United States Court of Appeals for the Federal Circuit

IN RE: NUVASIVE, INC.,
Appellant

2015-1672, 2015-1673

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2013-00507, IPR2013-00508.

Decided: November 9, 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 THOMAS W. KRAUSE, SCOTT WEIDENFELLER.

Before MOORE, WALLACH, and TARANTO, *Circuit Judges.*

TARANTO, *Circuit Judge.*

NuVasive, Inc. owns U.S. Patent No. 8,187,334, which describes and claims implants for spinal fusion surgery.

Medtronic, Inc.—which settled with NuVasive and has withdrawn from the present appeals—filed two petitions for inter partes review with the Patent and Trademark Office, which the Patent Trial and Appeal Board instituted as IPR2013-507 (IPR507) and IPR2013-508 (IPR508). The Board ultimately cancelled all but one of the challenged claims under 35 U.S.C. § 103, finding in one prior-art reference, *i.e.*, Michelson's U.S. Patent No. 5,860,973, a spinal fusion implant that meets two of the claim requirements of the '334 patent—having a length both greater than 40 mm and at least 2.5 times its width. *Medtronic, Inc. v. NuVasive, Inc.*, IPR2013-507, 2015 WL 996353 (PTAB Feb. 11, 2015) (*IPR507 Board Decision*); *Medtronic, Inc. v. NuVasive, Inc.*, IPR2013-508, 2015 WL 996354 (PTAB Feb. 11, 2015) (*IPR508 Board Decision*).

On appeal, NuVasive contends that it did not receive adequate notice of or opportunity to address that reading of Michelson and its consequences for the overall obviousness analysis. We agree in part. In IPR507, Medtronic's petition put NuVasive on notice that Medtronic was relying on particular portions of Michelson to teach the '334 patent's claimed long-and-narrow implants. In that proceeding, we see neither procedural nor other error in the Board's decision, and we therefore affirm. In IPR508, however, Medtronic's petition did not notify NuVasive of the assertions about the pertinent portions of Michelson that later became critical. In that proceeding, we conclude, the Board's ultimate reliance on that material, together with its refusal to allow NuVasive to respond fully once that material was called out, violated NuVasive's rights under the Administrative Procedure Act. Our affirmance in IPR507 resolves the unpatentability of the '334 patent's claims 1–5, 10, 11, 14, 15, and 19–28, but claims 16 and 17 are at issue only in IPR508. We vacate the Board's IPR508 decision and remand for further proceedings on claims 16 and 17.

I

The spinal fusion implant of the '334 patent is designed to be inserted between two vertebrae to replace a damaged or diseased intervertebral disc. '334 patent, col. 1, lines 29–36. The implant shares many features with prior-art implants, such as anti-migration teeth to hold the implant in place, *id.*, col. 2, lines 40–52, vertical holes (fusion apertures) to allow bone to grow through the implant, *id.*, col. 5, lines 36–40, and horizontal holes (visualization apertures) so that a doctor can see such bone growth, *id.*, col. 5, lines 54–66. Although the patent itself does not limit the methods of inserting the implant, its long-and-thin design is particularly suited to an approach from the side, through the psoas muscle, rather than from the front or back of the patient. *Id.*, col. 5, lines 29–35. The focus of the obviousness issue now on appeal is certain dimensions of the claimed implant, specifically, a length that is both greater than 40 mm and at least 2.5 times the maximum width. The relevant part of claim 1, the only independent claim, reads:

> 1. A spinal fusion implant of non-bone construction positionable within an interbody space between a first vertebra and a second vertebra . . .
>
> wherein said implant has a **longitudinal length greater than 40 mm** extending from a proximal end of said proximal wall to a distal end of said distal wall;
>
> wherein a central region of said implant includes portions of the first and second sidewalls positioned generally centrally between the proximal wall and the distal wall, at least a portion of the central region defining a maximum lateral width of said implant extending from said first sidewall to said second sidewall, **wherein said longitudinal length is at least two and half [sic]**

> **times greater than said maximum lateral width** . . . .

'334 patent, col. 12, line 32, through col. 13, line 4 (emphases added).

NuVasive asserted the '334 patent against Medtronic in *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, No. 3:12-cv-02738-CAB-MDD (S.D. Cal.). Medtronic thereafter filed two separate petitions for inter partes review of the '334 patent under 35 U.S.C. §§ 311–319.[1]

Medtronic's petition in what became IPR507 relied primarily on U.S. Patent Application Publication No. 2002/0165550 (published Nov. 7, 2002) (Frey), which teaches an implant whose length is at least 2.5 times the width. As relevant here, Medtronic argued that it would have been obvious to modify Frey to have a length greater than 40 mm, as taught by Michelson. But in one brief passage, Medtronic's petition went further. In pointing out that Michelson also teaches many of the '334 limitations, Medtronic stated that "[l]ike Frey, Michelson discloses example lateral fusion implants having an elongated shape" and "dimensions that are longer than wide," citing Michelson, col. 10, line 6, through col. 11, line 15. J.A. 172. That cited range includes a discussion of Michelson's Figure 18, which shows an "alternative embodiment . . . 1000 . . . similar to the spinal fusion implant 900, but [which] has a narrower width such that more than one spinal fusion implant 1000 may be combined in a modular fashion for insertion within the disc space D between the adjacent vertebrae." Michelson, col. 10, lines 48–55.

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[1] Medtronic separately sought review of NuVasive's U.S. Patent No. 8,361,156. The Board decision in that review, IPR2013-506, is before this court in *In re NuVasive*, No. 2015-1670.

Medtronic's petition in what became IPR508 relied primarily on the Synthes Vertebral Spacer-PR Brochure, Synthes Spine 2002 (SVS-PR), and the Telamon Verte-Stack PEEK Vertebral Body Spacer Brochure and the accompanying Telamon Posterior Impacted Fusion Devices Guide 2003 (jointly, Telamon), which teach implants whose lengths are at least 2.5 times their widths. Medtronic argued that it would have been obvious to modify either SVS-PR or Telamon to have lengths greater than 40 mm, as taught by Michelson. But in the SVS-PR/Telamon petition, unlike the Frey petition, Medtronic did not include an assertion about or citation to material encompassing Michelson's Figure 18.

In response to Medtronic's petitions, the Board, exercising institution authority delegated by the PTO Director, 37 C.F.R. §§ 42.4, 42.108, determined that there was a reasonable likelihood that Medtronic would establish, by a preponderance of the evidence, that claims 1–5, 10, 11, 14, 15, and 18–28 would have been obvious over Frey, in view of Michelson. On that basis, the Board instituted IPR507. The Board made comparable determinations as to claims 1–5, 10, 11, and 14–28 based on either SVS-PR or Telamon, in view of Michelson and U.S. Patent Application Publication No. 2003/0028249 (published Feb. 6, 2003) (Baccelli). On that basis, the Board instituted IPR508. The two proceedings involve all the same claims apart from claims 16 and 17, which are the subject of IPR508, but not IPR507.

When NuVasive filed its Patent Owner Responses, it argued that no single reference taught an implant that was both longer than 40 mm and had a length at least 2.5 times its width. NuVasive pointed to Michelson's Figures 16 (showing long-and-wide rectangular implant 900), 19 (showing a plurality of "narrower" implants 1000 lined up in the disc space), and 20 (showing another long-and-wide rectangular implant), as evidence that a person of ordinary skill reading Michelson would size an implant to be

both long and wide (not long and narrow) in order to maximize the surface area of contact with the vertebrae, as taught by Michelson. NuVasive further argued that there was no reason for a person of skill in the art to combine the length of Michelson with the length-to-width ratio of the primary references, because doing so would make the resulting implant an unsuitable size for the intended insertion path of the primary references, which NuVasive contends were inserted from the front or back, not the side.

In its replies, Medtronic pointed to Michelson's Figure 18 specifically and argued that it disclosed an implant whose length was greater than 40 mm and at least 2.5 times its width.

NuVasive objected to Medtronic's argument regarding Michelson's Figure 18, which it contended was a new ground of invalidity asserted for the first time on reply. It requested leave to file motions to strike or, alternatively, surreplies, which the Board denied. NuVasive also attempted to address the matter at oral argument, but the Board refused to allow NuVasive to make substantive arguments in response. When Medtronic made arguments relating to Michelson's Figure 18 in its rebuttal time, NuVasive objected again, but the Board assured NuVasive that it understood NuVasive's position and would consider the propriety of Medtronic's arguments when making a final decision.

The Board ultimately held, in IPR507, that claims 1–5, 10, 11, 14, 15, and 19–28 would have been obvious over Frey and Michelson, but it upheld claim 18. In IPR508, the Board held that claims 1–5, 10, 11, 14–17, and 19–28 would have been obvious over either SVS-PR or Telamon in view of Baccelli and Michelson, but it upheld claim 18.

The Board's decisions relied heavily on its findings that Michelson, by itself, discloses both disputed dimensional limitations in a single implant—one whose length

is both greater than 40 mm and at least 2.5 times its width—so that no combining of references was needed to arrive at an implant that meets both requirements. Thus, in IPR507, the Board never found that Frey teaches an implant with a length at least 2.5 times the width. Rather, it found that if one combined (1) Michelson's teaching that the preferred overall width of the implant was 26 mm with (2) Michelson's teaching that at least two "narrower" implants could be combined to fit that space, then at least one of the "narrower" implants would be at most 13 mm wide, which is less than the preferred length (42 mm) divided by 2.5. *IPR507 Board Decision* at *5. On that basis, the Board concluded that "it would have been obvious to one of ordinary skill in the art to have provided an implant with a length of greater than 40 mm (e.g., 42 mm) and at least 2.5 times the width." *Id.* at *6.

Similarly, in IPR508, the Board did not find that SVS-PR or Telamon discloses an implant whose length is at least 2.5 times its width. Rather it "credit[ed] the testimony [submitted along with Medtronic's reply] of Petitioner's Declarant (Dr. Richard A. Hynes) that Michelson discloses a spinal implant with a length that is greater than 40mm and at least 2.5 times the width," made the same calculations it made in IPR507, and came to the same conclusion verbatim. *IPR508 Board Decision* at *4.

NuVasive appeals. Medtronic had cross-appealed from the Board's decisions regarding claim 18, but Medtronic later withdrew, and we dismissed, the cross-appeals (Nos. 2015-1674, -1712). The Director of the PTO intervened to defend the Board's rulings against NuVasive's inadequate-process challenges. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

II

Under the Administrative Procedure Act, we must "hold unlawful and set aside agency action . . . not in accordance with law [or] . . . without observance of proce-

dure required by law." 5 U.S.C. § 706. In the non-IPR setting, we have made clear that whether a ground the Board relied on was "new," requiring a new opportunity to respond, is a question of law, subject to de novo review. *See In re Stepan Co.*, 660 F.3d 1341, 1343 (Fed. Cir. 2011). No different standard of review is called for on the closely related issue in the IPR context. *See Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1080 (Fed. Cir. 2015) (noting similarity of issues). Obviousness is a question of law based on underlying determinations of fact. *See*, *e.g.*, *id.* at 1073. We review the Board's conclusions of law de novo and its findings of fact for substantial evidence. *Id.*

We first address NuVasive's procedural challenges to the Board's reliance on Michelson's Figure 18 in the two IPRs. We then address NuVasive's remaining challenges.

A

"A patent owner in [NuVasive's] position is undoubtedly entitled to notice of and a fair opportunity to meet the grounds of rejection," based on due-process and APA guarantees. *Belden,* 805 F.3d at 1080. "For a formal adjudication like the inter partes review considered here, the APA imposes particular requirements on the PTO. The agency must 'timely inform[]' the patent owner of 'the matters of fact and law asserted,' 5 U.S.C. § 554(b)(3), must provide 'all interested parties opportunity for the submission and consideration of facts [and] arguments . . . [and] hearing and decision on notice,' *id.* § 554(c), and must allow 'a party . . . to submit rebuttal evidence . . . as may be required for a full and true disclosure of the facts,' *id.* § 556(d)." *Dell Inc. v. Acceleron, LLC*, 818 F.3d 1293, 1301 (Fed. Cir. 2016) (alterations in original). While "the rules and practices of the Board *generally* protect against loss of patent rights without the required notice and opportunity to respond," *Belden*, 805 F.3d at 1080 (emphasis added), those rules and practices protect against such loss in a given case only when, upon a proper re-

quest, the PTO actually provides the opportunities required by the APA and due process.

1

Although the Board is not limited to citing only portions of the prior art specifically drawn to its attention, in this case it is clear that the Board treated Michelson's Figure 18 as an essential part of its obviousness findings identifying claim elements in the prior art. It relied on Michelson's Figure 18 and nothing else for a prior-art disclosure of an implant having a length that is greater than 40 mm and at least 2.5 times its width. The Board made no findings that another reference disclosed an implant having both those characteristics. Nor did it find that such dimensions would have been obvious even if not found together in a single piece of prior art. Nor, indeed, did the Board find a prior-art implant having a length at least 2.5 times its width and then explain the obviousness of a combination of that limitation with the distinct requirement of sufficient length.

We are in no position to treat the Board's finding about Michelson's Figure 18 as immaterial given the limited other findings so far made by the Board. Nor can this factual finding be analogized to others that merely reinforce the meaning of another prior-art disclosure. Thus, the Figure 18 finding did not "merely serve[] to describe the state of the art [at the time of the invention]," informing the understanding of another, separate prior-art disclosure of a claim limitation. *Genzyme Therapeutic Prods. Ltd. v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1368–69 (Fed. Cir. 2016) (finding that the Board did not violate the APA by citing references not part of the combinations set forth in the institution decisions where those references "merely served to describe the state of the art [at the time of invention]," and were "not among the prior art references that the Board relied upon to establish any claim limitations"); *Belden*, 805 F.3d at 1079 (noting that

certain explanatory evidence was not "necessary to the prima facie case").

Under the APA's standards, NuVasive was entitled to an adequate opportunity to respond to this asserted fact about Michelson. And under the APA's fact-specific standard, common sense, and this court's precedent, that entitlement was not lessened in this case by virtue of the opportunity NuVasive had to respond to *other* factual assertions about Michelson. In *Dell*, we held that an opportunity to respond was needed when the petitioner, to make its anticipation showing, newly pointed to a previously unmentioned portion of the allegedly anticipatory prior-art patent, even though it had earlier focused extensively on other portions of that prior-art patent. 818 F.3d at 1301. In the related, non-IPR context, we have relied on the APA's requirements to find a "new ground" where "the thrust of the rejection" has changed, even when the new ground involved the same prior art as earlier asserted grounds of invalidity. *In re Leithem*, 661 F.3d 1316, 1319 (Fed. Cir. 2011). Here, the assertion about Figure 18 on which the Board ultimately relied is sufficiently distinct from Medtronic's other assertions about Michelson that NuVasive was entitled to the APA-required opportunity to respond to it.

2

In IPR507, NuVasive had that opportunity. There is no dispute that NuVasive's Patent Owner Response was an adequate opportunity to respond *if* Medtronic's petition put NuVasive on notice of the assertion about Figure 18. In IPR507, we conclude that the notice was at least minimally sufficient.

In IPR507, Medtronic's petition cited the Michelson text that specifically discusses Figure 18 in addition to nearby figures in Michelson. The petition did so in asserting that the text shows "longer than wide" implants. J.A. 172. The only limitation in the '334 patent addressing a

comparison of length to width is the one requiring length at least 2.5 times width. It is true that Medtronic did not make a clear or direct reference to that limitation or a clear or direct assertion that the 2.5 ratio is shown in Michelson, in Figure 18 or elsewhere. But we think that the citation of the text discussing Figure 18, plus the reference to "longer than wide" implants, should have put NuVasive on notice that it was obliged to use its Patent Owner Response to address Figure 18 and its relationship to the length/width ratio claim limitation.

3

IPR508 is different. In that proceeding, Medtronic did not include in its petition the same citations to or assertions about the Michelson passage that it included in the IPR507 petition. In IPR508, unlike IPR507, there was no notice of the Figure 18 point before NuVasive filed its Patent Owner Response. The opportunity to file that Response therefore did not provide the required opportunity to address the factual assertion about Figure 18 on which the Board ultimately relied.

Despite the consolidated hearing in the two proceedings, the Board treated each inter partes review as a separate, distinct proceeding, and it issued separate final written decisions, independently invalidating some of the same claims based on different mixes of prior art. The Director has furnished no persuasive basis on which we are prepared to hold that a (barely sufficient) notice in one proceeding constituted an obligation-triggering notice in the other proceeding in which a comparable notice was missing. Nor do we see a basis for concluding that the Board could rely on the Figure 18 point in IPR508, where no sufficient notice was given, just because NuVasive chose, in cut-and-paste fashion, to include highly similar discussions of Michelson in its Patent Owner Responses in the two proceedings. We note that neither of NuVasive's Responses addresses Figure 18, even while they do

address some of the content of the Michelson passage cited by Medtronic in the IPR507 petition.[2]

Not until Medtronic's Reply, after NuVasive's Patent Owner Response, was NuVasive given fair notice in IPR508 of the Figure 18 factual assertion on which the Board eventually relied. But at no point after the Reply did the Board give NuVasive the required opportunity to respond to that point. Despite requests from NuVasive, the Board refused to permit NuVasive to file a surreply or even to address the matter during oral argument.

The Director points out that, although NuVasive was prohibited from filing a motion to strike or a surreply, it was permitted to cross-examine Dr. Hynes, the relevant expert for Medtronic, and to file "observations" on the cross-examination. We have identified such observations as among the vehicles available to protect against APA violations, but we have not declared that vehicle always sufficient to ensure the required opportunity to respond. *Belden*, 805 F.3d at 1081. Here, the opportunity to file observations was not enough. "Observations" are not a vehicle for submitting new evidence, including new expert declarations, by the patent owner. Indeed, the permitted content and format of observations are tightly circumscribed, *see* Office Patent Trial Practice Guide, 77 Fed.

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[2] What NuVasive said in its Responses was enough to allow the Board to conclude that Medtronic's Reply assertions about Figure 18 came within the rule that "[a] reply may only respond to arguments raised in the corresponding opposition, patent owner preliminary response, or patent owner response." 37 C.F.R. § 42.23(b). But satisfying that rule does not mean that the pre-Response notice was sufficient. *See In re Biedermann*, 733 F.3d 329, 338 (Fed. Cir. 2013) ("A new ground of rejection is not negated by the fact that the Board is responding to an appellant's argument.").

Reg. 48,756, 48,768 (Aug. 14, 2012), and here the Board rejected portions of NuVasive's observations for being too argumentative. We cannot view "observations" as a substitute for the opportunity to present arguments and evidence.

B

1

Finding no procedural violation in IPR507, we consider NuVasive's remaining arguments against the Board's obviousness ruling in that IPR. NuVasive contends that the Board impermissibly relied on speculation to find that Michelson taught an implant whose length is 2.5 times its width and that the Board did not sufficiently find a reason to combine Michelson with the primary references. We reject those contentions.

As to what Michelson discloses: Far from relying on speculation, the Board had a solid basis in Medtronic's argument and in Michelson itself for finding that Figure 18 disclosed an implant having both the length and width characteristics at issue. The Board "base[d] its decision on arguments that were advanced by a party," *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016), and, "[i]n the circumstances here," could permissibly "rely on its own reading of [Michelson]—supported by the Petition's observations about it"—to find that the claim-required implant characteristics were disclosed, *Belden*, 805 F.3d at 1074.

Medtronic pointed the Board to Figure 18 and the corresponding description as supporting the proposition that Michelson disclosed longer-than-wide implants. Michelson's specification expressly states that the preferred length of embodiment 900 was 42 mm and the preferred width was 26 mm. Michelson, col. 10, lines 42–47. It then states that "spinal fusion implant 1000 is similar to the spinal fusion implant 900, but has a narrower width

such that more than one spinal fusion implant 1000 may be combined in a modular fashion for insertion within the disc space." *Id.*, col. 10, lines 50–55. Figure 18 shows implant 1000, and Figure 19 shows three implant 1000s lined up in the disk space. *Id.*, Figures 18 & 19. Even if Figure 19 were taken as showing only two implants (its point is to show more than one), this is substantial, and anything but speculative, evidence from which to infer that at least one of the set of "narrower" implants must be at most 13 mm wide (at its maximum), which is less than the preferred length (42 mm) divided by 2.5 (16.8 mm).

As to reasons to combine: The Board did not have to find a reason that a relevant artisan would combine the length of an implant from one prior-art reference with the length-to-width ratio of an implant from another reference, because it found that Michelson disclosed an implant meeting both limitations. Although the Board did not make findings as to whether any of the other claim limitations (such as fusion apertures or anti-migration teeth) are disclosed in the prior art, it did not have to: NuVasive did not present arguments about those limitations to the Board.

NuVasive's arguments before the Board focused only on the dimensions of the implant—(1) that it would not have been obvious to modify Frey to have a length greater than 40 mm because it would make Frey unsuitable for its intended path of insertion, (2) that it would not have been obvious to lengthen Frey to be longer than the intra-annulus region in which Frey was intended to sit, and (3) that if a skilled artisan had undertaken to modify Frey according to Michelson, the resulting implant would have been long and wide (not long and narrow) because Michelson stresses the importance of maximizing surface-area contact with the vertebrae. Substantial evidence supports the Board's specific findings that (1) "a spinal implant measuring up to 45 mm in length" would not render Frey "inoperable" for its intended purpose, even if Frey were

limited to use in transforaminal lumbar interbody fusion (TLIF) procedures, *IPR507 Board Decision* at *4; (2) an implant could be longer than 40 mm and not violate the teaching of Frey that it fit within the inner-annulus region, *id.* at *4–5; and (3) Michelson in fact teaches the relevant long-and-narrow implants, *id.* at *5. This was sufficient to make an affirmative, supported case for the obviousness of the challenged '334 claims, given the limited arguments presented by NuVasive. The Board, having found the only disputed limitations together in one reference, was not required to address undisputed matters.

In particular, NuVasive argues on appeal (1) that a skilled artisan would never have made a long-and-narrow implant for any use other than as a component to be assembled into a single, oversized, modular implant; (2) that, given the state of modular implants at the time of the invention, no one would have tried to make one; and (3) that the boomerang-shaped Frey implant would not have been suitable to be modified to be modular. But NuVasive did not present any meaningful argument to that effect to the Board. The Board cannot be faulted for not addressing such an argument where, as we have determined for IPR507, NuVasive was on notice, before it filed its Patent Owner Response, that Michelson's Figure 18 could be used to disclose the dimensional limitations of the '334 patent and therefore was on notice that those dimensions might be combined with other prior-art references.

2

In IPR508, we have found a procedural violation. That finding does not support reversal of the Board's cancellations. Rather, it warrants a remand for further proceedings.

NuVasive relies on the Board's statements finding inadequate Medtronic's showings with respect to claim 18,

which requires particular dimensions—namely, a length greater than 40 mm and a maximum width of 18 mm. *See IPR508 Board Decision* at *8; *see also IPR507 Board Decision* at *6. But those statements do not entail a failure of proof of obviousness as to claims lacking the particular dimensional requirements of claim 18. They do not decide more generally that it would not have been obvious to combine "one dimension from one implant with a second dimension from another implant." Resp. & Reply Br. 30–31; *see id.* at 39–40. Nor do they preclude the Board from considering the import of Michelson's Figure 18 after giving NuVasive a full opportunity to submit additional evidence and arguments on that point. *See In re Kumar*, 418 F.3d 1361, 1367–69 (Fed. Cir. 2005).

CONCLUSION

For the foregoing reasons, we affirm the Board's final written decision in IPR2013-507, invalidating claims 1–5, 10, 11, 14, 15, and 19–28 and upholding claim 18. We vacate the Board's decision in IPR2013-508 and remand for further proceedings regarding claims 16 and 17 in accordance with this opinion.

No costs.

AFFIRMED IN PART, VACATED IN PART, AND REMANDED