.e. back) or anterior (i.e. front) approach.”)). Meanwhile, the closest prior art, namely Kossmann, teaches that a lateral approach falling within the scope of the claims was known in the art at the time of the invention and known to be capable of being performed safely, i.e., in “the safe zone,” even without neuromonitoring.

Patent Owner’s evidence shows that at least some of the reported commercial success resulted, at least in part, from factors not associated with either the claims or the techniques or hardware of XLIF. Specifically, a Form 10-K filed by Patent Owner with the United States Securities and Exchange Commission for the fiscal year ending December 31, 2013, states the following:

Revenues. To date, the majority of our revenues have been derived from the sale of implants, biologics and disposables, and we expect this trend to continue for the foreseeable

future. We generally loan our proprietary software-driven nerve monitoring systems and surgical instrument sets at no cost to surgeons and hospitals that purchase disposables and implants for use in individual procedures. In addition, we place our proprietary software-driven nerve monitoring systems, MaXcess® and other MAS or cervical surgical instrument sets with hospitals for an extended period at no up-front cost to them.

Miles Decl., Attachment AA, at 69 (emphasis added). Thus, even if Patent Owner were able to show that XLIF embodies the claims of the '057 patent, the auxiliary products other than XLIF were the primary drivers of Patent Owner's commercial success because the procedure recited in the '057 patent, namely the "nerve monitoring systems and surgical instrument sets" were "loan[ed] at no cost to surgeons." *Id.*

Patent Owner's evidence also shows that the adoption of NuVasive's products was influenced by an aggressive campaign to have spinal surgeons around the country (and around the world) observe procedures using NuVasive's products first hand. Request 25; Miles Decl. ¶¶ 14("NuVasive put substantial resources into educating the spinal community to over that skepticism and show that XLIF was indeed a safe and effective solution for spinal fusion.") and 16 ("Through NuVasive's education efforts, surgeons began adopting XLIF into their practices.").

Patent Owner also argues that XLIF created an entirely new market segment. Request 28. In support, Patent Owner points to documents from Requester referring to a "minimally invasive fusion market" (Miles, Decl., Attachment X, at 8). It is unclear precisely what types of surgery these particular markets include. For example, Attachment X to Miles' Declaration shows Requester as having a larger share of the "minimally

invasive fusion market” than Patent Owner from the year 2005 to 2008, which does not support the Patent Owner’s contention. *Id.* Thus, the evidence Patent Owner presents is not sufficient to ascertain what is included in the markets to which Patent Owner refers. Claim 17 of the ’057 patent is directed generally to “[a] method of accessing a surgical target site within a spine” and includes a step of “inserting an implant . . . to the targeted lumbar spinal disc,” and is not limited to use in “minimally invasive fusion.” Thus, Patent Owner has not shown that its evidence directed to market share in a small fraction of spinal surgery is commensurate with the scope of the claims.

In sum, Patent Owner’s evidence is not sufficient to show its commercial success relative to the market or that any such commercial success is due to a product practicing the patent or, more precisely, due to the novel features of the ’057 patent claims.

Copying

Patent Owner contends that Petitioner and other competitors copied its XLIF technology. Request 30. According to the Federal Circuit,

[C]opying requires evidence of efforts to replicate a specific product, which may be demonstrated through internal company documents, direct evidence such as disassembling a patented prototype, photographing its features, and using the photograph as a blueprint to build a replica, or access to the patented product combined with substantial similarity to the patented product.

Wyers v. Master Lock Co., 616 F.3d 1231, 1246 (Fed. Cir. 2010).

Patent Owner, citing a financial analyst report (from J.P. Morgan) argues that other competitors introduced competing products and, thus,

copied XLIF. *Id.* (citing Miles Decl., Attachment AE, at 1). This evidence lacks sufficient detail to determine whether the competing products practice the claims or ascertain whether they were copied from XLIF. Patent Owner's evidence is entirely silent as to the structure or function of the allegedly competing products.

In sum, Patent Owner's evidence does not show efforts by Requester, or others, to replicate XLIF. Accordingly, we are not persuaded that objective indicia of copying evidences non-obviousness.

Conclusion of Obviousness

As explained above, the prior art teaches each limitation of amended claim 17. Requester introduced persuasive evidence that a skilled artisan would have had reasons to combine the prior art to arrive at these claims, which is supported by rational underpinnings. *See* Decision 14–16 and above. We have weighed the rationale based on the prior art against the objective evidence presented by Patent Owner. We consider that objective evidence to be entitled to little weight for the reasons given above.

In sum, upon consideration of all the evidence, including Patent Owner's objective indicia of non-obviousness, we conclude by a preponderance of the evidence that claim 17 as amended and the claims that depend therefrom would have been obvious over Branch, Kossmann, Koros, Kelleher, Michelson, and Tsou, in accordance with our prior Decision's discussion of claims 19–22 and 27 and for the reasons discussed above.

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PATENT OWNER:

WILSON, SONSINI, GOODRICH & ROSATI
650 Page Mill Road
Palo Alto, CA 94304-1050

THIRD-PARTY REQUESTER:

Jay Guiliano, Esq.
NOVAK DRUCE & QUIGG LLP
300 New Jersey Ave., NW
Fifth Floor
Washington, DC 20001