NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

NUVASIVE, INC.,
Appellant

v.

ANDREI IANCU, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Intervenor

2017-1666

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. 95/001,888.

Decided: November 9, 2018

MICHAEL T. ROSATO, Wilson, Sonsini, Goodrich & Rosati, PC, Seattle, WA, argued for appellant. Also represented by SONJA ROCHELLE GERRARD; GRACE J. PAK, PAUL DAVID TRIPODI, II, Los Angeles, CA; RICHARD TORCZON, Washington, DC.

BENJAMIN T. HICKMAN, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA,

argued for intervenor. Also represented by THOMAS W. KRAUSE, FRANCES LYNCH.

Before NEWMAN, CHEN, and HUGHES, *Circuit Judges.*

CHEN, *Circuit Judge*

NuVasive, Inc. (NuVasive) appeals from the decision of the U.S. Patent and Trademark Office, Patent Trial and Appeal Board (Board) in an *inter partes* reexamination proceeding holding claims 17–22 and 24–27 of U.S. Patent No. 7,691,057 obvious. The '057 patent is directed to a surgical access system and related methods for creating minimally invasive operative corridors through tissue with significant neural structures. '057 patent col. 2 l. 61–col. 3 l. 7. Because the PTO admits that its construction of "lateral, trans-psoas path to the targeted lumbar spinal disc" was too broad, we modify its construction to align with the construction we adopted in *In re NuVasive, Inc.*, 693 F. App'x 893 (Fed. Cir. 2017) (*NuVasive I*) for a very similar term. As to secondary considerations, we conclude that the Board erred in finding no nexus between NuVasive's claimed method and its commercial "eXtreme Lateral Interbody Fusion" (XLIF) surgical technique. And we conclude that further fact finding is needed as to whether WIPO Publication No. WO 01/37728 (Kelleher) teaches a nerve-monitoring technique for the iliohypogastric and ilioinguinal nerves. Accordingly, we vacate the Board's obviousness determination and remand for the Board to conduct a new analysis consistent with this opinion.

BACKGROUND

A

Interbody fusion is a commonly used surgical procedure to address pain associated with damaged intervertebral discs. The procedure involves removing some or all of

a damaged disc and inserting an implant in place of the disc. There are three primary approaches to this spinal surgical area: posterior, anterior, and lateral. While the lateral approach (from the side of the patient's body) provides the most direct route to the disc space, one major obstacle is the lumbar plexus, a network of nerves originating in the spinal column and exiting through the opening of the lumbar vertebra. The lumbar plexus runs through the psoas muscle and is found in the posterior portion of the muscle. The nerves of the lumbar plexus innervate (*i.e.*, supply) the leg and pelvic region with sensory and motor neurons. Surgery through the lumbar plexus is challenging because the nerves are anatomically tethered to the spinal column so they cannot be easily moved out of the surgical path. And damage to the nerves in the lumbar plexus can have serious side effects, including motor function impairment and extreme pain.

As a result, before the patented method, surgeons traditionally performed interbody fusion procedures from the posterior aspect (back) or anterior aspect (front) of a patient. These approaches, however, also had their drawbacks. The posterior approach required removing the bony processes from the spine and was associated with a higher incidence of neural complications from damage to the paraspinal nerves emanating from the rear of the spinal column. The anterior approach risked damaging internal organs and major blood vessels.

NuVasive's '057 patent addressed these challenges by making a lateral approach through the psoas muscle safer. NuVasive markets this trans-psoas surgical system and procedure under the tradename "eXtreme Lateral Interbody Fusion" or "XLIF."

The '057 patent, entitled "Surgical Access System and Related Methods," covers a surgical access system and related methods for creating a minimally invasive operative corridor through tissue with significant neural struc-

tures. '057 patent col. 2 l. 61–col. 3 l. 7. This access system and related method involve: (1) distracting the tissue between the patient's skin and surgical target site to create a distraction corridor, (2) retracting the distraction corridor to establish and maintain an operative corridor, and (3) detecting the existence of neural structures before and during the establishment of the operative corridor. *Id*. at col. 3 ll. 8–19. Nerve-monitoring (*i.e.*, electromyography (EMG)) is accomplished with electrodes attached to the instruments used to create the operative corridor. *Id*. at col. 12 ll. 17–52. These electrodes emit a charge as the instruments advance through the body. *Id*. When the charge reaches a nerve, the nerve stimulates the muscle group it controls, and a surgeon observes the associated muscle twitch. *Id*. This muscle twitch data can also be fed into a graphical user interface that displays information about an instrument's direction and relation relative to nearby nerves. *Id*.

Claim 17, from which all of the challenged claims depend, covers NuVasive's surgical access system and related methods. It reads:

> A method of accessing a surgical target site within a spine, comprising the steps of:
>
> (a) creating a distraction corridor along a lateral, trans-psoas path to a targeted lumbar spinal disc in a lumbar spine using a distraction assembly comprising at least two dilators that are sequentially inserted along the ***lateral, trans-psoas path to the targeted lumbar spinal disc***, and performing neuromonitoring during at least a portion of the time the distraction assembly is used in creating the distraction corridor along the ***lateral, trans-psoas path***, wherein the neuromonitoring comprises causing the emission of a plurality of electrical stimulation signals from a stimulation electrode provided on a distal

portion of at least one component of the distraction assembly and monitoring for resulting electromyographic (EMG) activity after the emission of each stimulation signal, and wherein the component of the distraction assembly is coupled to a control unit of a neuromonitoring system that is capable of displaying to a user an indication of at least one of proximity and direction of a nerve to the stimulation electrode provided on the component of the distraction assembly based on the monitored resulting electromyographic (EMG) activity;

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

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

> (d) actuating said handle assembly to move said plurality of retractor blades to the open position so that the plurality of retractor blades create an operative corridor along the lateral, trans-psoas path to the targeted lumbar spinal disc;
>
> (e) releasably engaging a fixation element with at least one of the plurality of retractor blades so that a distal portion of the fixation element extends distally from the at least one retractor blade and penetrates into a lateral aspect of the lumbar spine, wherein the fixation element secures the at least one retractor blade to the lumbar spine;
>
> (f) inserting an implant through the operative corridor created by the plurality of retractor blades along the ***lateral, trans-psoas path to the targeted lumbar spinal disc***.

Id. at col. 16 l. 28–col. 17 l. 3 (emphases added).

Like the method claimed in the '057 patent, NuVasive's XLIF procedure involves inserting an implant through a trans-psoas operative corridor. The operative corridor is created by inserting sequential dilators along a lateral trans-psoas path to the lumbar spine. A retractor instrument is then advanced over the last inserted dilator, and a fixation element is engaged to maintain the operative corridor. During this process, EMG electrodes mounted on the surgical instruments and connected to NuVasive's NeuroVision® System allows surgeons to monitor the placement of the surgical instruments relative to nearby neural structures.

B

NuVasive sued Globus Medical, Inc. for infringement of the '057 patent on October 5, 2010, and Globus filed a request for an *inter partes* reexamination on February 8,

2012, relying on several prior art references. The Examiner ordered a reexamination on claims 17–22 and 24–27.

1. Prior Art

Kossmann[1] describes establishing a narrow operative corridor from the side of the patient's body to repair injuries to the spine. After making an incision, surgeons used a table-fixed retractor system to open the path to the affected vertebra. "To reach the vertebral bodies of the lumbar spine, the psoas muscle was mobilized at least in part and pushed backwards to reach the lateral aspect of the vertebra. . . . Splitting of the psoas muscle along its fibers had to be done in very athletic patients, since the excessive size of the muscle did not allow a direct lateral access to the vertebra." J.A. 12636. This splitting was performed using a "blunt dissection" technique involving the surgeon's finger or a wet sponge mounted on a stick to carefully separate the tissue. J.A. 12635–36.

Branch[2] discloses using a retractor for creating surgical access channels and specifically contemplates interbody fusion and disc replacement surgeries. '933 patent (Branch) col. 2 ll. 47–51. After a surgeon makes an initial incision, she sequentially advances dilators through the incision to gradually widen the space of the operative corridor. *Id.* Once the operative corridor is the desired size, the surgeon positions a retractor over the last inserted dilator to maintain a working channel. *Id.*

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[1] Thomas Kossmann et al., *Minimally Invasive Vertebral Replacement with Cages in Thoracic and Lumbar Spine*, 6 Euro. J. of Trauma 292–300 (2001).

[2] U.S. Patent No. 6,945,933, entitled "Instruments and Methods for Minimally Invasive Tissue Retraction and Surgery."

Koros[3] teaches a variable length retractor designed to "hold organs, muscles, arteries, and other tissue out of the way" during surgery. '139 patent (Koros) col. 1 ll. 34–50.

Kelleher[4] describes a system for "detecting the presence of a nerve near a surgical tool or probe." WO 01/37728 (Kelleher), Abstract. Kelleher observes that "it 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." *Id.* at col. 1 ll. 15–17. The detection system relies on EMG to detect responses in the muscles controlled by the relevant nerves. *Id.* at col. 10 ll. 7–9. The system employs surgical tools with electrified cannuale through which other surgical tools are introduced into the patient. *Id.* at col. 16 ll. 15–27. These electrified cannulae emit an electric charge, which stimulates nerves, and these nerves in turn stimulate certain muscle groups to twitch. *Id.* at col. 12 ll. 21–34. The relevant muscle groups for lumbar spinal surgery are those in the patient's legs. *Id.* at col. 21 ll. 15–25. NuVasive is the assignee of the Kelleher application.

2. First Office Action and Board Decision

In the first office action in the reexamination, the Examiner rejected the claims as obvious over Kossmann, Branch, Koros, and Kelleher. The Examiner found that Kossmann discloses a trans-psoas approach to spinal surgery; Branch teaches using a series of sequential dilators and a retractor assembly for creating an operative corridor; Koros describes fixation screws that screw into the vertebrae at opposite sides of an affected disc;

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[3] U.S. Patent No. 5,928,139, entitled "Retractor with Adjustable Length Blades and Light Pipe Guides."

[4] WIPO Publication No. WO 01/37728, entitled "Electromyography Systems."

and Kelleher discloses EMG nerve-monitoring. Because all these references pertain to minimally invasive surgical techniques, the Examiner found that it would have been obvious to a skilled artisan to combine them to arrive at the claimed surgical system and related method.

In response, NuVasive presented two theories of non-obviousness and testimony from Dr. Jim Youssef, an orthopedic surgeon, to support these theories. First, NuVasive argued that none of the prior art taught creating an operative corridor along a lateral, trans-psoas path using dilators and retractors, as recited in the claims of the '057 patent. Kossmann primarily discussed moving the psoas muscle aside and only mentioned splitting the psoas muscle along its fibers in athletic patients with large psoas muscles. Even in those patients, surgeons split the psoas muscle with blunt dissection (using a finger or sponge on a stick), not with dilators and retractors. Blunt dissection, NuVasive asserted, was safer than dilation and retraction because surgeons viewed a sponge or finger as a safer tool than a dilator or retractor. Second NuVasive argued that while Kelleher is directed to systems for detecting the presence of nerves during surgical procedures, it does not teach monitoring nerves along a "lateral, trans-psoas path to the targeted lumbar spinal disc." J.A. 348. NuVasive also argued that there was no reasoned explanation in the office action or reexamination request to support Globus's motivation to combine Kelleher with Branch, Kossmann, and Koros.

Globus responded with expert testimony from Dr. Isador Lieberman, an orthopedic surgeon specializing in spinal surgery. Dr. Lieberman rejected NuVasive's theory that "blunt dissection" was safer than using dilators and retractors. Dr. Lieberman explained that "both techniques do the exact same thing for the exact same purpose" and that "one of ordinary skill in the art would have understood how to penetrate a distractor and retractor assembly through the psoas muscle." J.A. 435. This is

because skilled artisans were familiar with how to split psoas-muscle tissue in line with its fibers to minimize damage to the nerves, and NuVasive's approach merely used ubiquitous surgical tools such as retractors to do so. Dr. Lieberman also opined that, because "Kelleher discloses a nerve detection system for use with surgical tools or probes for spinal surgery, one of ordinary skill in the art would understand how to [use it to] achieve an even greater ability to negotiate around important neuronal structures during trans-psoas operations." J.A. 436.

After considering the evidence, the Examiner concluded that the challenged claims would not have been obvious. The Examiner found that the prior art did not expressly teach dissection of the psoas muscle using a dilator and retractor, and "Kossman[n] [taught] using a trans-psoas approach for only a few patients and even then, using blunt dissection." J.A. 530–31. The Examiner also found that Kelleher did not explicitly teach using nerve-monitoring in the lateral, trans-psoas context even though Kelleher did teach its use in lumbar spinal surgery. Globus appealed to the Board.

The Board reversed the Examiner, finding the "blunt-dissection" methods described in Kossmann not meaningfully different from the '057 patent's dilators and retractor. Specifically, the Board found that the Examiner "erred in concluding that one of ordinary skill in the art would not have considered the use of a dilator, as taught by Branch, to be an alternative 'blunt instrument' suitable for use in a 'blunt dissection' of the psoas muscle." J.A. 955. "Branch evinces that a dilator is an alternative 'blunt instrument' that would appear to provide a more precise and gradually increasing pathway as compared to a surgeon's finger or wet sponge on a stick, as taught by Kossmann." J.A. 856. The Board also disagreed with the weight the Examiner placed on the fact that Kossmann disclosed only splitting the psoas muscle in very athletic patients. "[A]ny need or problem known in the field of

endeavor at the time of the invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007). Thus, the Board determined that the problem of providing a lateral approach in "very athletic patients" is a reason that the skilled artisan would have used a lateral trans-psoas approach as taught by Kossmann.

The Board also disagreed with the Examiner's findings on Kelleher. The Board found that it would have been obvious to a skilled artisan to look to Kelleher's nerve-monitoring system because Branch and Kossmann both teach the desirability of avoiding nerves in spinal surgery, and Kelleher itself discloses use in a minimally-invasive spinal surgical system.

3. Claim Amendment

The Board's reversal of the Examiner's decision created a new ground of rejection. 37 C.F.R. § 41.77(f) (2016). NuVasive chose to reopen prosecution rather than seek reconsideration of the Board's decision. NuVasive amended claim 17 to include the use of nerve-monitoring technology—a limitation already recited in some of the other challenged claims—and offered objective evidence of nonobviousness supported by the declarations of three witnesses. After NuVasive submitted its new evidence, and before the Examiner issued the next office action, NuVasive and Globus settled, and Globus ended its participation in the reexamination.

4. Second Board Decision

After the claim amendment, the Examiner once again found the claims to be nonobvious. Specifically, the Examiner found that none of the references taught nerve-monitoring during a lateral, trans-psoas spinal procedure. For Kelleher to be properly combined with the other references, the Examiner stated that, "Kelleher must

provide some suggestion or teaching to apply the taught neuromonitoring during a lateral trans-psoas spinal procedure." J.A. 2801. And Kelleher, the Examiner concluded, does not. *Id*. The Examiner also found NuVasive's objective evidence of nonobviousness persuasive. The Examiner cited an article touting "the use of real-time directional neuromonitoring to ensure a safe passage through the psoas-muscle," as "a feature contributing to the success of the patent under reexamination." J.A. 2802.

Although Globus had ceased its participation in the reexamination proceedings, the Examiner's patentability decision returned to the Board for review under 37 C.F.R. § 41.77(f). The Board once again reversed the Examiner. In its second decision, the Board offered three additional rationales and reiterated its previous reasoning to support its obviousness findings.

First, the Board construed the phrase "lateral, trans-psoas path to the targeted lumbar spinal disc." J.A. 8–10. While it previously did not feel the need to construe the term, the Board found construction necessary after NuVasive introduced objective evidence of nonobviousness. *Id*. The Board concluded that the broadest reasonable interpretation of the phrase "encompasses a path, to the lumbar spinal disc, which passes through any portion of the psoas muscle, regardless of the portion, and which is to the lateral side of the body, to any significant degree, as compared to an anterior puncture." J.A. 10.

Second, the Board once again disagreed with the Examiner that Kelleher must provide some suggestion or teaching to apply neuromonitoring to a lateral trans-psoas spinal procedure. The Board found that Kelleher's neuromonitoring technology achieves Kossmann's and Branch's desire to avoid nerves, and Kelleher itself discloses the use of nerve-monitoring in a minimally invasive spinal surgical system. The Board found that it "is of no

moment that the nerves sought to be avoided in Kossmann[‘s lateral approach] are the iliohypogastric and ilioinguinal nerves[;] these are still nerves that Kossmann teaches should be avoided in a lateral approach." J.A. 12. While these nerves may not be present in the psoas muscle, both are still part of the lumbar plexus, which the ’057 patented method seeks to avoid. The Board also rejected NuVasive's argument that Kossmann only teaches traversing a "safe zone" of the psoas muscle where the important neural structures do not reside. The ’057 patent does not define any particular "lateral, trans-psoas path to the targeted lumbar spinal disc," and the claims themselves do not recite the step of navigating through the lumbar plexus or any particular nerves. Thus even if Kossmann's lateral trans-psoas path does not implicate the majority of the lumbar plexus, because Kossmann expressly teaches avoiding the iliohypogastric and ilioinguinal nerves, the Board found that no additional nerves need be avoided for the prior art to suggest that a skilled artisan would be motivated to include a nerve-monitoring step during the creation of the operative corridor.

Third, the Board found that NuVasive's objective evidence carried little weight due to a lack of nexus with the challenged claims. "For objective evidence to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention." *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995). In particular, the objective indicia "must be tied to the novel elements of the claim at issue" and "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). The Board concluded that NuVasive had failed to prove this nexus based on two grounds. Using its construction of "lateral, trans-psoas path," the Board noted that claim 17 of the ’057 patent is not limited to the lateral approach used in the

XLIF procedure, but instead encompasses any psoas-traversing approach that is lateral to the midline to any significant degree. The Board thus found that the XLIF procedure, is not reasonably commensurate with the scope of the claims. J.A. 19–20.

Next, the Board found that NuVasive's evidence failed to adequately establish what actually comprises the XLIF procedure and whether it is encompassed by claim 17 of the '057 patent. While NuVasive did provide a claim chart mapping the features of claim 17 to its XLIF system and procedure, the Board concluded it was unable to discern whether the MaXcess® II Access System and NeuroVision® System, to which the chart refers, were part of the XLIF system. The Board also noted that NuVasive's marketing materials at times used XLIF as a marketing term to identify a surgical technique and used XLIF at other times to identify groups of products. The Board concluded that, "when [NuVasive] uses the shorthand term 'XLIF' in its Request [to Reopen Prosecution], without clarification, we are unable to associate [NuVasive's] objective evidence with particular products or features." J.A. 18. Thus, while NuVasive presented evidence of long-felt need, skepticism followed by praise and recognition, and commercial success, the Board was not persuaded by NuVasive's evidence due to this lack of nexus. The Board additionally found NuVasive's objective evidence of nonobviousness insufficient.

Taking all of the evidence into consideration, the Board concluded that claim 17 as amended, and the claims that depend therefrom, would have been obvious. NuVasive appeals the Board's second decision under 35 U.S.C. §§ 141 and 142. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

A

"Obviousness is a question of law based on underlying findings of fact." *In re Kubin*, 561 F.3d 1351, 1355 (Fed. Cir. 2009). We review the Board's decisions under the standards set forth in § 706 of the Administrative Procedure Act (APA). We set aside the Board's decisions if they are "arbitrary, capricious an abuse of discretion, or otherwise not in accordance with law" or "unsupported by substantial evidence." 5 U.S.C. § 706(2) (2012). We review the Board's legal conclusions de novo and its factual findings for substantial evidence. *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2016). A finding of fact is supported by substantial evidence if a reasonable mind might accept the evidence as adequate support for the finding. *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938). "If the evidence in [the] record will support several reasonable but contradictory conclusions, we will not find the Board's decision unsupported by substantial evidence simply because the Board chose one conclusion over another plausible alternative." *In re Jolley*, 308 F.3d 1317, 1320 (Fed. Cir. 2002).

B

NuVasive presents three primary arguments on appeal. First, NuVasive contends that the Board erred in its construction of the term "lateral, trans-psoas path to the targeted lumbar spinal disc." Specifically, NuVasive argues that the Board erred by failing to consider how the term "lateral" was used in the context of the '057 patent. Second, NuVasive claims the Board erred in disregarding the evidence of secondary considerations by using its overly broad claim construction of "lateral, trans-psoas path to the targeted lumbar spinal disc" to conclude that the claims were not reasonably commensurate with the objective evidence and that the Board misunderstood the scope of the XLIF procedure. Third, NuVasive argues

that the Board committed legal error because its obviousness determination lacks a motivation to combine the prior art references. We address each of these issues in turn below.

C

Because NuVasive's appeal turns in part on the construction of "lateral, trans-psoas path to the targeted lumbar spinal disc," we address the claim construction issue below first.

The Board construed the term "lateral, trans-psoas path to the targeted lumbar spinal disc" as encompassing "a path to the lumbar spinal disc, which passes through any portion of the psoas muscle, regardless of the portion, and which is to the lateral side of the body, to any significant degree, as compared to an anterior puncture." J.A. 10. NuVasive contends that this construction is unreasonably broad, and on appeal, the PTO concedes that the Board's construction might be too broad in light of our opinion in *In re NuVasive, Inc.*, 693 F. App'x 893 (Fed. Cir. 2017) (*NuVasive I*). We issued a non-precedential opinion in *NuVasive I* shortly after NuVasive filed its notice of appeal in this case. *NuVasive I* was an appeal from an *inter partes* review filed by Medtronic, Inc. on U.S. Patent No. 8,016,767, which shares a very similar specification with the '057 patent. 693 F. App'x at 894–95. We concluded there that the broadest reasonable interpretation of the phrase "lateral, trans-psoas path to the lumbar spine" was "an approach to the lumbar spine that (1) approaches from the patient's lateral aspect; and (2) goes through the psoas muscle." 693 F. App'x at 900–901.

In light of the similarities between the '767 and '057 patents,[5] and because the parties agree that the appropriate construction of "lateral, trans-psoas path to the targeted lumbar spinal disc" is that which we enumerated for "lateral, trans-psoas path to the lumbar spine" in *NuVasive I*, we adopt that construction here. *See* Oral Arg. 1:33–2:00, 3:57–4:19; Intervenor Br. at 33. We review the Board's obviousness decision in accordance with that construction below.

D

Because this new construction is directly implicated in the Board's analysis of secondary considerations, we address this issue next. The Board concluded that NuVasive's evidence of secondary considerations was unpersuasive because NuVasive had failed to establish a nexus between the claimed invention and the XLIF surgical technique. The Board provided two separate grounds for its conclusion.

Under the first ground, the Board concluded that the XLIF procedure was not reasonably commensurate to the scope of the claims because the claims broadly covered a "lateral, trans-psoas path" that "encompasses a path to

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[5] The '057 and '767 patents both disclose a surgical access system that includes a tissue distraction assembly, a tissue retraction assembly, and nerve-monitoring. '057 patent, abstract; '767 patent, abstract. They also share many similar specification passages as well as figures. *Compare* '057 Patent, Figures 2–5 and 16–18 *with* '767 Patent, Figures 9–12 and 20–22. The fields of invention in both patents are identical, the discussion of the prior art is substantially similar, and the surgical systems and related methods described in the preferred embodiments are likewise substantially similar. *See* '057 patent col. 1 l. 30–col. 2 l. 57; '676 patent col. 1 34–col. 2 l. 60.

the lumbar spinal disc, which passes through any portion of the psoas muscle, regardless of the portion, and which is to the lateral side of the body, to any significant degree, as compared to an anterior puncture." J.A. 10, 20. On appeal, the PTO acknowledged that that this particular finding might be in error after our construction of the term in *NuVasive I*. Intervenor's Br. at 47. And we find it to be in error because the Board's construction is broader than that which we adopt in this opinion.

Second, the Board found that the record NuVasive produced contained insufficient evidence to demonstrate whether its XLIF surgical technique is, in fact, what the '057 patent claims. Characterizing the evidence as "nebulous," the PTO argues on appeal that the XLIF Surgical Technique Guide (Guide) NuVasive submitted uses the XLIF tradename at times in a manner that excludes limitations of the '057 patent claims. For example, the Guide depicts dilators but does specify that these dilators are part of the XLIF instrument system; rather, these dilators are part of the MaXcess® II System. J.A. 2636. And the guide does not consistently identify nerve-monitoring as a component of the XLIF system. J.A. 2638. Rather, the NeuroVision® System appears to be a standalone nerve-monitoring product that can be used with XLIF. *Id*. We disagree.

After reviewing the Guide, we conclude that there is a nexus between the claimed invention and the XLIF surgical technique. The Board and PTO suggest that only surgical tools and techniques labeled with the XLIF tradename are part of the XLIF surgical technique. But the Guide reveals otherwise. The Guide describes the "XLIF® technique" as utilizing "a direct lateral, retroperitoneal approach to access the intervetebral disc without muscular disruption or trauma to nearby structures." J.A. 2631. It does not describe any other surgical procedures. And the Guide specifically identifies the MaXcess® II Access System, MaXcess® XLIF System, and Neuro-

Vision® System as part of the required instruments to successfully complete the technique. J.A. 2639 ("To successfully complete this technique, the following instruments are required: Radiolucent bendable surgical table, C-Arm, Light source, MaXcess® II Access System, MaXcess XLIF® System, Triad® General Instrument Tray, and NeuroVision® JJB System."). While the Guide does list the components of the "XLIF Instrument System," it is very clear that the actual XLIF surgical technique requires more than just these instruments; it utilizes the MaXcess® II Access, MaXcess® XLIF, and NeuroVision® Systems in addition to general surgical tools such as nerve retractors, disc cutters, and curettes that are traditionally employed in interbody fusion procedures. J.A. 2633.

At oral argument the PTO argued that the Board found insufficient nexus due to the "overlapping nature of the products in the field." Oral Arg. at 29:13–29:18. The '057 patent covers method claims whereas NuVasive's XLIF-related products cover methods, devices, and systems. *Id.* at 29:18–29:31. While we agree with this characterization, it does not speak to whether the scope of the claimed invention is reasonably commensurate with the XLIF surgical technique. Due to the various devices and systems used in the XLIF procedure such as the MaXcess® II Access, MaXcess® XLIF, and NeuroVision® Systems, it is possible that the commercial success evidence NuVasive presented did not come entirely from the XLIF surgical technique but rather also from the sales of these devices/systems for use in other surgical procedures. However, this does not mean that there is no nexus between the claimed invention and the XLIF surgical procedure.

Moreover, "[w]hen the patentee has presented undisputed evidence that its product is the invention disclosed in the challenged claims, it is error for the Board to find to the contrary without further explanation." *PPC Broad-*

band, Inc. v. Corning Optical Communications RF, 815 F.3d 734, 747 (Fed. Cir. 2016). Here, while the Board did provide further explanation in finding the evidence NuVasive produced too nebulous to associate NuVasive's objective evidence of nonobviousness with the XLIF surgical technique, we find this explanation unpersuasive. As explained above, we find that the Guide clearly lays out the devices and systems used in the XLIF surgical technique, some of which are not necessarily labeled with the XLIF tradename but are nonetheless utilized in the surgical technique.

On remand, the Board should reevaluate NuVasive's objective evidence of nonobviousness such as long-felt need, skepticism followed by praise and recognition, and commercial success under our finding that there is a nexus between the claimed invention and the XLIF surgical technique. Our nexus finding, of course, does not mean that these secondary considerations require a finding of nonobviousness. We simply require the Board to evaluate these secondary considerations when considering the obviousness inquiry as a whole. Further, we note that "evidence that widespread efforts by ordinarily skilled artisans had failed" is not necessarily required to show long-felt need. *Millennium Pharm. Inc. v. Sandoz, Inc.*, 862 F.3d 1356, 1369 n. 5 (Fed. Cir. 2017) ("Although '[e]vidence is particularly probative of obviousness when it demonstrates both that a demand existed for the patented invention, and that others tried but failed to satisfy that demand,' a patent owner may establish a long-felt need without presenting evidence of failure of others.") (quoting *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1082 (Fed. Cir. 2012)). And we also note that the Board should not dismiss the testimony of paid experts. While the Board can and should weigh the credibility of any expert testimony, it should not outright disregard expert testimony from a witness simply because that individual

is compensated for his time and expense in testifying. Nothing in our opinion in *InTouch Techs., Inc. v. VGo Communications, Inc.*, cited in the Board's decision, stands for the proposition that paid expert testimony cannot be used to establish nonobviousness. 751 F.3d 1327, 1352 (Fed. Cir. 2014).

E

Finally, we address the Board's analysis of the scope of the prior art and motivation to combine Kossmann, Branch, Koros, and Kelleher to arrive at the claimed invention in the '057 patent. NuVasive makes two primary challenges to the Board's obviousness analysis on appeal. First, NuVasive argues that there is no motivation to combine the surgery of Kossmann with the surgical tools of Branch and Koros. Second, NuVasive contends that there is no motivation to use the EMG nerve-monitoring technology taught in Kelleher during a lateral, trans-psoas surgical approach to the lumbar spine. We address each argument in turn.

As an initial matter, we note that the Board's overly broad construction of the term "lateral, trans-psoas path to the targeted lumbar spinal disc" did not disturb its motivation to combine the prior art references analysis. In *NuVasive I,* the primary dispute between the parties centered on the meaning of the word "lateral." 693 F. App'x at 898. The specification of the patent in that case distinguished the "lateral" approach from the "postero-lateral" and "antero-lateral" approaches. '767 patent col. 7 ll. 43–51. And all nine figures in the '767 patent showing a path from the surgical incision to the spine depicted what amounts to a "3 o'clock or 9 o'clock approach to the spine—essentially along a line 90° to a plane defined by the (roughly parallel) front-of-body midline and the spine," which is much more restrictive than the Board's interpretation that covered any approach "lateral, to any degree, as compared to an anterior puncture." 693 F.

App'x at 899 (citing the '767 patent, Figs. 1, 9–10, 12–15, and 17–18). Accordingly, we concluded in *NuVasive I* that the broadest reasonable interpretation of "lateral" was an "approach to the lumbar spine that (1) approaches from the patient's lateral aspect (or side); and (2) goes through the psoas muscle." *Id.* at 900–901. Here, it is undisputed that Kossmann teaches a lateral approach to the spine. J.A. 12634 (Figure 1G), J.A. 12635. Moreover, when asked at oral argument, NuVasive's attorney did not identify any part of the obviousness analysis other than objective evidence of nonobviousness analysis that relied on the Board's overly broad construction of "lateral, trans-psoas path to the targeted lumbar spinal disc." Oral Arg. at 5:50–6:55.

1. Kossmann, Branch, and Koros

With this in mind, we do not find that the Board erred in concluding that a skilled artisan would be motivated to combine the surgery described in Kossmann with the tools described in Branch and Koros. NuVasive argues on appeal that Kossmann does not teach a trans-psoas surgical approach using retractors and dilators. Rather, NuVasive posits that Kossmann teaches retracting the psoas muscle in most patients and only uses blunt dissection with a surgeon's finger or a sponge on a stick to create a path through the psoas muscle in very athletic patients. As a result, NuVasive argues that a skilled artisan would not have been motivated to modify the blunt dissection techniques in Kossmann with the dilation and retraction technique disclosed in Branch because blunt dissection is safer for patients. During blunt dissection, a surgeon carefully feels for nerves and can easily back off when near a nerve. Blunt dissection also splits the muscle along its fibers, thus ensuring that no muscle fibers are cut in the process of dissection. In NuVasive's view, this technique is not interchangeable with the dilator-retractor approach taught in Branch because a

dilator is a hollow tube that cuts through fibers as it is pushed through muscle.

While NuVasive's argument is not meritless, the Board's finding that a skilled artisan would have been motivated to combine Kossmann with Branch and Koros is supported by substantial evidence. Dilators and retractors are ubiquitous surgical tools that skilled artisans knew how to use to penetrate tissue. J.A. 435–438. We are not persuaded that these instruments are inherently less safe means for dissection than a surgeon's finger or a wet sponge on a stick, particularly when the skilled artisan also simultaneously employs nerve-monitoring technology. Instead, the Board's finding to the contrary is reasonable in light of Dr. Lieberman's testimony that "[t]he use of instruments such as dilation and retraction assemblies is no more invasive than the use of blunt dissection, both techniques do the exact same thing for the exact same purpose." J.A. 435. Further, Branch itself teaches a technique that uses sequential dilators to slowly increase the size of a surgical site, and it teaches that this technique is broadly applicable in the field of spinal surgery. This, the PTO argued, is precisely what a surgeon's finger or a sponge on a stick accomplishes.

NuVasive also argues that the Board failed to demonstrate why a skilled artisan would be motivated to modify Branch's retractor to incorporate a fixation element as taught in Koros. According to NuVasive, Koros discloses a retractor with protruding screws that are specifically designed for an anterior surgical approach and cannot be used along a "lateral, trans-psoas path" without significant redesign. *See* J.A. 4547. We do not find NuVasive's argument persuasive. Our case law does not require that the Board explain exactly how the fixation elements of Koros physically incorporate into Branch's retractor. We agree with the Board that a skilled artisan would have recognized the stability and support the fixation element in Koros could add to the retractor assembly taught in

Branch. "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *KSR*, 550 U.S. at 417. NuVasive has not shown why adding a fixation element to Branch would be beyond the abilities of a skilled artisan. NuVasive's expert testimony regarding the inoperability of the combination of Branch and Koros is mere speculation and conclusory. Accordingly, the Board's finding that a skilled artisan would have been motivated to combine Kossmann, Branch, and Koros is supported by substantial evidence.

2. Kossmann and Kelleher

Next, as to whether a skilled artisan would be motivated to use the EMG nerve-monitoring technology taught in Kelleher during a lateral trans-psoas surgery, we remand this issue to the Board for the parties to address whether Kelleher could be used to monitor the presence of the iliohypogastric and ilioinguinal nerves. We emphasize that the scope of this remand on motivation to combine references is for the parties to address this narrow question. NuVasive asserts on appeal that a skilled artisan would not use the EMG nerve-monitoring taught in Kelleher in the Kossmann procedure because: (1) Kossmann teaches an approach to the lumbar spine through the anterior-most fibers of the psoas, which is a "safe zone" where the important structures of the lumbar plexus do not typically reside, and for which visual detection of nerves is adequate; and (2) Kelleher does not teach that its nerve-monitoring technology can be used for detecting the iliohypogastric and ilioinguinal nerves Kossmann teaches to avoid.

We disagree with NuVasive that a skilled artisan would not be motivated to use neuromonitoring in the Kossmann procedure. Both Kossmann and Branch teach

the desirability of avoiding nerves for patient safety. Moreover, the '057 patent does not require that the trans-psoas approach go through a specific part of the psoas, such as the lumbar plexus. Simply because surgeons could perform the procedure described in Kossmann with visual detection alone does not mean that a skilled artisan would not be motivated to use neuromonitoring to further ensure patient safety.

However, we conclude that the Board's position that a skilled artisan would be motivated to use Kelleher's nerve-monitoring technique to detect the presence of the iliohypogastric and ilioinguinal nerves should be remanded for further development. The Board's original rationale was that nerve-monitoring in general would be beneficial in spinal surgeries due to the need to avoid nerves, and thus a skilled artisan would be motivated to use Kelleher's nerve-monitoring technique in Kossmann, even if Kossmann does not traverse the lumbar plexus. J.A. 962–63. In its Request to Reopen Prosecution, NuVasive argued that Kossmann does not mention any danger of encountering nerves when splitting the psoas muscle. J.A. 1064. The two nerves Kossmann mentions, the iliohypogastric and ilioinguinal nerves, do not reside within the psoas muscle but rather are nerves that lie in the vicinity of the abdomen. *Id.* In response to this, the Board acknowledged in its second decision that the iliohypogastric and ilioinguinal nerves are not located in the psoas muscle, but noted that they are both still part of the lumbar plexus, which is what the trans-psoas approach taught in the '057 patent seeks to avoid. J.A. 12 n. 4. Thus, the Board found it "of no moment that the nerves sought to be avoided in Kossmann are the iliohypogastric and ilioinguinal nerves[;] these are still nerves that Kossmann teaches should be avoided in a lateral approach, which includes the approach taught by Kossmann that involves splitting the psoas muscle." J.A. 12. The Board's second decision thus appears to rest on a specific

theory: that a skilled artisan would be motivated to use Kelleher's nerve-monitoring technology to detect the presence of the iliohypogastric and ilioinguinal nerves.

On appeal to us, NuVasive argues that Kelleher's EMG nerve-monitoring method is ineffective for monitoring these two nerves because these nerves do not supply motor neurons to the legs. The iliohypogastric and ilioinguinal nerves supply sensory neurons to the leg and pubic region and motor neurons to the internal and transverse abdominal muscles. J.A. 2503–2504. EMG, the nerve-monitoring technique taught in Kelleher, relies on the detection of motor neurons, not sensory neurons, and Kelleher teaches that the relevant muscles for nerve detection in lumbar spinal surgery are those in a patient's legs. J.A. 10200, 10215. Thus, according to NuVasive, Kelleher does not teach that the iliohypogastric and ilioinguinal nerves are among those that may be detected with EMG nerve-monitoring technology. The PTO does not directly respond to this argument. It generally asserts that nerves in the psoas muscle are no different from other nerves in the body and that surgeons would have viewed existing nerve-monitoring technology as appropriate for a lateral, trans-psoas approach.

While we understand the PTO's position that the Board was only responding to NuVasive's arguments regarding the iliohypogastric and ilioinguinal nerves in its second decision, the question of whether Kelleher's nerve-monitoring technique is applicable to the iliohypogastric and ilioinguinal nerves is a new finding that NuVasive has not had an adequate opportunity to address in the midst of this ever-evolving proceeding. Accordingly, we remand this very narrow issue to the Board. We also note that there is nothing in our opinion precluding the Board from returning to its original position—a finding that we do not review in this appeal—that a skilled artisan would have been motivated to use Kelleher's nerve-monitoring technique in Kossmann's lateral, trans-psoas procedure

because Kossmann generally teaches that it is desirable to avoid nerves during surgical procedures.

CONCLUSION

We have considered NuVasive's remaining arguments and find them unpersuasive. We modify the Board's claim construction of "lateral, trans-psoas path to the targeted lumbar spinal disc" and construe the term in accordance with our opinion in *NuVasive I*. We reverse the Board's finding of a lack of nexus between the method claimed in the '057 patent and NuVasive's XLIF surgical technique and remand for the Board to conduct a new analysis of secondary considerations consistent with our nexus finding. And we affirm the Board's remaining obviousness analysis except for its finding that a skilled artisan would have been motivated to use the nerve-monitoring technique taught in Kelleher to detect the iliohypogastric and ilioinguinal nerves. We remand this narrow issue pertaining to the motivation to combine Kossmann, Branch, and Koros with Kelleher to the Board for further consideration.

AFFIRMED-IN-PART, REVERSED-IN-PART, AND REMANDED

COSTS

No costs.