United States Court of Appeals for the Federal Circuit

IN RE: NUVASIVE, INC.,

Appellant

2015-1670

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2013-00506.

Decided: December 7, 2016

MICHAEL T. ROSATO, Wilson, Sonsini, Goodrich & Rosati, PC, Seattle, WA, argued for appellant. Also represented by Andrew Swanson Brown; Richard Torczon, Washington, DC; Grace J. Pak, Paul David Tripodi II, Los Angeles, CA.

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

Before Moore, Wallach, and Taranto, Circuit Judges. Wallach, Circuit Judge.

Appellant NuVasive, Inc. ("NuVasive") appeals the final written decision of the U.S. Patent and Trademark

Office's ("USPTO") Patent Trial and Appeal Board ("PTAB"), finding claims 1–14, 19–20, and 23–27 of U.S. Patent No. 8,361,156 ("the '156 patent") invalid as obvious. See Medtronic, Inc. v. NuVasive, Inc., No. IPR2013-00506, 2015 WL 996352, at *2 (P.T.A.B. Feb. 11, 2015). We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A) (2012). We vacate and remand.

BACKGROUND

NuVasive is the assignee of the '156 patent, which generally relates to "[a] system and method for spinal fusion comprising a spinal fusion implant of non-bone construction releasably coupled to an insertion instrument dimensioned to introduce the spinal fusion implant into any of a variety of spinal target sites." '156 patent, Abstract. The '156 patent includes one independent claim (claim 1) and 26 dependent claims (claims 2–27). Illustrative claim 1 recites in relevant part:

A spinal fusion implant of non-bone construction positionable within an interbody space between a first vertebra and a second vertebra, said implant comprising:

. . .

at least first and second radiopaque markers oriented generally parallel to a height of the implant, wherein said first radiopaque marker extends into said first sidewall at a position proximate to said medial plane, and said second radiopaque marker extends into said second sidewall at a position proximate to said medial plane.

Id. col. 12 ll. 32–67 (emphases added).

In response to Medtronic, Inc.'s ("Medtronic") petition, the PTAB instituted the subject inter partes review to determine whether claims 1-14, 19-20, and 23-27 would have been obvious over, inter alia, a Synthes Ver-Spacer-PR brochure ("SVS-PR (J.A. 769–70), a Telamon Verte-Stack PEEK Vertebral Body Spacer brochure ("Telamon brochure") (J.A. 771–72), a Telamon Posterior Impacted Fusion Devices guide ("Telamon guide") (J.A. 773–82), and U.S. Patent Application Publication No. 2003/0028249 ("Baccelli") (J.A. 744-51). See Medtronic. Inc. v. NuVasive. Inc., No. IPR2013-00506, 2014 WL 1253040, at *11-12 (P.T.A.B. Feb. 13, 2014). The PTAB later issued the Final Written Decision concluding the claims would have been obvious over various combinations of, inter alia, the SVS-PR brochure, the Telamon brochure and Telamon guide (collectively, "the Telamon references"), and Baccelli. See Medtronic, 2015 WL 996352, at *14.

DISCUSSION

NuVasive argues that the PTAB's Final Written Decision should be reversed for two reasons: (1) "the [PTAB] erred in concluding that the SVS-PR brochure and Telamon references are printed publication prior art"; and (2) "the [PTAB] erred in concluding it would have been obvious to include radiopaque markers proximate to the medial plane." Appellant's Br. 22, 26 (capitalization omitted). After articulating the applicable standard of review, we address these arguments in turn.

I. Standard of Review

¹ Medtronic initially opposed NuVasive's appeal, but later withdrew as Appellee. The USPTO intervened pursuant to 35 U.S.C. § 143 (2012) and, although it did not file a brief, participated at oral argument.

We review the PTAB's factual determinations for substantial evidence and its legal determinations de novo. See In re Gartside, 203 F.3d 1305, 1316 (Fed. Cir. 2000). "Substantial evidence is something less than the weight of the evidence but more than a mere scintilla of evidence." In re Kotzab, 217 F.3d 1365, 1369 (Fed. Cir. 2000) (citation omitted). It is "such relevant evidence as a reasonable mind might accept as adequate to support a concluconclusion." In re Applied Materials, Inc., 692 F.3d 1289, 1294 (Fed. Cir. 2012) (internal quotation marks and citation omitted).

II. NuVasive Waived Its Arguments as to the PTAB's Treatment of the Prior Art References as Printed Publications

As an initial matter, the court must consider whether the SVS-PR brochure and Telamon references were publicly accessible such that they qualify as printed publications pursuant to 35 U.S.C. § 311(b)² and 35 U.S.C. § 102 (2006).³ Pursuant to § 311(b), "[a] petitioner in an interpartes review may request to cancel as unpatentable [one] or more claims of a patent only on a ground that could be

² Congress amended § 311 when it enacted the Leahy-Smith America Invents Act ("AIA"). Pub. L. No. 112-29, § 6(a), 125 Stat. 284, 299 (2011). Although the amendments to § 311 did not take effect until September 16, 2012, the amendments "apply to any patent issued before, on, or after th[e] effective date" and, thus, apply to the '156 patent. See id. § 6(c)(2)(A), 125 Stat. at 304.

³ Congress amended § 102 when it enacted the AIA. Pub. L. No. 112-29, § 3(b)(1), 125 Stat. at 285–87. However, because the application that led to the '156 patent was filed before March 16, 2013, the pre-AIA § 102 applies. See id. § 3(n)(1), 125 Stat. at 293.

We first must determine whether NuVasive preserved its public accessibility arguments for appeal. In appeals from the PTAB, "we have before us a comprehensive record that contains the arguments and evidence presented by the parties and our review of the [PTAB]'s decision is confined to the four corners of that record." *In re Watts*, 354 F.3d 1362, 1367 (Fed. Cir. 2004) (internal quotation marks and citation omitted). While the court "retains case-by-case discretion over whether to apply waiver," *Harris Corp. v. Ericsson Inc.*, 417 F.3d 1241, 1251 (Fed. Cir. 2005) (citations omitted), we have held that a party waives an argument that it "failed to present to the [PTAB]" because it deprives the court of "the benefit of the [PTAB]'s informed judgment," *Watts*, 354 F.3d at 1367–68.

NuVasive waived its public accessibility arguments before the PTAB and may not raise them on appeal. NuVasive challenged the public accessibility of the prior art references during the preliminary proceedings of the inter partes review, J.A. 159–63 (section of NuVasive's Preliminary Response that addresses public accessibility), but failed to challenge public accessibility during the trial phase, J.A. 227–93 (NuVasive's Trial Response that fails to address public accessibility). In fact, during oral argument before the PTAB, NuVasive explicitly declined to make further arguments as to public accessibility of the Telamon references:

[PTAB Judge]: I take it you no longer are disputing the public availability of the Telamon reference[s]?

[NuVasive's Attorney]: *That is correct*, we're leaving that issue aside. We're focusing *entirely* on the obviousness to modify these markers in the medial plane. We're not abandoning the other arguments in our Patent Owner response, specifically with the dependent claims, we're just not addressing them right now because they're already addressed.

So, we're going to assume that these are prior art....

J.A. 527 (emphases added). NuVasive abandoned its challenge to the public accessibility determination even though the PTAB had warned NuVasive that this would result in waiver. J.A. 201–02 (where the PTAB indicated in a scheduling order that "[t]he patent owner is cautioned that any arguments for patentability not raised and fully briefed in the response will be deemed waived"). Because NuVasive no longer contested the public accessibility of the prior art references, the PTAB did not address this issue in the Final Written Decision. See generally Medtronic, 2015 WL 996352. As a result, we do not have "the benefit of the [PTAB]'s informed judgment" on the public accessibility issue, Watts, 354 F.3d at 1368, and NuVasive waived its arguments on this issue.

III. The PTAB Did Not Adequately Explain How Claim 1 of the '156 Patent Would Have Been Obvious Over the Prior Art

Having determined that NuVasive waived its arguments that the SVS-PR brochure and Telamon references were publicly accessible prior art, we examine whether the PTAB adequately set forth findings and explanations to support the conclusion that a combination of these prior art references would have rendered claim 1 of the '156 patent obvious. It did not.

A. Legal Standard for Obviousness

A patent claim is invalid as obvious "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the [relevant] art [('PHOSITA')] " 35 U.S.C. § 103(a) (2006).4 The ultimate determination of obviousness is a question of law, but that determination is based on underlying factual findings. See Gartside, 203 F.3d at 1316. The underlying factual findings include (1) "the scope and content of the prior art," (2) "differences between the prior art and the claims at issue," (3) "the level of ordinary skill in the pertinent art," and (4) the presence of secondary considerations of nonobviousness such "as commercial success, long felt but unsolved needs, failure of others," and unexpected results. Graham v. John Deere Co., 383 U.S. 1, 17–18 (1966); United States v. Adams, 383 U.S. 39, 50–52 (1966).

In assessing the prior art, the PTAB "consider[s] whether a PHOSITA would have been motivated to combine the prior art to achieve the claimed invention." In re Warsaw Orthopedic, Inc., 832 F.3d 1327, 1333 (Fed. Cir. 2016) (internal quotation marks, brackets, and citation omitted); see KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 418 (2007) ("[I]t can be important to identify a reason that would have prompted a [PHOSITA] to combine the elements in the way the claimed new invention does."). Although we review this factual finding for substantial evidence, "[t]he factual inquiry whether to combine references must be thorough and searching," and "[t]he need

⁴ Congress amended § 103 when it enacted the AIA. Pub. L. No. 112-29, § 3(c), 125 Stat. at 287. However, because the application that led to the '156 patent was filed before March 16, 2013, the pre-AIA § 103 applies. See id. § 3(n)(1), 125 Stat. at 293.

for specificity pervades [our] authority" on the PTAB's findings on motivation to combine. *In re Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002) (internal quotation marks and citations omitted); *see id.* (stating that "[t]his precedent has been reinforced in myriad decisions[] and cannot be dispensed with" and listing supporting precedent).

B. The PTAB Failed to Articulate a Motivation to Combine the Prior Art References

NuVasive argues that, inter alia, the PTAB's Final Written Decision did not make adequately explained findings as to why a PHOSITA would have been motivated to combine the prior art references and place the radiopaque markers on the medial plane. Appellant's Br. 27–28. According to NuVasive, the PTAB relied on only one conclusory statement by Medtronic's expert that the modification would provide "additional information." *Id.* (emphasis omitted). We agree with NuVasive.

Two distinct yet related principles are relevant to our review. First, the PTAB must make the necessary findings and have an adequate "evidentiary basis for its Lee, 277 F.3d at 1344. findings." Second, the PTAB "must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (internal quotation marks and citation omitted); see Synopsys, Inc. v. Mentor Graphics Corp., 814 F.3d 1309, 1322 (Fed. Cir. 2016) (stating that, as an administrative agency, the PTAB "must articulate logical and rational reasons for [its] decisions" (internal quotation marks and citation omitted)).

This explanation enables the court to exercise its duty to review the PTAB's decisions to assess whether those decisions are "arbitrary, capricious, an abuse of discretion, or . . . unsupported by substantial evidence" 5 U.S.C. § 706(2)(A)–(E) (2012); see Dickinson v. Zurko, 527 U.S.

150, 152 (1999) (holding that § 706 governs our reviews of the USPTO's findings of fact and providing the framework for this review). We "cannot exercise [our] duty of review unless [we] are advised of the considerations underlying the action under review." SEC v. Chenery Corp., 318 U.S. 80, 94 (1943). Indeed, "the orderly functioning of the process of review requires that the grounds upon which the [PTAB] acted be clearly disclosed and adequately sustained." Id. Although we do not require perfect explanations, we may affirm the PTAB's findings "if we may reasonably discern that it followed a proper path, even if that path is less than perfectly clear." Ariosa Diagnostics v. Verinata Health, Inc., 805 F.3d 1359, 1365 (Fed. Cir. 2015) (citation omitted).

The relevant principles apply with equal force to the PTAB's motivation to combine analysis. Our precedent dictates that the PTAB must make a finding of a motivation to combine when it is disputed. See, e.g., Lee, 277 F.3d at 1343–45; see also KSR, 550 U.S. at 418 (stating that the PTAB's motivation to combine "analysis should be made explicit" (citation omitted)). Although identifying a motivation to combine "need not become [a] rigid and mandatory formula[]," KSR, 550 U.S. at 419, the PTAB must articulate a reason why a PHOSITA would combine the prior art references.

Our recent decisions demonstrate that the PTAB knows how to meet this burden. For example, in *Nike*, *Inc. v. Adidas AG*, we affirmed the PTAB's finding of a motivation to combine where it determined that a PHOSITA "interested in Nishida's preference to *minimize* waste in the production process would have logically consulted the well-known practice of flat-knitting, which eliminates the cutting process altogether." 812 F.3d 1326, 1337 (Fed. Cir. 2016) (emphasis added). Thus, a PHOSITA "would have been motivated to address the problem identified in Nishida by applying the teachings of the Schuessler References to arrive at the invention in

Id.Nike's proposed substitute claims." Similarly, in Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC, we affirmed the PTAB's explanation that "a skilled artisan could modify Caterpillar in view of Ogawa by treating the first jaw like the second" to "allow [] for a greater degree of movement between the jaws, without impacting the quick change functionality " 825 F.3d 1373, 1381 (Fed. Cir. 2016) (emphasis added) (citations omitted). In each of these cases, the PTAB identified a reason why a PHOSITA would have combined the prior art references—i.e., "minimiz[ing] waste" (Nike, 812 F.3d at 1337) and "allow[ing] for a greater degree of movement" (Allied, 825 F.3d at 1381)—that had a foundation in the prior art.

The PTAB must provide "a reasoned basis for the agency's action," and "we will uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Bowman Transp., Inc. v. Ark.-Best Freight Sys., Inc.*, 419 U.S. 281, 285, 286 (1974). The PTAB's own explanation must suffice for us to see that the agency has done its job and must be capable of being "reasonably... discerned" from a relatively concise PTAB discussion. *In re Huston*, 308 F.3d 1267, 1281 (Fed. Cir. 2002).

We have, however, identified some insufficient articulations of motivation to combine. First, "conclusory statements" alone are insufficient and, instead, the finding must be supported by a "reasoned explanation." *Lee*, 277 F.3d at 1342, 1345. Second, it is not adequate to summarize and reject arguments without explaining why the PTAB accepts the prevailing argument. *See Cutsforth, Inc. v. MotivePower, Inc.*, 636 F. App'x 575, 578 (Fed. Cir. 2016) ("The majority of the [PTAB]'s Final Written Decision is spent summarizing the parties' arguments and offers only conclusory analysis of its own. While the decision does specify when it is rejecting a party's argument, the [PTAB] does not explain why it accepts the remaining arguments as its own analysis.

This leaves little explanation for why the [PTAB] found the claimed invention obvious."). Third, although reliance on common sense may be appropriate in some circumstances, see KSR, 550 U.S. at 421 ("Rigid preventative deny factfinders recourse to sense . . . are neither necessary under our case law nor consistent with it."), the PTAB cannot rely solely on common knowledge or common sense to support its findings, see Arendi S.A.R.L. v. Apple Inc., 832 F.3d 1355, Cir. 1362 (Fed. 2016) ("[R]eferences to sense'...cannot be used as a wholesale substitute for reasoned analysis and evidentiary support "); see also In re Rouffet, 149 F.3d 1350, 1357 (Fed. Cir. 1998) (explaining that the Board of Patent Appeals and Interferences cannot simply invoke "the high level of skill in the art" as proof positive of its findings).

With these principles in mind, we turn to the PTAB's findings regarding motivation to combine. Here, the PTAB acknowledged that the key issue was "whether it would have been obvious to [a PHOSITA] to combine the cited references," Medtronic, 2015 WL 996352, at *6, and then found that independent claim 1 would have been obvious over a combination of Baccelli and either the SVS-PR brochure or the Telamon references, see id. at *5-8. In reaching this conclusion, the PTAB failed to explain the reason why a PHOSITA would have been motivated to modify either the SVS-PR or Telamon implants, in light of Baccelli, to place radiopaque markers "proximate to said medial plane" (i.e., near the middle of the implant), as the '156 patent teaches. The majority of the PTAB's analysis was limited to summaries of the parties' arguments, as the USPTO acknowledged during oral argument. Oral Argument at 14:30–15:55, http://oralarguments.cafc. uscourts.gov/default.aspx?fl=2015-1670.mp3. began by summarizing Medtronic's and NuVasive's arguments on whether the "additional information" that could be obtained from placing radiopaque markers near the middle of the implant would benefit a PHOSITA.

Medtronic, 2015 WL 996352, at *6-7 (citing, inter alia, J.A. 591 (Medtronic's expert's statement that a PHOSITA "would have considered it to be common sense" to place radiopaque markers along the medial plane "to provide additional information regarding the orientation or location of an implant")). The PTAB stated "[w]e are not persuaded by [NuVasive]'s argument, because the guestion is whether it would have been obvious to [a PHOSITAl to combine the cited references, and not whether any specific implants on the market contain a radiopaque marker in a central region." Id. at *6. addition, the PTAB invoked the high level of skill in the art when it "agree[d]" with Medtronic's assertion that "the addition of markers along the medial plane would not confuse" a PHOSITA and found that NuVasive's argument "vastly underestimates the ordinary skill of surgeons in this field." *Id.* at *7 (citation omitted). However, the PTAB never actually made an explanation-supported finding that the evidence affirmatively proved that the PHOSITA would have sought this additional information.

The PTAB avers that it "effectively" adopted Medtronic's arguments. Oral Argument at 14:52–15:11, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=20 15-1670.mp3, but the PTAB neither expressly did so nor provided reasoned explanations for crediting the arguments. Medtronic's arguments amount to nothing more than conclusory statements that a PHOSITA would have been motivated to combine the prior art references to obtain additional information. In its summary of Medtronic's arguments, the PTAB never articulated why the additional information would benefit a PHOSITA when implanting a posterior lumbar interbody fusion implant. such as the implants disclosed by the SVS-PR brochure and the Telamon references. It also failed to explain the type of additional information a PHOSITA would obtain or how the PHOSITA would use that information. Although the PTAB did "credit the testimony" of NuVasive's expert that placing radiopaque markers along the medial plane "would provide . . . better alignment of the implant," *Medtronic*, 2015 WL 996352, at *7 (internal quotation marks, brackets, and citation omitted), NuVasive's expert's statement was made in reference to benefits recognized *after* the priority date of the '156 patent, J.A. 4893 (explaining that these "uses were not disclosed in the cited prior art references"). This statement addresses neither the benefits that could have been obtained by combining the prior art references nor the PHOSITA's motivation to combine at the time of the invention.

In sum, the PTAB failed to articulate a reason why the PHOSITA would have been motivated to modify the SVS-PR or Telamon implants, in light of Baccelli, to obtain this additional information. Because we cannot "reasonably discern" the PTAB's reasoning as to motivation to combine, Ariosa, 805 F.3d at 1365 (citation omitted), judicial review cannot "meaningfully [be] achieved," Lee, 277 F.3d at 1342. Therefore, the PTAB's decision is vacated and the case remanded for additional PTAB findings and explanations regarding the PHOSITA's motivation to combine the prior art references.

CONCLUSION

We have considered the parties' remaining arguments and find them unpersuasive. For these reasons, the Final Written Decision of the U.S. Patent and Trademark Office's Patent and Trial Appeal Board is

VACATED AND REMANDED

Costs

Each party shall bear its own costs.