IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CONFORMIS, INC.,

Plaintiff,

v.

MEDACTA USA, INC.,

Defendant.

Civil Action No. 19-1528-RGA

Consolidated

MEMORANDUM OPINION

Karen L. Pascale, Robert M. Vrana, YOUNG CONAWAY STARGATT & TAYLOR LLP, Wilmington, DE; Matthew M. Wolf, Paul Margulies (argued), Rebecca Neubauer, Victoria L. Reines (argued), ARNOLD & PORTER KAYE SCHOLER LLP, Washington, DC, Attorneys for Plaintiff.

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March 4, 2021

/s/ Richard G. Andrews
ANDREWS, UNITED STATES DISTRICT JUDGE:

Before me is the issue of claim construction of multiple terms in U.S. Patent Nos. 8,377,129 ("the '129 patent"), 8,460,304 ("the '304 patent"), 9,186,161 ("the '161 patent"), and 9,295,482 ("the '482 Patent). I have considered the Parties' Joint Claim Construction Brief (D.I. 98) and Appendix (D.I. 99–101). I held remote oral argument on January 7, 2021. (D.I. 110).

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) (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 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.*, 135 S. Ct. 831, 841 (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*.

"A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GMBH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (citation and internal quotation marks omitted).

II. BACKGROUND

This case is about surgical tools and implants used in joint replacement surgeries and joint arthroplasties, which are procedures that aim to restore some degree of function to a

diseased or damaged joint. The '129 patent and '304 patents share the same specification, as do the '161 and '482 patents. (D.I. 98 at 1 n.2).

The following claims are the most relevant for the purposes of this Markman:

Claim 1 of the '129 Patent

> 1. A patient-specific instrument system for surgery of a diseased or damaged knee joint of a patient, the instrument system comprising:
>
> a patient-specific surface for engaging at least a portion of *a substantially uncut joint surface of the diseased or damaged knee joint of the patient, the patient-specific surface including cartilage information derived from image data of the diseased or damaged knee joint of the patient*; and
>
> a guide for directing a surgical instrument, wherein the guide has a predetermined position relative to the patient specific surface and relative to from at least one of an anatomical axis and a biomechanical axis associated with said knee joint;
>
> wherein the guide defines a drilling path through at least a portion of the knee joint, the drilling path having a position based on a predetermined internal rotation angle or external rotation angle of an orthopedic implant.

(D.I. 99, Exh. 1 ("'129 Patent"), claim 1) (emphasis added).

Claim 13 of the '304 Patent

> 1. A surgical instrument for use in surgically repairing a joint of a patient, the surgical instrument comprising:
>
> a mold having an internal surface that includes joint information derived from image data of the joint of the patient; and
>
> two or more guide holes, each configured to guide a surgical pin,
>
> wherein at least one of the two or more guide holes has a position based on anatomical information of the joint of the patient to facilitate the placement of an articular repair system when the internal surface of the mold is aligned with the joint of the patient,
>
> wherein the articular repair system has a predetermined rotation angle and wherein the position is based on the predetermined rotation angle.
>
> 13. The surgical instrument of claim 1, wherein the joint of the patient is a knee joint, *wherein at least one guide hole of the two or more guide holes is configured to guide a surgical pin on a medial tibial plateau of the knee joint.*

(D.I. 99, Exh. 2 ("'304 Patent"), claim 1, 13) (emphasis added).

Claim 1 of the '482 Patent

> 1. A joint arthroplasty system for repairing a diseased or damaged joint of a patient comprising:
>
> an implant; and
>
> a patient-specific surgical instrument configured to facilitate the placement of the implant into the diseased or damaged joint, the instrument comprising:
>
> a patient-specific surface for engaging a corresponding portion of the diseased or damaged joint, the patient-specific surface including cartilage information derived from image data of the diseased or damaged joint,
>
> wherein the corresponding portion of the diseased or damaged joint includes an osteophyte,
>
> *wherein the patient-specific surface references the osteophyte when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged joint*; and
>
> a guide sized and shaped to accommodate a surgical tool, wherein the guide has a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool.

(D.I. 99-1, Exh. 4 ("'482 Patent"), claim 1) (emphasis added).

Claim 17 of the '482 Patent

> 17. A joint arthroplasty system for use in surgically repairing a diseased or damaged joint of a patient, comprising:
>
> an implant; and
>
> a block having a patient-specific surface having a first portion configured to have a shape that is substantially a negative of *an articular surface of the diseased or damaged joint*,
>
> a second portion configured to have a shape that is substantially a negative of a cortical bone surface of the diseased or damaged joint,
>
> wherein the patient specific surface is configured to reference an osteophyte of the diseased or damaged joint, and the guide being sized and shaped to accommodate a

surgical tool and have a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool that is aligned through a portion of the diseased or damaged joint.

(*Id.*, claim 17) (emphasis added).

III. CONSTRUCTION OF AGREED-UPON TERMS

I adopt the following agreed-upon constructions:

Claim Term	**Construction**
"position" ('129 Patent, '304 Patent)	no construction necessary
"orientation" ('129 Patent, '304 Patent)	no construction necessary
"position and/or orientation" ('161 Patent)	no construction necessary
"position and orientation" ('482 Patent)	no construction necessary

IV. CONSTRUCTION OF DISPUTED TERMS[1]

1. Group 1 Terms: "surface includ[ing] . . . information" ('129/1, 23, 62, 78; '304/1, 9; '161/1, 12, 19; '482/1)

a. *Plaintiff's proposed constructions*:
   i. plain and ordinary meaning
b. *Defendant's proposed constructions:*
   i. "the [patient-specific surface] having at least a portion shaped to match the patient's [cartilage] based on [cartilage] information"
c. *Court's construction*:
   i. "the [patient-specific surface] is based on [cartilage] information"

2. **Group 2 Terms: "substantially uncut joint surface" ('129 Patent/1, 16, 17, 23, 62)**

a. *Plaintiff's proposed constructions:*
   i. Not indefinite
b. *Defendant's proposed construction*:
   i. Indefinite, or
   ii. "a joint surface of [the diseased or damaged knee joint/knee joint/a tibia of the knee joint] as exists before any surgical procedures are performed that would alter said surface"

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

c. *Court's construction*: Not indefinite; "unresected joint surface"

The parties agree that "substantially" is a relative term that introduces a degree of approximation. (D.I. 98 at 22, 24–25). The parties dispute whether the modifier "substantially uncut" creates sufficient ambiguity as to render indefinite the claims-at-issue. (*Id.*).

Plaintiff argues that the phrase "substantially uncut joint surface" has a plain and ordinary meaning "that is readily ascertainable" and therefore not indefinite. (*Id.* at 20). Citing to portions of the specification recognizing that the invention "provides for the preparation of an implantation site with a single cut or a few relatively small cuts" (D.I. 99-1, Exh. 1 at 5:23–25) and describing tools used to make these cuts (*id.* at 51:19–24), Plaintiff maintains that the intrinsic evidence differentiates between less invasive preparatory cuts and more invasive surgical resection of the diseased or damaged joint (D.I. 98 at 21). While surgical resection involves cutting "of the entire, or a majority of the, articular surface" of the bone, the preparation for joint implantation can be done "with a single cut or a few relatively small cuts." (D.I. 99-1, Exh. 1 at 3:27–30, 5:23–25). Plaintiff argues that a POSA, therefore, would understand that a "substantially uncut joint surface" is one that has not been resected. (D.I. 98 at 20).

Plaintiff also asserts that the '129 patent's prosecution history provides sufficient guidance to a POSA "as to what is *not* substantially uncut." (*Id.* at 33). The parent of the '129 patent, App. No. 10/724,010, includes similar language when claiming a component "having a surface for engaging a substantially uncut joint surface." (D.I. 101, Exh. 17, 2/14/2008 Amend., 2). In that patent, the limitation "substantially uncut" was added to overcome a prior art reference, Burkinshaw (U.S. Patent No. 6,007,537) claiming "a nested cutting block that engages a cut joint surface." (*Id.*). Plaintiff argues that the "cut joint surface" in Burkinshaw resembles resection by a saw blade, in contrast to less invasive preparatory surgical techniques. (D.I. 98 at 32) (citing D.I. 101, Exh. 14, ¶¶ 45–49). Plaintiff also notes that in response to another prior art

reference, Rosa (U.S. Patent No. 7,141,053), the patentee used the same amended claim for a "*substantially uncut joint surface*" to differentiate that term from Rosa's "*resected* surface of the tibia." (D.I. 101, Exh. 17, 11/4/2008, Amend., 10). Plaintiff maintains that these examples from the intrinsic evidence provide sufficient guidance for a POSA to understand that a "substantially uncut joint surface" means an "unresected" joint surface and is therefore not indefinite. (D.I. 98 at 33).

Defendant, on the other hand, argues that it is unclear how much cutting must take place before a joint surface is no longer "substantially uncut," rendering the claim term indefinite. (*Id.* at 24). Because "substantially uncut" is a term of degree without definite bounds, Defendant argues, the term it modifies must be held indefinite if there is no baseline or standard for measuring the degree within the intrinsic evidence. (*Id.* at 25) (citing *Liberty Ammunition, Inc. v. U.S.*, 835 F.3d 1388, 1395–96 (Fed. Cir. 2016); *Seattle Box Co., Inc. v. Indus. Crating & Packing, Inc.*, 731 F.2d 818, 826 (Fed. Cir. 1984)). Defendant maintains that neither of the pertinent requirements in the claim—that the "patient specific surface 'include' cartilage information' or that the "patient specific surface 'engages' the substantially uncut joint surface"—provides a baseline. (*Id.* at 25).

Defendant also argues that the specification fails to provide a baseline for "substantially uncut" with reasonable certainty. (*Id.* at 25–26). For example, Defendant points to its expert's opinion to argue that even if the preparatory "cuts" described in the specification (*see, e.g.*, D.I. 99-1, Exh. 1 at 11:30–35; 11:46–49) are not "focused on the joint surface, . . . a POSITA would certainly consider them to be substantial" (D.I. 98 at 25) (citing D.I. 101, Exh. 20, D'Lima Dec., ¶ 38). Defendant argues, furthermore, that some of the prosecution history amendments asserted by Plaintiff are inapplicable because there have been continuation-in-part ("CIP") applications

filed between the '010 application and the '161 patent (*id.* at 28), and the Federal Circuit has held that information added during a CIP application constitutes new matter that is not part of the prosecution history. *See Goldenberg v. Cytogen, Inc.*, 373 F.3d 1158, 1167 (Fed. Cir. 2004).

"[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). The question, therefore, is whether a POSA can determine from what the patent what constitutes a "substantially uncut joint surface."

Although "substantially" is a term of degree, it is not sufficiently ambiguous as to make the claim term indefinite by its mere inclusion. The Federal Circuit has "repeatedly confirmed that relative terms such as 'substantially' do not render patent claims so unclear as to prevent a person of skill in the art from ascertaining the scope of the claim." *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1367 (2001).

Because the words "substantially uncut" are not used or otherwise explained in the specification (D.I. 110 at 41–42), the prosecution history is dispositive as to indefiniteness. Plaintiff correctly notes that claim term 26 in the parent application was amended to include "substantially uncut" specifically to overcome prior art challenges involving resections. (D.I. 98 at 33). Defendant's objections to the applicability of these portions of the prosecution history are irrelevant for two reasons. First, the Burkinshaw and Rosa references were asserted against the parent application, not the '161 application, so there is no question as to whether intervening CIP applications prevent reference to the prosecution history of the parent application. Second, the Federal Circuit in *Goldenberg* held that "new-matter content" introduced, for example, by CIP applications could not be used to construe claims for patents with a shared parent when those

claims involved the added content. *Goldenberg*, 373 F.3d at 1167–68. In this case, the claim at issue in the '129 patent is also found in the parent application, so *Goldenberg* is inapposite.

The prosecution history shows the patentee included "substantially uncut" to distinguish between resected and unresected joint surfaces. Defendant agrees that a resection unambiguously constitutes a "substantial cut." (D.I. 110 at 35). A POSA should therefore be able to determine with reasonable certainty the difference between a resected and unresected joint surface. I agree with Plaintiff that the claim term is not indefinite, and accordingly adopt the following construction of "substantially uncut joint surface" for clarity: "unresected joint surface."

3. **Group 3 Terms: "on a [medial/lateral] tibial plateau" ('304/13; '129/12, 13, 73; '161/16)**

    a. *Plaintiff's proposed construction*:
        i. Plain and ordinary meaning; "tibial plateau" is "surface of the top of the tibia"
    b. *Defendant's proposed construction*:
        i. wherein [at least one guide hole of the two or more guide holes/the first guide/the second guide] is configured to guide a surgical from atop the [medial/lateral] portion of the top surface of the tibia"
    c. *Court's construction*:
        i. No construction necessary

4. **Group 5 Terms: "references an osteophyte" ('482/1, 13, 17)[2]**

    a. *Plaintiff's proposed construction*:
        i. Not indefinite
    b. *Defendant's proposed construction*:
        i. Indefinite
    c. *Court's construction*:
        i. Not indefinite

The parties dispute whether "referencing" an osteophyte informs a POSA as to claim scope with reasonable certainty. (D.I. 98 at 49). Both parties assert testimony from their expert to

[2] The "Group 4 Terms" were no longer disputed by the time of the claim construction hearing.

argue whether "referencing" would be readily understandable to a POSA. (*Id.* at 50, 53). I accept the opinion of Plaintiff's expert. I think it is consistent with the intrinsic evidence.

Plaintiff argues that Figures 32 and 33 of the '482 Patent show how the patient-specific surface can interact with the osteophyte by showing how the joint-facing surface can be designed to "avoid the osteophyte." (*Id.* at 50) (citing D.I. 99-1, Exh. 4 at Fig. 32, Fig. 33, 82:42–48). The specification further notes that the frame of the surgical tool can be "attached to one or preferably more previously defined anatomic reference points." (D.I. 99-1, Exh. 4 at 78:63–67). A POSA, Plaintiff argues, would recognize an osteophyte as such an "anatomic reference point." (D.I. 98 at 51).

Defendant, on the other hand, argues that because Figures 32 and 33, as well as the portions of the specification that Plaintiff cites, never use the word "reference," it remains unclear what "reference" means in the patent. (*Id.* at 55). Defendant contends that the process of creating a patient-specific surface requires—under other claim terms—"engaging" or providing a "substantial negative" of the joint surface. (*Id.* at 60). These claim terms render "reference" superfluous and make its scope unclear. (*Id.*).

I agree with Plaintiff. Although the specification may not use the word "reference," the processes described to avoid osteophytes, as exemplified in embodiments 32 and 33, intuitively suggests, and would be so understood by a POSA, that the osteophyte is used as an "anatomic reference point" when preparing the frame of the surgical tool. Whether "reference" is superfluous, as Defendant argues, is ultimately a non-issue because redundancy does not necessarily make a claim indefinite. *Eli Lilly & Co. v. Teva Parenteral Meds.*, 845 F.3d 1357, 1371-72 (Fed. Cir. 2017). I therefore construe this claim term as not indefinite.

5. **Group 6 Terms: "an articular surface" ('482/17)**

    a. *Plaintiff's proposed construction*:
        i. Plain and ordinary meaning, or
        ii. "[the patient-specific surface having a first portion configured to have a shape that is substantially a negative of] a cartilage and/or subchondral bone surface of an articulating bone of the diseased or damaged joint"
    b. *Defendant's proposed construction*:
        i. "[the patient-specific surface having a first portion configured to have a shape that is substantially a negative of] a cartilage and/or subchondral bone surface of an articulating bone of the diseased or damaged joint, excluding any bone surfaces of the joint exposed through a surgeon removing cartilage"
    c. *Court's construction*:
        i. "[the patient-specific surface having a first portion configured to have a shape that is substantially a negative of] a cartilage and/or subchondral bone surface of an articulating bone of the diseased or damaged joint"

The parties agree that "articular surface" means "a cartilage and/or subchondral bone surface of an articulating bone of the diseased or damaged joint." (D.I. 98 at 66). The parties dispute whether an articular surface "exclude[es] any bone surfaces of the joint exposed through a surgeon removing cartilage. (*Id.* at 65, 67).

Plaintiff argues that "articular surface" is not limited to bone surfaces already exposed before a surgeon removes cartilage. (*Id.* at 70). References to "articular surface" in the specification, Plaintiff notes, describe that it "can comprise cartilage and/or subchondral bone" or "may be at least one of an articular cartilage surface and a bone surface" but are not otherwise limiting. (*Id.* at 70) (citing D.I. 99-1, Exh. 4 at 6:58–60, 23:48–49). Defendant, on the other hand, argues that an "articular surface" specifically refers to the surface of the damaged joint before it undergoes any restorative surgical procedures. (*Id.* at 67). Defendant also argues that, in prior litigation, Plaintiff construed "articular surface" to not include the bone surface of a joint exposed after cartilage had been scraped away. (*Id.* at 69) (citing D.I. 101, Exh. 22 at 25).

Plaintiff's arguments in the prior litigation are in the context of the degree of "direct contact" required, which differs from its use in the '482 patent. (D.I. 110 at 92).

Embodiments 14A, 14D, and 14G(2) show that the articular surface remains intact after removing cartilage from the joint or undergoing other preparatory surgical procedures.

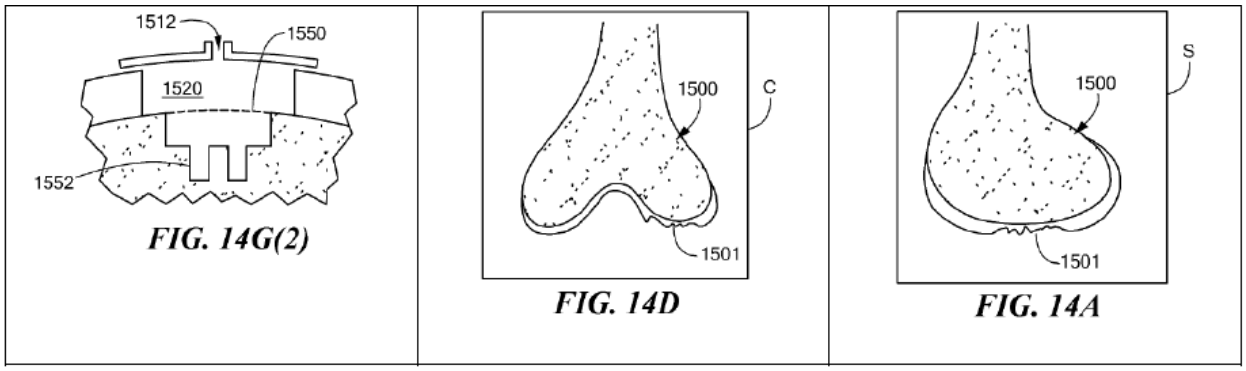

FIG. 14G(2) *FIG. 14D* *FIG. 14A*

The articular surface 1500 in Figs. 14A and 14D, for example, is present both before and after cartilage removal. (D.I. 99-1, Exh. 4 at Fig. 14A, 14D). Fig. 14G(2) follows from the previous figures and shows that at least part of the articular surface is present even after the joint has experienced more invasive surgical intervention. (*Id.* at Fig. 14G(2)). Because the specification and Figs. 14A, D, and G(2) show that the articular surface remains after cartilage removal, Defendant's additional limitation is inappropriate. I therefore adopt Plaintiff's proposed construction: "[the patient-specific surface having a first portion configured to have a shape that is substantially a negative of] a cartilage and/or subchondral bone surface of an articulating bone of the diseased or damaged joint."

V. CONCLUSION

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion suitable for submission to the jury.