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Paper 49
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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 IPR2014-00075
Patent 8,016,767 B2

Before FRANCISCO C. PRATS, SCOTT E. KAMHOLZ, and DAVID C. McKONE, *Administrative Patent Judges.*

PRATS, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Statement of the Case

Medtronic, Inc. ("Petitioner") filed a Corrected Petition (Paper 6, "Pet.") requesting *inter partes* review of claims 1, 2, 4, 5, 10, 15, 17, and 18 of U.S. Patent 8,016,767 B2 (Ex. 1018, "the '767 patent"). NuVasive, Inc. ("Patent Owner") filed a Preliminary Response (Paper 10, "Prelim. Resp.").

We instituted trial based on the following ground of unpatentability:

References	Basis	Claims challenged
Branch,[1] Obenchain,[2] Blewett,[3] and Koros '493[4]	§ 103(a)	1, 2, 4, 5, 10, 15, 17, and 18

Decision to Institute 22 (Paper 14, "Dec.").

After trial was instituted, Patent Owner filed a Response (Paper 26, "PO Resp.") and Petitioner filed a Reply (Paper 31, "Reply").

Petitioner filed a Motion to Exclude Evidence. Paper 34 ("Mot. to Exclude"). Patent Owner filed an Opposition to the Motion to Exclude Evidence. Paper 40 ("PO Opp."). Petitioner filed a Reply to the Opposition to the Motion to Exclude Evidence. Paper 43 ("Reply to Opp.").

Patent Owner filed a Motion for Observations on Cross Examination. Paper 38 ("PO Mot. Obs."). Petitioner filed a Response to that Motion. Paper 39 ("Resp. to Mot. Obs.").

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[1] U.S. Patent No. 6,945,933 B2 (issued Sept. 20, 2005) (Ex. 1013).

[2] U.S. Patent No. 5,313,962 (issued May 24, 1994) (Ex. 1003).

[3] WO 03/005887 A2 (published Jan. 23, 2003 (filed July 11, 2002)) (Ex. 1014).

[4] U.S. Patent No. 6,139,493 (issued Oct. 31, 2000) (Ex. 1006).

Petitioner supported its Petition with Declarations by Robert G. Watkins, IV, M.D. ("Watkins Decl." (Ex. 1016)), Daniel Schwartz, Ph.D. ("Schwartz Decl." (Ex. 1017)), and David Hacker ("Hacker Decl." (Ex. 1015)). Petitioner supported its Reply with a second Declaration by Dr. Watkins ("Watkins Reply Decl." (Ex. 1024)).

In support of its Response, Patent Owner relied on Declarations by Frank Phillips, M.D. ("Phillips Decl." (Ex. 2020)), Patrick Miles ("Miles Decl." (Ex. 2024)), and Theodore G. Obenchain, M.D. ("Obenchain Decl." (Ex. 2025)).

Oral Hearing was held on December 4, 2014, and the Hearing Transcript ("Tr.") has been entered in the record. Paper 48.

We have jurisdiction under 35 U.S.C. § 6(c). This Final Written Decision is entered pursuant to 35 U.S.C. § 318(a). "In an inter partes review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence." 35 U.S.C. § 316(e).

We conclude that Petitioner has proved by a preponderance of the evidence that claims 1, 2, 4, 5, 10, 15, 17, and 18 of the '767 patent are unpatentable. Petitioner's Motion to Exclude Evidence is denied-in-part, and dismissed-in-part as moot.

B. Related Cases

Patent Owner has asserted the '767 patent against Petitioner in *Warsaw Orthopedic Inc. v. NuVasive Inc.*, Case No. 3:12-cv-02738-CAB-MDD (S.D. Cal.). Pet. 1; Paper 9 at 2.

In *Medtronic, Inc. v. NuVasive, Inc.*, IPR2014-00076, the Board declined to institute *inter partes* review of claims 1, 2, 4, 5, 10, 15, 17, and

18 of the ’767 patent based on grounds presented by Petitioner which differed from the ground considered herein. IPR2014-00076, Paper 13. Petitioner also has challenged a number of related patents in the following proceedings in which trials were instituted: IPR2014-00034 (Patent 8,000,782), IPR2014-00073 (Patent 8,192,356), IPR2014-00074 (Patent 8,192,356), IPR2014-00081 (Patent 8,005,535), and IPR2014-00087 (Patent 8,005,535). These proceedings also were argued at the December 4, 2014, oral hearing.

C. The ’767 Patent

The ’767 patent describes methods and apparatuses for accessing a surgical target site, such as the lumbar spine, using minimally invasive techniques. Ex. 1018, 1:34–2:60. In particular, the ’767 patent discloses a surgical access system which includes “[1] a tissue distraction assembly and [2] a tissue retraction assembly, both of which may be equipped with one or more electrodes for use in detecting the existence of (and optionally the distance and/or direction to) neural structures.” *Id.* at 3:11–15.

The tissue distraction assembly “is capable of, as an initial step, distracting a region of tissue between the skin of the patient and the surgical target site. The tissue retraction assembly is capable of, as a secondary step, being introduced into this distracted region to thereby define and establish the operative corridor.” *Id.* at 3:17–21. Once the operative corridor is established, “any of a variety of surgical instruments, devices, or implants may be passed through and/or manipulated within the operative corridor depending upon the given surgical procedure.” *Id.* at 3:21–24.

Nerve detection is performed by a nerve monitoring system which causes the electrodes on the tissue distraction/retraction instruments to emit

electrical stimulation signals. *Id.* at 11:26–28. Depending on the location of the instruments within the patient, the emitted signals cause muscle groups to innervate, thus generating EMG (electromyographic) responses which can be sensed by electrodes positioned on the patient's muscles. *See id.* at 11:29–44.

The '767 patent explains that, because it allows surgeons to safely and reproducibly avoid nerves when forming a surgical operative corridor, the disclosed system "may be particularly suited [in spinal surgery] for establishing an operative corridor to an intervertebral target site in a postero-lateral, trans-psoas fashion so as to avoid the bony posterior elements of the spinal column." *Id.* at 11:51–54.

Claim 1, the only independent claim Petitioner challenges in this proceeding, reads as follows:

1. A method of accessing a surgical target site, comprising:

> forming an initial distraction corridor using an elongate stimulation instrument that is delivered to a lateral aspect of a targeted spinal disc along a lateral, trans-psoas path to the lumbar spine while a stimulation electrode of the elongate stimulation instrument outputs an electrical stimulation signal from a distal tip portion for nerve monitoring during delivery of the elongate stimulation instrument along the lateral, trans-psoas path to the lumbar spine;
>
> activating a nerve monitoring system that controls the electrical stimulation signal output from the stimulation electrode of the elongate stimulation instrument during delivery of the elongate stimulation instrument along the lateral, trans-psoas path to the lumbar spine, the nerve monitoring system detecting electromyographic (EMG) activity via a set of EMG sensor electrodes in communication with muscle myotomes associated with nerves in the vicinity of the targeted spinal disc;

receiving nerve monitoring information from a video display device of the nerve monitoring system that contemporaneously displays: a numeric stimulation threshold required to obtain the EMG activity in at least one of said leg muscle myotomes, and a graphical representation of a patient, wherein the video display device is operable to alert a user to at least one of a presence and absence of a nerve near the elongate stimulation instrument;

positioning an inner wire member in a disc annulus at the lateral aspect of the targeted spinal disc, the inner wire member being slidably disposed within a tubular distraction member of the elongate stimulation instrument such that a distal tip of the inner wire member is inserted along the lateral, trans-psoas path and penetrates into the disc annulus at the lateral aspect of the targeted spinal disc;

after forming the initial distraction corridor using the elongate stimulation instrument, advancing a plurality of sequential dilators to further dilate tissue along the lateral, trans-psoas path to the lumbar spine while the inner wire member remains engaged with the disc annulus at the lateral aspect of the targeted spinal disc;

slidably advancing a plurality of retractor blades of a retractor assembly simultaneously over an outer dilator of the plurality of sequential dilators and toward the targeted spinal disc along the lateral, trans-psoas path to the lumbar spine, the retractor assembly including the plurality of retractor blades and a handle assembly having pivotable arm portions that extend generally perpendicularly relative to the plurality of retractor blades, wherein the plurality of retractor blades are simultaneously advanced over the outer dilator while in a closed position, wherein the retractor blades are operable to adjust to an opened position by rotation of a rotatable knob element of the handle assembly that mates with teeth of a rack member so as to move a first retractor blade relative to a second retractor blade of the plurality of retractor blades, wherein each

> of the pivotable arm portions is arranged between the plurality of retractor blades and the rotatable knob element and is pivotable so as to reposition one arm portion relative to another;
>
> removing the plurality of sequential dilators away from the retractor assembly so that the plurality of retractor blades form a lateral operative corridor to the lateral aspect of the targeted spinal disc along the lateral, trans-psoas path to the lumbar spine, and
>
> removably engaging a fixation element with the first retractor blade of the plurality of retractor blades so that a distal portion of the fixation element extends from a distal end of the first retractor blade and secures into a portion of the lumbar spine; and
>
> inserting an implant through the lateral operative corridor formed by the plurality of retractor blades along the lateral, trans-psoas path to the lumbar spine.

II. ANALYSIS

A. Claim Construction

The Board interprets claims using the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, No. 2014-1301, 2015 WL 448667, at *5–*7 (Fed. Cir. Feb. 4, 2015). Under that standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech. Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

"Although an inventor is indeed free to define the specific terms used to describe his or her invention, this must be done with reasonable clarity,

deliberateness, and precision." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Also, "while 'the specification [should be used] to interpret the meaning of a claim,' courts must not 'import[ ] limitations from the specification into the claim.' . . . [I]t is improper to 'confin[e] the claims to th[e] embodiments' found in the specification . . . ." *In re Trans Texas Holdings Corp.*, 498 F.3d 1290, 1299 (Fed. Cir. 2007) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) (citations omitted, bracketed text in internal quotes in original).

1. "positioning an inner wire member"

In the Institution Decision, we construed the positioning step of claim 1 of the '767 patent (Ex. 1018, 13:24–31) to require positioning the inner wire member in a disc annulus at the lateral aspect of a target spinal disc while the wire member is slidably disposed within a tubular distraction member of the elongate stimulation instrument. Dec. 8–9. Neither party challenged this construction during the trial. We maintain it in light of the record developed during trial.

2. "lateral, trans-psoas path to the lumbar spine"

Claim 1 of the '767 patent requires delivery of an initial elongate stimulation instrument, an inner wire member, a plurality of sequential tissue dilators, and a plurality of retractor blades, along a "lateral, trans-psoas path to the lumbar spine," thereby forming an operative corridor to the lumbar spine along that path, through which an implant is inserted. Ex. 1018, 12:63–14:3. Although we did not expressly construe the phrase "lateral, trans-psoas path to the lumbar spine" in the Institution Decision, we do so now, in view of the parties' contentions discussed below.

Petitioner contends that a "lateral approach refers to a path to the spine starting from the side of the patient, and a trans-psoas path is a path in which the surgical instrument(s) passes through the psoas muscle." Pet. 7 (citing Ex. 1016 ¶ 20 (Watkins Decl.)). Patent Owner does not contend that this construction is unreasonable, but notes that the Institution Decision acknowledged the disclosure in the '767 patent of allowing "surgeons to safely and reproducibly avoid nerves when forming a later[al] trans-psoas surgical corridor, which is particularly suited for lateral trans-psoas spinal surgery." PO Resp. 43 (citing Dec. 5).

We acknowledge again the '767 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. Ex. 1018, 11:51–54. Claim 1, 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. Moreover, the '767 patent does not expressly define "trans-psoas path." *See also* Tr. 39:12–40:1, 113:5–114:3 (conceding that the claims are not limited to any particular approach through the psoas muscle). Accordingly, we conclude that the broadest reasonable construction, consistent with the '767 patent specification, of "trans-psoas path," encompasses a path which passes through any portion of the psoas muscle, regardless of the degree or extent of the passage.

As to the lateral approach of the trans-psoas path required by claim 1, the '767 patent refers to a "lateral or far lateral access path (so-called trans-psoas approach) to the lumbar spine" (Ex. 1018, 2:37–38), but does not expressly define "lateral." Regarding the accepted meaning of the term,

Patent Owner's witness, Dr. Obenchain, testified that "[l]ateral would be anything that's basically lateral to an anterior puncture. I mean, again, you get into anterolateral or lateral, but it's a fairly broad basis as to what 'lateral' means." Ex. 1039, 36:2–5 (Obenchain Deposition). Given Dr. Obenchain's qualifications (Ex. 2025, ¶¶ 1–4, Exhibit A), we credit his testimony on this issue.

Accordingly, we conclude that the broadest reasonable construction, consistent with the specification of the '767 patent, of "lateral, trans-psoas path to the lumbar spine," encompasses a path, to the lumbar spine, which passes through any portion of the psoas muscle, regardless of the portion, degree, or extent of passage through the psoas, and which is lateral, to any degree, as compared to an anterior puncture.

No other terms require express construction for purposes of this Decision.

B. Obviousness of Claims 1, 2, 4, 5, 10, 15, 17, and 18 over Branch, Obenchain, Blewett, and Koros '493

1. Prior Art Evidence of Obviousness

Petitioner summarizes its position by contending that "the method of claim 1 uses known minimally invasive spinal access instruments, in a known path used in minimally invasive spinal surgery, with nerve monitoring that was known for use with minimally invasive spinal access instruments." Pet. 51.

To support those contentions, Petitioner cites Branch as teaching a process of accessing a surgical site on the spine, using a guidewire, dilators, and retractor blades, deployed in a manner encompassed by the steps of claim 1. *Id.* at 45–48. Petitioner cites Koros '493 as evidence that a person of ordinary skill in the art would have considered it obvious to equip

Branch's retractor blades with fixation screws, as also required by claim 1. *Id.* at 49 (citing Ex. 1016 ¶¶ 51, 74 (Watkins Decl.)). Petitioner cites Obenchain as evidence that the trans-psoas path to the lumbar spine required by claim 1 was known to be a suitable surgical approach. *Id.* at 50. Petitioner cites Blewett as evidence that an ordinarily skilled artisan would have considered it obvious to equip the initial dilators used in Branch's methods with nerve-monitoring electrodes as part of an EMG monitoring system, and to perform the nerve monitoring steps required by claim 1 using those instruments. *Id.* at 50–51.

Patent Owner, in addition to the secondary considerations of nonobviousness discussed below, argues that Petitioner's contentions regarding the prior art, as well as the testimony of Petitioner's supporting witnesses, are based on improper hindsight. PO Resp. 2–3, 34–36, 39–40, 50–52. Patent Owner argues also that the teachings in the cited references would not have motivated an ordinarily skilled artisan to disregard the conventional wisdom in the art at the time of the '767 patent invention, that the nerve rich portions of the psoas muscle should be avoided entirely when performing lumbar spinal surgery. *Id.* at 44–52. Patent Owner argues, moreover, that the cited prior art does not disclose or suggest a procedure that produces, through the psoas muscle, an operative corridor of sufficient size to introduce an implant into the disc space. *Id.* at 53–54.

As the Supreme Court has stated, when evaluating claims for obviousness, "the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) (quoting *Graham v.*

John Deere Co., 383 U.S. 1, 17–18 (1966)). Secondary considerations, if present, also must be considered. *See id.*

As to the level of ordinary skill in the pertinent art, the parties, as discussed below, challenge their opposing experts' conclusions and qualifications. Nonetheless, neither party asserts specifically that the ultimate conclusion of obviousness turns on adoption of a particular level of ordinary skill. In that regard, the parties' experts advance slightly different opinions as to the level of ordinary skill in the pertinent art. *See* Ex. 1016 ¶ 11 (Watkins Decl.)); Ex. 2020 ¶ 17 (Phillips Decl.). Both experts, nonetheless, agree generally that an ordinarily skilled artisan at the critical time would have been an experienced spinal surgeon, or an experienced engineer or professional involved in the implementation or design of surgical instruments for use in spinal surgery, with significant access to orthopedic or neurosurgeons. *See id.* When evaluating the parties' contentions regarding the scope and content of the prior art, and the differences between the prior art and the challenged claims, we take into consideration both parties' assertions regarding the level of ordinary skill. We note also that the level of ordinary skill in the art may be evidenced by the cited references. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

Having reviewed the parties' contentions and supporting evidence regarding the scope and content of Branch, Obenchain, Blewett, and Koros '493 as compared to the subject matter recited in claims 1, 2, 4, 5, 10, 15, 17, and 18 of the '767 patent, we determine that Petitioner has shown, based on the teachings in the prior art, that an ordinarily skilled artisan would have

been prompted to perform a process having all of the steps and features required by those claims.

Specifically, as Petitioner discusses (Pet. 45–47), Branch describes a minimally invasive spinal surgery procedure involving the formation of an initial tissue distraction corridor using sequentially larger tissue dilators, followed by insertion of retractor blades over the final dilator, as claim 1 requires. *See* Ex. 1013, 6:20–67. As Petitioner discusses (Pet. 47–49), Branch discloses that its retractor blades may employ a knob/rack arrangement, encompassed by claim 1, to separate the blades. Ex. 1013, 7:58–62, Fig. 7.

As Petitioner discusses (Pet. 46), Blewett describes electrode-equipped tissue distracting elements similar to those described in Branch, which may be used to access a spinal site, in a process that includes using a wire to penetrate a spinal disc annulus, as required by claim 1's inner wire member positioning step:

> An initial dilating cannula 26 is advanced towards the target site, preferably after having been aligned using any number of commercially available surgical guide frames. An obturator (not shown) may be included inside the initial dilator 26 and may similarly be equipped with one or more stimulating electrodes. Once the proper location is achieved, the obturator (not shown) may be removed and the K-wire 24 inserted down the center of the initial dilating cannula 26 and docked to the given surgical target site, such as the annulus of an intervertebral disc. Cannulae of increasing diameter are then guided over the previously installed cannula 26 until the desired lumen is installed.

Ex. 1014, 9:18–10:2.

As Petitioner discusses (Pet. 50–51), Blewett discloses "a system and related methods for determining nerve proximity and nerve direction to surgical instruments employed in accessing a surgical target site, as well as monitoring the status or health (pathology) of a nerve or nerve root during surgical procedures." Ex. 1014, 2:28–31. Blewett discloses equipping surgical instruments, including initial tissue dilating instruments, with electrodes that allow a surgeon to detect and avoid nerves. *Id.* at 3.

Given Blewett's teachings, Petitioner persuades us that an ordinarily skilled artisan, creating initial access into a patient for spinal surgery, using guidewires and a plurality of dilators as taught by Branch, would have been prompted to equip the initial dilator with a nerve monitoring electrode, as required by claim 1 of the '767 patent, to allow the surgeon to avoid nerves.

Petitioner persuades us also that an ordinarily skilled artisan would have been prompted to equip Branch's retractor blades with a fixation element, as claim 1 requires. Specifically, Koros '493 discloses that, in a system for providing spinal access similar to that described by Branch, providing two fixation screws that extend distally from the retractor blades, is "advantageous to provide stability and improve support for the distractor system." Ex. 1006, 6:57–58.

Lastly, as to the lateral, trans-psoas path to the lumbar spine required by claim 1, while Obenchain focuses on approaches other than a trans-psoas path, *see* Ex. 1003, 1:48–66, Obenchain discloses, nonetheless, that minimally invasive surgery of the lumbar spine can use a lateral trans-psoas approach:

> If desired, the surgery may traverse through the psoas muscle. Where the surgery site is between L-5 and S-1, the dissection is preferably generally close to the midline between the iliac

> branches of the great vessels. Alternatively, for example, where the patient has extensive abdominal adhesions, it may be preferred to use a lateral puncture of the abdomen to avoid bowel perforation, and entry into the disc space is lateral, transversing the psoas muscle, or immediately in front of it.

Id. at 6:22–31. Accordingly, Petitioner persuades us that an ordinarily skilled artisan would have considered that approach suitable for performing surgery on the lumbar spine.

In sum, given the teachings of Branch, Obenchain, Blewett, and Koros '493, Petitioner persuades us that an ordinarily skilled artisan would have been prompted to perform a process having all of the steps and features of claim 1 of the '767 patent. Patent Owner's arguments do not persuade us to the contrary.

Patent Owner advances evidence, including the testimony of Dr. Obenchain, the named inventor on the Obenchain reference, that ordinarily skilled artisans avoided traversing the psoas muscle when performing lumbar spinal surgery, for fear of causing nerve damage. PO Resp. 5–7 (citing Ex. 2025 ¶¶ 7, 13–16, 21 (Obenchain Decl.); Ex. 2020 ¶¶ 18–21, 45–47 (Phillips Decl.)). Accordingly, Patent Owner contends, the Branch and Obenchain references would not have suggested using the lateral trans-psoas path to the lumbar spine required by claim 1 of the '767 patent, because the conventional wisdom in the art at the critical time, as supported by the testimony of Drs. Obenchain and Phillips, was to avoid the psoas muscle unless traversing it was necessary. *Id.* at 44–47. Patent Owner notes in particular that "Dr. Obenchain feels strongly that his patent[] does not 'teach toward' a transpsoas approach, but instead teaches away from that

approach." *Id.* at 45 (citing Ex. 2025 ¶ 7 (Obenchain Decl.); Ex. 2020 ¶ 60 (Phillips Decl.)).

"A reference does not teach away . . . if it merely expresses a general preference for an alternative invention but does not 'criticize, discredit, or otherwise discourage' investigation into the invention claimed." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009) (quoting *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004)).

In the instant case, as noted above, the Obenchain reference teaches expressly the suitability of a lateral, psoas-traversing pathway when performing minimally invasive surgery on the lumbar spine. Ex. 1003, 6:22–31 ("If desired, the surgery may traverse through the psoas muscle. . . . [F]or example, where the patient has extensive abdominal adhesions, it may be preferred to use a lateral puncture of the abdomen to avoid bowel perforation, *and entry into the disc space is lateral, transversing the psoas muscle* . . . .") (emphasis added). Given this express teaching, Petitioner persuades us (Reply 2, 13–14) that the Obenchain reference does not teach away from the lateral trans-psoas pathway required by claim 1 of the '767 patent.

We acknowledge Patent Owner's assertions, and supporting testimony, that, despite the teachings in the Obenchain reference, ordinarily skilled artisans avoided the psoas muscle when performing lumbar spinal surgery. We acknowledge also Patent Owner's assertions and supporting testimony that lateral approaches to the lumbar spine that simply involved retracting the entire psoas muscle were known in the art. PO Resp. 54 (citing Ex. 2065; Ex. 2020 ¶ 46 (Phillips Decl.)). Patent Owner, nonetheless, effectively concedes that the lateral trans-psoas pathway, taught

expressly in the Obenchain reference, and required by claim 1 of the '767 patent, was, at worst, an unpreferred rather than unsuitable approach in lumbar spinal surgery, and was actually necessary in certain circumstances:

> One of skill would have also understood that it is only in cases where avoiding the psoas muscle entirely is not possible—such as the infrequent case where there is scarring from a prior surgery—that Obenchain suggests using a trans-psoas approach. . . . *But doing that was not the preferred approach; it was simply done out of necessity* when entirely avoiding the psoas muscle using Obenchain's preferred method was not possible.

PO Resp. 46 (citing Ex. 2025 ¶ 14 (Obenchain Decl.)) (emphasis added).

It is well settled that "all disclosures of the prior art, including unpreferred embodiments, must be considered." *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) (quoting *In re Lamberti*, 545 F.2d 747, 750 (CCPA 1976)). Thus, the fact that ordinarily skilled artisans might not have preferred the lateral trans-psoas approach described in the Obenchain reference, and might have used it only infrequently, does not undermine Obenchain's suggestion of using that approach, under the appropriate circumstances.

As to Patent Owner's contention that the approach taught in the Obenchain reference would have been understood by ordinarily skilled artisans as traversing only the psoas's most anterior fibers incidentally (PO Resp. 46–47), we note that the reference's express teaching of a lateral approach traversing the psoas contains no such qualifying language. While it might be true that ordinarily skilled artisans would have traversed only certain portions of the psoas when following the teachings in the Obenchain reference, claim 1 of the '767 patent does not contain language requiring any

particular portion or degree of psoas traversal, as Petitioner argues (Reply 3), and as discussed above. Accordingly, Petitioner persuades us that claim 1 encompasses traversing the psoas to the degree suggested to ordinarily skilled artisans by the Obenchain reference.

Patent Owner contends that Branch provided multiple alternative approaches to the spine, which would have eliminated any concerns regarding the bowel perforation the Obenchain reference sought to avoid through use of the lateral trans-psoas pathway. PO Resp. 48. Thus, Patent Owner contends, an ordinarily skilled artisan would not have abandoned the approaches taught by Branch in favor of the lateral trans-psoas approach taught in the Obenchain reference, which would have effectively increased the chance of bowel perforation as compared to the approaches outlined in Branch. *Id.*

We are not persuaded. We acknowledge Branch's disclosure that its instruments were useful in non-lateral surgical approaches to the spine. Ex. 1013, 2:46–50. Nonetheless, Patent Owner does not direct us to any specific disclosure in Branch explaining which particular approach, lateral, non-lateral, or otherwise, should be used when performing surgery on the lumbar spine. In contrast, as discussed above, the Obenchain reference states expressly that, when performing surgery on the lumbar spine, a lateral trans-psoas pathway may be used. As also discussed above, Patent Owner concedes that that pathway, though unpreferred, is appropriate, and even necessary, under certain circumstances. Thus, we are not persuaded that Branch offered, with specificity, alternative approaches to the lumbar spine that an ordinarily skilled artisan would have selected in preference to the Obenchain reference.

Patent Owner contends that, given the conventional wisdom in the art, only through hindsight would ordinarily skilled artisans would have thought to use nerve monitoring to traverse the psoas muscle to create an initial tissue distraction corridor for use in lumbar spinal surgery. PO Resp. 48–52; *see also id.* at 34–36, 38–40 (contending that testimony of Drs. Watkins and Schwartz is based on improper hindsight). Petitioner replies that Patent Owner improperly considers the cited references in piecemeal fashion, and that Patent Owner's own admissions provide reasons for combining the references as proposed in the Petitioner. Reply 12–15.

We find that Petitioner has the better position.

As discussed above, the Obenchain reference teaches expressly the use of a lateral trans-psoas approach to the lumbar spine, and Patent Owner concedes that that approach, though unpreferred, was needed in certain circumstances. As noted above, Blewett describes equipping surgical instruments, including initial tissue dilating instruments, with electrodes that allow a surgeon to detect and avoid nerves, as well as monitoring the status and health of a nerve or nerve root during surgical procedures. Ex. 1014, 2–3. Blewett focuses its disclosure on spinal surgery (*id.* at 6), and in particular describes positioning its detecting electrodes at locations that allow monitoring of nerves associated with the lumbar spine. *Id.* at 9.

Given Blewett's disclosure, we are not persuaded that an ordinarily skilled artisan would have combined the cited references' teachings only through impermissible hindsight, or that the cited prior art fails to support the testimony of Drs. Watkins and Schwartz. Rather, because Blewett teaches that its nerve monitoring system was desirable when performing spinal surgery potentially encountering nerve roots associated with the

lumbar spine, Petitioner persuades us that Blewett would have prompted an ordinarily skilled artisan, performing lumbar spinal surgery, to equip an initial tissue distracting instrument with an electrode for use in a nerve-monitoring system, as required by claim 1 of the '767 patent, when using the Obenchain reference's lateral trans-psoas approach.

It may be true, as Patent Owner argues (PO Resp. 50), that Blewett does not mention specifically the psoas muscle when discussing the potential of nerve damage in spinal surgery. Nonetheless, that fact underscores Blewett's suggestion that, rather than being useful only in certain circumstances, its nerve monitoring system was desirable, in general, whenever performing spinal surgery, including lumbar spinal surgery. Thus, although Patent Owner characterizes the dangers of traversing certain portions of the psoas as only "relatively low nerve risk" (PO Resp. 5 (citing Ex. 2025 ¶ 14 (Obenchain Decl.); Ex. 2020 ¶ 45 (Phillips Decl.))), given Blewett's suggestion that it was desirable to use its system whenever performing spinal surgery, Petitioner persuades us that an ordinarily skilled artisan, performing surgery on the lumbar spine, would have been prompted to equip an initial tissue distracting implement with a nerve-detecting electrode, as taught by Blewett and required by claim 1 of the '767 patent, when using the lateral trans-psoas approach taught in the Obenchain reference.

Patent Owner argues that the cited prior art does not disclose or suggest a procedure that produces, through the psoas muscle, an operative corridor of sufficient size to introduce an implant into the disc space. *Id.* at 53–54. In particular, Patent Owner contends that the operative corridor of 10 millimeters described in the Obenchain reference is well suited for a

discectomy procedure, but not a procedure in which an implant is inserted. *Id.* at 53 (citing Ex. 2025 ¶¶ 13–15 (Obenchain Decl.); Ex. 2020 ¶¶ 45, 59–65 (Phillips Decl.)). Patent Owner contends further that Petitioner failed to advance evidence suggesting that an ordinarily skilled artisan applying Obenchain's teachings would have used Branch's system to form an operative corridor sufficiently large for an implant. *Id.* at 53–54.

We are not persuaded. We again acknowledge the testimony of Drs. Obenchain and Phillips regarding their surgical experience and their understanding that the psoas muscle was to be avoided. Ex. 2025 ¶¶ 13–15 (Obenchain Decl.); Ex. 2020 ¶¶ 45, 59–65 (Phillips Decl.). Patent Owner fails to direct us, however, to any specific evidence credibly supporting its assertion that the operative corridor described in the Obenchain reference would have been unsuitable for insertion of an implant. Claim 1, moreover, does not place any limitation on the size or type of the inserted implant. Further, Dr. Watkins testifies that an ordinarily skilled artisan would have had a reason to use the implants described in Branch, in the discectomy procedure taught in the Obenchain reference, to maintain vertebral positioning in the absence of the removed disc. Ex. 1016 ¶ 77 (Watkins Decl.) (citing Ex. 1013, 2:31–37); *id.* ¶ 38. Accordingly, Petitioner persuades us that an ordinarily skilled artisan had a reason to insert an implant through an operative corridor formed through the psoas muscle according to the Obenchain reference's teachings.

In sum, having considered the prior art advanced by Petitioner in light of Patent Owner's arguments regarding the cited references' teachings, Petitioner persuades us, based on those teachings, that an ordinarily skilled artisan would have been prompted to perform a process having all of the

steps and features of claim 1 of the '767 patent. As to claim 1's dependent claims 2, 4, 5, 10, 15, 17, and 18, Patent Owner does not direct us to any deficiency in Petitioner's contentions that the teachings in Branch, Obenchain, Blewett, and Koros '493 would have suggested a process having the additional steps and features recited in those claims. We have analyzed Petitioner's evidence regarding those references as compared to claims 2, 4, 5, 10, 15, 17, and 18 (*see* Pet. 51, 58–60), and agree, based on this evidence, that the prior art teaches each limitation of those claims. Petitioner persuades us further that, based on the references' teachings, an ordinarily skilled artisan would have been prompted to prepare a system practicing all of the steps and features required by those claims.

2. Secondary Considerations/Objective Indicia

Patent Owner contends that objective evidence shows that the claimed process would not have been obvious to an ordinarily skilled artisan. PO Resp. 7–9. In particular, Patent Owner contends that its surgical procedure and system solved a long-felt need (*id.* at 9–14), overcame significant skepticism (*id.* at 14–16), elicited significant praise and recognition among practitioners in the art as being advantageous as compared to other lumbar surgical techniques (*id.* at 16–26), experienced significant commercial success (*id.* at 26–31), and was copied by competitors (*id.* at 31–34).

Petitioner replies that Patent Owner has failed to establish adequately a nexus between the objective indicia advanced by Patent Owner and the subject matter recited in the claims. Reply 1, 7–10. Moreover, Petitioner contends, because the asserted benefits of Patent Owner's commercial embodiment "are tied to the extreme/direct lateral approach, to the exclusion of other transpsoas approaches," and because the claims of the '767 patent

are not limited to that particular approach, the asserted objective indicia of nonobviousness are not commensurate in scope with the claimed subject matter. *Id.* at 9.

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*, 383 U.S. at 17–18. 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).

Although Petitioner bears the ultimate burden of persuasion under 35 U.S.C. § 316(e), "[f]or 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 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)).

In the instant case, Petitioner persuades us that the evidence of secondary considerations is not entitled to substantial weight, because Patent Owner has not established a sufficient nexus between the claimed subject

matter and that evidence. Petitioner persuades us also that the evidence of secondary considerations is not reasonably commensurate in scope with the claimed subject matter.

In asserting that the claimed surgical system solved a long-felt need, Patent Owner focuses its contentions on an alleged need for a lateral, trans-psoas pathway. PO Resp. 9–12. That a vast majority of prior art practitioners might have preferred anterior or posterior approaches to the lumbar spine rather than a lateral psoas-traversing approach (*id.* at 9–11) does not persuade us, however, that there existed a long-felt unresolved need for the lateral trans-psoas pathway.

To the contrary, 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 resolved. That those alternative approaches may have presented their own difficulties does not persuade us that there was a long-felt need for the lateral trans-psoas pathway, absent evidence that widespread efforts by ordinarily skilled artisans had failed in that approach. *See Iron Grip Barbell Co. 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); *see also 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."). In the instant case, although Patent Owner directs us to evidence that practitioners attempted to develop a lateral trans-psoas approach, Patent Owner concedes that those

efforts were not widespread, but instead involved no more than "a small handful of patients." PO Resp. 12.

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. *Id.* at 1, 12–14. The "XLIF procedure and systems" are described in Exhibit 2028. *Id.* at 13. Patent Owner contends that Dr. Phillips— "a board certified orthopaedic surgeon—compared XLIF to the independent claim of the '767 patent . . . [and] concluded that the XLIF procedure and systems embody at least the independent claims of the '767 patent." *Id.* at 14 (citing Ex. 2020 ¶¶ 22–23, 27, Attachment D (Phillips Decl.)).

We acknowledge that Dr. Phillips's Declaration includes a chart mapping the features of claim 1 of the '767 patent to various disclosures in Exhibit 2028. *See* Ex. 2020, 148–166 (Attachment D). None of this explanation appears in Patent Owner's Response, however. Nor does Patent Owner's Response include any other specific discussion of how the features of XLIF correspond to the limitations in claim 1, or any of the other challenged claims. Accordingly, we conclude that Patent Owner's Response improperly incorporates by reference these arguments from the Phillips Declaration into the Response. *See* 37 C.F.R. § 42.6(a)(3) ("Arguments must not be incorporated by reference from one document into another document.").[5]

[5] Also in contravention of 37 C.F.R. § 42.6(a)(3), Patent Owner seeks to incorporate by reference, into its Response, the arguments made in its Preliminary Response. PO Resp. 54.

Even disregarding the procedural infirmities in Patent Owner's Response, however, Petitioner persuades us that Patent Owner has not established a sufficient nexus between the claimed subject matter and the objective evidence of nonobviousness. Petitioner persuades us also that the evidence of secondary considerations is not reasonably commensurate in scope with the claimed subject matter.

In its arguments regarding initial skepticism, the evidence advanced by Patent Owner is directed to the contention that ordinarily skilled practitioners did not believe that the lumbar spine could be accessed safely using the lateral trans-psoas approach employed in the XLIF procedure. PO Resp. 14–16 (citing Ex. 2020 ¶¶ 28–33 (Phillips Decl.), Ex. 2024 ¶¶ 12–15 (Miles Decl.), Ex. 2025 ¶¶ 14–15, 21 (Obenchain Decl.)). Patent Owner's evidence of industry praise, as well as improved patient outcomes, focuses similarly on the use of the XLIF technique in a lateral trans-psoas approach. PO Resp. 16–26.

As Petitioner contends (Reply 3), and Patent Owner acknowledges, the XLIF procedure "approaches the spine with sequential dilators orthogonal to the disc space in a true lateral position." PO Resp. 13 (citing Ex. 2030, S370). 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." Ex. 2043, 28.

In contrast, as Petitioner contends (Reply 3), and as discussed above, claim 1 of the '767 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 degree. As discussed above also, Patent

Owner acknowledges that the purportedly unpreferred lateral trans-psoas approach taught in the Obenchain reference, and encompassed by claim 1, was known to present only "relatively low nerve risk." PO Resp. 5 (citing Ex. 2025 ¶ 14 (Obenchain Decl.), Ex. 2020 ¶ 45 (Phillips Decl.)); *see also id.* at 46–47 (asserting that traversing psoas according to teachings of Obenchain reference was done only "out of necessity" and that psoas "would have only been incidentally traversed at its most anterior fibers"). Thus, even assuming for argument's sake that ordinarily skilled artisans were skeptical of the particular approach used in the XLIF procedure, claim 1 of the '767 patent is not limited to that 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 skepticism. Similarly, because it is not limited to the surgical approach used in the XLIF procedure, claim 1 encompasses lateral trans-psoas surgical approaches Patent Owner acknowledges were known in the art, but for which Patent Owner advances no persuasive evidence as to improved patient outcomes and industry praise. Accordingly, Petitioner persuades us that the evidence of skepticism, improved patient outcomes, and industry praise is not commensurate in scope with the claimed subject matter.

Further, as Petitioner argues (Reply 7–10), Patent Owner acknowledges that a key aspect to the acceptability and success of the XLIF technique is its directional nerve monitoring system, which allowed safe navigation of the psoas. *See* PO Resp. 17 ("[T]he NeuroVision nerve monitoring system . . . along with [Patent Owner] NuVasive's techniques

and other instruments, were the linchpin to safety and reproducibility."), *id.* at 18 ("XLIF . . . uses real-time directional neuromonitoring to ensure a safe passage through the psoas muscle, avoiding the nerves of the lumbar plexus.") (emphasis removed), *id.* at 19 ("It is safe and reproducible with few complications due to the use of automated neuromonitoring (NeuroVision®).") (emphasis removed).

Claim 1 of the '767 patent, however, does not recite positively the use of directional nerve monitoring, but instead recites only that its system's display device is "operable to alert a user to at least one of a presence and absence of a nerve near the elongate stimulation instrument." Ex. 1018, 13:21–23. Patent Owner does not explain how detecting the presence or absence of a nerve accomplishes directional nerve monitoring. Patent Owner, moreover, does not explain which features of claim 1 correspond to the directional nerve monitoring employed in XLIF, which it acknowledges contributes significantly to XLIF's asserted success.

Patent Owner acknowledges also that the XLIF procedure uses three dilators, each of which includes a stimulation electrode, and we note that at least one of the retractor blades is equipped also for use with the nerve detection system. Ex. 2020, 152, 158 (Phillips Decl., Attachment D); Ex. 2028, 8, 16, 17, 19.[6] In contrast, claim 1 of the '767 patent requires only the initial tissue-distracting instrument to emit a nerve-detecting stimulation signal. Ex. 1018, 12:63–14:3. Patent Owner does not advance any specific credible evidence explaining whether a system having only a single initial

[6] In citing to Exhibit 2028, we cite to the page numbers at the bottom center of each page.

tissue distracting element capable of detecting nerve presence or absence, as recited in claim 1, would elicit the same praise or produce the same patient outcomes as asserted for XLIF, in which each of the tissue-distracting dilators and at least one retractor blade is part of the nerve monitoring system. Accordingly, Petitioner persuades us that the XLIF system includes a number of important features, which Patent Owner concedes contribute significantly to any praise that may have been elicited, but which are not recited in claim 1 of the '767 patent. Petitioner persuades us also, therefore, that Patent Owner has not established a nexus between the features of the XLIF procedure and system which are asserted to have elicited praise, and the elements of the sole claim for which Patent Owner presents specific argument as to secondary considerations. *See* Ex. 2020, 148–166 (Phillips Decl. Attachment D) (comparing XLIF (Ex. 2028) to claim 1 of the '767 patent).

As to commercial success, Patent Owner contends that the growth in its revenue, from about $38 million in 2004 to about $685 million in 2013, is a direct result of XLIF, which was introduced in 2003. PO Resp. 27–28. Patent Owner contends that XLIF created the lateral spine fusion market, which it held exclusively until Petitioner's entry into the market in 2006. *Id.* To support its contentions regarding commercial success, Patent Owner relies (PO Resp. 28–30) on the Declaration of its company executive Patrick Miles (Ex. 2024 ¶ 1), its own internal report (Ex. 2040), as well as market research reports from financial analysts (Ex. 2041 (www.idataresearch.net)); Ex. 2056 (J.P. Morgan); Ex. 2058 (Canaccord Genuity); Ex. 2059 (Caris & Co)).

Patent Owner summarizes its commercial success contentions as follows:

> As the evidence shows, XLIF's commercial success (and by extension [Patent Owner] NuVasive's) is a direct result of the novel combination of the minimally invasive nerve monitoring enabled distractor(s)/dilator(s) and working corridor instrument (retractor) (also optionally nerve monitoring enabled) with NuVasive's nerve monitoring system to safely and reproducibly perform a lateral transpsoas approach to the lumbar spine as claimed by the '767 patent. . . . Not only is this technology key to XLIF, but it is key to creating an entirely new market for fusion.

PO Resp. 30–31 (citing Ex. 2024 ¶¶ 24–29 (Miles Decl.)).

Petitioner persuades us (Reply 4, 7–11), that Patent Owner has not explained with adequate specificity the nexus between its assertions of commercial success and the claimed subject matter.

Similar to the discussion above, Patent Owner acknowledges that the nerve monitoring techniques employed in the XLIF system are critical to the asserted commercial success of the system. *See* PO Resp. 28 (XLIF "makes use of NuVasive's proprietary NeuroVision neuromonitoring software to protect nerve bodies") (citing Ex. 2041), *id.* at 29 (navigating around key nerves facilitated "through a proprietary technology (the foundation of the company, in fact) called NeuroVision") (citing Ex. 2056 (emphasis removed)), *id.* at 29–30 ("The critical component obviously lies within its NeuroVision offering and its MaXcess retractor system.") (citing Ex. 2058 (emphasis removed)), *id.* at 30 ("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 [Patent Owner] launched its Inter-operative Nerve monitoring system.") (emphasis removed). Patent Owner's

own Exhibit 2043[7] attests to the importance of the nerve-monitoring system to XLIF:

> It is impossible to overemphasize the importance of reliable, timely monitoring of the neural elements as the surgeon traverses the psoas. Visual identification of the lumbar plexus is not possible, but the plexus can be protected by using an automated electrophysiology technology. The NeuroVision system, in detection mode, uses a patented hunting algorithm that provides five pulses of increasing amplitude current per second until a recording myotome has responded. Once the maximum current level to elicit a response is achieved, the current output will stabilize at this level.

Ex. 2043, 28–29.

Thus, in addition to the strict adherence to the direct lateral 90° degree approach, directional nerve monitoring, and use of nerve-detecting electrodes on each of the tissue-distracting dilators, discussed above, Patent Owner acknowledges that XLIF includes a proprietary software-driven nerve monitoring system as a key feature of its asserted success. Patent Owner does not, however, explain where that feature is recited in claim 1 of the '767 patent, or how claim 1 embodies that acknowledged key feature of XLIF. Nor does Patent Owner present any specific argument explaining how the features of the remaining challenged claims correspond to the elements of the XLIF system.

Further, Petitioner directs us to evidence supporting its contention that the commercial success asserted by Patent Owner resulted, at least in part,

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[7] W. Blake 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 2007, 28–32.

from factors not associated with either the claims under challenge or the techniques or hardware of XLIF. Specifically, as Petitioner points out (Reply 1), 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:

> 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.

Ex. 2038, 69 (10-K filing by Patent Owner).

As the Federal Circuit has explained, "evidence of commercial success alone is not sufficient to demonstrate nonobviousness of a claimed invention." *In re DBC*, 545 F.3d 1373, 1384 (Fed. Cir. 2008). Instead, "the proponent 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.'" *Id.* (quoting *In re Huang,* 100 F.3d 135, 140 (Fed. Cir. 1996)).

Here, while Patent Owner's 2013 Form 10-K states that, to date, the majority of its revenue had come from sales of implants, biologics, and disposables (Ex. 2038, 69), claim 1 of the '767 patent recites no details regarding the implant inserted in the claimed procedure, and does not expressly mention biologics or disposables. *See* Ex. 1018, 12:63–14:3. Thus, Patent Owner acknowledges that the majority of its revenue had come

from sales of implants, biologics, and disposables, but does not explain persuasively how this is consistent with its contention that its commercial success resulted directly from the elements of the XLIF system included within claim 1. Also, that Patent Owner loaned its proprietary software-driven nerve monitoring systems and surgical instruments, at no cost to surgeons and hospitals that purchased its disposables and implants, supports further Petitioner's contention that Patent Owner failed to show that its commercial success directly resulted from the unique characteristics of the invention, as opposed to factors unrelated to the features of the claimed invention.

As to Patent Owner's contentions regarding market share, as Petitioner discusses (Reply 5), Patent Owner asserts an initial 100% share of the "Lateral IB Market" for calendar year 2004, which decreased to a 71% share in 2008. PO Resp. 28 (citing Ex. 2003, 10). Patent Owner, however, cites also a 2008 J.P. Morgan report stating that Patent Owner had "under 5% of the US lumbar fusion market, while the XLIF procedure can treat an estimated 35% of all lumbar fusions." *Id.* at 29 (citing Ex. 2056, 3). Accordingly, the contradictions in Patent Owner's assertions regarding overall market penetration render that evidence unclear, and undercut its probative value.

In sum, for the reasons provided, Petitioner persuades us that Patent Owner has not established a sufficient nexus between the features of the XLIF procedure and system, asserted as providing commercial success, and the subject matter recited in claim 1 of the '767 patent and its dependents. For the reasons provided, Petitioner persuades us also that Patent Owner has not established that claim 1 is commensurate in scope with the features of

XLIF asserted to provide commercial success, and that Patent Owner did not explain convincingly that XLIF held a significant portion of a relevant market.

As to Patent Owner's contentions regarding copying, we find that Petitioner has the better position as well.

The Federal Circuit has explained that "[n]ot every competing product that arguably falls within the scope of a patent is evidence of copying; otherwise, 'every infringement suit would automatically confirm the nonobviousness of the patent.'" *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010) (quoting *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d at 1325). Rather,

> copying 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.

Id.

In the instant case, Patent Owner directs us to a 2004 internal document from Petitioner discussing XLIF's direct lateral trans-psoas approach, including its NeuroVision nerve monitoring system. PO Resp. 32 (citing Ex. 2086, 1, 3). Patent Owner asserts that Petitioner subsequently introduced its own version of the XLIF system, "DLIF," in 2006. *Id.* at 32–33. Patent Owner cites the following passage from a 2011 Caris & Company financial analysis report to show that DLIF system included the features of the challenged claims of the '356 patent:

> [Petitioner] MDT which is the dominant player in spine (just under 40% market share) has offered its version of XLIF, DLIF (Direct Lateral Interbody Fusion) for the past 3 years, and it struggled to gain footing against XLIF. Part of the problem was the lack [of] integration of a neuro monitoring system, but they are addressing now with a newly integrated system, though our checks still indicate that it's not quite on par with [Patent Owner] NUVA offerings, it is competitive.

Id. at 33 (quoting Ex. 2059, 4). Although this discussion suggests that DLIF may have a nerve monitoring system similar to XLIF, Patent Owner does not direct us to any evidence that describes the specific components or procedures of the DLIF system, nor does Patent Owner otherwise explain with specificity why the particular features required by claim 1, or any of the other challenged claims of the '767 patent, are in the DLIF system.

Patent Owner cites the following passage from a 2008 J.P. Morgan financial analysis report to show that other competitors also copied Patent Owner's XLIF system: "[n]early every competitor now offers a lateral access and/or neuromonitoring system and while [Patent Owner] NuVasive can lay claim to the superiority of Nuerovision [sic] and the sophistication and experience of XLIF, Medtronic, Globus, Depuy, and others are all fighting back." *Id.* (quoting Ex. 2066, 1) (emphasis omitted). Again, however, although this discussion suggests that Patent Owner's competitors may have nerve monitoring systems similar to XLIF, Patent Owner does not direct us to any evidence that describes the specific components of its competitors' systems or the surgical steps performed, nor does Patent Owner otherwise explain with specificity why the particular features required by claim 1, or any of the other challenged claims of the '767 patent, are in its competitors' systems.

Accordingly, in the absence of evidence credibly demonstrating that the products of Petitioner and other competitors of Patent Owner include the features required by the challenged claims of the '767 patent, we are not persuaded that Patent Owner has provided an adequate basis to find that Petitioner or Patent Owner's other competitors copied the methods recited in the challenged claims.

3. Conclusion of Obviousness

In sum, as discussed above, having considered the prior art advanced by Petitioner in light of Patent Owner's arguments regarding the cited references' teachings, Petitioner persuades us, based on the teachings in Branch, Obenchain, Blewett, and Koros '493, that an ordinarily skilled artisan would have been prompted to perform a process having all of the steps and features of claims 1, 2, 4, 5, 10, 15, 17, and 18 of the '767 patent. As also discussed above, having considered Patent Owner's evidence and arguments regarding objective indicia of nonobviousness, Petitioner persuades us that Patent Owner's evidence does not show a sufficient nexus between the claimed subject matter and the objective indicia. Accordingly, under these circumstances, taking into consideration the record as a whole, we conclude that Petitioner has shown by a preponderance of the evidence that an ordinarily skilled artisan would have considered the processes recited in claims 1, 2, 4, 5, 10, 15, 17, and 18 obvious in view of Branch, Obenchain, Blewett, and Koros '493.

C. Petitioner's Motion to Exclude Evidence

Petitioner moves to exclude as hearsay Exhibits 2033, 2035, and 2036, which are asserted to be printouts from websites of Dr. Burak Ozgur and Dr. Jonathan R. Stieber, because neither Dr. Ozgur nor Dr. Stieber

provided testimony in this proceeding, and because Patent Owner's attorney admitted not knowing the doctors, but instead merely printed the exhibits from the internet. Mot. to Exclude 1–2.

Patent Owner contends that Exhibits 2033, 2035, and 2036 are presented for non-hearsay purposes, to show what was being said about XLIF as praise and recognition by the industry, rather than the truth of the matter asserted. PO Opp. 2–3.

We agree that Exhibits 2033, 2035, and 2036 are offered for non-hearsay purposes. Therefore, we do not exclude them.

Petitioner moves to exclude as hearsay Exhibits 2039, 2041, 2056, 2058, 2059, and 2066, which are asserted to be financial industry documents evidencing commercial success and praise. Mot. to Exclude 3. Petitioner contends that these exhibits are not reliable because Patent Owner has admitted that it has no knowledge of whether the authors of the documents are skilled artisans. *Id.*

Patent Owner argues that these documents are introduced for non-hearsay purposes, such as showing industry praise and the states of mind of the documents' authors, and that the credentials of the authors go to the weight of the evidence, not its admissibility. PO Opp. 5–7.

We agree with Patent Owner that the Exhibits were presented for non-hearsay purposes, and that the credentials of the authors go to the weight of the evidence, not its admissibility. Accordingly, we deny the motion to exclude Exhibits 2039, 2041, 2056, 2058, 2059, and 2066.

We dismiss Petitioner's Motion to Exclude Exhibits 2034, 2042, 2051, 2062, and 2070–73 as moot, because we do not rely on those Exhibits.

III. ORDER

For the reasons given, it is

It is ORDERED that claims 1, 2, 4, 5, 10, 15, 17, and 18 of the '767 patent have been shown by a preponderance of the evidence to be unpatentable under 35 U.S.C. § 103(a) as obvious over Branch, Obenchain, Blewett, and Koros '493;

FURTHER ORDERED that Petitioner's Motion to Exclude is denied-in-part, and dismissed-in-part as moot; and

FURTHER ORDERED that, because this is a final written decision, parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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