NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

IN RE: NUVASIVE, INC.,
Appellant

2015-1841

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2014-00075.

Decided: May 31, 2017

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

SARAH E. CRAVEN, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for intervenor Michelle K. Lee. Also represented by NATHAN K. KELLEY, THOMAS W. KRAUSE, JOSEPH MATAL, SCOTT WEIDENFELLER.

Before DYK, O'MALLEY, and TARANTO, *Circuit Judges.*

TARANTO, *Circuit Judge*.

NuVasive, Inc.'s U.S. Patent No. 8,016,767 (filed. Apr. 23, 2007) describes and claims surgical methods for inserting a spinal fusion implant along a lateral, trans-psoas path to the spine using nerve monitoring to avoid damaging sensitive motor neurons (particularly those in nerve-rich portions of the psoas muscle). After NuVasive asserted the '767 patent against Medtronic, Inc. in *Warsaw Orthopedic Inc. v. NuVasive Inc.*, No. 3:12-cv-02738-CAB-MDD (S.D. Cal.), Medtronic filed with the Patent and Trademark Office (PTO), under 35 U.S.C. §§ 311–312, a petition for an inter partes review (IPR) of claims 1, 2, 4, 5, 10, 15, 17, and 18 of the '767 patent. Acting as the delegee of the PTO's Director, 37 C.F.R. § 42.4(a), the Patent Trial and Appeal Board instituted a review of all of the challenged claims. Institution of Inter Partes Review, *Medtronic, Inc. v. NuVasive, Inc.*, No. IPR2014-00075, 2014 WL 1410362, at *13 (P.T.A.B. Apr. 8, 2014) (*Institution Decision*). After conducting the review, the Board held all the claims in the IPR to be unpatentable for obviousness under 35 U.S.C. § 103. Final Written Decision, *Medtronic, Inc. v. NuVasive, Inc.*, No IPR2014-00075, 2015 WL 1546572, at *23 (P.T.A.B. Apr. 5, 2015) (*Final Written Decision*).

In the present appeal, NuVasive challenges the Board's construction of the claim phrase "lateral, trans-psoas path," focusing its challenge on the term "lateral" in that phrase. NuVasive also challenges the Board's finding of a motivation to combine the prior-art references and its treatment of objective-indicia evidence, concerning commercial success, industry praise, and other non-prior-art considerations, that NuVasive presented in arguing against obviousness. We hold that the Board's claim construction was incorrect. We vacate the Board's decision and remand the matter.

I

A

One common treatment for chronic back pain is interbody spinal fusion surgery, in which the surgeon removes damaged disc material between vertebrae and inserts an implant in its place. According to the patent, prior-art methods of interbody fusion surgery generally required approaching the spine from the front (anterior) or back (posterior) of the patient. '767 patent, col. 2, lines 38–43. Those approaches each had recognized disadvantages—anterior approaches often required an additional surgeon to assist in navigating around the bowels and major blood vessels, while posterior approaches often required removing portions of the bony processes of the spine. *Id.*, col. 2, lines 44–57. Approaching from the side of the patient might avoid those particular problems, but the patent explains the risks of doing so: the insertion of instruments to create an operative corridor might damage the lumbar plexus, a bundle of leg-control nerves in the psoas muscle, which runs along the side of the lower spine. *Id.*, col. 2, lines 29–38.

The '767 patent proposes techniques that, in one featured application, would enable lateral access to a patient's spine "in spite of the neural structures required to be passed through (or near) in order to establish an operative corridor to the surgical target site." *Id.*, col. 6, lines 12–16. This is accomplished by equipping the surgical instruments used to create the operative corridor with electrodes. *Id.*, col. 6, lines 16–21; *id.*, col. 9, lines 61–66. The electrodes emit electrical signals that cause nearby nerves to depolarize, which in turn cause the muscles controlled by those nerves to contract. *Id.*, col. 9, line 66, through col. 10, line 11; *id.*, col. 11, lines 29–38. The effect on the muscles can be electromyographically monitored and communicated to the surgeon, enabling adjust-

ment of the path of the instruments to avoid the nerves. *Id.*, col. 10, lines 12–28.

The instruments that may be so equipped are: an "elongate stimulation instrument," including an inner wire housed within a narrow, initial dilating cannula, which is the first instrument advanced through the patient's body to the spine, *id.*, col. 8, line 67, through col. 9, line 26; a series of sequentially larger dilators, which are inserted over the initial dilator to widen the opening to the spine, *id.*, col. 9, lines 27–40; and a retraction assembly, which is inserted over the dilating cannulas and used to hold the operative corridor open when the dilating cannulas are removed, *id.*, col. 9, lines 40–66.

Claim 1 is representative but lengthy; we will not reproduce it here. It generally claims a "method of accessing a surgical target site" comprising the steps of inserting a nerve-sensing "elongate stimulation instrument . . . *along a lateral, trans-psoas path to the lumbar spine*"; activating the nerve monitoring capability of the elongate stimulation instrument; displaying received nerve-monitoring information on a screen; positioning an inner wire from the elongate stimulation instrument into the disc annulus "at the lateral aspect of the targeted spinal disc"; "advancing a plurality of sequential dilators to further dilate tissue *along the lateral, trans-psoas path to the lumbar spine* while the inner wire member remains engaged with the disc annulus"; advancing retractor blades over the dilators; removing the dilators; "removably engaging a fixation element" on the retractor; and "inserting an implant through the lateral operative corridor formed by the plurality of retractor blades *along the lateral, trans-psoas path*." '767 patent, col. 12, line 63, through col. 14, line 3 (emphasis added). Only the initial "elongate stimulation instrument" is required to have nerve-monitoring capability. All instruments are inserted "along a lateral, trans-psoas path," a limitation that is recited eight times in the claim.

B

In its petition, Medtronic rested its challenge on the following claim construction of "lateral, trans-psoas path to the lumbar spine": a "lateral approach refers to a path to the spine starting from the side of the patient, and a trans-psoas path is a path in which the surgical instrument(s) passes through the psoas muscle." J.A. 95–96 (explaining that, for purposes of its IPR challenge, Medtronic was accepting the claim constructions asserted by NuVasive in the related litigation). In its preliminary response, NuVasive specifically contested only one construction, not at issue here. Patent Owner NuVasive, Inc.'s Preliminary Response at 14, *Medtronic, Inc. v. NuVasive, Inc.*, No. IPR2014-00075 (P.T.A.B. Jan. 31, 2014), Paper No. 10.

The Board instituted a review on one ground—that claims 1, 2, 4, 5, 10, 15, 17, and 18 would have been obvious over a combination of U.S. Patent No. 6,945,933 (Branch); U.S. Patent No. 6,139,493 (Koros); International Publication No. WO 03/005887 (Blewett); and U.S. Patent No. 5,313,962 (Obenchain '962). *Institution Decision*, 2014 WL 1410362, at *10–13. Of the five claim terms for which Medtronic had proposed constructions in its petition, the Board addressed only the one NuVasive had specifically contested, giving other terms their ordinary meaning. *Id.* at *5–6.

NuVasive did not address the construction of "lateral, trans-psoas path" in its patent owner's response filed after the review was instituted. But it argued that Obenchain '962 did not disclose a "lateral, trans-psoas path" but instead was limited in its teachings to an "anterior or anterolateral" approach that traversed only the psoas muscle's "most anterior fibers," which do not contain the sensitive nerves that NuVasive's patent was designed to avoid. J.A. 429–30. NuVasive also presented evidence to support its contentions that there was a long-

felt need for a safe and reproducible lateral, trans-psoas approach before the priority date and that NuVasive's eXtreme Lateral Interbody Fusion (XLIF) surgical technique, which uses nerve monitoring to achieve safe passage through the psoas muscle, had first met with skepticism but later was praised, commercially successful, and the object of copying by competitors.

In its final written decision, the Board held that "the broadest reasonable construction, consistent with the specification of the '767 patent, of 'lateral, trans-psoas path to the lumbar spine,' encompasses a path, to the lumbar spine, which passes through any portion of the psoas muscle, regardless of the portion, degree, or extent of passage through the psoas, and which is lateral, to any degree, as compared to an anterior puncture." *Final Written Decision*, 2015 WL 1546572, at *6. With respect to the word "lateral," the Board's analysis was limited. It said that the specification did not define that word, and it relied on the deposition testimony of Dr. Obenchain, the inventor of the Obenchain '962 reference, that "[l]ateral would be anything that's basically lateral to an anterior puncture. I mean, again, you get into anterolateral or lateral, but it's a fairly broad basis as to what 'lateral' means." *Id.* (alteration in original).

The Board found that Obenchain '962 taught an approach "along the lateral, trans-psoas path," as the Board had construed that claim phrase. The Board explained that even if, as NuVasive contended, those of ordinary skill in the art would have understood the approach disclosed in Obenchain '962 as traversing only the neurologically safe, anterior-most portion of the psoas muscle, the challenged claims were not limited to traversing the dangerous, nerve-rich part of the psoas. *Id.* at *11. Furthermore, the Board found that "the Obenchain reference teaches expressly the suitability of a lateral, psoas-traversing pathway when performing minimally invasive surgery on the lumbar spine." *Id.* at *10. The Board cited

the following passage in Obenchain '962 as that "express" teaching:

> If desired, the surgery may traverse through the psoas muscle. Where the surgery site is between L5 and S-1, the dissection is preferably generally close to the midline[1] between the iliac branches of the great vessels. Alternatively, for example, where the patient has extensive abdominal adhesions, it may be preferred to use a lateral puncture of the abdomen to avoid bowel perforation, and entry into the disc space is lateral, traversing the psoas muscle, or immediately in front of it.

Obenchain '962, col. 6, lines 22–31.

The Board relied on Branch to disclose a method for accessing a surgical site on a spine using a guidewire, sequential dilators, and retractor blades; on Koros for teaching the use of fixation screws on retractor blades; and on Blewett to disclose the use of nerve-monitoring electrodes on tissue-distracting instruments. The Board found that "because Blewett teaches that its nerve monitoring system was desirable when performing spinal surgery potentially encountering nerve roots associated with the lumbar spine, . . . Blewett would have prompted an ordinarily skilled artisan, performing lumbar spinal surgery, to equip an initial tissue distracting instrument with an electrode for use in a nerve-monitoring system, as required by claim 1 of the '767 patent, when using the Obenchain reference's lateral trans-psoas approach." *Final Written Decision*, 2015 WL 1546572, at *12. The Board gave little weight to NuVasive's evidence of long-

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1 Obenchain '962 defines the "midline" as "a spatially defined line extending from the sternum through the umbilicus to the center of the pubic bone." Obenchain '962, col. 7, lines 11–13.

felt need, commercial success, etc., because NuVasive had "not show[n] a sufficient nexus between the claimed subject matter and the objective indicia." *Id.* at *22. The Board concluded that Medtronic had "shown by a preponderance of the evidence that an ordinarily skilled artisan would have considered the processes recited in claims 1, 2, 4, 5, 10, 15, 17, and 18 obvious in view of Branch, Obenchain, Blewett, and Koros." *Id.*

NuVasive appeals. While the appeal was being briefed, Medtronic withdrew, and the PTO's Director intervened to defend the Board's decision. Medtronic, Inc.'s Motion to Withdraw as Appellee, ECF No. 47 (Aug. 25, 2016); Order, ECF No. 48 (Aug. 30, 2016) (granting motion to withdraw); Notice of Intervention by the United States Patent and Trademark Office, ECF No. 49 (Sept. 29, 2016); *see* 35 U.S.C. § 143. We have jurisdiction. 28 U.S.C. § 1295(a)(4)(A).

II

NuVasive contends that the Board's construction of "lateral, trans-psoas path to the spine" is unreasonably broad. We agree.

A

The Board gives claims their broadest reasonable interpretation in light of the specification. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016). "Even under the broadest reasonable interpretation, the Board's construction cannot be divorced from the specification and the record evidence and must be consistent with the one that those skilled in the art would reach. A construction that is unreasonably broad . . . will not pass muster." *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (internal quotation marks and citations omitted). Here, the Board relied on expert testimony in reaching its claim construction, and we review its interpretation of that testimony, a

factual matter, for reasonableness under the substantial-evidence standard. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015); *Apple, Inc. v. Ameranth, Inc.*, 842 F.3d 1229, 1236 (Fed. Cir. 2016).

The Board was unreasonable in relying on Dr. Obenchain's testimony, given in response to questions about the meaning of the word "lateral" in the context of his own, prior-art patent, as establishing how a person of ordinary skill would understand "lateral" when considering the subject of the '767 patent. It is clear from the testimony surrounding the passage cited by the Board that his interpretation of "lateral" was specific to the context of one of his own patents, which he maintained discloses a species of anterior approach that does not involve traversing the nerve-rich part of the psoas. After quoting from U.S. Patent No. 5,195,541, a different Obenchain patent with a disclosure similar to that of the Obenchain '962 reference, NuVasive's attorney asked:

> Q. And *in that context* the term "lateral," are you referring to a true lateral, posterolateral?
>
> A. I'm *referring to a puncture that's generally in the lateral direction in the abdominal wall, not the disc space*, but the abdominal wall.
>
> Q. How would you equate this term "lateral" with respect to the terms we just refer to as respect to true lateral, posterolateral, anterolateral?
>
> MR. KANE: Object to the form.
>
> A. *In referring to an abdominal puncture*, it's less precise. Lateral would be anything that's basically lateral to an anterior puncture. I mean, again, you get into anterolateral or lateral, but it's a fairly broad basis as to what "lateral" means.

Videotape Deposition of Theodore Obenchain, M.D. at p. 35, line 16, through p. 36, line 5, *Medtronic, Inc. v. NuVa-*

sive, Inc., No. IPR2014-00075 (P.T.A.B. Dec. 3, 2014), Ex. No. 1039 (Obenchain Dep.) (emphases added). As this exchange illustrates, the word "lateral" can mean different things in different contexts. Indeed, when asked about the term "lateral" in the context of NuVasive's XLIF system, Dr. Obenchain had a different answer:

> Q. When you say "lateral," you're talking about a true lateral?
>
> A. Yeah, you could say 9 o'clock, 3 or 9 o'clock technique. I mean, there may be minor variations in that, but basically it's a lateral approach.

Obenchain Dep. p. 96, lines 11–21. Thus, even if we accept the Board's determination that Dr. Obenchain's testimony was credible, *Final Written Decision*, 2015 WL 1546572, at *6 ("Given Dr. Obenchain's qualifications, we credit his testimony on this issue." (citation omitted)), it was error for the Board to interpret Dr. Obenchain's statement that "lateral" meant "anything that's basically lateral to an anterior puncture" as establishing how a person of ordinary skill would read the term "lateral" in the context presented by the '767 patent.

In this court, the Director points to a portion of Dr. Obenchain's deposition not invoked by the Board. When asked "Is there a bright line distinction as to where a true lateral ends and a posterolateral begins?," Dr. Obenchain answered: "Not really. It's a continuum. 9 o'clock is pure lateral by my—by my nomenclature. 12 o'clock is pure posterior. Everything in between there is posterolateral, but it's not more further defined that that." Obenchain Dep. p. 34, line 20, through p. 35, line 2. But that testimony, like the excerpt the Board relied on, is not about "lateral" in the setting addressed in the '767 patent. The testimony simply responded to questioning about how to align a clock face with a patient's body to ensure that the attorney and Dr. Obenchain were referring to the same anatomical locations, unconnected to any particular

surgical technique. Immediately after this exchange, Dr. Obenchain specifically contrasted his statement that "lateral" is a "continuum" going all the way around a patient's body to how "lateral" is used in his own patent: "I'm referring to a puncture that's generally in the lateral direction in the abdominal wall, *not the disc space*"; "In referring to an abdominal puncture, it's *less* precise." The testimony reinforces the idea that "lateral" can mean different things in different contexts.

Beyond relying on an unreasonable interpretation of Dr. Obenchain's testimony, the Board had no meaningful basis for its interpretation. And that interpretation not only departs from the construction Medtronic accepted for purposes of its patentability challenges. It also runs counter to the specification of the '767 patent, which, though it does not define the term "lateral," does provide meaningful guidance.

The specification refers to a lateral approach as one that goes through the lumbar plexus nerves. '767 patent, col. 2, lines 36–38 ("[N]eural plexus structures in the psoas muscle have rendered a lateral or far lateral access path (so-called trans-psoas approach) to the lumbar spine virtually impossible."). It is relevant, in understanding the language of the just-quoted passage, that Dr. Obenchain testified about "a general understanding" before 2003 that "[f]ar lateral could . . . mean coming in, say, anywhere from maybe 8 to 10 o'clock. Somewhere in the . . . general 9 o'clock area." Obenchain Dep. p. 38, lines 3–6. The specification also distinguishes the "lateral" approach depicted in Figure 1 from "postero-lateral" and "antero-lateral" approaches. *Id.*, col. 7, lines 43–51 ("Moreover, although described and shown herein with reference to a generally lateral approach to a spinal surgical target site . . . , it will be appreciated that the retractor assembly 10 of the present invention may find use in any number of different surgical approaches, including generally posterior, generally postero-lateral,

generally anterior and generally antero-lateral."). And all nine figures that show a path from the surgical incision to the spine depict 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. *See* '767 patent, figs.1, 9–10, 12–15, 17–18.

Those disclosures indicate that the proper scope of "lateral" is more restrictive than the Board's interpretation, which covers any approach "lateral, to any degree, as compared to an anterior puncture."

The Director points to another part of the specification, which refers to the "surgical access system" as being "particularly suited for establishing an operative corridor to an intervertebral target site in a postero-lateral, trans-psoas fashion so as to avoid the bony posterior elements of the spinal column." '767 patent, col. 11, lines 50–54. The Director argues that the described postero-lateral approach is a preferred embodiment that should not be excluded from the claims, all of which recite a "lateral, trans-psoas approach." But the specification elsewhere distinguishes "lateral" from "postero-lateral"; and the specification describes many matters that are manifestly not covered by the claims, thus confirming that NuVasive has chosen not to claim all that the patent discloses. *See* '767 patent, col. 12, lines 31–44 (explaining that the "surgical access system of the present invention can be used in any of a wide variety of surgical or medical applications . . . including but not limited to discectomy, fusion (including PLIF [posterior lumbar interbody fusion], ALIF [anterior lumbar interbody fusion], TLIF [transforaminal lumbar interbody fusion] and any fusion effectuated via a lateral or far-lateral approach . . .), total disc replacement, etc"); *id. passim* (describing the "surgical access system" but claiming only methods). In these circumstances, the reference to a "postero-lateral" approach must be understood as distinct from, not included in, the claim term

"lateral." *See PPC Broadband, Inc. v. Corning Optical Commc'ns RF, LLC*, 815 F.3d 747, 755 (Fed. Cir. 2016).

Stripped of Dr. Obenchain's supporting testimony and read in conjunction with the specification, the Board's interpretation of the term "lateral" as "lateral, to any degree, as compared to an anterior puncture" is unreasonably broad. Indeed, the Board's construction seemingly drains the term of meaning in the claim phrase. The psoas muscle does not cross the midline, so any approach that traverses the psoas to get to the spine would seem to be "lateral" in the Board's sense. By claiming a "lateral, trans-psoas approach"—not a "trans-psoas approach" or a "postero-lateral, trans-psoas approach"—NuVasive must be taken to have limited its claim beyond what "trans-psoas approach" would cover. *Merck & Co., Inc. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) ("A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so."). The Board's interpretation does not give "lateral" that limiting function.

We note that NuVasive's brief repeatedly suggests that an approach "from the side" is necessarily one that passes through the *nerve-rich portion of* the psoas muscle. Appellant's Br. 43 ("Because the approach is from the side of the patient, the approach passes through the nerve-rich portion of the psoas muscle."); Appellant's Br. 46 ("[T]his Court should determine that 'lateral, trans-psoas path to the spine' as recited in the claims requires a lateral approach to the lumbar spine through the nerve-rich portion of the psoas muscle—in other words, an approach from the patient's lateral aspect (or side)."); Appellant's Br. 48 ("[T]he 'lateral, trans-psoas path to the lumbar spine,' as recited in the claims, requires an approach from the patient's lateral aspect (or side) to the lumbar spine through the nerve-rich portion of the psoas muscle."). But at oral argument in this court, NuVasive confirmed that it was not seeking to construe the phrase to require an

approach through the nerve-rich part of the psoas. Oral Arg. 12:49–13:41, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2015-1841.mp3.

A proper construction must be consistent with the specification, which demonstrates at least that a "lateral" approach is one that—without the claimed nerve monitoring—was rendered "virtually impossible" by "the exiting nerve roots and neural plexus structures in the psoas muscle." '767 patent, col. 2, lines 34–38. While the patent does not specify numerically what range of degrees around 90º (or around 270º) is covered by "lateral," Medtronic itself proposed that the term means from the patient's side. On the record before us, we conclude that the broadest reasonable interpretation is an "approach to the lumbar spine that (1) approaches from the patient's lateral aspect (or side); and (2) goes through the psoas muscle."

B

In finding that Obenchain '962 in fact discloses a "lateral, trans-psoas" approach, the Board relied on the claim construction we have concluded is unreasonably broad. We cannot say that the error was harmless in assessing what Obenchain '962 discloses—and there was no other reference found to have disclosed that claim element. We remand for the Board to apply the proper (broadest reasonable) construction in the first instance.

We briefly mention one aspect of Obenchain '962 that warrants attention on remand. Obenchain '962 states:

> [T]he patient is positioned in the supine or lithotomy position. While it is contemplated that the incision site for entry of the apparatus shown in FIGS. 1–6 can be located anywhere along the abdomen surface, the incision is preferably made below the epigastric and hypochondriac regions of the abdomen and is preferably *lateral, that is, to*

> *the right or left of the abdominal midline.* More preferably, the incision is directly adjacent to the abdominal midline. . . . As understood to those skilled in the art, laparoscopic trocars are punctured through the abdominal wall for insertion of multiple instruments for dissection and exposure of the front of the spine.

Obenchain '962, col. 7, lines 2–17 (emphasis added). This passage may suggest three things of possible relevance to whether the reference as a whole teaches what the '767 patent requires. One is that the patient is lying on his back. *See also id.*, col. 6, lines 5–7 (placing the patient on his back prior to the alleged "lateral, trans-psoas" disclosure in Obenchain '962); *compare* J.A. 6466 (showing, in the context of NuVasive's XLIF procedure, how to place the patient on his side in the "direct lateral decubitus (90°) position," and showing the surgeon leaning over the table to access the upward-facing side of patient). A second is that the passage may be defining "lateral," at least in the context of this example and perhaps for the entire patent, as simply to one side of the midline but still from the patient's front, not his side. A third is that the terms "abdomen" and "abdominal wall" may refer to anatomical locations on the front of the patient.

In highlighting the above passage and possible meanings, we are not drawing conclusions of our own. We note what the passage "may" suggest to focus attention on an aspect of Obenchain '962 that at present seems relevant and requires attention. We leave questions about what Obenchain '962 discloses to be answered initially by the Board.

III

For the foregoing reasons, we hold that the Board misconstrued "lateral, trans-psoas path," and we remand for consideration of whether Obenchain '962 discloses such a path under the proper construction. Although

NuVasive also contests the Board's finding of a motivation to combine and its treatment of NuVasive's objective evidence of nonobviousness, we do not address those matters here. The Board should reconsider those matters on remand in light of what it finds about Obenchain '962 using the proper claim construction.

VACATED AND REMANDED