NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

SURGALIGN SPINE TECHNOLOGIES, INC., FKA RTI SURGICAL, INC., Appellant

v.

LIFENET HEALTH, Cross-Appellant

2021-1117, 2021-1118, 2021-1236

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2019-00569, IPR2019-00570.

Decided: April 11, 2022

DAVID HEADRICK, McAndrews, Held & Malloy, Ltd., Chicago, IL, argued for appellant. Also represented by HERBERT D. HART, III, PETER LISH, BEN MAHON.

VINCENT JOHN GALLUZZO, Crowell & Moring LLP, Washington, DC, argued for cross-appellant. Also represented by MICHAEL H. JACOBS, SHANNON LENTZ.

Before NEWMAN, SCHALL, and PROST, *Circuit Judges*. Opinion for the court filed by *Circuit Judge* SCHALL. Opinion dissenting in part filed by *Circuit Judge*

NEWMAN.

SCHALL, Circuit Judge.

LifeNet Health ("LifeNet") is the owner of U.S. Patent No. 8,182,532 ("the '532 patent") and U.S. Patent No. 6,458,158 ("the '158 patent"). After LifeNet sued Surgalign Spine Technologies, Inc., formerly known as RTI Surgical, Inc. ("Surgalign"), for infringement of those patents, Surgalign petitioned the Patent Trial and Appeal Board ("Board") for inter partes review ("IPR") of both patents.¹ In the IPR for the '532 patent, the Board issued a final written decision in which it determined that Surgalign had proved claims 12–21 to be unpatentable but had not proved claims 4 and 6–11 to be unpatentable. Surgalign Spine Techs., Inc. v. LifeNet Health, No. IPR2019-00570, 2020 Pat. App. LEXIS 12593, at *76 (P.T.A.B. Aug. 26, 2020) ("532 FWD"). In the final written decision in the IPR for the '158 patent, the Board determined that Surgalign had failed to prove unpatentability for the claims of that patent, Surgalign Spine Techs., Inc. v. LifeNet claims 1-15. Health, No. IPR 2019-00569, 2020 Pat. App. LEXIS 12576, at *48 (P.T.A.B. Aug. 26, 2020) ("158 FWD").

Surgalign appeals the Board's determination that claims 4 and 6–11 of the '532 patent and claims 1–15 of the '158 patent were not proven to be unpatentable. LifeNet cross-appeals the Board's determination that claims 12–21 of the '532 patent were proven to be unpatentable. We affirm in part, reverse in part, and remand.

 $\mathbf{2}$

¹ LifeNet brought suit for infringement of three additional patents, and Surgalign sought IPRs for those patents as well. Those patents are not at issue in this appeal.

3

BACKGROUND

I. General

Some spinal injuries and diseases can be treated by surgical removal of all or part of an intervertebral disc and insertion of an implant that contacts the adjacent vertebrae. After the implantation procedure, the natural healing process of bones causes the vertebrae to fuse together over time. Implants for spinal fusion can be made from various materials, including bone obtained from the patient (autologous bone), or bone obtained from a human donor (allogenic bone). A bone graft made from autologous bone is referred to as an autograft; a graft made from allogenic bone is called an allograft.

Bones are comprised of cortical bone tissue and cancellous bone tissue. Cortical bone is strong and dense and supports the structural weight of the body, but is less receptive to cellular growth. Cancellous bone is soft, spongy, and has properties that promote the formation of bone, such as osteoconductivity.

II. The Patents

The '532 and '158 patents have substantially identical specifications and are both directed to bone grafts for use in spinal fusion. The patents purport to describe a composite bone graft that can be sized for any application, that promotes the growth of patient bone at the implantation site, that provides added stability and mechanical strength, and that does not shift, extrude, or rotate after implantation. '532 patent col. 1 ll. 33–37, col. 2 ll. 5–11; '158 patent col. 1 ll. 26–33, col. 2 ll. 1–7. Figure 1 of both patents depicts bone graft 1 having a cancellous bone portion 3 between a first cortical bone portion 2 and a second cortical bone portion 4. Bone pins 7 are provided in through holes 5.



'532 patent Fig. 1, col. 19 ll. 17–20, 67; '158 patent Fig. 1, col. 19 ll. 38–43.

Pertinent to Surgalign's appeal, independent claim 4 of the '532 patent recites a composite bone graft that includes two cortical bone portions that are "plate-like." '532 patent col. 46 ll. 52–55. Also pertinent to Surgalign's appeal, claim 4 of the '532 patent and all of the independent claims of the '158 patent (claims 1, 2, 13, 14, and 15) recite a composite bone graft that includes "bone pins." *Id.* col. 46 ll. 60–61; '158 patent col. 45 ll. 8, 20, col. 46 ll. 47, 66, col. 48 l. 15. These pins are generally made of allogenic cortical bone.

Pertinent to LifeNet's cross-appeal, independent claim 12 of the '532 patent recites that "one or more osteoconductive substances are *disposed between* [a] first cortical bone portion and [a] second cortical bone portion." '532 patent col. 47 ll. 60–62 (emphasis added).

4

 $\mathbf{5}$

III. The Prior Art

Three prior art references are relevant to this appeal: (1) U.S. Patent Application Publication No. 2002/0138143 to Grooms et al. ("Grooms"), J.A. 2494; (2) U.S. Patent No. 6,258,125 to Paul et al. ("Paul"), J.A. 2580; and (3) Wolter et al., "Bone Transplantation in the Area of the Vertebral Column," Accident Medicine: Scientific and Clinical Aspects of Bone Transplantation, vol. 185, pp. 166–75 ("Wolter"), J.A. 2657.²

Grooms describes "[a]n implant composed substantially of cortical bone" that is machined to form a "substantially 'D'-shaped" implant that has "a canal running therethrough" that may be filled with osteogenic, osteoinductive, or osteoconductive material. Grooms at Abstract, J.A.2494. Grooms explains that the D-shaped cortical bone implant can have "flat upper and lower surfaces." *Id.* at ¶33, J.A. 2520. Grooms Fig. 8A, below, shows implant 800 composed of two side-by-side halves, 801A and 801B.

² Citations to Wolter in this opinion refer to the English translation of the original German document. *See* J.A. 2672–707.



Grooms Fig. 8A & ¶ 49, J.A. 2506, 2523.

Paul describes an "allogenic intervertebral implant for fusing vertebrae" having "top and bottom surfaces [that] can be flat planar surfaces." Paul at Abstract & col. 2 ll. 17–18, J.A. 2580, 2589. Paul's Figure 9, below, shows a perspective view of one embodiment, where "[f]irst lateral sides 18 of first and second implants 70, 70' are scalloped to have a C-shape." *Id.* col. 5 ll. 13–16, J.A. 2591.

6





Paul Fig. 9, J.A. 2585.

Wolter describes a "composite corticospongial block" made of two or three pieces of autologous iliac crest bone, fastened together with a metal screw.³ J.A. 2697. Wolter states that it "appears to be necessary" to use "exclusively" autologous bone to make a graft because it is "the best transplant material," allogenic bone is "exposed to an elevated risk of infection and heal[s] more poorly," and "[e]very additional risk from the implant and transplant material should be avoided in the area of the vertebral column, since secondary operations have proven to be particularly difficult." J.A. 2660; *see also* J.A. 2665 ("Only autologous material should be used."). Figure 1e of Wolter

³ Iliac crest bone is bone harvested from a patient's ilium, the uppermost and largest part of the hipbone.

shows an exemplary corticospongial block, also referred to as a "sandwich block":



J.A. 2666.

IV. The IPRs

In the '532 FWD, the Board adopted Surgalign's initial proposed construction of "plate-like" in the '532 patent to mean "generally flat." '532 FWD, 2020 Pat. App. LEXIS 12593, at *31. The Board noted that Surgalign had made clear through its briefing and during the hearing that the "construction applies to the overall shape of the bone portion." *Id.*

Applying this construction and stating that it was considering the "overall shape, not merely whether [the bone portions] include a region that is generally flat," the Board determined that Surgalign had not shown that Grooms discloses cortical bone portions that are "plate-like." *Id.* at *49. The Board explained that it was not persuaded that Grooms's cortical bone portions are "generally flat," because they "have a generally flat base with legs or curved portions that extend away from the base so that the two

9

cortical portions meet away from the flat base portion." *Id.* The Board also determined that Surgalign had not shown that Paul discloses cortical bone portions that are "plate-like." *Id.* at *53–54. The Board noted that, "[w]hile certain surfaces of Paul's cortical bone portions could be considered generally flat, [it] assess[es] the overall shape of Paul's cortical bone portions to determine if they are 'plate-like." Doing so, the Board concluded they were not. *Id.* Having concluded that Grooms and Paul did not disclose "plate-like" bone portions, the Board determined that Surgalign had not proven that claim 4 and its dependent claims 6–11 were obvious.

Relevant to LifeNet's cross-appeal, in the '532 FWD, the Board construed the term "disposed between," as recited in claim 12 of the '532 patent, not to require that the first and second cortical bone portions be completely separated throughout the graft. Id. at *29. The Board began by noting that "[l]ooking only at the words of the claim, ... the ordinary meaning of 'disposed between' does not require complete separation." Id. at *25. The Board found persuasive that claims 1 and 2 of the related '158 patent include the same "disposed between" language and also recite that the first and second cortical bone portions "are not in physical contact." '158 patent col. 45 ll. 5–11. Citing to Trustees of Columbia University v. Symantec Corp., 811 F.3d 1359, 1369 (Fed. Cir. 2016), and Stumbo v. Eastman Outdoors, Inc., 508 F.3d 1358, 1362 (Fed. Cir. 2007), the Board stated that "[i]f 'disposed between' required complete separation . . . there would be no need for claims 1 and 2 [of] the '158 patent to additionally recite that the first and second cortical bone portions are not in physical contact." '532 FWD, 2020 Pat. App. LEXIS 12593, at *25-26. The Board acknowledged that the "consistent usage" of "disposed between" in the specification "provides some support" for a construction requiring complete separation, but it concluded that that usage was "outweighed by the contrary evidence, particularly the breadth of the claim

language itself and the differences between claim 12 of the '532 patent and the claims of the related '158 patent." *Id.* at *29. Applying this construction, the Board held that Grooms rendered obvious independent claim 12, and its dependent claims 13–21 of the '532 patent. *Id.* at *35–37, 47– 48. It did so because it agreed with Surgalign that Grooms teaches placing osteoconductive substances in the canal of the implant, i.e., between the cortical bone portions shown in Fig. 8A above. The Board thus determined that Surgalign had shown that claims 12–21 of the '532 patent were unpatentable.

In both IPRs, Surgalign challenged the patentability of various claims over Wolter alone or in combination with other references. *See* '532 FWD, 2020 Pat. App. LEXIS 12593, at *55–56 (claims 4 and 6–11 of the '532 patent); '158 FWD, 2020 Pat. App. LEXIS 12576, at *19, 24, 38–41 (claims 1–15 of the '158 patent). Surgalign's arguments required modifying Wolter in two ways: (1) to use allogenic bone instead of autologous bone; and (2) to use a bone pin instead of a metal screw. '532 FWD, 2020 Pat. App. LEXIS 12593, at *56; '158 FWD, 2020 Pat. App. LEXIS 12593, at *56; '158 FWD, 2020 Pat. App. LEXIS 12576, at *8, 19, 22–23.⁴

In its final written decisions, the Board determined that the challenged claims would not have been unpatentable over Wolter. The Board's conclusion hinged on its

⁴ Surgalign's proposed combination required the first modification even for claims that did not specifically recite using allogenic bone. '532 FWD, 2020 Pat. App. LEXIS 12593, at *57–58 & n.20; '158 FWD, 2020 Pat. App. LEXIS 12576, at *19, 22–23 & n.18.

The second modification of Wolter was required because Wolter describes fastening pieces of bone with a metal screw, whereas claims 4 and 6–11 of the '532 patent and claims 1–15 of the '158 patent recite using non-metallic "bone pins."

11

determination that an ordinarily skilled artisan would not have been motivated to modify Wolter in the proposed manner (using allogenic bone instead of autologous bone and using a bone pin instead of a metal screw) and would not have had a reasonable expectation of success in doing so. '158 FWD, 2020 Pat. App. LEXIS 12576, at *24–37.⁵ Specifically, the Board determined that an ordinarily skilled artisan would not have been motivated to modify Wolter's sandwich block to use allogenic bone against the reference's teachings that autologous bone was preferable. Rejecting Surgalign's arguments that Wolter's teaching away from allograft in 1987 would be "outdated" by 1999, the Board credited the explanation of Surgalign's expert, Dr. Jeffrey Fischgrund, that allografts were "already known, available, and used by the time Wolter was published." Id. at *23, 27. The Board also relied on testimony from LifeNet's expert, Dr. Mark Shaffrey, that "it makes no sense to make an allograft by stacking two or three iliac crest bones" because their irregular surfaces would prohibit a precise fit between the bone blocks. Id. at *30. The Board also was persuaded that Wolter was "tailored to the demands of filling a large defect using an autograft that can be made during surgery." Id.

Turning to whether one of skill in the art would have been motivated to replace Wolter's metal screw with a bone pin, or would have had success in doing so, the Board concluded that Surgalign had not proved this to be the case. The Board agreed with LifeNet that substitution of a bone pin would run counter to Wolter's goal to fulfill a recognized need for "a transplant that is as large and stressable as possible," because bone pins are weaker than metal screws. *Id.* at *32–33 (quoting J.A. 2661). The Board also found persuasive evidence that there would be "technical

⁵ To avoid duplication, we cite only to the '158 FWD when discussing the Board's analysis of Wolter.

difficulties" in making the proposed substitution. Id. at *31–33. In making this finding, the Board found persuasive LifeNet's arguments and supporting testimony from Dr. Shaffrey and LifeNet employee Mr. Barton Gaskins that it would be difficult to line up Wolter's stack of large, irregularly shaped pieces of iliac crest bone, and that it is doubtful that a bone pin could withstand the force needed to impel it through the three sections and their irregular interfaces. Id. at *33–35, citing J.A. 4724, J.A. 4769.

As noted, Surgalign appeals the Board's determination that claims 4 and 6–11 of the '532 patent and claims 1-15of the '158 patent were not shown to be unpatentable, while LifeNet cross-appeals the Board's determination that claims 12–21 of the '532 patent were shown to be unpatentable. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

We review the Board's factual findings for substantial evidence and its legal conclusions de novo. In re Cuozzo Speed Techs., LLC, 793 F.3d 1268, 1280 (Fed. Cir. 2015). Thus, we review the Board's ultimate determination of obviousness de novo and its underlying factual determinations for substantial evidence. Ariosa Diagnostics v. Verinata Health, Inc., 805 F.3d 1359, 1364 (Fed. Cir. 2015). The underlying factual findings include "findings as to the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill in the art, the presence or absence of a motivation to combine or modify with a reasonable expectation of success, and objective indicia of non-obviousness." Id.

"Claim construction is ultimately a question of law, decided de novo on review, as are the intrinsic-evidence aspects of a claim-construction analysis." Intel Corp. v. Qualcomm Inc., 21 F.4th 801, 808 (Fed. Cir. 2021) (citations omitted). However, "we review any underlying fact findings about extrinsic evidence ... for substantial-

13

evidence support when the appeal comes from the Board." *Id.* (citations omitted).

I.

Surgalign's first argument on appeal focuses on claims 4 and 6–11 of the '532 patent. Surgalign contends that the Board "incorrectly applied" a claim construction for the term "plate-like" that was different from the claim construction the Board adopted. Surgalign Br. 35–48. According to Surgalign, the Board's construction of "plate-like" to mean "generally flat" was correct, but when the Board purported to apply that construction to Grooms and Paul, the Board improperly excluded bone portions in the references that were "generally flat" in the horizontal plane, i.e., the plane in which they are inserted. Id. at 29, 37, 40. Surgalign argues such an effective construction conflicts with other claim language, the figures of the '532 patent, and a prior art reference U.S. Patent No. 5.961,554 to Janson et al., which uses the term "plate-like" to describe spinal spacers with a similar shape to Grooms and Paul. Id. at 40–48.

Surgalign separately argues that the Board's fact findings that the Grooms and Paul cortical bone portions are not "plate-like" lack substantial evidence. This is because, Surgalign contends, the bone portions of Grooms and Paul are "generally flat" horizontally, i.e., in the plane in which the grafts are implanted into the spine. Surgalign Br. 48– 50.

LifeNet responds that, since the Board adopted and applied the construction that Surgalign requested—that "plate-like" be construed to mean "generally flat" and that "plate-like" be tested against the "overall shape" of each cortical bone portion—what Surgalign actually challenges is the Board's findings that Grooms and Paul do not have "plate-like" cortical bone portions, a factual issue we review for substantial evidence. LifeNet Br. 28–29, 32. Should we consider Surgalign's claim construction argument, LifeNet

argues that Surgalign's position on appeal contradicts Surgalign's argument before the Board that "plate-like" "addresses the 'overall shape' of a bone portion." Id. at 34– 35 (quoting J.A. 1965).

"We have reversed or vacated and remanded final written decisions of the Board when the Board departs from the proper construction [of a claim term] when assessing patentability in view of the prior art." Google LLC v. Lee, 759 F. App'x 992, 996 (Fed. Cir. 2019) (citing Corning v. Fast Felt Corp., 873 F.3d 896, 900-01 (Fed. Cir. 2017), and D'Agostino v. MasterCard Int'l Inc., 844 F.3d 945, 950 (Fed. Cir. 2016)). In Corning, the Board construed the claim term "roofing or building cover material" in a manner that would "not require an asphalt-coated substrate." 873 F.3d at 900. When evaluating obviousness, however, the Board made clear that it understood its construction to require materials that either had been or would eventually be coated with asphalt. Id. We determined this was error. Id. at 901.

Similarly, here the Board indicated it was applying its "generally flat" construction and that it was testing that construction against the "overall shape" of each cortical bone portion. It is clear, however, that the Board analyzed the "general flat[ness]" of the Grooms and Paul cortical bone portions only with respect to the vertical plane. With respect to Grooms, the Board analyzed only whether the parts of the bone portions from which the "legs or curved portions" extend were "generally flat." '532 FWD, 2020 Pat. App. LEXIS 12593, at *49–50. The Board did not consider the flatness of the bone portions as they extend in the horizontal direction. As for its analysis of Paul, the Board pointed out that, although "certain surfaces of Paul's cortical bone portions could be considered generally flat," Paul's cortical bone portions have curved surfaces that are "Cshape[d]." Id. at *53–54. Accordingly, while the Board again stated it was applying its construction to the "overall shape" of Paul's bone portions, it considered only the "C-

14

15

shape[d]" vertical plane of Paul," and did not address the flatness of the bone portions as they extend in the horizontal direction.

Contrary to the Board's as-applied construction, the '532 patent clearly contemplates cortical bone portions having curvature in the vertical plane. Indeed, the language of claim 4 itself contemplates cortical bone portions with vertical curvatures. Claim 4 recites that the bone graft can be shaped like a "cylinder, a flattened curved block, [and] a tapered cylinder." '532 patent col 46 ll. 60–65. For the cortical bone portions to embody these shapes, there must be some vertical curvature. In addition, figures 14, 35, 37, 38, 43, and 44, which both parties have asserted show "platelike" bone portions, *see* '532 FWD, 2020 Pat. App. LEXIS 12593, at *29–30; J.A. 2925 ¶ 38, depict bone portions that have curved surfaces in the vertical plane. One such figure is Figure 14, shown in part below:



'532 patent Fig. 14.

Thus, we agree with Surgalign that it was error for the Board to effectively construe "generally flat" to exclude

consideration of the horizontal plane. As the Board initially noted, the proper construction should consider the "overall shape" of the cortical bone portion.

The evidence and arguments presented to the Board support only one possible evidence-supported finding: that substantial evidence does not support the Board's determination that Grooms and Paul do not teach "plate-like" bone portions when the correct construction is employed. *See Google*, 759 F. App'x at 996; *Corning*, 873 F. 3d at 901–02. The Board's obviousness determination for claims 4 and 6–11 was based solely on this erroneous determination. We therefore reverse the Board's obviousness determination with respect to these claims insofar as it was based on the Grooms and Paul references failing to teach the "plate-like" claim limitation.⁶

II.

Surgalign's second argument on appeal is that the Board erred when it held claims 4 and 6–11 of the '532 patent and claims 1–15 of the '158 patent not unpatentable over several combinations where Wolter is the primary reference. Surgalign Br. 50–72. Its arguments in that regard are directed to the Board's analysis regarding modifying Wolter to use allogenic bone instead of autologous bone and modifying Wolter to use a bone pin instead of a metal screw. As to the first modification, Surgalign contends that the Board erred because it did not frame its obviousness analysis in terms of what a person of ordinary skill in the art would have been motivated to do at the time of the invention in 1999, and instead focused on Wolter's 1987 statements that autologous bone was preferable to allogenic bone. Surgalign's Br. 52–56. Surgalign also contends

⁶ On remand, the Board should proceed to analyze the remaining issues raised by Grounds 2 and 5 of the petition.

17

that the Board erroneously focused its motivation to combine analysis on whether making a Wolter-type graft from allogenic bone would have been the preferred solution. Id. at 56-59. As to the second modification, Surgalign contends that the Board erred when it found lack of motivation to combine and no reasonable expectation of success with respect to replacing the metal screw used in Wolter with a bone pin. According to Surgalign, the Board erroneously combined these two considerations-motivation to combine, expectation of success-into a single inquiry into whether the proposed combination would have been "difficult." Id. at 60-62. Surgalign also argues that the Board's findings of lack of motivation to combine and reasonable expectation of success are not supported by substantial evidence. Surgalign takes issue with (a) the Board's finding that Wolter's graft lacked a precise fit, because Wolter describes its iliac crest bone portions as fitting in a "preciselyfitting manner," J.A. 2661; (b) the Board's reliance on Dr. Shaffrey's testimony about how an ordinary artisan would not have expected success in pushing an allograft bone pin through Wolter's graft, because Surgalign contends this testimony was not directed to using a bone pin with an allograft; and (c) the Board's reliance on fact-witness Mr. Gaskins' testimony. Id. at 65–70.

LifeNet responds that the Board properly addressed the question of whether an ordinarily skilled person in 1999 would have been motivated to modify Wolter's autograft to an allograft, and that the Board's factual findings were supported by substantial evidence. Specifically, LifeNet contends, the Board found that a skilled artisan in 1999 would not have been motivated to "beg[in] with Wolter" and to "adapt[] it to an allograft against the reference's teachings," including because the Wolter-style graft was "tailored to the demands of filling a large defect using an autograft that can be made during surgery." LifeNet Br. 53 (quoting '158 FWD, 2020 Pat. App. LEXIS 12576, at *30).

With respect to whether one of skill in the art would have replaced Wolter's metal screw with a bone pin, LifeNet argues that the Board simply found that the "technical difficulties" inherent in Surgalign's proposed modification to Wolter undermined Surgalign's arguments on both motivation to combine *and* reasonable expectation of success, not that the two findings had been combined. *Id.* at 54–60. But, even if the Board did conflate the two issues, LifeNet urges, the Board made sufficient factual findings to support its judgment. *Id.* at 59.

As to whether substantial evidence supports the Board's findings of lack of motivation to combine and reasonable expectation of success, LifeNet responds in kind to each of Surgalign's arguments. First, LifeNet contends that the Board's findings were not premised entirely on a lack of a precise fit in Wolter. According to LifeNet, it was just one point of many that undercut Surgalign's obviousness case. Id. at 61–64. Second, LifeNet contends that Dr. Shaffrey's testimony included testimony pertaining to a bone pin with an allograft, even if the Board quoted a paragraph pertaining to an autograft. Id. at 64–65 (citing J.A. 4726-27, J.A. 30-33, J.A. 157-61). Third, LifeNet contends that Surgalign did not move to exclude Mr. Gaskins' testimony, that there is nothing improper about the Board's reliance on fact testimony, and that Surgalign is improperly seeking a re-weighing of the credibility of the witnesses and evidence. Id. at 65-67.

We turn to the "bone pin" issue first. We agree with LifeNet that, even if the Board did conflate motivation to combine and reasonable expectation of success, the FWDs contain sufficient factual findings supported by substantial evidence of no reasonable expectation of success, even if the Board had held there was a motivation to combine. As noted above, the Board found that a bone pin is weaker than a metal screw. '158 FWD, 2020 Pat. App. LEXIS 12576, at *32–33. The Board also found that "Wolter's stack of three large, irregularly shaped pieces of iliac bone

19

would be difficult to precisely line up for a bone pin, and [that] it is doubtful that a bone pin could withstand the force needed to impel a bone pin through the three sections and their irregular surface." *Id.* at *33–34.

Substantial evidence supports these findings. Both Dr. Shaffrey and Mr. Gaskins testified that a bone pin is significantly weaker than a metal screw. See id. at *32–33 (quoting J.A. 4724-25 ¶103 (Shaffrey) and J.A. 4769 ¶16 (Gaskins)); see also id. at *33 (stating that Surgalign's expert Mr. Sherman also agreed that a small-fragment cancellous bone screw is stronger than a cortical bone pin in all axes). In addition, the Board credited Dr. Shaffrey's testimony explaining that a person of skill in the art "would not expect success in pushing an allograft bone pin through Wolter's graft because passing a bone pin through 'the thick bone tissue and across the irregular interfaces of the iliac crest would be considered unfeasible."" Id. at *35 (quoting J.A. 4724–25 ¶103). As the Board noted, Dr. Shaffrey specifically explained that "using a bone pin to hold three stacked iliac crest allografts together would not work for the same reasons [he] discussed with respect to an autograft." Id. (quoting J.A. 4727 ¶106). For its part, Mr. Gaskins' testimony explains that the technologies known at the time of the invention would not have resolved the technical difficulties of inserting a bone pin into a graft. Id. (citing J.A. 4769–70, J.A. 4772, J.A. 4773–74 ¶¶ 17–18, 22, 26–28). And, finally, we see no error in the Board's reliance on Mr. Gaskins' testimony. See Fanduel, Inc. v. Interactive Games LLC, 966 F.3d 1334, 1344 (Fed. Cir. 2020) (indicating that expert testimony is not required for the Board to make factual findings based on its view of the record).

Thus, even if the Board improperly analyzed motivation to combine, the Board's ultimate conclusion that claims 4 and 6–11 of the '532 patent and claims 1–15 of the '158 patent were not rendered obvious by Wolter is supported by its finding that one of skill in the art would not have had a reasonable expectation of success in

substituting a bone pin for Wolter's metal screw, which is itself supported by substantial evidence. See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd., 821 F.3d 1359, 1367 (Fed. Cir. 2016) ("[T]his court sits to review judgments, not opinions. And while the Board conflated two different legal concepts—reasonable expectation of success and motivation to combine—it nevertheless made sufficient factual findings to support its judgment that the claims at issue are not invalid." (internal quotation marks and citation omitted)). Because the Board found no reasonable expectation of success, and because that finding is supported by substantial evidence, the Board's determination that the claims are not invalid is supported.

Having found that the Board's analysis for expectation of success for replacing Wolter's screws with bone pins is not legally erroneous, we need not reach Surgalign's arguments regarding modification of Wolter to allogenic bone.

III.

In cross-appealing the Board's holding that Surgalign had shown claims 12–21 of the '532 patent to be unpatentable, LifeNet challenges the Board's construction of the term "disposed between," as recited in independent claim 12. As noted, that claim requires an osteoconductive substance that is "disposed between" two cortical bone por-LifeNet argues that the Board erred when it tions. construed the term to not require complete separation of the cortical bone portions. LifeNet Br. 69-74. This is because, LifeNet contends, the '532 patent refers to the cortical bone portions as being "disposed apart" from each other, uses different language such as "disposed in" when describing a material that does not completely separate the pieces that surround it, and consistently uses the phrase "disposed between" with reference to figures that show complete separation between the cortical bone portions. LifeNet Br. 70–74; see also LifeNet Reply Br. 3–4, 8–13 (arguing that the '532 patent implicitly defined "disposed

21

between" to require complete separation through its repeated, consistent, and exclusive use of the term in that manner).

In addition, LifeNet urges, the Board erred by giving too much weight to the language of the claims of the '158 patent without properly analyzing the specification of the patent. Because the specification of the '158 patent is substantially similar to that of the '532 patent, and because the Board acknowledged that the specification of the '532 patent did provide some support for a construction requiring complete separation, LifeNet asserts that the '158 patent similarly supports such a construction. LifeNet Br. at 74–76.

Surgalign responds by pointing out that LifeNet has not challenged the Board's finding that, looking solely at the claim language, the ordinary meaning of "disposed between" does not require complete separation. Surgalign Resp. & Reply Br. 53. Nor do the specification, prosecution history, and figures of the '532 patent clearly redefine the term to require complete separation, Surgalign contends. Id. at 54–57. For example, Surgalign argues, as the Board found when addressing obviousness over Grooms, the patent's use of "disposed in" to describe material in a channel does not suggest that material "disposed between" two cortical bone portions must completely separate them, *id.* at 58 (citing '532 FWD, 2020 Pat. App. LEXIS 12593, at *36); see also id. at 61–63, nor does the use of "disposed apart" elsewhere in the patent clearly redefine "disposed between," id. at 58–59. Surgalign also contends that the drafters of the '532 patent knew how to, but chose not to, claim structures in which the cortical bone portions were "not in physical contact," as illustrated by the claims of the '158 patent. Surgalign Resp. & Reply Br. 60, 63-67.

As we explained in *Trustees of Columbia University*, "[o]ur case law does not require explicit redefinition or disavowal." 811 F.3d at 1363–65. Instead, the specification

should be consulted to determine a term's meaning, since "a claim term may be clearly redefined without an explicit statement of redefinition" and "[e]ven when guidance is not provided in explicit definitional format, the specification may define claim terms by implication such that the meaning may be found in or ascertained by a reading of the patent documents." Id. at 1364 (quoting Philips v. AWH *Corp.*, 415 F.3d 1303, 1320–21 (Fed. Cir. 2005) (en banc)); see also In re Abbott Diabetes Care Inc., 696 F.3d 1142, 1148–50 (Fed. Cir. 2012) (concluding that the broadest reasonable construction of "electrochemical sensor" would not include a sensor with external cables and wires where the patent "repeatedly, consistently, and exclusively" depicted an electrochemical sensor without external cables or wires and disparaged sensors with external cables or wires); Groove Digital Inc. v. United Bank, 825 F. App'x 852, 856 (Fed. Cir. 2020) (concluding that a district court's construction of "applet" to require geotargeting was not error, where the patent "repeatedly, consistently, and exclusively" depicted applets as being geotargeted and the patent's Field of the Invention described the "present invention" as "delivering and serving local content and advertisements"). Here, it is true that the figures and language of the '532 patent's specification exclusively show "disposed between" as completely separating, but, unlike in Abbott and Groove, there is both an uncontested ordinary meaning that is not limited as LifeNet urges and evidence in the form of the claims of the '158 patent suggesting that "disposed between" was not so limited, since the separate "not in physical contact" language was separately and expressly recited in claims 1 and 2 of the '158 patent. Thus, we cannot say that there has been a clear redefinition of "disposed between," either explicitly or implicitly, to require complete separation.

Because we see no error in the Board's construction of "disposed between," we affirm the Board's obviousness

23

determination with respect to claim 12 of the '532 patent, and its dependent claims 13–21.

CONCLUSION

We have considered the parties' remaining arguments and do not consider them to be persuasive. For the reasons set forth above, we affirm the Board's decision in the '158 FWD that claims 1–15 of the '158 patent have not been proven to be unpatentable. We also affirm the Board's decision in the '532 FWD that claims 12–21 have been proven to be unpatentable and that claims 4 and 6–11 have not been proven to be unpatentable over Wolter. We reverse the Board's decision in the '532 FWD that claims 4 and 6– 11 have not been proven to be unpatentable over Grooms and Paul. The case is remanded to the Board for further proceedings consistent with this opinion.

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

COSTS

No costs.

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

SURGALIGN SPINE TECHNOLOGIES, INC., FKA RTI SURGICAL, INC., Appellant

v.

LIFENET HEALTH, Cross-Appellant

2021-1117, 2021-1118, 2021-1236

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2019-00569, IPR2019-00570.

NEWMAN, Circuit Judge, dissenting, in part.

This appeal concerns LifeNet's invention of a novel bone graft for implant into the spinal column. LifeNet's spinal graft is a composite of layers of cortical bone and cancellous bone, in a new structure that promotes the growth of patient bone at the implantation site by processes of osteoinductivity and cellularization. The LifeNet graft is reported to provide enhanced stability and strength to the spinal column.

 $\mathbf{2}$

On LifeNet's suit for patent infringement, Surgalign filed petitions for inter partes review of several LifeNet patents. The two patents on this appeal are U.S. Patent No. 8,182,532 ("the '532 patent") and U.S. Patent No. 6,458,158 ("the '158 patent"). I focus on my colleagues' erroneous reversal of the PTAB's decision sustaining validity of claims 4 and 6–11 of the '532 patent.¹ The references on which the majority relies to invalidate claims 4 and 6–11 of the '532 patent, the Grooms and Paul references, do not show or suggest the claimed structure of plate-like layers of cortical and cancellous bone. The novelty of the claimed structure is undisputed, and the PTAB's ruling of nonobviousness is well supported by the specification and the prior art.

I respectfully dissent from my colleagues' reversal of the PTAB decision sustaining validity of claims 4 and 6– 11.

Novelty is conceded for the composite spine structure recited by claims 4 and 6–11 of the '532 patent

The '532 patent summarizes its new spine graft structure as

including a graft unit having one or more through-holes configured to accommodate [one] or more pins, the graft unit including a first plate-like cortical bone, a second plate-like cortical bone, a plate-like cancellous bone disposed between the first plate-like cortical bone and the second plate-like cortical bone to form the graft unit, and one or more cortical bone pins for holding together the graft unit.

¹ Surgalign Spine Techs., Inc. v. LifeNet Health, No. IPR2019-00570, (P.T.A.B. Aug. 26, 2020) ("532 Decision"); No. IPR2019-00569 (P.T.A.B. Aug. 26, 2020 ("158 Decision").

3

'532 patent, col. 6, ll. 4–12. The graft unit is pictured as follows, showing the outer layers of cortical bone and the inner layer or cancellous bone:



LifeNet Br. 7 (annotating '532 patent Figure 1, cancellous bone (3) in green; cortical bone (2), (4) in red; bone pins (7) in blue).

The Grooms and Paul references describe spinal bone graft structures, illustrating the complexity of the problem and the need for improved solutions. For the '532 structure, LifeNet describes the advantage whereby this structure "distribute[s] the stresses of the spinal column between the two parallel and flush cortical bone portions," resulting in "little to no stress distribution toward the center of the graft." Declaration of Barton Gaskins ¶ 33; LifeNet Br. 7–8.

Claim 4 of the '532 patent describes the composite spinal bone graft structure of layers of cortical and cancellous bone, as follows:

4. A composite spinal bone graft comprising:

a graft unit having one or more through-holes configured to accommodate one or more pins, said graft unit comprising:

a first plate-like cortical bone portion configured to contact a portion of the host bone;

a second plate-like cortical bone portion configured to contact a portion of the host bone;

a plate-like cancellous bone portion disposed between said first plate-like cortical bone portion and said second plate-like cortical bone portion and configured to contact a portion of the host bone to form said graft unit; and

one or more cortical bone pins connecting bone portions of said bone graft unit, said composite spinal bone graft having a shape selected from the group consisting of a parallelepiped, a parallel block, a square block, a trapezoid wedge, a cylinder, a flattened curved block, a tapered cylinder, and a polyhedron,

wherein said composite spinal bone graft comprises one or more textured surfaces comprising a plurality of closely spaced continuous protrusions in a linear arrangement and said spinal bone graft is configured for implantation into the anterior spinal column of the host.

'532 patent, col. 46, l. 48–col. 47, l. 3.

As the '532 specification describes and the claims recite, the assembled "composite spinal bone graft" as a

4

 $\mathbf{5}$

whole may have a specified shape such as a cylinder or a wedge as recited in claim 4, and any of these shapes must be made of layered bone portions that are "plate-like." All the drawings illustrate this essential structure. For example, Figure 1 shows a trapezoidal wedge made of two plate-like cortical bone portions. '532 Patent, Fig. 1; *id.* at col. 19, ll. 16–24 (describing same).

The panel majority reverses the Board's finding that "the Grooms and Paul references fail[] to teach the 'platelike' claim limitation." Maj. Op. at 16. The majority errs, for the Grooms and Paul grafts are explicitly not plate-like, and cannot be so viewed. The Grooms and Paul references, separately or together, do not show or suggest the structure described and claimed in the '532 patent.

The Grooms reference, United States Patent Appl. 2002/0138143, does not render obvious the '532 structure, alone or in combination other references

Grooms describes a spinal bone graft that "is machined to form a symmetrically or asymmetrically shaped (e.g. a substantially "D"-shaped) implant having a canal running therethrough." Grooms, Abstract. The Grooms spinal graft is pictured as follows:



Grooms Reference, Figure 8A.

The Grooms spinal graft is composed substantially of cortical bone, with "a canal running therethrough" that may be "packed" with "[o]steogenic, osteoinductive, or osteoconductive materials." Grooms, Abstract.

The Board defined the claim term "plate-like" as meaning "generally flat," as the parties agree. The Board found that "plate-like" refers to "overall shape, not merely whether [the bone portion] include[s] a region that is generally flat." '532 Decision at 48.

The Board explained that Grooms teaches "cortical bone portions [that] have a generally flat base with legs or curved portions that extend away from the base so that the two cortical portions meet away from the flat base portion." '532 Decision at 47. The Board found that Grooms does not describe or teach a plate-like structure of cortical bone, for the Grooms spinal implant is "D- or bread loaf-shaped." '532 Decision at 48 (citing Grooms, ¶ 9). The Board further found that the bone portions of Grooms do not meet at the generally flat faces of the bone portions of the implant, but

6

7

at the legs and curved ends of the bone portions. '532 Decision at 48. Error has not been shown in these Board findings.

The Board stated "that in considering whether Grooms' cortical bone portions are 'plate-like,' we consider their overall shape, not merely whether they include a region that is generally flat." '532 Decision at 47–48. It is beyond debate that Grooms' "bread-loaf-shaped" structure in not "generally flat." The Board's analysis was consistent with the testimony of Mr. Michael Sherman, Surgalign's expert, who identified only "the top" of the Grooms bone portion as "generally flat." Sherman Dep. 85:10–86:25, No. IPR2019-00570, Ex. 2032; Appx4924–Appx4925. The Board considered the "overall shape" of the cortical bone portions of Grooms and Paul and found that they were not "generally flat." '532 Decision at 48.

The Paul reference, U.S. Patent No. 6,258,125, does not render obvious the '532 structure, alone or in combination with other references

Paul describes a "C-shaped" "allogenic intervertebral implant" of cortical bone. '532 Decision at 52. The Paul structure is depicted as follows:



Paul, Figure 9.

8

Paul's structure consists of two cortical half-shell portions that are "scalloped to have a C-shape" with a deep concave surface; and when placed together they "form 'cylindrical space 72' between them." Paul, col. 5, ll. 13–15; '532 Decision at 52 (quoting *id.*); *see also* '532 Decision at 52 ("[W]e assess the overall shape of Paul's cortical bone portions to determine if they are 'plate-like."").

The Board recognized that "certain surfaces" of the Paul reference "could be considered generally flat." '532 Decision at 52. However, as Surgalign states: "A single flat surface would not make a bone portion generally flat." Surgalign Br. 40. The Board found that Paul's overall

9

structures are not plate-like, as the '532 claims require. '532 Decision at 72–73.

The panel majority errs in ruling that since "plate like" may include some curvature, the Grooms and Paul structures are therefore plate-like. The panel majority agrees that the Board's construction of "plate like" as meaning "generally flat" is correct, and appears to agree that "the proper construction should consider the 'overall shape' of the cortical bone portion." Maj. Op. at 16. However, the majority holds that the curved portions of the Grooms and Paul structures render obvious the '532 structure.

The majority finds that "the '532 patent clearly contemplates cortical bone portions having curvature in the vertical plane," citing claim 4's recitation that the bone graft can be shaped like a "cylinder, a flattened curved block, a tapered cylinder, a trapezoid" Maj. Op. at 15. The majority appears to misunderstand the '532 invention, for the specification states and the drawings illustrate that the term "plate-like" refers to the layers of cortical and cancellous bone within the bone graft. *E.g.*, '532 patent, col. 6, ll. 6–11 ("the graft unit including a first plate-like cortical bone, a second plate-like cortical bone, a plate-like cancellous bone disposed between the first plate-like cortical bone and the second plate-like cortical bone to form the graft unit").

The panel majority states that the Board "did not address the flatness of the bone portions as they extend in the horizontal direction." Maj. Op. at 15. That statement does not accord with the record: The Board treated this aspect at length, for it was the core of Surgalign's invalidity argument. While Surgalign now argues that the Board "disregard[ed] the horizontal plane," that argument cannot be squared with the Board's discussion of the horizontal planes of the various structures and the Board's determination that the bone portions of Grooms and Paul are not generally flat. '532 Decision at 48; 52; Surgalign Br. 37.

The parties generally agreed that "plate-like" means "generally flat." The majority's finding that the Grooms and Paul "C-" and "D-shaped" grafts are plate-like does not withstand analysis.

LifeNet's expert, Dr. Shaffney, explained the advantages of the '532 structure, and that the grafts of Grooms and Paul "have proven to be less efficacious" because they "do not have consistent mechanical strength and load-bearing along their entire length." Second Declaration of Dr. Mark Shaffney, ¶ 129, No. IPR2019-00570, Ex. 2028; Appx4738. These advantages, in a field of complex medical physiology, contribute to the factual premises of nonobviousness.

CONCLUSION

The Board's findings are supported by substantial evidence. See, e.g., Medtronic, Inc. v. Barry, 891 F.3d 1368, 1375 (Fed. Cir. 2018). Substantial evidence "means such relevant evidence as reasonable minds might accept as adequate to support a conclusion." Consol. Edison Co. of New York v. N.L.R.B., 305 U.S. 197, 229 (1938). My colleagues err in reversing the Board's decision and holding claims 4 and 6–11 of the '532 patent unpatentable on the ground of obviousness over Grooms and Paul. I respectfully dissent.