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Paper 49
Entered: April 3, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.
Petitioner

v.

NUVASIVE, INC.
Patent Owner

Case IPR2014-00074
Patent 8,192,356 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 8, "Pet.") requesting an *inter partes* review of claims 21, 22, 24–26, 30, and 33–37 of U.S. Patent No. 8,192,356 B2 (Ex. 1018, "the '356 patent"). NuVasive, Inc. ("Patent Owner") filed a Preliminary Response (Paper 10, "Prelim. Resp.").

Petitioner relied upon the following references to show unpatentability:

Ex. 1001	Cistac	DE 100 48 790 A1 (as translated, Ex. 1002)	Apr. 25, 2002
Ex. 1003	INS-1	NuVasive, Inc., INS-1 Intraoperative Nerve Surveillance Sys., Food & Drug Admin. submission under 510(k) No. K002677 (printed Aug. 25, 2011)	
Ex. 1004	Obenchain	US 5,313,962	May 24, 1994
Ex. 1005	Mathews	US 5,171,279	Dec. 15, 1992
Ex. 1006	Koros	US 6,139,493	Oct. 31, 2000
Ex. 1007	Michelson	US 5,772,661	June 30, 1998
Ex. 1008	Jones	US 4,595,013	June 17, 1986
Ex. 1009	Foley	US 5,782,044	Aug. 11, 1998
Ex. 1010	Onimus	WO 00/27291 A1 (as translated, Ex. 1011)	May 18, 2000
Ex. 1012	Kelleher	WO 01/37728 A1	May 31, 2001
Ex. 1013	NIM Guide	Medtronic Xomed Surgical Products, Inc., NIM-Response, Nerve Integrity Monitor, Intraoperative EMG Monitor User's Guide (2000).	

We instituted *inter partes* review of claims 21, 22, 24, 30, and 33–37 on the following grounds of unpatentability:

References	Basis	Claims challenged
Foley, Koros, Onimus, Mathews, Obenchain, and Kelleher	§ 103(a)	21, 22, 24, 30, 33, and 34
Foley, Koros, Onimus, Mathews, Obenchain, Kelleher, and NIM Guide	§ 103(a)	35
Foley, Koros, Onimus, Mathews, Obenchain, Kelleher, NIM Guide, and Jones	§ 103(a)	36 and 37

Decision to Institute 25–26 (Paper 15, "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.").

Petitioner supported its Petition with Declarations by Robert G. Watkins, IV, M.D. ("Watkins Pet. Decl." (Ex. 1015)), Daniel Schwartz, Ph.D. ("Schwartz Decl." (Ex. 1016)), and David Hacker ("Hacker Decl." (Ex. 1017)). 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 21, 22, 24, 30, and 33–37 of the '356 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 '356 patent against Petitioner in *Warsaw Orthopedic Inc. v. NuVasive Inc.*, Case No. 3:12-cv-02738-CAB-MDD (S.D. Cal.). Pet. 1; Paper 6 at 2.

In *Medtronic, Inc. v. NuVasive, Inc.*, PR2014-00073, we instituted review of claims 21, 22, 24, 30, and 33–37 of the '356 patent, on a distinct set of grounds presented by Petitioner. IPR2014-00073, Paper 14. Petitioner also has challenged a number of related patents in the following proceedings in which trials were instituted: IPR2014-00034 (Patent 8,000,782), IPR2014-00075 (Patent 8,016,767), 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 '356 Patent

The '356 patent describes methods and apparatuses for accessing a surgical target site, such as the lumbar spine, using minimally invasive techniques. Ex. 1018, 1:30–2:58. The surgical target site is accessed by first advancing a rigid, generally narrow (diameter about 1.5 millimeters), "K-wire" through the patient's tissue to the target site. *Id.* at 6:51–59. Then, tissue dilators of increasing diameter are advanced over the K-wire to the target site, so as to sequentially distract, that is, open up, an initial pathway through the tissue to the site. *Id.* at 6:65–7:23.

Once the initial pathway through the tissue is formed, an operative corridor for performing the surgery may be prepared by advancing a set of retractor blades into the tissue opening, and attaching the blades to a pivot linkage. *Id.* at 8:15–30, *see also* Figs. 8, 32 (showing pivot linkage 14, and attached retractor blades 90, 92). The pivot linkage has handle-like pivot arms that allow the surgeon to spread the tissue-distracting elements farther apart. *See id.* at Fig. 8 (showing pivot arms 60, 62, 64, and 66).

The '356 patent explains that "retractor blades 90, 92 may be locked in a desired position by tightening the respective nuts 82, 86 of the locking assemblies 32, 34." *Id.* at 8:28–30, *see also* Fig. 8. Once an operative corridor is established, the surgeon can perform surgical procedures, such as installing a spinal fusion implant. *Id.* at 6:31–35.

The '356 patent discloses that any of the tissue-distracting instruments, including dilators and retractor blades, may be equipped with stimulation electrodes that allow the surgeon to monitor the location of

nerves in the patient, so as to avoid and not damage the nerves during surgery. *See id.* at 9:40–59. The electrodes emit a stimulation signal that, when sufficiently close to a nerve, causes an innervation response in the muscle associated with the nerve. *Id.* at 9:51–57. Response to the stimulation signal may be monitored visually, by a twitch in the muscle, or detected using an electromyography (EMG) system, which includes electrodes positioned on the patient's muscles. *Id.* at 9:60–10–23, 11:14–32.

Claim 21, the only independent claim Petitioner challenges in this proceeding, reads as follows:

> 21. A system for accessing a spinal disc of a lumbar spine through an operative corridor, comprising:
>
> a distraction assembly to create a tissue distraction corridor to a lumbar spine, wherein said distraction assembly comprises: an elongate penetration member ***deliverable to a spinal disc along a lateral, trans-psoas path to the lumbar spine*** such that a distal tip region of the elongate penetration member penetrates into an annulus of a spinal disc in the lumbar spine, and at least two dilators of sequentially larger diameter ***deliverable to the spinal disc along the lateral, trans-psoas path to the lumbar spine,*** a first dilator of the at least two dilators having a lumen configured to slidably receive the elongate penetration member, at least one of said at least two dilators including a stimulation electrode ***to deliver electrical stimulation for nerve monitoring when said stimulation electrode is positioned in the lateral, trans-psoas path to the lumbar spine;*** and
>
> a retraction assembly comprising a plurality of retractor blades that enlarge the tissue distraction corridor ***to thereby form an operative corridor along the***

> ***lateral, trans-psoas path to the lumbar spine*** when the plurality of retractor blades are delivered to the lumbar spine, the retraction assembly further comprising a blade holder apparatus that is configured to releasably lock with the plurality of retractor blades,
>
> ***wherein when the plurality of retractor blades enlarge the tissue distraction corridor to form the operative corridor along the lateral, trans-psoas path to the lumbar spine, the operative corridor is dimensioned so as to pass an implant through the operative corridor along the lateral, trans-psoas path to the lumbar spine.***

Id. at 18:60–19:24 (emphases added).

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. *See In re Translogic Tech. Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

In the Decision to Institute we concluded that the recitations in claim 21 regarding the "lateral trans-psoas path to the lumbar spine" relate to an intended use of the claimed apparatus. Dec. 8. Accordingly, we attributed to those intended use recitations no particular structural limitations, beyond

an ability to be used in, or follow, a trans-psoas path in the manner recited in the claim. *Id.* Neither party disputes that claim construction and we maintain it in light of the record developed during trial. No other terms require express construction for purposes of this Decision.

B. Asserted Grounds of Unpatentability

1. Obviousness of Claims 21, 22, 24, 30, 33, and 34 in view of Foley, Koros, Onimus, Mathews, Obenchain, and Kelleher

a. Prior Art Evidence of Obviousness

In the Institution Decision, we instituted review of claims 21, 22, 24, 30, 33, and 34 as obvious in view of Foley, Koros, Onimus, Mathews, Obenchain, and Kelleher. Dec. 15–22, 26.

Petitioner cites Foley as evidence that systems for performing minimally invasive surgery on the lumbar spine were known to include an elongate penetration member, in the form of a guidewire, as well as a plurality of tissue dilators of sequentially larger diameter, as required by claim 21 of the '356 patent. Pet. 42, 52–53; *see also* Ex. 1009, 10:11–50. Petitioner cites Koros as evidence that an ordinarily skilled artisan would have considered it obvious to include retractor blades, as required by claim 21, in a system for performing minimally invasive lumbar surgery, instead of the operative corridor-forming cannula of Foley. Pet. 43; *see also* Ex. 1006, 2:42–46. Petitioner cites Onimus as evidence that, as claim 21 also requires, an ordinarily skilled artisan would have considered it obvious to configure retractor blades used in spinal surgery to releasably lock to blade holders, by snap-fitting or screwing. Pet. 43–44; *see also* Ex. 1011, 9.

Petitioner cites Kelleher as evidence that an ordinarily skilled artisan would have considered it obvious to equip the dilators and retractor blades

described by Foley and Koros with nerve-monitoring electrodes, as claims 21 and 33 require, to allow a surgeon to detect and avoid nerves while performing spinal surgery. Pet. 45–46, 48, 53–54, 56–57; *see also* Ex. 1012, 1–4. Petitioner cites Mathews as evidence that an ordinarily skilled artisan would have considered it obvious to configure minimally invasive surgical instruments intended for lumbar spine surgery to be dimensioned so as to allow surgical implants to pass through them, and to allow penetration of a guidewire into the disc annulus. Pet. 46–47; *see also* Ex. 1005, 1:60–2:15, 4:5–31. Petitioner cites Obenchain as evidence that the trans-psoas path to the lumbar spine was known to be a suitable surgical approach to the lumbar spine. Pet. 44–45; *see also* Ex. 1004, 6:26–31.

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. Patent Owner argues also that the only motivation alleged in the Petition for combining the cited references is for using a lateral, trans-psoas path to the spine. *Id.* at 42, 45. Patent Owner argues, however, that neither the cited prior art, nor the knowledge of ordinarily skilled artisans at the time of the invention, supports that rationale. *Id.* at 3–7, 42–46.

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. *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. 1015 ¶ 11 (Watkins Decl.)); Ex. 2020 ¶ 17 (Phillips Decl.). Both experts, nonetheless, generally agree that an ordinarily skilled artisan at the critical time would have been either 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 Foley, Koros, Onimus, Mathews, Obenchain, and Kelleher, as compared to the subject matter recited in claims 21, 22, 24, 30, and 34 of the '356 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 prepare a surgical system having all of the features required by those claims.

Specifically, as to the substitution of Koros's retractor blades for Foley's cannula, Koros teaches that the fixation screws on its blades provide positional stability to the operative corridor, while still allowing adjustability of corridor size. *See* Ex. 1006, 3:15–17 ("The non-fixed blades may be tilted to provide a wider field of view . . . ."). Accordingly, we are persuaded that an ordinarily skilled artisan would have considered it obvious to include Koros's retractor blades, as well as the dilators and guidewire of Foley, in a surgical system for minimally invasive surgery of the lumbar spine, as claim 21 requires. As to claim 21's requirement that the retractor blades be releasably locked with the blade holder apparatus, we note Onimus's disclosure that snap-fitting or screwing retractor blades to a holding apparatus was known to be a useful feature on devices for providing surgical access to the spine. *See* Ex. 1011, 9.

As to the nerve-monitoring stimulation electrode required by claim 21, Kelleher discloses a nerve detection system which has "an electrode or electrodes positioned on the distal end of the surgical tool or probe, with an electromyographic system used to detect whether a spinal nerve is positioned adjacent to the surgical tool or probe." Ex. 1012, 2–4. Kelleher explains:

> A conclusion is made that the surgical tool or probe is positioned adjacent to a spinal nerve when a neuro-muscular (e.g.: EMG) response to a stimulus pulse emitted by the electrode or electrodes on the surgical tool or probe is detected (at a distant myotome location, such as on the patient's legs) at or below certain neuro-muscular response onset values (i.e.:

> pre-determined current intensity levels) for each of the plurality of spinal nerves.

Id.

Kelleher discloses that in "preferred aspects, the surgical tool or probe may be introduced into the patient in a minimally invasive cannulated approach." *Id.* at 2. Kelleher further discloses that its electrified probes "can be any manner of surgical tool, including (electrified) cannulae through which other surgical tools are introduced into the patient." *Id.* at 16.

We agree with Petitioner that an ordinarily skilled artisan, advised by Kelleher of the desirability of equipping surgical instruments with electrodes to detect nerves during spinal surgery when using a minimally invasive cannulated approach, would have been prompted to equip Foley's dilators with a stimulating electrode as required by claim 21 of the '356 patent, in order to allow the surgeon to detect and avoid spinal nerves. In view of Mathews's teaching of the desirability of delivering implants through a spine-accessing minimally invasive operative corridor, *see* Ex. 1005, 5:50–6:16, we also agree with Petitioner that, as required by claim 21, an ordinarily skilled artisan would have ensured that the operative corridor created by Foley's system was dimensioned to permit implant passage.

As to the intended use of the system recited in claim 21, as discussed above, we attribute to the intended use recitations no particular structural limitations, beyond an ability to be used in, or follow, a trans-psoas path, in the manner recited in the claim. Because Foley teaches instruments sized for minimally invasive access to the lumbar spine using any approach, *see* Ex. 1009, 10:6–65, we are persuaded, on the current record, that those instruments have would been capable of the intended use recited in claim 21.

Moreover, although Obenchain focuses on approaches other than a trans-psoas path, *see* Ex. 1004, 1:48–66, Obenchain discloses, nonetheless, that minimally invasive surgery of the lumbar spine can use a trans-psoas approach:

> 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, or immediately in front of it.

Id. at 6:22–31.

In sum, given the discussed teachings of Foley, Koros, Onimus, Mathews, Obenchain, and Kelleher, Petitioner persuades us that an ordinarily skilled artisan would have been prompted to prepare a system having all of the elements of claim 21 of the '356 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. PO Resp. 3–7 (citing Ex. 2020 ¶¶ 18–21, 36–47 (Phillips Decl.); Ex. 2025 ¶¶ 7, 13–16 (Obenchain Decl.)). As noted above, however, the psoas-traversing pathway recited in claim 21 is merely an intended use of the recited apparatus, and Patent Owner does not point with specificity to any feature in the prior art apparatuses that would have rendered them unsuitable or unusable in such an approach.

Further, Kelleher teaches expressly that its nerve-sensing electrodes were generally desirable when performing spinal surgery. *See* Ex. 1012, 1

("[I]t is especially important to sense the presence of spinal nerves when performing spinal surgery, since these nerves are responsible for the control of major body functions."). As noted above, Kelleher teaches also that its nerve-sensing electrodes were suitably deployed on any surgical instrument. *Id.* at 16. Accordingly, we are not persuaded that Kelleher would have been combined with Foley only through hindsight, as Patent Owner argues (PO Resp. 34–36, 39–40). Patent Owner argues that Drs. Watkins and Schwartz lack proper qualifications and that their testimony suffered from improper hindsight and the use of incorrect legal standards. PO Resp. 38–41. Nevertheless, even if we accept this criticism, given the express teachings in Kelleher, Petitioner persuades us that an ordinarily skilled artisan would have been prompted to equip at least one of Foley's dilators with Kelleher's nerve-sensing electrodes, as claim 21 of the '356 patent requires.

In addition, Kelleher discloses the usefulness of its electrodes in cervical and thoracic surgeries (Ex. 1003, 7, 12), as well as illustrating their use in lumbar spinal applications (*id.* at 12, Fig. 1), yet makes no express mention of traversing the psoas muscle in any of these contexts. We are not persuaded, therefore, that the sole reason for combining Kelleher and Foley would have been to allow navigation of the nerve plexus in the psoas muscle, as Patent Owner contends. PO Resp. 42–46. In that regard, we note that, although Petitioner explained why an ordinarily skilled artisan would have consider it obvious to use Foley's system in a lateral trans-psoas approach, Petitioner stated expressly that "a lateral, trans-psoas path is not relevant to the patentability of the claim." Pet. 44. Petitioner also urged

combining Foley with Kelleher without reference to the trans-psoas pathway:

> It would have been obvious to one of ordinary skill in the art to use a nerve monitoring system that outputs electrical stimulation signals from an electrode provided on the distal tips of the dilators 151–153 of Foley. As taught by Kelleher, using such a nerve monitoring system with the dilators of Foley would have warned the surgeon if the dilators approached nerves as they were delivered to the surgical site in the lumbar spine.

Id. at 45–46.

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 the teachings in those references, that an ordinarily skilled artisan would have been prompted to prepare a system having all of the elements of claim 21 of the '356 patent. As to claim 21's dependent claims 22, 24, 30, 33, and 34, Patent Owner does not direct us to any deficiency in Petitioner's contentions that the teachings in Foley, Koros, Onimus, Mathews, Obenchain, and Kelleher would have suggested a system having the additional features recited in those claims. We have analyzed Petitioner's evidence regarding those references as compared to claims 22, 24, 30, 33, and 34 (*see* Pet. 47–48, 55–57), 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 having all of the elements required by those claims.

b. Secondary Considerations/Objective Indicia

Patent Owner contends that objective evidence shows that the claimed surgical system would not have been obvious to an ordinarily skilled artisan. PO Resp. 7–9. In particular, Patent Owner contends that its surgical 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, 7–11. Moreover, Petitioner argues, the guidance along a trans-psoas pathway upon which Patent Owner bases its contentions regarding the objective indicia is not a required element of the challenged claims, which are directed to apparatuses. *Id.* at 2–3, 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 decision maker 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 the alleged need for a lateral, trans-psoas pathway. PO Resp. 9–12. Similarly, in its contentions 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. *Id.* at 14–16 (citing Ex. 2020 ¶¶ 28–33 (Phillips Decl.); Ex. 2024 ¶¶ 12–15 (Miles Decl.); Ex. 2025 ¶¶ 14–15, 21 (Obenchain Decl.)). As noted above, however, the recitations in claim 21 regarding the lateral, trans-psoas pathway relate only to the intended use of the claimed apparatus, and do not require the apparatus to be used in that fashion. Indeed, the '356 patent

acknowledges that, rather than being limited or unique to the lateral trans-psoas intended use, "the access system of the present invention is suitable for use in any number of additional surgical procedures, including those wherein tissue having significant neural structures must be passed." Ex. 1018, 3:19–21.

Moreover, even if practitioners preferred anterior or posterior approaches to the lumbar spine rather than a lateral psoas-traversing approach (PO Resp. 9–11), that does not persuade us that there existed a long-felt but 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 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 surgical system allowed surgeons to traverse the psoas muscle safely and reproducibly in order to access the lumbar spine. PO Resp. 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 claims of the '356 patent . . . [and] concluded that the XLIF procedure and systems embody at least the independent claims of the '356 patent." *Id.* at 14 (citing Ex. 2020 ¶¶ 22–23, 27, Attachment C (Phillips Decl.)).

We acknowledge that Dr. Phillips's Declaration includes a chart mapping the features of claim 21 of the '356 patent to various disclosures in Exhibit 2028. *See* Ex. 2020, 139–147 (Attachment C). 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 21, 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.").

Even disregarding the procedural infirmities in Patent Owner's Response, Petitioner persuades us, nonetheless, that Patent Owner has not established a sufficient nexus between the claimed subject matter and the objective evidence of nonobviousness. Specifically, Patent Owner's evidence of industry praise, as well as improved patient outcomes, focuses

on the use of the XLIF technique in a lateral trans-psoas approach. PO Resp. 16–26. As noted above, however, because it is directed to an apparatus, claim 21 simply does not require using that approach.

Moreover, as Petitioner argues (Reply 7–10), Patent Owner acknowledges that a key aspect to the acceptability of the XLIF technique was its 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), *id.* at 20 ("Dynamic, discrete-threshold EMG is an integral and necessary part of the XLIF procedure.") (emphasis removed). Patent Owner acknowledges also that the XLIF system includes three dilators, each of which includes a stimulation electrode. Ex. 2020, 142 (Phillips Decl., Attachment C).

In contrast, claim 21 does not recite or require real-time, directional, or automated nerve monitoring. Ex. 1018, 18:60–19:24. Rather, as to nerve monitoring, the system of claim 21 merely includes two dilators, only one of which must have a stimulation electrode for nerve monitoring. *Id.* at 19:6–10. 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 21. Petitioner persuades us also, therefore, that Patent

Owner has not established a nexus between the features of the XLIF system that are asserted to have elicited praise, and the sole claim for which Patent Owner presents specific argument as to secondary considerations. *See* Ex. 2020, 139–147 (Phillips Decl. Attachment C) (comparing XLIF (Ex. 2028) to claim 21 of the '356 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 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 '356 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 30 ("The critical component obviously lies within its NeuroVision offering and its MaXcess retractor system.") (citing Ex. 2058 (emphasis removed)), *id.* ("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).

Thus, although Patent Owner acknowledges that XLIF includes certain features that are critical to its success, including a software-driven nerve monitoring system and the use of the trans-psoas pathway, those features are either not recited in, or not required by, claim 21. As to the remaining claims under challenge, Patent Owner does not present any specific argument explaining how the features of those claims correspond to the elements of the XLIF system.

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

part, 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, 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 21 of the '356 patent. Also, Petitioner's contention,

that the success asserted by Patent Owner was attributable to factors unrelated to the features of the claimed invention, is supported by the fact 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.

In sum, for the reasons provided, Petitioner persuades us that Patent Owner has not explained with adequate specificity the nexus between its evidence of commercial success and the subject matter recited in claim 21 and its dependents.

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) (citing *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004)). 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. 32–33 (citing Ex. 2086, 1, 3). Patent Owner asserts that Petitioner subsequently introduced its own version of the XLIF system, "DLIF," in 2006. *Id.* at 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. (citing Ex. 2059, 4). Although this evidence 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 of the DLIF system, nor does Patent owner otherwise explain with specificity why the particular features required by claim 21, or any of the other challenged claims of the '356 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." PO Resp. 33 (citing Ex. 2066, 1) (emphasis omitted). Again, however, although this evidence 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, nor does Patent Owner otherwise explain with specificity why the particular features required by the claim 21, or any of the other challenged claims of the '356 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 '356 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 apparatuses recited in the challenged claims.

c. 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 Foley, Koros, Onimus, Mathews, Obenchain, and Kelleher, that an ordinarily skilled artisan would have been prompted to prepare a system having all of the elements of claims 21, 22, 24, 30, 33, and 34 of the '356 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 surgical systems recited in 21, 22, 24, 30, 33, and 34 obvious in view of Foley, Koros, Onimus, Mathews, Obenchain, and Kelleher.

2. Remaining Grounds

In the Institution Decision, in addition to the ground discussed above, we instituted review of (1) claim 35 for obviousness over Foley, Koros, Onimus, Mathews, Obenchain, Kelleher, and NIM Guide, and (2) claims 36 and 37 for obviousness over Foley, Koros, Onimus, Mathews, Obenchain, Kelleher, NIM Guide, and Jones. Dec. 26. Each of claims 35, 36, and 37 depends ultimately from claim 21, and adds additional features to the system recited in claim 21. Ex. 1018, 19:25–20:46. Petitioner cited the NIM Guide and Jones references to show that an ordinarily skilled artisan would have considered those features obvious components of the system suggested by Foley, Koros, Onimus, Mathews, Obenchain, and Kelleher. Pet. 48–51, 57–59. We have considered that evidence, and agree that the prior art teaches the remaining limitations of claims 35–37. Other than the arguments addressed above, Patent Owner does not assert specifically any defect in Petitioner's contentions or findings as to those grounds or references, nor does Patent Owner assert any defect or deficiency in our analysis of those grounds in the Institution Decision. *See* PO Resp. 47.[1] Accordingly, for the reasons discussed above, we conclude that Petitioner has shown by a preponderance of the evidence that claims 35–37 would have been obvious

[1] Patent Owner seeks to incorporate by reference the arguments made in its Preliminary Response into its Response. PO Resp. 47. As noted above, however, "[a]rguments must not be incorporated by reference from one document into another document." 37 C.F.R. § 42.6(a)(3).

to an ordinarily skilled artisan at the time the claimed subject matter was invented.

3. 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. Mot. to Exclude 3–4.

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. 6–7.

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. CONCLUSION

For the reasons given, we are persuaded that Petitioner has shown by a preponderance of the evidence that claims 21, 22, 24, 30, and 33–37 of the '356 patent are unpatentable based on the following grounds of unpatentability:

(1) Claims 21, 22, 24, 30, 33, and 34 under 35 U.S.C. § 103(a) as obvious over Foley, Koros, Onimus, Mathews, Obenchain, and Kelleher;

(2) Claim 35 under 35 U.S.C. § 103(a) as obvious over Foley, Koros, Onimus, Mathews, Obenchain, Kelleher, and NIM Guide; and

(3) Claims 36 and 37 under 35 U.S.C. § 103(a) as obvious over Foley, Koros, Onimus, Mathews, Obenchain, Kelleher, NIM Guide, and Jones.

IV. ORDER

It is ORDERED that claims 21, 22, 24, 30, and 33–37 of the '356 patent have been shown by a preponderance of the evidence to be unpatentable;

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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