

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RSB SPINE, LLC,

Plaintiff,

v.

MEDACTA USA, INC.,

Defendant.

Civil Action No. 18-1973-RGA

RSB SPINE, LLC,

Plaintiff,

v.

PRECISION SPINE, INC.,

Defendant.

Civil Action No. 18-1974-RGA

RSB SPINE, LLC,

Plaintiff,

v.

DEPUY SYNTHES SALES, INC., and
DEPUY SYNTHES PRODUCTS, INC.,

Defendants.

Civil Action No. 19-1515-RGA

MEMORANDUM OPINION

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November 16, 2021


ANDREWS, UNITED STATES DISTRICT JUDGE:

Before me is the issue of claim construction of multiple terms in U.S. Patent Nos. 6,984,234 (the '234 Patent) and 9,713,537 (the '537 Patent).¹ I have considered the Parties' Amended Joint Claim Construction Brief. (D.I. 102). I held oral argument on October 18, 2021. (D.I. 109). I have also considered the supplemental briefing I requested at oral argument regarding the term "lip osteophyte." (D.I. 110, 111).

I. LEGAL STANDARD

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (cleaned up). "[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324) (alteration in original). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (cleaned up).

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [Which is] the meaning that the term would have to a person of ordinary skill in the art in

¹ The '234 patent application was filed April 21, 2003. The '537 patent application was filed January 24, 2017; it claims priority to April 21, 2003. The specifications of the two patents have some common material.

question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Id.* at 1312-13 (cleaned up). “[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent.” *Id.* at 1321 (cleaned up). “In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.” *Id.* at 1314.

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court’s construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Phillips*, 415 F.3d at 1317-19 (cleaned up). Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

II. BACKGROUND

The patents at issue describe a device (and its method of use) that assists in surgical arthrodesis or fusion of the spine. (D.I. 102 at 2). The following claims are the most relevant for the purposes of this opinion:

Claim 1 of the '234 Patent

1. A method for joining first and second bones having top surfaces and *side surfaces* generally facing each other, the method comprising:

inserting between the *side surfaces* of the bones a *base plate* having a *first end* nearer the first bone and a *second end* nearer the second bone, wherein the *base plate* has a first

screw hole extending through the *first end* and a second screw hole extending through the *second end*;

introducing a first bone screw through the first screw hole and into the first bone, wherein the first bone screw is introduced at an angle relative to the top surface of the bone ranging from about 20° to about 60°,

introducing a second bone screw through the second screw hole and into the second bone, wherein the second bone screw is introduced at an angle relative to the top surface of the bone ranging from about 20° to about 70°, and

covering at least a part of the first bone screw and at least a part of the second bone screw to prevent the first and second bone screws from backing out of the first and second bones, respectively.

(D.I. 102 at 9) (emphasis added).

Claim 6 of the '234 Patent

6. The method according to claim 1, wherein the first and second bones are first and second vertebral bodies, respectively, and wherein the first bone screw is introduced into the *lip osteophite* of the first vertebral body and the second bone screw is introduced into the *lip osteophite* of the second vertebral body.

(D.I. 102 at 9) (emphasis added).

Claim 35 of the '234 Patent

35. A bone stabilization plate system including a *base plate* for retaining bone graft material between first and second longitudinally-aligned, adjacent bone bodies and for permitting force transmission between the first and second bone bodies through the bone graft material, the *base plate* being *sized to have an inter-fit between* the first and second adjacent bone bodies and adjacent to lateral extents of the bone graft material such that the first and second bone bodies engage the bone graft material, and at least first and second bone screws for extending into the first and second bone bodies, respectively, to retain the *base plate* between the first and second bone bodies, the *base plate* having *means for interacting* with the first and second bone screws, the *means for interacting* including *means for permitting movement* of at least one of the first and second bone bodies relative to the *base plate*.

(D.I. 102 at 9) (emphasis added).

III. CONSTRUCTION OF AGREED-UPON TERMS

I adopt the following agreed-upon construction:

Claim Term	Construction
“primarily”	“mainly” (and does not connote a temporal aspect)

IV. CONSTRUCTION OF DISPUTED TERMS²

A. Term 1: “base plate” (’234, cls. 1, 5, 7-8, 14, 19-20, 22, 24-25, 29, 32, 35, 37, 39; ’537, cls. 1, 3, 6, 10, 12-13, 15, 18-19, 21-22, 24, 27-29)

1. *Plaintiff’s proposed construction*: “a fixation plate of a bone plate stabilization system to stabilize adjacent vertebrae for fusion and distinct from a spacer and bone graft material deployed across a bone graft site.”
2. *Defendants’ proposed construction*: indefinite; alternately, “a fixation plate to stabilize adjacent vertebrae for fusion that is used without a separate load-bearing fusion cage.”
3. *Court’s construction*: “Fixation plate to stabilize adjacent vertebrae for fusion.”

Plaintiff’s proposed construction requires the base plate to be part of a “bone plate stabilization system” and to be distinct from a “spacer and bone graft material.” Defendants argue that the term is indefinite, or that it is a fixation plate that must be used without a “load-bearing fusion cage.” Plaintiff and Defendants agree that there is no commonly known usage in the field. (D.I. 109 at 38:22-25; D.I. 102 at 18).³

To support its contention that the base plate is part of a stabilization system, Plaintiff points to claim preambles and the patents’ specifications. (D.I. 102 at 12). For instance, the Summary of the Invention in the ’234 Patent provides:

The present invention is directed to a bone stabilization device and a method for its use. In one embodiment, the invention is directed to a method for joining first and second bones having top surfaces and side surfaces generally facing each other. . . . In another

² I ruled on some of the disputes at the claim construction hearing. For those, I merely repeat the ruling without any further explanation.

³ All docket citations are to the docket for case 18-1973.

embodiment, the invention is directed to bone stabilization plate system comprising a base plate having bottom surface and first and second ends.

'234 Patent, 2:40-44, 60-62. The '537 Patent uses similar language. *See* 4:59-61.

Defendants argue that the PTAB rejected “bone plate stabilization system” part of RSB’s proposal. (D.I. 102 at 16 (citing D.I. 95-1 at 634)). In rejecting Plaintiff’s construction, the PTAB pointed to variations in the language used to describe the bone stabilization system. The title of the '234 patent includes “bone plate stabilization system” while the claims use “bone stabilization plate system” and the specification describes a “bone stabilization device.”

Medacta USA, Inc. v. RSB Spine, LLC, No. IPR2020-00274 (P.T.A.B. May 22, 2020). Second, the PTAB reasoned that the doctrine of claim differentiation supported its position: “although the preambles of each independent apparatus claim (numbers 22, 35, and 40) recite a ‘bone stabilization plate system,’ each independent method claim (numbers 1, 34, and 41) recites a ‘base plate’ but does not recite a ‘bone stabilization plate system’ (or any other ‘system’).” *Id.*

Plaintiff’s argument has some basis. Parts of the specification suggest that the method is in fact directed to the use of the “bone stabilization plate system.” The title, for instance is “Bone Plate Stabilization System and Method for Its Use.” The description states, “The present invention is directed to a bone stabilization plate system . . . as well as to methods for its use.” '234 Patent, 3:64-67. I do not think the variation between “bone plate stabilization system” and “bone stabilization system” is of much significance. I do not think, however, the patentee acted as his own lexicographer such that I should read language into the claims that the patentee sometimes chose to put in and other times chose not to put in. In other words, I think that claim differentiation has applicability in regard to the construction of “base plate.” Thus, I agree with Defendants on the “bone plate stabilization system” dispute.

Plaintiff's arguments that the base plate must be distinct from a spacer are not very strong. The '234 patent describes a "bone graft" as separate from the base plate but does not use the term "spacer." (4:16-22; 6:47-50). Plaintiff suggests that a person of skill in the art (a "POSA") would understand the bone graft to be a spacer, but Plaintiff suggested in oral argument that the base plate could, in some situations, itself be a bone graft. (D.I. 109 at 15:11-17; *see also* D.I. 102 at 18 ("The Patent Office has also found that a structure made of bone graft is a base plate[.]"). Thus, there is scant intrinsic evidence for Plaintiff's proposition that a POSA would understand the bone plate necessarily to be distinct from a spacer and bone graft. I therefore reject Plaintiff's proposed claim construction.

Defendants urge me to find "base plate" to be invalid for indefiniteness. I decline to do so. The PTAB was able to construe the term. At oral argument, Defendants quibbled with the PTAB's treatment of the Michaelson prior art but did not identify any legal error in the PTAB's reasoning as to the construction of the term "base plate." (D.I. 109 at 58:17-59:21).

Defendants argue (correctly) that it is not unprecedented to find a claim term indefinite that the PTAB has already construed. (D.I. 109 at 55:8-10 (citing *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364 (Fed. Cir. 2014))). The term at issue in *Interval Licensing*, however, was "unobtrusive manner." 766 F.3d at 1370. Not only is "unobtrusive manner" a "term of degree," but it is also "highly subjective." *Id.* at 1370-72. In contrast, the term at issue here is a definite structure. Defendants have failed to satisfy their burden of showing indefiniteness by clear and convincing evidence. *See BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017) (breadth of a term is different than indefiniteness of a term).

Defendants alternately propose a construction that requires the plate to be "used without a separate load-bearing fusion cage." (D.I. 102 at 12). In support, Defendants point to one

statement in the '234 patent: “Bone will not heal if it is stress shielded from all weight bearing. The fixation device needs to allow for this weight sharing along with the micromotion that happens during weight sharing until the fusion is complete[.]” (1:58-61). Since the purpose of the '234 patent is to prevent stress shielding, Defendants argue, the claimed base plate must lack a separate load-bearing fusion cage, which can cause stress shielding.

Defendants’ argument on this point is thin. There is nothing in the specification that would indicate to a POSA that the claims specifically exclude use with a load-bearing fusion cage. In fact, the term “load-bearing fusion cage” is not mentioned at all in the specification. I therefore reject Defendants’ proposed construction.

B. Term 2: “lip osteophyte” / “lip osteophyte” ('234, cls. 6, 16; '537, cls. 1, 10, 12, 15, 21, 27)

1. *Plaintiff’s amended proposed construction*: “the hard, ossified bone located at the lip region circumferentially surrounding the end of a vertebral body.”
2. *Defendants’ amended proposed construction*: “bony outgrowth formed at the lip between the top surface and side surface.”
3. *Court’s construction*: “bony outgrowth at the lip.”

The parties have submitted supplemental briefing on this term. (D.I. 110, 111). Plaintiff argues that the lip osteophyte is the strongest part of the bone, which a POSA would understand to be the “hard, ossified bone located at the lip region,” and that it is not limited to a “bony outgrowth.” (D.I. 110 at 1-3). Defendants argue that the term “osteophyte” had an ordinary meaning of “bony outgrowth” and that the lip must be between the side surface and the top surface. (D.I. 111 at 2).

It is undisputed that “osteophyte” had a well-known meaning at the relevant time. (D.I. 109 at 68:2-23). “Lip osteophyte,” however, was not used in the literature. (D.I. 102 at 28-29).

While it is true that the claim consistently refers to the lip osteophyte as the “strongest part of the bone,” this does not rise to the level of lexicography. *See Baxalta Inc. v. Genentech, Inc.*, 972 F.3d 1341, 1349 (Fed. Cir. 2020) (“Indeed, the standard for lexicography is exacting, requiring the patentee to clearly express an intent to redefine a term.” (cleaned up)). Plaintiff argues, “As used in the patents, the term ‘lip osteophyte’ cannot be limited to exclusively ‘bony outgrowth’ because it is unrebutted that not all bony outgrowths would be structurally the strongest part of the bone or would be suitable for keeping a base plate anchored to the vertebral bones.” (D.I. 110 at 3, citing D.I. 103-2, Ex. 3, ¶ 38). Even if not all osteophytes are the strongest part of the bone, all that means is that the claimed system and methods will not work on all patients. Plaintiff’s proposal to construe the term as a “hard, ossified” bone presents its own challenges. As Defendants point out, the terms are “unclear, unnecessary, and not used in the specification.” (D.I. 111 at 4). Essentially, Plaintiff wants to substitute a functional definition (hard and ossified) for the structural term that was used in the patents. Absent a clear disavowal in the patents of the well-known meaning of “osteophyte,” which I do not see, I will adopt Defendants’ proposed language of “bony outgrowth.”

The parties also dispute the precise region of the lip osteophyte. Defendants previously argued that it is the corner of the bone, distinct from the side surface. (D.I. 109 at 81:23-25). Now Defendants define the lip as being “between the top and side surface.” (D.I. 111). Plaintiff asserts that there can be overlap between the lip and the side surface. (*See* D.I. 110 at 5). I agree. As Plaintiff points out, “the three-dimensional ‘lip osteophyte’ may share or include a portion of the two-dimensional ‘side surface,’ and nothing in the intrinsic record suggests that the terms *must* be mutually exclusive.” (D.I. 102 at 58-59). I agree with Plaintiff. I do not, however, think it necessary to include the vague word “region” in the construction. I therefore

reject Plaintiff's suggestion of "lip region" and Defendants' suggestion of "between the top and side surface."

C. Term 3: "sized to have an inter-fit between" (the first and second adjacent bone bodies) ('234, cl. 35)

1. *Plaintiff's proposed construction*: "sized to fit between the first and second adjacent bone bodies to allow partial sharing of the weight of the bone bodies across the bone graft site."
2. *Defendants' proposed construction*: "sized to fit completely in between the first and second adjacent bone bodies;" alternatively, indefinite.
3. *Court's construction*: "sized to fit between."

D. Term 4: "means for interacting" ('234, cl. 35)

1. *Plaintiff's proposed construction*: §112 ¶ 6. Function: "interacting with the first and second bone screws." Structure: "a portion of the base plate that comprises the three-dimensional structure of either the bone screw hole or the bone screw slot."⁴
2. *Defendants' proposed construction*: indefinite.
3. *Court's construction*: §112 ¶ 6. Function: interacting with the first and second bone screws. Structure: the portion of the base plate containing the bone screw slot.

Claim 35 of the '234 Patent recites in part, "the base plate having means for interacting with the first and second bone screws, the means for interacting including means for permitting movement of at least one of the first and second bone bodies relative to the base plate." The function identified in claim 35 is "interacting with the first and second bone screws."

Defendants correctly observe that the term "interacting" does not appear in the '234 specification. (D.I. 102 at 44). This is not fatal. At the heart of the inquiry is whether the

⁴ Plaintiff originally proposed the structure, "a portion of the base plate that receives a screw and screw head, plus equivalents thereof." (D.I. 102 at 43). At oral argument, Defendants pointed out that this language is functional, not structural. (D.I. 109 at 101:24-102:2). I agreed and had Plaintiff propose a new structure, which I have reproduced here. (*Id.* at 103:1-105:10).

structure is clearly linked to a function in the specification. *Default Proof Credit Card Sys., Inc. v. Home Depot U.S.A., Inc.*, 412 F.3d 1291, 1298 (Fed. Cir. 2005).

Plaintiff notes, “The ‘means for interacting’ term . . . includes ‘means for permitting movement,’ and necessarily incorporates its corresponding structure[.]” (D.I. 102 at 43). I ruled orally that the term “means for permitting movement” includes the bone screw slot but not the bone screw holes. (D.I. 109 at 123:7-17). I find that the specification adequately links the “means for interacting” with the screws to the bone screw slots on the base plate. The specification describes, “The top surface **28** can have any suitable design so that it can receive one or more bone screws and perform as described further below.” (’234 Patent at 4:28-30). The specification goes on to note, “The secondary member **22** includes a bone screw hole in the form of an elongated bone screw slot **48** for receiving a second bone screw **25**.” (*Id.* at 4:63-65). The “top surface” and “secondary member” are elsewhere described as being part of the base plate. (*See id.* at Figs. 1-3, 4:3-9, 4:24-25). Thus, the specification adequately links the structure to the function.

E. Term 5: “means for permitting movement” (’234, cl. 35)

1. *Plaintiff’s proposed construction*: § 112 ¶ 6 Function: “permitting movement of at least one of the first and second bone bodies relative to the base plate.” Structure: “the surface of the portion of the base plate that receives a screw and screw head, and engages the surface of the screw, plus equivalents thereof.”
2. *Defendants’ proposed construction*: § 112 ¶ 6 Function: “permitting movement of at least one of the first and second bone bodies relative to the base plate.” Structure: “the bone screw slot.”

3. *Court's construction*: § 112 ¶ 6 Function: permitting movement of at least one of the first and second bone bodies relative to the base plate. Structure: the bone screw slot.⁵

F. Term 6: “bone screw retaining means” (’234, cl. 22)

1. *Plaintiff's proposed construction*: § 112 ¶ 6 Function: “securedly covering at least a part of the [first, second, and/or third] bone screws to prevent the bone screws from backing out.” Structure: “A single retaining plate, multiple retaining plates that cover different bone screws, or one or more screws with heads that overlap at least a portion of one or more bone screws, plus equivalents thereof.”
2. *Defendants' proposed construction*: § 112, ¶ 6 Function: “securedly covering at least a part of the [first, second, and/or third] bone screws to prevent the bone screws from backing out.” Structure: “A single retaining plate and set screw, multiple retaining plates with set screws that cover different bone screws, or one or more screws with heads that overlap at least a portion of one or more bone screws.
3. *Court's construction*: § 112, ¶ 6 Function: securedly covering at least a part of the [first, second, and/or third] bone screws to prevent the bone screws from backing out. Structure: A single retaining plate and set screw, multiple retaining plates with set screws that cover different bone screws, or one or more screws with heads that overlap at least a portion of one or more bone screws.

G. Term 7: “side surface” (’234, cls. 1-4, 19-20, 39; ’537, cls. 1, 15, 21)

1. *Plaintiff's proposed construction*: Plain and ordinary meaning.
2. *Defendants' proposed construction*: “superior or inferior surface, excluding the lip osteophyte and corner of the bone;” alternatively, indefinite.
3. *Court's construction*: Plain and ordinary meaning.

This term is related to the construction of “lip osteophyte.” As Defendants note, “The parties’ real dispute is whether the ‘side surface’ of the bone is distinct from the ‘lip

⁵ Undoubtedly, Plaintiff is correct that a means plus function claim includes structural equivalents. It is not so clear that the construction should include the language, “plus equivalents thereof.” Plaintiff may reraise this issue at an appropriate time.

osteophyte.” (D.I. 102 at 56). I have already determined that the “lip osteophyte” can overlap with the side surface. I therefore reject Defendants’ construction.

H. Term 8: “bottom surface” (’234, cls. 22, 24-25, 29; ’537, cls. 1, 3, 10, 15, 21, 24)

1. *Plaintiff’s proposed construction*: Plain and ordinary meaning.
2. *Defendants’ proposed construction*: “surface that sits against the bone graft material.”
3. *Court’s construction*: Plain and ordinary meaning.

I. Term 9: “first end” and “second end” (of the base plate) (’234, cls. 1, 14, 22, 29, 39; ’537, cls. 1, 14, 15, 21, 24)

1. *Plaintiff’s proposed construction*: Plain and ordinary meaning.
2. *Defendants’ proposed construction*: “portion of the base plate nearer the [first/second] bone that excludes the middle portion of the plate.”
3. *Court’s construction*: Plain and ordinary meaning.

J. Term 10: “screw retainer” (’537, cls. 4, 5, 6, 18, 30)

1. *Plaintiff’s proposed construction*: Plain and ordinary meaning.
2. *Defendants’ proposed construction*: § 112, ¶6 Function: “preventing at least one of the bone screws from backing out.” Structure: “A single retaining plate and set screw, multiple retaining plates with set screws that cover different bone screws, or one or more screws with heads that overlap at least a portion of one or more bone screws.”
3. *Court’s construction*: Plain and ordinary meaning.

K. Term 11: “lateral tabs” (’234, cl. 37; ’537, cls. 10, 27)

1. *Plaintiff’s proposed construction*: Plain and ordinary meaning.
2. *Defendants’ proposed construction*: “projections extending from the bottom surface of the primary member fitting between the lip osteophytes and around the bone graft.”
3. *Court’s construction*: Plain and ordinary meaning.

V. CONCLUSION

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion.