# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ROGER P. JACKSON, M.D.,

Plaintiff,

v.

Civil Action No. 21-53-RGA

NUVASIVE, INC.,

Defendant.

# MEMORANDUM OPINION

Stephen J. Kraftschik, POLSINELLI PC, Wilmington, DE; Thomas Gemmell, POLSINELLI PC, Chicago, IL; Darren E. Donnelly, POLSINELLI LLP, San Francisco, CA; Aaron M. Levine (argued), POLSINELLI PC, Houston, TX.

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Attorneys for Defendant.

May 30, 2023

T JUDGE:

Before me is the issue of claim construction of a single term in U.S. Patent Nos. 9,788,866 ("the '866 patent"), 10,722,273 ("the '273 patent"), and 11,051,856 ("the '856 patent") ("the Asserted Markman Patents").<sup>1</sup> The parties submitted a Joint Claim Construction Brief (D.I. 110) and Appendix (D.I. 111), and I heard oral argument on May 19, 2023 (Markman Tr. <sup>2</sup>).

## I. BACKGROUND

On January 19, 2021, Plaintiff Dr. Jackson filed his Complaint alleging infringement of the '866 and '273 patents, among others, against Defendant NuVasive, Inc. ("NuVasive"). (D.I. 1). On July 21, 2021, Plaintiff filed his First Amended Complaint additionally alleging infringement of the '856 patent. (D.I. 17). On October 21, 2022, Plaintiff filed his Second Amended Complaint, the amendments to which are not relevant to this opinion (D.I. 77).

The '866 and '273 patents belong to the same patent family and share a specification. The '856 patent has a different specification, but all three patents are directed to a compression or pressure insert in spinal implant systems that fixes the rod and screw components of a spinal stabilization system in place. ('866 patent, 2:8–15; '856 patent, 3:42–48).

## II. 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) (internal quotation marks omitted). ""[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate

<sup>&</sup>lt;sup>1</sup> The parties also disputed claim terms in U.S. Patent No. 10,561,444 ("the '444 patent") and U.S. Patent No. 9,808,292 ("the '292 patent") but resolved all disputes regarding those patents prior to oral argument.

<sup>&</sup>lt;sup>2</sup> Citations to the transcript of the argument, which is not yet docketed, are in the format "Markman Tr. \_\_."

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 (internal quotation marks omitted).

"[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 question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312–13 (citations and internal quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). "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 (internal quotation marks omitted). 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.* 

#### III. PATENTS AT ISSUE

The '866 and '273 patents have a priority date of May 27, 2005. The '856 patent has a priority date of October 30, 2007. Plaintiff is asserting the following claims of the Asserted Markman Patents: claims 1 and 9 of the '866 patent, claims 1, 12, 15 and 35 of the '273 patent, and claims 1 and 9 of the '856 patent. (D.I. 110 at 6–7). The following claims are representative and most relevant for purposes of claim construction:

#### Claim 1 of the '866 Patent

- 1. A bone anchor assembly for securing an elongate rod to a bone, the bone anchor assembly comprising:
- a shank having a proximal capture portion and an anchor portion extending distally from the proximal capture portion for fixation to the bone;
- a receiver having a longitudinal axis, an upper portion defining a U-shaped channel with inner sidewall surfaces configured to receive the elongate rod, and a lower portion defining a cavity communicating with the U-shaped channel and a receiver bottom opening for receiving the proximal capture portion of the shank therethrough, the inner sidewall surfaces including a *guide and advancement structure* and a discontinuous downwardfacing shoulder formed therein between the guide and advancement structure and the cavity;
- a retainer sized and shaped for loading into the cavity to engage and hold the shank proximal capture portion in spaced relation with respect to the receiver while an outer surface of the retainer engages an interior surface of the cavity to allow a pivotal motion between the receiver and the shank; and
- a pressure insert sized and shaped to be positioned downwardly within the receiver into a first position, the pressure insert having upward-facing contact surfaces and being rotatable with a tool into a second position that locates the upward-facing contact surfaces under the discontinuous downward-facing shoulder of the receiver to prevent the pressure insert from moving back up within the receiver.

('866 patent at 29:41–30:3 (disputed term italicized and bolded)).

#### Claims 12 and 35 of the '273 Patent

**12.** A bone anchor assembly for securing an elongate rod to a bone, the bone anchor assembly comprising:

- a shank having a proximal capture portion with an outer spherical surface and an anchor portion extending distally from the proximal capture portion for fixation to the bone;
- a receiver having a longitudinal axis, an upper portion defining a U-shaped channel with inner sidewall surfaces configured to receive the elongate rod, and a lower portion defining a cavity communicating with the U-shaped channel and a receiver bottom opening, the shank positionable within the receiver with the shank anchor portion extending through the bottom opening, the inner sidewall surfaces including a *guide and advancement structure* formed therein, the receiver having an internal downward-facing surface located between the guide and advancement structure and the receiver bottom opening; and
- a pressure insert sized and shaped to be disposed downwardly into a first position within the receiver adjacent the receiver downward-facing surface, after the shank has been positioned within the receiver, with the shank proximal capture portion outer spherical surface frictionally engageable with the pressure insert for directly receiving downward pressure from the pressure insert, the pressure insert having an upward-facing surface configured to engage the receiver downward-facing surface,
- wherein the pressure insert is rotatable with a tool about the receiver longitudinal axis into a second position within the receiver, with the insert upward-facing surface entering into frictional engagement with the receiver downward-facing surface, so as to apply downward pressure to the shank proximal capture portion outer spherical surface by biased overlapping engagement therebetween so as to provide a frictionally articulatable relationship for the shank with respect to the receiver prior to the elongate rod being received within the receiver.
- **35.** A bone anchor assembly for securing an elongate rod to a bone via a closure, the bone anchor assembly comprising:
- a shank having a proximal portion and an anchor portion extending distally from the proximal portion for fixation to the bone;
- a receiver having a longitudinal axis, an upper portion defining a U-shaped channel with inner sidewall surfaces configured to receive the elongate rod, and a lower portion defining a cavity communicating with the U-shaped channel and a receiver bottom opening for receiving the proximal portion of the shank therethrough, the inner sidewall surfaces including a *guide and advancement structure* and opposed discontinuous non-threaded downward-facing surfaces formed therein between the guide and advancement structure and the receiver cavity;
- a retainer sized and shaped for loading into the receiver cavity to engage and hold the shank proximal portion in spaced relation with respect to the receiver while an outer surface of the retainer engages an interior surface of the receiver cavity to allow a pivotal motion between the receiver and the shank; and
- a pressure insert sized and shaped to be positioned downwardly within the receiver into a first position, the pressure insert having non-threaded upward-facing surfaces and being rotatable with a tool into a second final position that locates the insert upward-facing surfaces under the receiver downward-facing surfaces to prevent the pressure insert from moving back up within the receiver prior to the elongate rod and the closure being placed within the receiver channel.
- ('273 patent at 30:54–31:25; 33:26–34:18 (disputed term italicized and bolded)).

## Claims 1 and 9 of the '856 Patent

1. A pivotal bone anchor assembly for securing an elongate rod to a bone of a patient via a closure top, the pivotal bone anchor assembly comprising:

a receiver comprising a base defining a cavity with a seating surface adjacent a bottom opening, and a pair of upright arms extending upward from the base to define a receiver channel configured to receive the elongate rod, the receiver channel opening upwardly onto top surfaces on the upright arms and opening laterally onto front and back outer faces of the upright arms, the cavity communicating with the channel to define an axial bore centered about a receiver longitudinal axis and extending upwardly from the bottom opening to the top surfaces of the upright arms, the base and upright arms together defining a substantially-cylindrical outer shape, and at least one inwardly-protruding structure integrally-formed with the receiver and projecting inwardly into the axial bore, the upright arms further including:

- opposed interior surfaces with a discontinuous helically wound *guide and advancement structure* formed therein and configured to rotatably mate with the closure top to lock the elongate rod within the channel;
- side outer surfaces opposite the interior surfaces extending downward across the base toward a bottom of the receiver; and
- a non-threaded radiused tool engagement groove extending horizontally and circumferentially entirely around the side outer surface of each upright arm to the front surface and the back surface of the receiver, each tool engagement groove being isolated from the axial bore and located below the top surface of the respective upright arm;
- a shank comprising a proximal capture portion configured for positioning within the cavity of the receiver and having an at least partially-spherical upper surface, and a distal anchor portion opposite the capture portion configured to attachment to the bone; and
- a pressure insert configured for positioning within in the axial bore of the receiver above the capture portion of the shank and comprising:

a substantially cylindrical body with a through-bore centered about an insert longitudinal axis;

- a downwardly-facing bottom surface surrounding the through-bore and being sized and shaped to frictionally engage and mate with the partially-spherical upper surface of the capture portion;
- an upwardly open insert channel formed into an upper portion of the pressure insert and configured to receive the elongate rod; and
- at least one vertically-elongate groove or notch formed into an outer side surface of the pressure insert,
- wherein the at least one groove or notch formed into the outer side surface of the pressure insert is configured to receive and engage the at least one inwardly-protruding structure of the receiver when the pressure insert is positioned within the axial bore with the pressure insert channel co-aligned with the receiver channel.

9. The pivotal bone anchor assembly of claim 1, further comprising:

at least one downwardly facing surface formed into the axial bore below the discontinuous helically wound *guide and advancement structure*; and

at least one flange projecting radially outward from the outer side surface of the pressure insert,

wherein the at least one flange is rotatably positionable under the at least one downwardly facing surface to prohibit upward movement of the pressure insert out of the receiver.

('856 patent at 24:39-25:31; 25:66-26:9 (disputed term italicized and bolded)).

#### IV. CONSTRUCTION OF AGREED-UPON TERMS

I adopt the following agreed-upon constructions (D.I. 114):

Claim Term	Claims	Construction
"radiused upper surface"	Claims 1, 15 and 25 of the '292 Patent.	"curved upper surface"
"helically"	Claims 1 and 9 of the '856 Patent.	Ordinary and customary meaning
"discontinuous"	Claim 1 of the '444 Patent.	"not continuous"
"external"	Claims 19 and 25 of the '292 Patent.	"outside"

#### V. CONSTRUCTION OF DISPUTED TERM

# 1. "guide and advancement structure" (claims 1 and 9 of the '866 patent; claims 1, 12, 15 and 35 of the '273 patent; claims 1 and 9 of the '856 patent)

- a. *Plaintiff's proposed construction*: Ordinary and customary meaning, defined as "a structure that directs the progress of a component as it moves along its course."
- b. Defendant's proposed construction: "thread or flange form."
- c. Court's construction: "thread or flange form."

The parties dispute whether the claimed "guide and advancement structure" should be limited to threads or flange forms.

Plaintiff argues that there is "neither lexicography nor disclaimer that would justify limiting the ordinary meaning to preferred embodiments" (D.I. 110 at 44). To support this argument, Plaintiff maintains that "various types of threads and flanges are disclosed as specific examples of the more-general 'guide and advancement structure.'" (*Id.* at 46). Similarly, Plaintiff cites to portions of the '273 patent specification to argue that the patents describe threads and flange forms as embodiments rather than as a limitation of the inventions. (*Id.* (citing '273 patent at 7:21–33)). Plaintiff also notes that the specification discloses alternatives following the description of the embodiments, such as "non-thread like" structures, which are neither threads nor flange forms. (*Id.* at 47). Plaintiff points to the description in the '273 patent specification of a thread-like "helical rib" as an alternative structure. (*Id.* at 47–48). Specifically, the '273 patent states:

Although a simple helical rib **98** is shown in the drawings, it is foreseen that other helical structures including other types of threads, such as buttress and reverse angle threads, and non-threads, such as helically wound flanges with interlocking surfaces, may be alternatively used in an alternative embodiment of the present invention.

('273 patent at 8:60–66). According to Plaintiff, the phrase "other helical structures including" indicates that there are additional helical structures that are not encompassed in "thread" or "flange forms." (D.I. 110 at 48). Plaintiff contends that because the intrinsic evidence signals the inventor's intention not to limit "guide and advancement structure" to only threads and flange forms, the term should be given its ordinary and customary meaning. (*Id.* at 49).

Defendant counters that "guide and advancement structure" is a coined term. (Markman Tr. at 26:14–17). Defendant argues that the specifications repeatedly describe the "guide and advancement structure" as a type of thread or flange form and that Plaintiff does not identify any "guide and advancement structure" that would not be either a thread or flange form. (*Id.* at 50–51). Defendant also points out that the "non-thread like" alternatives refer to "helically wound flanges" in the specifications. (*Id.* at 51–52). Regarding "helical rib," Defendant argues that the

specification makes clear that a "helical rib" is a type of thread,<sup>3</sup> highlighting the language "including other types of threads" in the above passage, which modifies "helical rib.". (*Id.* (citing '273 patent at 8:60-66)).

In reply, Plaintiff argues that he is not required to identify additional structures for "guide and advancement structure." (*Id.* at 53). I asked Plaintiff, after the conclusion of briefing but before the Markman hearing, to identify a "guide and advancement structure" that is not a thread or flange (D.I. 113). Plaintiff identified a "cam" and "raceway" structure and a "ratchet" structure. (D.I. 115 at 2–5). Plaintiff also disputes Defendant's grammatical analysis of the '273 patent's specification that a "helical rib" can be a thread or a flange. Plaintiff argues that the phrase "including other types of threads" modifies "other helical structures," not "helical rib." (D.I. 110 at 54).

I also asked Plaintiff, after briefing and before the Markman hearing, to specify the ordinary and customary meaning of "guide and advancement structure." (D.I. 113). Plaintiff defines the ordinary and customary meaning of "guide and advancement structure" as "a structure that directs the progress of a component as it moves along its course." (*See* D.I. 115 at 1). Defendant argues this definition is a "structure" followed by functional language. (Markman Tr. 33:14–24).<sup>4</sup> Plaintiff disagrees. (Markman Tr. 56:3–24). I agree with Defendant that Plaintiff's definition of the term is completely a functional definition, and I therefore decline to adopt it.

I also agree with Defendant that "guide and advancement structure" is a coined term. No evidence has been presented that "guide and advancement structure" was known or readily understandable to a person of ordinary skill in the art (POSA). Plaintiff concedes that the term is

<sup>&</sup>lt;sup>3</sup> Defendant alternatively notes that the definition of a "flange" includes "rib." (D.I. 110 at 51 (citing to The American Heritage Dictionary of the English Language (4th ed. 2006) entry for "flange")).

<sup>&</sup>lt;sup>4</sup> Essentially, Plaintiff's plain and ordinary meaning is a means plus function construction where the means is everything that can perform the function.

not a term of art. (D.I. 115 at 1). I gave Plaintiff the opportunity to search for the use of the term "guide and advancement structure" prior to the earliest priority date of the patents—May 27, 2005. (Markman Tr. at 59:11–60:12). "Plaintiff was not able to find the phrase 'guide and advancement structure' used prior to May 2[7], 2005." (D.I. 117 at 1). Dr. Jackson was the first person ever to use the phrase "guide and advancement structure." I find "guide and advancement structure" is a coined term.

Because coined terms have no "ordinary and customary meaning" known to a POSA, the relevant inquiry is to examine the intrinsic evidence for "objective boundaries to the scope of the term." Iridescent Networks, Inc. v. AT&T Mobility, LLC, 933 F.3d 1345, 1353 (Fed. Cir. 2019). The specifications of the Asserted Markman Patents consistently refer to "guide and advancement structure" as a type of thread or flange form. The specification of the '866 patent,<sup>5</sup> for example, describes the "guide and advancement structure" as a simple thread or "other structures including other types of threads...and non-threads, such as helically wound flanges" (6:32–42), "non-threads like helically wound advancement structures" (7:15-25), or a preferred "helically wound flange form." (11:37-44). The specification also states that "other types of helical guide and advancement structures may be used" other than a V-shaped thread (11:56-58) and describes "guide and advancement structures" as "types of threads or flange forms." (19:21-32; 25:15-26). Similarly, the '856 patent specification describes the "guide and advancement structure" as having a "generally helical pattern or configuration that is typical of threads" (7:56-61), or "other threadlike or non-thread-like guide and advancement structures, such as flange form helically wound advancement structures." (8:2-8). The specification also states that "other types of helical guide and advancement structures may be used" other than a V-shaped thread (12:43-45) and describes

<sup>&</sup>lt;sup>5</sup> The '273 patent shares the same specification as the '866 patent.

preferred "helically wound flange forms." (18:6–10). The consistent and numerous references to "guide and advancement structure" as a type of thread or flange form operates as an objective boundary to the scope of the term.

Plaintiff argues that the "helical rib" discussion in the specification, *see supra* p. 7, shows that "guide and advancement structure" is broader than just thread or flange form. I disagree. I read the quoted passage to imply that a "helical rib" is a type of thread. (*See* '273 patent at 8:60–66). The phrase "other helical structures" refers to a "simple helical rib," meaning a helical rib is included in the category of helical structures. The specification goes on to include "other types of threads," where "other types" must be referring to a type of thread that has already been named, i.e., a simple helical rib. The specification also includes non-threads and gives an example of "helically wound flanges." The passage therefore includes all kinds of threads, including a simple helical rib, and flanges. There are no other additional guide and advancement structures described.

Plaintiff's identification of a "cam" and "raceway" structure or a "ratchet" structure as alternative structures is similarly unavailing. Neither structure is identified as a "guide and advancement structure" in the Asserted Markman Patents. The '273 and '866 patents disclose some components of the inventions as having ratchet teeth below the guide and advancement structure. ('273 patent at 8:30–44). But the patents do not disclose ratchet teeth as part of any guide and advancement structure. If ratchet teeth were included in "guide and advancement structure," the specifications would describe "ratchet" structures as being so included, as they do with threads and flange forms, instead of disclosing ratchet structures separately.

Coined terms, which have "no plain or established meaning" in the art, "cannot be construed broader than the disclosure in the specification." *Indacon, Inc. v. Facebook, Inc.*, 824

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F.3d 1352, 1357 (Fed. Cir. 2016). As a coined term, I find that "guide and advancement structure" is limited by the patent specifications.

I therefore adopt Defendant's construction of "guide and advancement structure": "thread or flange form."

# VI. CONCLUSION

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