NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

NUVASIVE, INC.,
Appellant

v.

ANDREW HIRSHFELD, PERFORMING THE FUNCTIONS AND DUTIES OF THE UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Intervenor

2020-1708

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

Decided: August 18, 2021

MICHAEL T. ROSATO, Wilson, Sonsini, Goodrich & Rosati, Seattle, WA, argued for appellant. Also represented by SONJA ROCHELLE GERRARD, JAD ALLEN MILLS; RICHARD TORCZON, Washington, DC.

MONICA BARNES LATEEF, Office of the Solicitor, United

States Patent and Trademark Office, Alexandria, VA, argued for intervenor. Also represented by BENJAMIN T. HICKMAN, THOMAS W. KRAUSE, FARHEENA YASMEEN RASHEED.

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

CHEN, *Circuit Judge*.

This *inter partes* reexamination of NuVasive, Inc.'s (NuVasive's) U.S. Patent No. 7,691,057 ('057 patent) appears before us a second time. The patentability of claims 17–22 and 24–27 under 35 U.S.C. § 103(a)[1] remains at issue. In the first appeal to our court, *NuVasive, Inc v. Iancu*, 752 F. App'x 985 (Fed. Cir. 2018) (*NuVasive I*), we vacated the Patent Trial and Appeal Board's (Board's) obviousness determination, overturning the Board's finding that NuVasive's "eXtreme Lateral Interbody Fusion" (XLIF) surgical technique lacked a nexus to the claimed method. We remanded for the Board to (1) conduct a new analysis of the objective indicia of nonobviousness consistent with our nexus finding, and (2) make sufficient factual findings to support its conclusion about the existence of a motivation to combine two prior art references.

After reconsidering the prior art references and NuVasive's objective evidence of nonobviousness, the Board again found that claims 17–22 and 24–27 would have been

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[1] Congress amended § 103 when it enacted the Leahy-Smith America Invents Act (AIA). Pub. L. No. 112-29, § 3(c), 125 Stat. 284, 287 (2011). As the challenged claims of the '057 patent have an effective filing date before March 16, 2013, the pre-AIA version of § 103 applies. *See id.* § 3(n)(1), 125 Stat. at 293.

obvious.[2] NuVasive challenges this holding. Because the Board's fact findings are supported by substantial evidence and its conclusion of obviousness is correct, we *affirm*.

BACKGROUND

A

Our prior opinion, *NuVasive I*, provides a thorough overview of the '057 patent and technical background. In relevant part, the '057 patent covers a surgical-access system and related methods for creating a minimally invasive operative corridor to the lumbar spine through the psoas muscle, a tissue comprising significant neural structures (e.g., the lumbar plexus, a network of nerves originating in the spinal column and exiting through the opening of the lumbar vertebra). '057 patent col. 2 l. 61–col. 3 l. 7. The access system and methods include detecting the presence of neural structures before and during establishment of the operative corridor. *Id.* at col. 3 ll. 14–19. Specialized nerve-monitoring (i.e., electromyography (EMG)) using electrodes attached to the surgical instruments employed for creating the operative corridor detects any nerves present. *See id.* at col. 12 ll. 17–52. The electrodes emit a charge as they go through the body, and if the charge reaches a nerve, the nerve stimulates the muscle group it controls, resulting in a muscle twitch. *See id.* When a surgeon observes a muscle twitch, the surgeon knows that the instrument may be too close to a nerve. *See id.* The data about muscle movement can also be fed to a graphical user interface that

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[2] The Board issued three decisions during this *inter partes* reexamination. The third decision, J.A. 1–37, is the subject of the present appeal. The second decision, J.A. 2895–2927, was the subject of the first appeal decided in *NuVasive I*. Following the Board's first decision, J.A. 957–79, NuVasive chose to reopen prosecution, J.A. 1058–90.

displays information to the surgeon about the instrument's direction and location relative to a nerve. *See id.*

Claim 17, from which all of the challenged claims depend, covers NuVasive's surgical method. NuVasive amended claim 17 during the reexamination proceeding to incorporate neuromonitoring. J.A. 1059–60. The amended claim, in relevant part, recites:

> 17. A method of accessing a surgical target site within a spine, comprising the steps of:
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> (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 . . . .

Id.

In *NuVasive I*, we ordered that the Board on remand "conduct a new [obviousness] analysis consistent with [our] opinion." 752 F. App'x at 986. Regarding the Board's position that a skilled artisan would be motivated to combine Kossmann[3] and Kelleher,[4] we observed that the Board's finding that Kelleher's nerve-monitoring technique is applicable to the iliohypogastric and ilioinguinal nerves—nerves Kossmann's lateral, trans-psoas spinal surgery technique sought to avoid—was a new finding that NuVasive never had an opportunity to address. *Id.* at 998–99. Therefore, in reconsidering obviousness, we instructed the Board to do further fact finding to address NuVasive's argument that Kelleher's nerve-monitoring technique could not detect the iliohypogastric and ilioinguinal nerves.[5] *Id.* at 986.

In considering NuVasive's objective indicia of nonobviousness, we found nexus between the claimed invention and NuVasive's XLIF procedure, noting that "the scope of the claimed invention is reasonably commensurate with the XLIF surgical technique." *Id.* at 995. Accordingly, we directed the Board to "reevaluate NuVasive's objective evidence of nonobviousness such as long-felt need, skepticism followed by praise and recognition, and commercial

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

[4] WIPO Publication No. WO 01/37728.

[5] In *NuVasive I*, we affirmed the Board's obviousness analysis as to the combination of Kossmann, Branch (U.S. Patent No. 6,945,933), and Koros (U.S. Patent No. 5,928,139). We concluded that substantial evidence supported the Board's finding that a skilled artisan would have been motivated to combine Kossmann's lateral, trans-psoas approach to spinal surgery with the surgical tools of Branch and Koros. 752 F. App'x at 997.

success" when "considering the obviousness inquiry as a whole." *Id.* at 996. Yet we made clear that our nexus finding did "not mean that these secondary considerations require[d] a finding of nonobviousness." *Id.*

B

On remand, the Board again found that claims 17–22 and 24–27 would have been obvious, doing so without additional briefing from the parties. The Board returned to its original position, articulated in its first decision, J.A. 971–73,[6] that a skilled artisan would have been motivated to use Kelleher's neuromonitoring in Kossmann's lateral, trans-psoas spinal surgery procedure because Kossmann teaches that it is desirable to avoid nerves during surgeries. J.A. 10. The Board withdrew its reliance on the theory that a skilled artisan would be motivated to use Kelleher's nerve-monitoring technique to detect the iliohypogastric and ilioinguinal nerves, explaining the withdrawal "render[ed] the need for additional briefing moot." J.A. 13.

Evaluating the objective indicia of nonobviousness, the Board did not find NuVasive's evidence of commercial success, long-felt need, skepticism followed by praise and

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[6] Before amendment during the reexamination, claim 17 did not recite any neuromonitoring, J.A. 10, but claim 19, dependent on claim 17, did, *id.* In finding original claim 17 unpatentable as obvious in the first decision, the Board relied on the combination of Branch, Koros, and Kossmann. *Id.* For claim 19, the Board used the combination of Branch, Koros, Kossmann, and Kelleher, finding that Branch and Kossmann "teach[] the [desirability] of avoiding nerves for patient safety and Kelleher's neuromonitoring would achieve this." J.A. 972. Thus, in the third decision, the Board "consider[ed] whether the amendments to claim 17 [overcame] the rejection originally applied to claim 19 further based on Kelleher." J.A. 10 n.11.

recognition, and copying "sufficiently persuasive [to] weigh in favor of nonobviousness[] in light of the teaching in the art." *Id.* at 35. Accordingly, the Board again concluded that amended claim 17, and claims dependent therefrom, would have been obvious to the skilled artisan at the time of the invention. J.A. 35. NuVasive appeals the Board's 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). The factual findings include "(1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art at the time the invention was made; and (4) objective evidence of nonobviousness, if any." *Id.*; *see also Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). Whether a person of ordinary skill in the art would have been motivated to combine references is also a factual finding. *See In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). We review the Board's legal conclusions de novo and its factual findings for substantial evidence. *Id.* 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). We review the Board's ultimate conclusion of obviousness de novo. *In re Mouttet,* 686 F.3d 1322, 1330–31 (Fed. Cir. 2012).

B

NuVasive presents three main arguments on appeal: (1) a skilled artisan would not be motivated to employ Kelleher's nerve-monitoring in Kossmann's lateral, transpsoas surgical approach to the lumbar spine; (2) the objective evidence of nonobviousness, including commercial

success, long-felt need, and skepticism followed by praise, provides a basis for reversal; and (3) the Board's remand decision is infirm because it improperly presented a new ground of rejection. We disagree and address each issue in turn.

1

Substantial evidence supports the Board's finding that a skilled artisan would be motivated to combine the neuromonitoring of Kelleher with the spinal surgery technique of Kossmann. NuVasive argues that a skilled artisan would not use Kelleher's EMG nerve-monitoring in the Kossmann procedure because (1) the evidence of record does not support a conclusion that nerve-monitoring would make Kossmann's approach safer, as Kossmann's surgical procedure already safely displaces nerves using visual detection alone and does not depart from the "safe zone"[7] of the psoas muscle; and (2) the Board cites no evidence that if Kossmann is limited to the "safe zone" of the psoas muscle, a skilled artisan would still employ neuromonitoring because nerves might be present. These arguments, however, were thoroughly addressed by us in *NuVasive I* or by the Board.

As stated in *NuVasive I*, "[w]e disagree with NuVasive that a skilled artisan would not be motivated to use neuromonitoring in the Kossmann procedure." 752 F. App'x at 998. Kossmann teaches "the desirability of avoiding nerves for patient safety." *Id.* "Simply because surgeons could perform [Kossmann's procedure] with visual detection alone does not mean that a skilled artisan would not be motivated to use neuromonitoring to further ensure patient safety." *Id.* With regard to NuVasive's contention

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[7] NuVasive argues that the anterior-most fibers of the psoas muscle are a "safe zone" where nerves do not reside. Appellant's Br. 25.

that Kossmann's procedure passes solely through the "safe zone," we again note that "the '057 patent does not require that the trans-psoas approach go through a specific part of the psoas [muscle], such as the lumbar plexus." *Id.* Instead, a surgeon performing the claimed method of the '057 patent could pass through the psoas muscle's alleged "safe zone."

Looking to the Board's remand decision, the record amply supports the Board's return to its original finding that a skilled artisan would have been motivated to use Kelleher's neuromonitoring in Kossmann's technique because Kossmann generally teaches it is desirable to avoid nerves during surgical procedures. Kossmann discloses a lateral, trans-psoas surgical procedure to repair spinal injuries, which involves splitting the psoas muscle in "some very athletic patients [because] the excessive size of the muscle did not allow . . . direct lateral access to the vertebra." J.A. 12732; *see also* J.A. 14. It was known in the art that nerves "form a complex and unpredictable maze within the psoas muscle," J.A. 2278–79 ¶¶ 18–19, and must be avoided during spinal surgeries, *see, e.g.*, *id.* ("Damage to the nerve roots exiting the spine into the psoas muscle can result in a wide variety of neurologic deficits, ranging from paralysis to variable loss of motor function throughout the lower extremities, and severe pain."). To help surgeons avoid nerves, Kelleher discloses a solution—EMG neuromonitoring. *See* J.A. 10276 (detailing that Kelleher's "invention relates to [EMG] and to systems for detecting the presence of nerves during surgical procedures"); *see also* J.A. 10285 (noting that Kelleher's "system involves applying a signal with a current level to a probe near a nerve and determining whether an [EMG] response for a muscle coupled to the nerve is present"). In view of these teachings, the Board reasonably found that a skilled artisan seeking to ensure patient safety during Kossmann's trans-psoas procedure would be motivated to select Kelleher's known nerve-monitoring technology. Doing so would be nothing "more than

the predictable use of prior art elements according to their established functions" to arrive at a method to monitor and avoid the psoas muscle's variable array of nerves. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 401 (2007); *see also* J.A. 11.

Even if Kossmann's procedure is limited to the psoas muscle's "safe zone," substantial evidence still supports the Board's finding that a skilled artisan would combine Kossmann and Kelleher. NuVasive contends that it presented unrebutted testimony that the "safe zone" was known to (1) "contain no underlying nerves," J.A. 2447; and (2) be "devoid of significant neural structures," J.A. 2442. But the record, as discussed by the Board, also includes evidence indicating that within the psoas muscle, a large degree of variation in the "network of important lumbar plexus nerve structures" exists, J.A. 2298 ¶ 63, and "nerves form a complex and unpredictable maze," J.A. 2278–79 ¶ 19. *See also* J.A. 2589–94. Unpredictable, variable nerve locations in patients create risk of serious nerve injury during spinal procedures. *See, e.g.*, J.A. 2278–79 ¶ 19; J.A. 2298 ¶ 63. Considered in its totality, this evidence supports the Board's conclusion that a skilled artisan performing Kossmann's technique, even only in the "safe zone," would have been motivated to use Kelleher's nerve-monitoring to ensure that the surgical path avoided nerves, making the procedure safer for patients. *See In re Jolley*, 308 F.3d 1317, 1320 (Fed. Cir. 2002) ("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."). Moreover, the Board's conclusion aligns with our statements in *NuVasive I* about a skilled artisan's motivation to use neuromonitoring in Kossmann's spinal surgery, discussed *supra*.

NuVasive also argues that the Board's finding that a skilled artisan would be motivated to use EMG nerve-

monitoring in Kossmann's approach is "an unsupported, hindsight-based reconstruction of the claims." Appellant's Br. 40. But the Board relied on the teachings of Kossmann and Kelleher as a whole, i.e., knowledge that was within the level of ordinary skill at the time the claimed invention was made. *See, e.g.*, *In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971) ("Any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper."). Further, the Board identified a reason to combine Kelleher and Kossmann: avoiding nerves for patient safety during a surgical procedure. Identification of such a teaching or motivation to combine in the prior art guards against any hindsight-based reconstruction of the claims. *See In re Gartside*, 203 F.3d at 1319 (noting "that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references" (internal quotations omitted)).

In view of the foregoing, we conclude that the Board's finding of a motivation to combine Kossmann and Kelleher, and, therefore, its finding of a motivation to combine Kossmann, Branch, Koros, and Kelleher, is supported by substantial evidence.

2

We next consider NuVasive's argument that the Board erred by ignoring NuVasive's objective evidence of nonobviousness. Objective indicia are an important part of the obviousness analysis and must, when present, be considered. *See Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012); *see also Graham*, 383 U.S. at 17–18. But even when

present, objective indicia "do not necessarily control the obviousness determination." *Bristol–Myers Squibb Co. v. Teva Pharms. USA, Inc.*, 752 F.3d 967, 977 (Fed. Cir. 2014). Here, the Board considered and weighed NuVasive's evidence of commercial success, long-felt need, and skepticism followed by praise and recognition. Substantial evidence supports the Board's conclusions on each of these objective indicia.

With respect to commercial success, we do not agree with NuVasive's contention that the Board ignored our finding in *NuVasive I* of a nexus between the claimed invention and the XLIF surgical technique. In fact, the Board explicitly acknowledged our finding of nexus but stated that "the weight to which the commercial success evidence is entitled could be impacted by the degree to which any success arguably turns on other factors, such as techniques not covered by the instant claims." J.A. 31.

Turning to the evidence presented, the Board found that NuVasive's revenue numbers were mainly due to sales of auxiliary products (e.g., implants, biologics, and disposables), not sales of the nerve-monitoring systems and surgical instrument sets recited in the claims. J.A. 32 (noting that the systems and instrument sets were loaned to surgeons at no cost). Although we do not necessarily agree with the Board that the claims must recite the particular products sold or how they are used to illustrate the claimed invention's commercial success,[8] *id.*, we understand the Board's position to be that NuVasive did not adequately

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[8] For example, if NuVasive could establish that sales of its auxiliary products were significant and due to customer desire to use these products in performing the claimed method and/or in gaining the rights to use the claimed method, then that might be an instance in which such sales could represent "commercial success" of the claimed method.

demonstrate that the XLIF procedure was the primary driver of auxiliary product sales. In other words, nothing in the record necessarily tied the sales of these products to customer demand for the XLIF procedure as opposed to other uses for the products. The Board also considered NuVasive's "minimally invasive fusion" market share data but found that NuVasive never explained which types of surgeries are part of that market and whether that market is much broader than the XLIF procedure. Ample record evidence suggesting that NuVasive's sales and market data for its sold products encompass more than just performance of the XLIF procedure supports these findings. *See, e.g.*, J.A. 2756 ("MaXcess[, NuVasive's minimally invasive spinal surgery system,] can be used for multiple surgical approaches, including TLIF [transforaminal lumbar interbody fusion], PLIF [posterior lumbar interbody fusion], ALIF [anterior lumbar interbody fusion] decompression . . . , and NuVasive's own XLIF procedure. The company continues to enhance its MAS [maximum access surgery] platform by launching new products designed specifically for the MaXcess approach."); J.A. 1826 ("NuVasive is actively expanding their MIS [minimally invasive surgery] product portfolio and has products in the TLIF, spinous process fixation[,] and other MIS segments."); J.A. 2142 ("The individual components of NuVasive's MAS platform, and many of the [c]ompany's products, can also be used in open or traditional spinal surgery.").

Because the Board did not disregard NuVasive's evidence of commercial success and NuVasive did not provide contextual information necessary to fully assess its sales and market data, we cannot say the Board's review of the evidence was legally erroneous or unsupported by the record. Substantial evidence thus supports the Board's conclusion that NuVasive's commercial success evidence was insufficient to alter the obviousness determination.

Additionally, the Board found that NuVasive did not establish a long-felt, unmet need for a lateral, trans-psoas

surgical method, a finding supported by substantial evidence. NuVasive asserts that to prove long-felt need, the Board impermissibly required NuVasive to show failure of others. But the Board merely concluded that the lack of widespread efforts by skilled artisans to develop a lateral, trans-psoas approach and the presence of alternative lateral approaches to the lumbar spine indicated no long-felt need for the lateral trans-psoas pathway existed.

As for skepticism followed by praise and recognition, NuVasive argues the Board erred by disregarding the evidence presented. The Board did not. Instead, the Board evaluated the evidence and gave little weight to hearsay and expert testimony and research funded by NuVasive. *See* J.A. 23, 27–28. Under a deferential substantial evidence standard, the record supports the Board's decision to afford this evidence minimal weight.

Balancing the Board's findings as to both the prior art and NuVasive's objective evidence of nonobviousness, we see no error in the Board's ultimate legal conclusion of obviousness. The objective evidence lacked sufficient weight in this instance compared to the persuasive evidence of obviousness found in the prior art. Thus, we agree with the Board's ultimate legal conclusion that claims 17–22 and 24–27 would have been obvious.

3

Finally, we consider NuVasive's argument that the Board's remand decision is infirm because it (1) "failed to permit NuVasive to address the Board's rejection of" amended claim 17; and (2) presented "a materially different argument that change[d] the thrust of the rejection," specifically, that a skilled artisan would use Kelleher's nerve-monitoring in Kossmann's approach to make it safer because nerves might be present in the psoas muscle's "safe zone." Appellant's Br. 62, 64.

But NuVasive had an opportunity to address the substance of the Board's rejection of amended claim 17, as the Board used the combination of Kossmann and Kelleher in its first decision, J.A. 971–73, to reject claim 19, a claim dependent from claim 17. When reopening prosecution after the Board's first decision, NuVasive amended claim 17 to include neuromonitoring similar to the monitoring recited in then-rejected dependent claim 19. At that time, NuVasive presented arguments against the Board's finding of a motivation to combine Kossmann's spinal procedure and Kelleher's nerve-monitoring because Kossmann generally teaches it is desirable to avoid nerves during surgical procedures. *See* J.A. 1067–69. The rationale underlying the Board's finding in its first decision is the same one the Board returned to in the remand decision.

Furthermore, the decision from remand did not change the thrust of the Board's rejection. As we already detailed in *NuVasive I*, a skilled artisan would be motivated to use neuromonitoring in Kossmann's surgery to make the procedure safer, whether passing through the "safe zone" or not. We see no error in the Board's obviousness conclusion.

CONCLUSION

We have considered NuVasive's remaining arguments and find them unpersuasive. For the reasons stated above, we affirm the Board's judgment as to obviousness.

AFFIRMED