IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CONFORMIS, INC., Plaintiff, v. DEPUY SYNTHES, INC., DEPUY SYNTHES PRODUCTS, INC., and DEPUY SYNTHES SALES, INC., Defendants.	Civil Action No. 21-640-RGA

MEMORANDUM ORDER

This Memorandum Order addresses the issue of claim construction of multiple terms in U.S. Patent No. 8,623,026 (the "'026 Patent"), U.S. Patent No. 8,377,129 (the "'129 Patent"), U.S. Patent No. 9,186,161 (the "'161 Patent"), U.S. Patent No. 8,460,304 (the "'304 Patent"), and U.S. Patent No. 9,295,482 (the "'482 Patent"), and U.S. Patent No. 9,326,780 (the "'780 Patent") (the "Asserted Patents"). The parties submitted a Joint Claim Construction Brief addressing seven disputed terms. (D.I. 102 (terms A through G)). I heard oral argument on April 18, 2023. (D.I. 124).

Before the *Markman* hearing, I proposed tentative constructions for the disputed terms. (D.I. 116). In response to my tentative constructions, the parties agreed that "no oral argument is necessary" for three of the seven terms. (D.I. 119 (terms A, C, and D)). After the hearing, the parties agreed to defer consideration of two terms to a later stage of the case. (D.I. 121 (term E), D.I. 147 (term F)). The parties filed supplemental briefing on the two remaining terms. (D.I. 125, 128, 132 (term G, "mold"); D.I. 126, 127, 133 (term B, "includes/including")). I turn to those two terms now.

I. BACKGROUND

The Asserted Patents relate to patient-specific surgical tools and systems for use in joint-replacement surgery or joint arthroplasty. (D.I. 102 at 4). The Asserted Patents are part of the same family and claim dependency from common patent applications. The '780 Patent is a continuation from the '026 Patent application (U.S. Patent Application No. 13/207,396). (*Id.* at 4–5). The '129 and '304 Patents are continuations of Application No. 10/724,010 and have substantively identical specifications. (*Id.* at 4). Similarly, the '161 and '482 Patents are continuations of Application No. 12/048,764 (which became the '745 Patent) and have substantively identical specifications. (*Id.*).

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 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) (alteration in original) (quoting *Phillips*, 415 F.3d at 1324). 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 Pharms. 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 (quoting *Markman*, 52 F.3d at 980). 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] 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). Inferring indefiniteness because a claim's scope is broad, however, is "legally incorrect: 'breadth is not indefiniteness.'" *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1367 (Fed. Cir. 2017) (quoting *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331,

1341 (Fed. Cir. 2005)). The party raising indefiniteness bears the burden of proving it by clear and convincing evidence. *See BASF*, 875 F.3d at 1365 (Fed. Cir. 2017).

III. PATENTS AT ISSUE

The parties agree that, for claim construction purposes, the following claims are representative. (D.I. 102 at 7–9; D.I. 125 at 1–2; D.I. 127 at 1–3).

A. '161 Patent

1. A surgical system including an articular repair system and 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 and/or orientation based on anatomical information of the joint of the patient to facilitate the placement of the 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 and/or orientation is based on the predetermined rotation angle.

('161 Patent, Claim 1) (disputed terms bolded).

B. '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.

('304 Patent, Claim 1) (disputed terms bolded).

C. '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.

('129 Patent, Claim 1) (disputed terms bolded).

D. '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.

('482 Patent, Claim 1) (disputed terms bolded).

E. '780 Patent

1. A system for joint arthroplasty for repairing a joint of a patient, the system comprising:

a first template, the first template including:

a contact surface for engaging a first articular surface of the joint of the patient, **the contact surface including shape information derived from electronic image data of at least a portion of the first articular surface**; at least a relieved portion of the contact surface further including an anatomical relief configured such that when the contact surface engages the first articular surface, the relieved portion does not engage an anatomical structure of the first articular surface; and

at least one guide for directing movement of a surgical instrument; and

wherein the guide has a predetermined orientation relative to one of an anatomical and a biomechanical axis associated with the joint of the patient.

('780 Patent, Claim 1) (disputed terms bolded).

IV. CONSTRUCTION OF DISPUTED TERMS

A. "mold" ('161 Patent: Claim 1; '304 Patent: Claims 1, 17)

a. *Plaintiff's Proposed Construction*: "a device or a portion of a device having a patient-specific surface"

b. *Defendants' Proposed Construction*: "deformable structure used to create a shape"

c. *Court's Construction*: "a device or a portion of a device having a patient-specific surface"

The parties dispute whether a "mold" must be "deformable." I think the answer is no.[1]

Defendants argue that the specifications of the '161 Patent and '304 Patent consistently use the term "mold" to refer to "a deformable structure that forms a shape." (D.I. 128 at 1–3). According to Defendants, the specifications[2] disclose two ways to create a shape from a deformable mold.

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[1] I understand "deformable" to mean "capable of being reshaped."

[2] The'161 Patent and the '304 Patent have different (albeit similar) specifications. The parties do not argue that the differences lead to different results here.

(*Id.* at 2). In the first way, the mold is "a re-useable structure that forms a shape in one patient, then can be re-used in another patient." (*Id.*). Defendants' example is an "adjustable pins" embodiment, in which an array of closely-spaced pins are adjusted to match the topography of a joint surface. (*Id.* (citing '161 Patent, 79:18–21; '304 Patent, 48:27–30)). In the second way, the mold "can be customized for a specific patient, for example when the deformable material is 'flowable' or otherwise 'curable,' and hardens into the shape of the patient's joint." (*Id.*). Defendants' example is a "putty" embodiment. (*Id.* (citing '161 Patent, 80:60–81:45; '304 Patent, 49:58–50:25)).

I agree with Plaintiff that Defendants' analysis is "backwards," as it "starts with the desired result (two embodiments), then argues how the specification supports that result." (D.I. 132 at 1). Although the specifications support "putty" and "adjustable pins" embodiments, that does not justify limiting the claims to those embodiments, especially where other embodiments are equally well-supported. As Plaintiff points out (D.I. 125 at 7–10), the specifications reasonably support non-deformable molds as well. For example, both specifications state that molds can be made from a wide variety of materials, including rigid materials, like metal. '161 Patent, 98:44–46, 45:44–49 (various suitable metals); '304 Patent, 46:64–47:6 (metal, plastic, or polymer). And both specifications disclose manufacturing processes that create non-deformable molds, such as milling (cutting away from a block) and rapid prototyping (printing 2-D layers on top of one another to form a 3-D shape). *E.g.*, '161 Patent, 68:29–31 (milling), 68:23–25 (rapid prototyping); '304 Patent, 43:10–12 (rapid prototyping). Nothing in the specifications precludes non-deformable molds.

Defendants' response—that deformable molds could be made of metal or plastic, and that milling or rapid prototyping could, potentially, be used to create a deformable mold (*see* D.I. 128

at 4–5)—is beside the point. "At leas[t] where claims can reasonably [be] interpreted to include a specific embodiment, it is incorrect to construe the claims to exclude that embodiment, absent probative evidence [to] the contrary." *Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1277 (Fed. Cir. 2008). No such probative evidence exists here.

Defendants make a similar argument with respect to the shared priority application (D.I. 104, Ex. 10) of the '161 and '304 Patents—namely that, in the priority application, "mold" refers to a deformable structure. (D.I. 128 at 1–3). I generally agree with Plaintiff (D.I. 132 at 4–5) that the priority application is not limited to deformable molds. I also agree with Plaintiff that, even if the priority application gave a narrower description of "mold," the question becomes one of priority, not claim construction. *Sycamore IP Holdings LLC v. AT&T Corp.*, 2017 WL 1045949, at *6 (E.D. Tex. Mar. 16, 2017). Priority is an issue for another day. *Id.*

Finally, Defendants contend that if their construction is not adopted, the claims are indefinite. (D.I. 128 at 7–10). I do not find this argument convincing either. Defendants say, "Plaintiff's definition is grossly overbroad in attempting to sweep in ***any*** device or even ***any portion*** of any device." (D.I. 128 at 8) (emphasis in original). Defendants improperly conflate breadth and indefiniteness. *See BASF*, 875 F.3d at 1367 (Fed. Cir. 2017). Although the claim's scope is broad, it is not unclear. Furthermore, I agree with Plaintiff (D.I. 125 at 4–7) that the "device or portion of a device" construction finds support in the specification. The '161 and '304 Patents describe (1) a "one-piece" embodiment where the "mold" and surgical instrument are a single device, Figure 27 (both patents); '161 Patent, 98:47–55; '304 Patent, 52:36–44; and (2) a "two-piece" embodiment where the mold is a patient-specific surface portion of a device. Figure 25 (both patents); '161 Patent, 97:39–51; '304 Patent, 52:7–19. Counter to Defendants' contentions (D.I. 128 at 9), I do not think that Plaintiff's "patient-specific" construction excludes part of Figure 23 of the '161

Patent. That figure presents a distinction between selecting "Best Fitting" molds (from a library of preexisting molds) and generating "Custom Patient Specific Molds." '161 Patent, Figure 23, 82:17–20. As Plaintiff notes (D.I. 132 at 3–4), both types of molds are "patient-specific."

Thus, I conclude that "mold" means "a device or a portion of a device having a patient-specific surface."

B. "surface that includes/surface including ... information" terms ('161 Patent, Claim 1; '304 Patent, Claim 1; '129 Patent, Claim 1; '482 Patent, Claim 1; '780 Patent, Claim 1)[3]

a. *Plaintiff's Proposed Construction*: plain and ordinary meaning

b. *Defendants' Proposed Construction*: "the information is physically incorporated into the surface"

c. *Court's Construction*: "the [patient-specific surface] is based on ... information"

Plaintiff originally argued that "including" means that the surface is "based on" the information derived from the image data. (D.I. 102 at 29–40). In a prior matter in which I construed the same or similar terms—*Conformis, Inc. v. Zimmer Biomet Holdings, Inc.*, No. 19-1528-RGA (consolidated with *Conformis, Inc. v. Medacta USA, Inc., et al.*, No. 19-1618-RGA) (the "Medacta Action")—I agreed with Plaintiff's "based on" construction. (*See* Medacta Action, D.I. 125 at 6). I adopt that construction again here.

Defendants argue that these terms "mean[] that the image information is physically incorporated in the surface, not merely used to design the surface." (D.I. 126 at 1). Defendants draw an analogy to a cell phone. They say, "[W]hen a person says their phone 'includes' something, the listener understands that—whether the something is information digitally input and stored in memory (*e.g.*, photos, contact information, software, etc.) or a mechanical part manually

[3] The parties agree that this term has the same meaning in each disputed limitation. (D.I. 126 at 1).

affixed to other components (*e.g.*, camera lens, battery, etc.)—it is actually ***in*** the phone." (D.I. 126 at 1 (emphasis in original)). Defendants explain that, similarly, for joint information to be "included" in the patient-specific surface, there must be "some sort of memory, something to hold [the information] …." (D.I. 124 at 17–18). Here, the "memory" is the patient-specific surface itself. (*Id.*). Defendants point to two embodiments from the specifications: the "adjustable pins" embodiment and a "coordinate entry" embodiment, in which the information (e.g., a set of coordinates) is manually dialed in or electronically transferred into the device to create a surface. (D.I. 126 at 3 (citing, e.g., '780 Patent, 76:41–52; '161 Patent, 76:41–52; '129 Patent, 47:43–54)).

I am not convinced. First, I don't think Defendants' construction is consistent with the ordinary usage of the word "includes." "Includes" is broad.[4] Defendants' cell phone analogy is instructive. As Plaintiff notes, cell phones often receive information, process it, and generate a human-understandable form of the information received (e.g., pixels). (D.I. 127 at 10–11, n. 10). It is not clear to me that information is any less "included" in the phone when it is processed and transformed in this fashion. Similarly, I am not convinced that joint information is any less "included" in the patient-specific surface when the joint information is—as Plaintiff puts it—"received, processed, and used to create a patient-specific surface representative of the information received."[5] (*Id.* at 10–11).

Plaintiff's construction finds support in the specifications, which disclose "including" the information derived from patient image data by creating a patient-specific surface "based on" the

[4] The Merriam-Webster Online Dictionary offers several definitions of the word "include," the first of which is most apt here: "to take in or comprise as a part of a whole or group." Merriam-Webster, https://www.merriam-webster.com/dictionary/include (last visited July 28, 2023).

[5] Nor, for that matter, I am persuaded that joint information is not "physically incorporated" into a patient-specific surface that is based on the joint information. Defendants' "physically incorporated" language yields more questions than answers. It remains unclear to me what, exactly, it means for information to be "physically incorporated" into a physical object.

image data. *See, e.g.*, '129 Patent, 50:34–38; '161 Patent, 17:3–11, 17:22–31, 32:3–19; '482 Patent, 32:3–18, '780 Patent, 13:5–9, 15:65–16:5. The specifications disclose multiple processes for "including" information derived from patient image data in the patient-specific surface. For example, in one embodiment, image-derived cartilage information may be "included" in the design of the patient-specific surface using image processing techniques. *See, e.g.*, '161 Patent, 65:25–46; '304 Patent, 40:4–25; '129 Patent, 39:66–40:21; '482 Patent, 65:24–45; '780 Patent, 49:12–33. In another, the patient-specific surface may be "selected or shaped" using scans that characterize articular surface information. *See, e.g.*, '161 Patent, 40:24–37; '304 Patent, 17:9–22; '129 Patent, 17:5–18; '482 Patent, 40:22–35; '780 Patent, 32:53–66. Even in the "adjustable pins" and "coordinate entry" embodiments upon which Defendants rely, joint information is "used to create a surface and shape that will match all or portions of the articular and/or bone surface and shape...." '161 Patent, 76:41–52; '304 Patent, 47:44–55; '129 Patent, 47:43–54; '482 Patent, 76:41–52; '780 Patent, 60:22–33. The patient-specific surface, in short, is "based on" the joint information.

Defendants' prosecution disclaimer argument does not change my mind. Defendants say, "[Plaintiff] intentionally narrowed the claims by adding the 'includ[es]' limitation, as a prosecution strategy, during prosecution of the '304 and '129 patents, from which the '161 and '780 patents descend." (D.I. 126 at 4). The relevant prosecution history is as follows. When the application for the '129 Patent was filed, it claimed, among other things, a "patient-specific surface conforming to and being substantially a negative of ... the joint of the patient." (D.I. 104, Ex. 19 at 16). The examiner rejected the claims based on two prior art references: Robie (D.I. 127, Ex. 7) and Delp (D.I. 127, Ex. 8). (D.I. 104, Ex. 19 at 6–7). Plaintiff requested an interview with the Examiner, and during that interview, "the parties agreed that the cited art [Robie and Delp] does not teach or

suggest a patient-specific surface that includes joint information **derived from image data** of the patient's joint." (D.I. 104, Ex. 19 at 29 (emphasis added)). Plaintiff agreed to amend the claims to add the limitation at issue. (*Id.* at 16).[6]

In sum, Plaintiff narrowed the claim to cover only those patient-specific surfaces created using information derived from patient image data, where Plaintiff had previously claimed a surface that could be created using non-image-based techniques. The amendment did not bear on the manner in which the image-derived joint information is to be included.

Thus, I conclude that the "surface that includes/surface including … information" terms require the patient-specific surface to be based on joint information derived from image data.

IT IS SO ORDERED.

Entered this 9th day of August, 2023.

United States District Judge

[6] Defendants point to two additional prior art references that Plaintiff brought to the Examiner's attention during the interview. (D.I. 126 at 4 (Radermacher and Schuster)). Defendants say nothing about the substance of that discussion, which is not described in the Interview Summary that Defendants cite. (D.I. 104, Ex. 19 at 29–30). "[F]or prosecution disclaimer to attach … the alleged disavowing actions or statements made during prosecution" must be "both clear and unmistakeable." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325–26 (Fed. Cir. 2003). Here, Defendants point to no clear actions or statements that could constitute disavowal. Defendants' reliance on these references is therefore unavailing.