IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SPINAL GENERATIONS, LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 22-1368 (MN)
	)	
DEPUY SYNTHES, INC.; SYNTHES USA, LLC; DEPUY SYNTHES SALES, INC.; and SYNTHES USA PRODUCTS, LLC,	)	
	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington, this 16th day of October 2024:

IT IS HEREBY ORDERED that the claim terms of U.S. Patent Nos. 7,575,572 ("the '572 patent"), 7,572,611 ("the '611 patent"), 8,808,337 ("the '337 patent"), and 8,062,270 ("the '270 patent") with agreed-upon constructions are construed as follows (*see* D.I. 111-1 at 2 *and* D.I. 123 at 1):

1. "at least one end of the bone screw" means "one or both ends of the bone screw" ('572 patent, claims 1, 9 & 11)

2. "at least one end of the insert" means "one or both ends of the insert" ('337 patent, claim 1; '270 patent, claim 1)

3. "at least one end of the bone screw or insert" means "one or both ends of the bone screw or insert" ('611 patent, claim 5)

4. "is a fixation screw" means "is designed to hold two or more bones or bone pieces in a fixed spatial relationship with respect to each other" ('572 patent, claim 5)

5. "is cannulated" and "cannulation" respectively mean "comprises a hollow cavity disposed inside at least part of its shaft" and "a hollow cavity disposed inside at least part of its shaft" ('572 patent, claims 1 & 4; '611 patent, claim 1; '337 patent, claims 1-3; '270 patent, claim 1)

6. "is self-tapping" means "has one or more cutting edges for creating a thread when driven into bone" ('572 patent, claim 6)

7. "fenestration" means "a slot, gap, or perforation that defines an opening between the inside of the cannulated portion of the screw or insert to the outside of the screw or insert, excluding the opening at the proximal end of the screw or insert" ('572 patent, claims 1 & 2; '611 patent, claims 1 & 2; '337 patent, claims 1 & 3; '270 patent, claim 1)

Further, as announced at the hearing on August 1, 2024, IT IS HEREBY ORDERED that the disputed claim terms of the '572, '611, '337 and '270 patents are construed as follows:

1. "bone screw" means "screw, tack, pin, nail or a like device, whether threaded or unthreaded, for implantation into bone" ('572 patent, claims 1-2, 4-7, 9, 11; '611 patent, claims 1-3, 5-6; '337 patent, claims 1-3, 8; '270 patent, claims 1, 8)

2. "material" shall be given its plain and ordinary meaning, which is "physical matter" ('572 patent claim 1)

3. "is threaded" shall be given its plain and ordinary meaning, which is "has a projecting helical rib by which parts can be screwed together" ('611 patent, claim 1)

4. "disposed along the cannulated portion of the insert" shall be given its plain and ordinary meaning, which is "located along the hollow internal cavity disposed inside at least part of the shaft of the insert" ('572 patent, claim 1; '611 patent, claim 1; '337 patent, claim 1; '270 patent, claim 1)

5. "at least a portion of the shaft of the insert substantially prevents material from entering the cannulated portion of the bone screw through the one or more bone-screw fenestrations' means "at least part of the insert shaft prevents a clinically significant amount of material from entering the cannulated portion of the bone screw through one or more of the bone-screw fenestrations," and is definite ('572 patent, claim 1)

6. "first position wherein a surface of the bone screw blocks the insert fenestration preventing the substance from exiting the cannulated portion of the insert via the insert fenestration" means "a position wherein a surface of the bone screw blocks the insert fenestration preventing any detectable amount of the substance from exiting the cannulated portion of the insert via the insert fenestration" ('337 patent, claim 1; '270 patent, claim 1)

Further, as also announced at the hearing on August 1, 2024, IT IS HEREBY ORDERED that the preamble of the '611 patent is limiting, and the preambles of the '337, '270, and '572 patents are not limiting.

The parties briefed the issues (D.I. 101) and submitted intrinsic and extrinsic evidence, (D.I. 102) including declarations from experts (D.I. 103, 104). The Court carefully reviewed all submissions in connection with the parties' contentions regarding the disputed claim terms, heard oral argument and testimony from both parties' experts (D.I. 116, D.I. 146) and applied the following legal standards in reaching its decision:

I. LEGAL STANDARDS

A. Claim Construction

"[T]he ultimate question of the proper construction of the patent [is] a question of law," although subsidiary fact-finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325-27 (2015). "[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." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (cleaned up). Although "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Id.* at 1314. "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id*. at 1321 (internal quotation marks omitted).

The patent specification "is always highly relevant to the claim construction analysis . . . [as] it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would

otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. "Even when the specification describes only a single embodiment, [however,] the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotation marks omitted) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence, . . . consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

In some cases, courts "will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 574 U.S. at 331. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. Expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field."

Phillips, 415 F.3d at 1318. Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id*. Overall, although extrinsic evidence "may be useful to the court," it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id*. at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co*., 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

B. <u>Indefiniteness</u>

"The primary purpose of the definiteness requirement is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, *e.g*., competitors of the patent owner, can determine whether or not they infringe." *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779-80 (Fed. Cir. 2002) (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28-29 (1997)). Put another way, "[a] patent holder should know what he owns, and the public should know what he does not." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002). A patent claim is indefinite if, "viewed in light of the specification and prosecution history, [it fails to] inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014). A claim may be indefinite if the patent does not convey with reasonable certainty how to measure a claimed feature. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015). But "[i]f such an understanding of how to measure the claimed [feature] was within the scope of knowledge possessed by one of ordinary skill in the art, there is no requirement for the specification to identify a particular measurement technique." *Ethicon Endo-Surgery, Inc. v.*

Covidien, Inc., 796 F.3d 1312, 1319 (Fed. Cir. 2015). Like claim construction, definiteness is a question of law, but the Court must sometimes render factual findings based on extrinsic evidence to resolve the ultimate issue of definiteness. *See, e.g., Sonix Tech. Co. v. Publications Int'l, Ltd.*, 844 F.3d 1370, 1376 (Fed. Cir. 2017); *see also Teva*, 574 U.S. at 334-36. "Any fact critical to a holding on indefiniteness . . . must be proven by the challenger by clear and convincing evidence." *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1366 (Fed. Cir. 2003); *see also Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1338 (Fed. Cir. 2008).

II. THE COURT'S RULING

The Court's Ruling regarding the disputed claim terms of the '572, '611, '270, and '337 patents was announced from the bench at the conclusion of the hearing as follows:

> At issue, there are seven disputed claim terms in four patents, all of which are related to each other either as continuations or continuations-in-part. I am prepared to rule on the disputes.
>
> I will not be issuing a written opinion, but I will issue an order stating my rulings. I want to emphasize before I announce my decisions that although I am not issuing a written opinion, we have followed a full and thorough process before making the decisions I am about to state. I have reviewed the patents and all the evidence submitted by the parties. There was full briefing on each of the disputed terms and we had argument in May and again today, as well as expert testimony. All of that has been carefully considered.
>
> As to my rulings, I am not going to read into the record my understanding of claim construction law and indefiniteness. I have a legal standard section that I have included in earlier opinions, including somewhat recently in *REX Computing, Inc. v. Cerebras Systems Inc.*, Civil Action No. 21-525 (MN). I incorporate that law and adopt it into my ruling today and will also set it out in the order that I issue.
>
> Let me also note that although the parties have not agreed entirely on the definition of a person of ordinary skill in the art, they seem to agree that my construction of the terms should be the same regardless of which definition is used.[1]

[1] (*See* D.I. 104 at 16).

The first dispute is the term "bone screw."[2] Plaintiff proposes the construction "screw, tack, pin, nail or a device like a tack, pin or nail, whether threaded or unthreaded, for implantation into bone."[3] Defendants assert that no construction is needed, or alternatively "screw, tack, pin, or nail for implantation into bone."[4] The crux of the dispute is Plaintiff's addition of the words "or a like device."[5] Here, I agree with Plaintiff.

The specification of each of the patents sets off the term "bone screw" in quotation marks,[6] stating:

> the term "bone screw" is intended to refer to screws of all types which are presently known or hereafter devised for implantation into bone. In this regard, cancellous screws, cortical screws, and machine screws are all contemplated as being within the scope of the types of screws useful in the practice of the present invention. The bone screws of the present invention will typically comprise threads along at least a portion of the exterior of the screw shaft, but it should be appreciated that tacks, pins, nails and the like may also be included within the definition of a bone screw for the

2 Among the asserted patents, this term appears in claims 1-2, 4-7, 9 and 11 of the '572 patent, claims 1-3 and 5-6 of the '611 patent, claims 1-3 and 8 of the '337 Patent and claims 1, 8 of the '270 patent.

3 The parties' Amended Joint Claim Construction Chart defined this term as "screw, tack, pin, nail, or a like device, whether threaded or unthreaded, for implantation into bone." (D.I. 111-2 at 3). Counsel for Plaintiff subsequently argued that "or a like device" applied to each of the preceding four terms. (D.I. 116 at 25:16-26:20). The patent specifications, however, discuss "tacks, pins, nails and the like" separately from "screws." *See* n. 7 *infra*. The Court can therefore only find that the phrase "or a like device" means "a device like a tack, pin or nail."

4 (D.I. 111-2 at 3).

5 (*See* D.I. 101 at 26-30).

6 A term's being set off by quotation marks in the specification is "often a strong indication that what follows is a definition." *Sinorgchem Co., Shandong v. International Trade Com'n*, 511 F.3d 1132, 1136 (Fed. Cir. 2007) (citing *Cultor Corp. v. A.E. Staley Mfg. Co.*, 224 F.3d 1328, 1331 (Fed. Cir. 2000)).

> purposes of the present invention, whether threaded or unthreaded.[7]
>
> Defendants argue that the phrase "or a like device" improperly injects ambiguity and makes the term indefinite.[8] I disagree. A claim is "insolubly ambiguous" and therefore indefinite "only where a person of ordinary skill in the art could not determine the bounds of the claims … based on the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant art area."[9] Here, Defendants offer little support for their assertion of indefiniteness. The term is not overly complicated or technical and a person of skill in the art would not have difficulty determining whether a given fixation device is "like" a "tack, pin, or nail" for purposes of the invention. The patent makes clear that a need exists for a device capable of "delivering a substance to a bone, especially to specific areas within the bone."[10] This language suggests that a person of skill in the art would not see "bone screw," for purposes of this patent, as being limited to a particular embodiment, as long as it constituted a "device" that a POSA would recognize as a bone screw and it could meet this need (and any other requirements of the claim).
>
> I also disagree with Defendants' argument that the language "threaded or unthreaded" in Plaintiff's proposal is superfluous because an "'unthreaded' screw is simply a 'nail.'"[11] In the [Plaintiff's proposed construction], this phrase comes immediately after "or [a like] device" and can apply to that phrase.[12]

7 ('572 patent at 4:13-4:24; *see also* '611 patent at 6:30-6:41; '337 patent at 6:30-6:41; '270 patent at 7:41-7:52).

8 (D.I. 101 at 28-29).

9 *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249-50 (Fed. Cir. 2008).

10 ('572 patent at 1:46-51; '611 patent at 1:57-62; '337 patent at 1:57-62; '270 patent at 1:64-2:2).

11 (D.I. 101 at 30).

12 At the hearing, the Court stated "in the specification, this phrase comes immediately after 'or other device,'" (D.I. 146 at 131:22-24), but as discussed above, the correct phrase is "for a like device" and the Plaintiff's proposed construction is in fact where this phrasing appears. (D.I. 111-2 at 3).

The next disputed term is "material" in claim 1 of the '572 patent. Plaintiff proposes the plain and ordinary meaning and says no construction is necessary.[13] Defendants propose "bone fragments, blood, fat, or other bodily fluids or tissues."[14] Here, I agree with Plaintiff.

The '572 patent does not define the term "material." The specification uses the term in its ordinary usage, meaning physical matter. For example, it repeatedly discusses embodiments "preventing bone fragments, blood, fat, or other materials from entering the cannulated portion."[15] In other places it uses the same word to address the material that makes up the bone screw.[16] So I think that its plain and ordinary meaning should apply.

I am not opining as to whether the substance claimed is also the material in the claim. The experts may opine as a factual matter as to whether a substance in an accused product or a piece of prior art is the material required by the claims to the extent that is an issue.

I am going to construe material according to its plain and ordinary meaning which is "physical matter."

The next term is "is threaded" in claim 1 of the '611 patent, which claims "a bone screw comprising two ends connected by a shaft, wherein the shaft is threaded."[17] Plaintiff proposes "having at least one helical or stepwise variation in profile" and Defendants propose that the plain and ordinary meaning should apply, which apparently is "has a projecting helical rib by which parts can be screwed together."[18] Here, I agree with Defendants.

13 (D.I. 111-2 at 4).

14 (*Id.*).

15 ('572 patent at 2:34-35, 6:29-35, 7:19-23).

16 (*Id*. at 4:63-65, 6:25-29).

17 ('611 patent at 14:22-23).

18 Defendants initially proposed this as an alternative to the plain and ordinary meaning. (D.I. 111-2 at 4). At the May 31st hearing, however, Counsel for Defendants told the Court that "there can be no legitimate dispute [that] it's [a] projecting helical rib [by] which parts can be screwed together." (D.I. 116 at 37:14-16).

Plaintiff's construction would include a single stepwise variation in profile.[19] That seems inconsistent with the plain and ordinary meaning of what threads on a screw are. And nothing in the patent or specification says anything about a stepwise variation in profile or suggests that term is used in anything other than by its plain and ordinary meaning.

Instead, Plaintiff's support for its construction come entirely from [the] declaration of its expert.[20] Although Plaintiff's expert testified here today, she did not testify as to this term.[21] The Federal Circuit has warned that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence," and that while extrinsic evidence "may be useful to the court," it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence."[22] That is particularly a concern here where there was no cross-examination on this point.

To the extent that Plaintiff argues that using the plain and ordinary meaning of threaded would read out embodiments,[23] I disagree. Nothing in the embodiments cited by Plaintiff requires more than or is inconsistent with the plain and ordinary meaning.

Therefore, I will decline to adopt Plaintiff's proposed construction. Given the Federal Circuit's preference for using the

19 (D.I. 111-2 at 4).

20 (D.I. 101 at 35-36).

21 (D.I. 146).

22 *Phillips*, 415 F.3d at 1318-19.

23 Plaintiff argues that this construction would "omit a preferred embodiment from the scope of the relevant claim," the embodiment in which the thread is used to "increase the screw's purchase in bone." (D.I. 101 at 36). This is incorrect; the plain and ordinary meaning of "threaded" allows for screw threads to serve this purpose, even if it does not require that they do so. Plaintiff also argues that this construction omits embodiments of the invention that include more than one thread. (D.I. 101 at 36). The two figures Plaintiff cites, however, show one thread each on the exterior of the screw and interior of the cannulation. (D.I. 102 at 26, 29). Claim 1 of the '611 patent also states that the bone screw "is threaded along at least a portion" of both its exterior and its interior. '611 patent at 14:22-14:26. The plain and ordinary meaning of "threaded" therefore comports with Claim 1's text.

plain and ordinary meaning,[24] I will adopt the plain and ordinary meaning of "threaded" and construe it to mean "has a projecting helical rib by which parts can be screwed together."

The next disputed term is "disposed along the cannulated portion of the insert."[25] Plaintiff's proposal is "positioned along the hollow cavity disposed inside at least part of the insert shaft, and not at either end of the insert."[26] Defendants' proposal is that the plain and ordinary meaning applies or alternatively "located along the hollow internal cavity disposed inside at least part of the shaft of the insert."[27] The thrust of the dispute is Plaintiff's addition of the words "and not at either end of the insert." Here, I agree with Defendants.

First, I think that the words themselves are pretty clear and straightforward. Additionally, I think Plaintiff's construction is at odds with language in each patent's specification that mentions possible fenestrations "at the ends of the screws and inserts."[28]

The plain and ordinary meaning avoids this problem; it allows for fenestrations at the end of the shaft, but flush with it (rather than flush with the tips).

Additionally, as Defendants pointed out,[29] during prosecution patentee added the language "between the two ends" to another claim – claim 1 of the '572 patent. It was not added to the claims at issue in this dispute. I see no reason to do so. Indeed, Plaintiff's attempt to read in that limitation here, in the absence of

24 *See Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (noting that "claim terms are generally given their plain and ordinary meaning," except when the patentee either "acts as his own lexicographer" or "disavows the full scope of a claim term") (internal quotations and citations omitted).

25 (Claim 1 of the '611 patent, claim 1 of the '337 patent, claim 1 of the '270 patent, claim 1 of the '572 patent).

26 (D.I. 111-2 at 4-5).

27 (*Id.*).

28 (*See* '572 patent at 4:8-10, '611 patent at 5:23-26, '337 patent at 5:24-26, '270 patent at 6:34-36).

29 (D.I. 116 at 45:3-21).

the words it added to the claim in the '572 patent would render that language superfluous in claim 1 of the '572 Patent.

Thus, I will adopt Defendants' proposal and construe the term according to its plain and ordinary meaning, which is "located along the hollow internal cavity disposed inside at least part of the shaft of the insert."

The next dispute is whether the language that "at least a portion of the shaft of the insert substantially prevents material from entering the cannulated portion of the bone-screw through the one or more bone-screw fenestrations" in claim 1 of the '572 patent is indefinite.[30] The dispute in this case turns on the phrase "substantially prevents." Defendants say that term is indefinite – while Plaintiff says that it means prevents a "clinically significant amount of material" from entering the cannulated portion of the bone screw.[31]

Today I heard testimony from the parties' experts on the definiteness of this term. Defendants' expert pointed out that "substantially prevents" is not defined in the intrinsic evidence.[32] That is true. That, however, is not the end of the analysis.

Claim terms are not indefinite so long as "the intrinsic record provides objective boundaries by which a skilled artisan could determine the scope of the claims."[33] Here, it seems that the intrinsic evidence shows that "substantially prevents" means preventing the entrance of an amount of material that would interfere with treatment. The specification shows that this feature is designed for safe, effective treatment. For example, at 7:19-7:29, the '572 patent states: "In addition, the bone-screw inserts of the present invention, even when fenestrated, may be advantageously used to significantly hinder[34] bone fragments, blood, fat, or other

30 (D.I. 101 at 49-73).

31 (D.I. 111-2 at 5-6).

32 (D.I. 146 at 40:5-21).

33 *Niazi Licensing Corp. v. St. Jude Med. S.C.*, Inc., 30 F.4th 1339, 1349–50 (Fed. Cir. 2022).

34 Defendants argue that hinder and prevent have different meanings. "Hinder" means to make something more difficult, while "prevent" means to stop something from happening. (D.I. (Tr. No.) at 41:11-16). Here, however, the words are "significantly hinder" and

> materials from entering the cannulated portion of the bone screw, especially during insertion of the bone screw into the bone, for example. In this case it may be desirable to initially position the insert and bone screw such that the insert fenestrations do not align with the bone-screw fenestrations. The insert may then be subsequently re-positioned at a later time to align one or more of the insert fenestrations with the bone screw fenestrations to facilitate substance delivery."[35]
>
> I disagree that "clinically significant" adds ambiguity. As Plaintiff's expert opined, this is a patent about a surgical implant that's used by clinicians in a clinical setting.[36] Aspects of the design of the invention focus on avoiding "adverse effects to the patient"[37] and meeting the "particular needs of the patient."[38] So clinically significant amount seems to be an amount that would result in adverse effects to the patient or not meet the needs of a patient.
>
> So based on what I have heard today, I do not think that Defendants have met their burden of proving this term in the claims that contain it is indefinite. And I will construe it as Plaintiff requests as prevents a "clinically significant amount of material" from entering the cannulated portion of the bone screw.
>
> The next term is "first position wherein a surface of the bone screw blocks the insert fenestration preventing the substance from exiting the cannulated portion of the insert via the insert fenestration" in claim 1 of the '337 patent and claim 1 of the '270 patent. Plaintiff proposes the construction "position in which a surface of the bone screw blocks the insert fenestration, preventing a clinically significant amount of the substance from exiting the insert through the insert fenestration."[39] Defendants propose the plain and ordinary meaning or alternatively "a position wherein a

"substantially prevent" – both of which seem to allow some material to enter the cannulated portion of the screw.

35 ('572 patent at 7:19-29).

36 (D.I. 146 at 51:24-25).

37 ('572 patent at 7:32-33).

38 ('572 patent at 7:50-65).

39 (D.I. 111-2 at 6).

surface of the bone screw blocks the insert fenestration preventing any detectable amount of the substance[40] from exiting the cannulated portion of the insert via the insert fenestration."[41] The real dispute is whether the amount of substance exiting is "any detectable amount" or "clinically significant." Here, I agree with Defendants.

The intrinsic evidence supports Defendants' alternative construction. The claim language simply says it "blocks the insert fenestration preventing the substance."[42] It provides no qualifying or moderating language like "substantially," "mostly," "significantly" like that used in other claims.[43] Clearly the patentee knew how to add that language when it wanted to qualify a term as it did so in connection with other claims.

The position of Plaintiff's expert is that that does not matter and the qualifying terms in those other claims is essentially superfluous.[44] I disagree.

Additionally, the specification discusses preventing the substance from leaking out. For example, it states "the outside of the insert is pressed snuggly against the inside of the cannulation … in order to prevent the substance to be delivered from leaking between the insert and the bone screw and escaping through a bone screw fenestration from which it was not intended to escape."[45]

Similarly, the prosecution history of the '337 Patent confirms this interpretation. To overcome an anticipation rejection

40 Defendants' original proposed construction stated, "a position wherein a surface of the bone screw blocks the insert fenestration preventing any of the substance from exiting the cannulated portion of the insert via the insert fenestration." (D.I. 111-2 at 6). Defendants' expert clarified that this proposed construction meant "any detectable amount," and that a molecule of substance could escape undetected. (D.I. 146 at 105:5-13).

41 (D.I. 111-2 at 6).

42 ('337 patent at 14:33-34; '270 patent at 22:18-21).

43 (*See* '572 patent at 9:55-57 ("substantially prevents") *and* '337 patent at 15:24-25 ("substantially seals")).

44 (D.I. 146 at 82:1-5).

45 ('337 patent at 5:29-35).

the patentee stated: "because [the prior art] discloses that there is a gap between the outer surface … and the inner surface … [the prior art] does not identically disclose an insert moveable between a first position 'wherein a surface of the bone screw blocks the insert fenestration preventing the substance from exiting the cannulated portion of the insert via the insert fenestration' … as recited in claim 1."[46] The patentee distinguished his claims which prevent the substance from exiting from the prior art which had a gap that allowed substance to leak out. There was no discussion of the leakage being clinically significant or not. I am not saying there was a disclaimer here, but simply using the prosecution history à la *Phillips* to help me understand the meaning of the term.

So based on the intrinsic evidence, I will adopt the Defendants' proposed alternative construction and construe the term to mean, "a position wherein a surface of the bone screw blocks the insert fenestration preventing any detectable amount of the substance from exiting the cannulated portion of the insert via the insert fenestration." There was discussion today of a few molecules of substance and whether that would be impossible to prevent.[47] I think that a person of skill would understand that what is being prevented is what can be detected. So I am not construing this term to cover an impossibility.

Finally, we have the dispute about whether the preambles of the claims in the four patents are limiting.[48] Plaintiff argues that the preambles are not limiting. Defendants disagree.[49]

According to the Federal Circuit generally preambles are not limiting.[50] They may, however, be limiting when "without the preamble a POSA would not understand the utility of the system described or the invention claimed," [and] when "nowhere in the

46 (D.I. 102 at 253-54).

47 (D.I. 146 at 88:22-89:23, 104:18-105:9).

48 (*See* D.I. 111-2 at 7 *and* '572 patent at 9:40 ("a device for delivering a substance to a bone"); '611 patent at 14:20 and '337 patent at 14:21 ("a system for delivering a substance to a bone"); '270 patent at 21:57 ("a system for implantation within a bone")).

49 (D.I. 111-2 at 7).

50 *See Allen Engineering Corp. v. Bartell Industries, Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002) ("Generally, the preamble does not limit the claims").

body of the claim" is the invention's purpose clear[51] or if they provide "an important structural limitation, which is repeatedly underscored as important by the specification."[52]

Based on my review of the preambles in the asserted claims of the four patents, I find that the preamble to the '611 patent is limiting. Claim 1 of that patent claims "a system for delivering a substance to a bone, the system comprising."[53] Without that preamble, the claims could be for any bone implant, not necessarily one used for substance delivery. It thus seems that that preamble gives meaning to the claim.

I do not, however, find that to be the case for the preambles of the other asserted claims and find that those are not limiting.

Maryellen Noreika

The Honorable Maryellen Noreika
United States District Judge

51 *Ecobee, Inc. v. EcoFactor, Inc.*, No. CV 21-323 (MN), 2023 WL 2784936, at *4 (D. Del. Apr. 5, 2023).

52 *MiiCs & Partners Am., Inc. v. Toshiba Corp.,* No. CV 14-803-RGA, 2016 WL 4573103, at *8 (D. Del. Aug. 31, 2016).

53 ('611 patent at 14:20-21).