IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OSTEOPLASTICS, LLC, Plaintiff, v. CONFORMIS, INC., Defendant.	C.A. No. 20-405-MN-JLH
OSTEOPLASTICS, LLC, Plaintiff, v. DEPUY SYNTHES, INC., DEPUY SYNTHES PRODUCTS, INC., and SYNTHES, INC., Defendants.	C.A. No. 20-406-MN-JLH

REPORT AND RECOMMENDATION

Pending before the Court are the parties' claim construction disputes related to terms in United States Patent Nos. 8,781,557 (the "'557 Patent"), 9,292,920 (the "'920 Patent"), 9,330,206 (the "'206 Patent"), 9,626,756 (the "'756 Patent"), 9,672,617 (the "'617 Patent"), 9,672,302 (the "'302 Patent"), and 9,275,191 (the "'191 Patent"). I held a *Markman* hearing on August 9, 2021. I recommend that the Court adopt the constructions set forth below.

I recommend that the claim term with an agreed-upon construction be construed as follows (*see* D.I. 85 at 1[1]):

	Term	**Construction**
2	"normative shape" '557, '206, '756, and '617 Patents	"shape of anatomy that has not been distorted by disease, birth defect, or trauma, which for the purposes of clarification may include shapes of anatomy represented by data such as mirror image data, average data, or standard data"

The parties' proposed constructions for the disputed terms are set forth in their Amended Consolidated Joint Claim Construction Chart, as further amended by the Joint Submission Regarding Claim Construction Pursuant to Court's Oral Order. (D.I. 83, 85.) As announced at the hearing, and as further explained below, I recommend that the following disputed claim terms be construed as follows:

	Term	**Construction**
1	"template" '557, '206, '920, '756, '617, '302, and '191 Patents	"wire frame pattern representing a shape of patient tissue"

[1] Docket citations refer to C.A. No. 20-405 unless otherwise noted.

3	"superimposing on the computer generated 3-dimensional representation [of the defective portion and the non-defective portion of the tissue] a template" / "superimposing on the image a 3-dimensional template" / "superimposing a three-dimensional template onto the 3-dimensional representation" / "superimposing a template onto the 3-dimensional representation" / "superimposing onto the rendered computer-generated three-dimensional representation of the target tissue a three-dimensional template" / "superimposing onto the mapped external surface a three-dimensional template" '557, '206, '920, '617, '302, and '191 Patents	"automatically matching the anatomical landmarks of the template with the same anatomical landmarks on the representation of the target tissue using only a computer algorithm" For purposes of clarification, this construction does not preclude the manual identification of anatomical landmarks on the representation of target tissue before the superimposing step or manual correction after the superimposing step.
4	"deforming the template to match the anatomical landmarks" / "deforming the template to match the anatomical landmarks on the image" / "deforming the three-dimensional template to the computer-generated 3-dimensional representation" / "deforming the template to the computer-generated 3-dimensional representation to create a deformed template" / "deforming the three-dimensional template to match the identified anatomical landmarks" / "deforming the three-dimensional template to match at least a portion of the mapped external surface" '557, '206, '920, '617, '302, and '191 Patents	Defendants have not met burden at this stage to establish indefiniteness. Defendants may reraise indefiniteness at summary judgment stage.

5	"matching a computer-rendered three-dimensional template onto a computer-rendered three dimensional surface of tissue surrounding the patient's target tissue of interest" '756 Patent	Defendants have not met burden at this stage to establish indefiniteness. Defendants may reraise indefiniteness at summary judgment stage. If the claim is not found to be indefinite, the Court should construe the claim to require that the matching occur with respect to "landmarks" and occur "automatically . . . using only a computer algorithm." The Court should also clarify that its construction does not preclude the manual identification of anatomical landmarks on the representation of tissue before the matching step or manual correction after the matching step.
6	"medical device" '206, '920, '756, '617, and '302 Patents	Plain and ordinary meaning
7	"anatomical landmarks" '920, '302, and '191 Patents	"specific points of reference on the anatomy or images of anatomy"
8	"to determine the [three]/[3]-dimensional shape of the medical device" / "to determine the 3-dimensional implant shape" / "determining the [three]/[3]-dimensional shape of the medical device" / "determining a 3-dimensional shape of the implant" '557, '206, '920, '617, '302, and '191 Patents	"[to determine]/[determining] the three-dimensional shape of [a medical device]/[an implant] as a function of the respective shapes of the defective portion of the patient image and the template"
9	"fits the patient's target tissue of interest" '756 Patent	Plain and ordinary meaning
10	"obtaining a computer readable image" / "obtaining computer readable image data" '557, '206, '920, and '191 Patents	Plain and ordinary meaning
11	"optimal adjacency" '920 and '191 Patents	Defendants have not met burden at this stage to establish indefiniteness. Defendants may reraise indefiniteness at summary judgment stage.

12	"rendering a volumetric image at least a portion of a patient from image data of the patient" '756 Patent	Parties agree that Defendants may raise indefiniteness at summary judgment stage and Plaintiff may propose construction in response.
13	"extracting a region of interest from the volumetric image of the patient, wherein the volumetric image comprises target tissue of interest of a patient" '756 Patent	Parties agree that Defendants may raise indefiniteness at summary judgment stage and Plaintiff may propose construction in response.

I. LEGAL STANDARDS

A. Claim Construction

The purpose of the claim construction process is to "determin[e] the meaning and scope of the patent claims asserted to be infringed." *Markman v. Westview Instruments*, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). When the parties have an actual dispute regarding the proper scope of claim terms, their dispute must be resolved by the judge, not the jury. *Id.* at 979. The Court only needs to construe a claim term if there is a dispute over its meaning, and it only needs to be construed to the extent necessary to resolve the dispute. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

"[T]here is no magic formula or catechism for conducting claim construction." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1324 (Fed. Cir. 2005). But there are guiding principles. *Id.*

"The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation." *Id.* at 1313. In some cases, the ordinary meaning of a claim term, as understood by a person of ordinary skill in the art, is readily apparent even to a lay person and requires "little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314. Where the meaning is not readily apparent, however, the court may look to "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004). Those sources include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.*

"The claims themselves provide substantial guidance as to the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314. For example, "the context in which a term is used in the asserted claim can be highly instructive." *Id*. Considering other, unasserted claims can also be helpful. *Id.* "For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15.

In addition, the "claims must be read in view of the specification, of which they are a part." *Id.* at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). The specification "is always highly relevant to the claim construction analysis." *Id.* (quoting *Vitronics*, 90 F.3d at 1582). The specification may contain a special definition given to a claim term by the patentee, in which case, the patentee's lexicography governs. *Id.* at 1316. The specification may also reveal an intentional disclaimer or disavowal of claim scope. *Id.* However, "even when the specification describes only a single embodiment, 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 marks omitted).

Courts should also consider the patent's prosecution history. *Phillips*, 415 F.3d at 1317. It may 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.* Statements made by a patentee or patent owner during *inter partes* review may also be considered. *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1362 (Fed. Cir. 2017).

In appropriate cases, courts may also consider extrinsic evidence, which "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. For example, dictionaries, especially technical dictionaries, can be helpful resources during claim construction by providing insight into commonly accepted meanings of a term to those of skill in the art. *Phillips*, 415 F.3d at 1318. Expert testimony can also 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." *Id.*; *see also Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331-32 (2015).

B. Indefiniteness

Section 112 of Title 35 imposes a definiteness requirement on patent claims. 35 U.S.C. § 112(b) (requiring that the claims "particularly point[] out and distinctly claim[] the subject matter which the inventor . . . regards as the invention"). "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).

"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). Definiteness, like claim construction, should be assessed from the viewpoint of a person of ordinary skill in the art at the time the patent was filed, and it should be considered in view of the patent's specification and prosecution history. *Id.* at 908.

The party asserting indefiniteness has the burden to prove it by clear and convincing evidence. *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017).

I. DISCUSSION

A. Constructions Announced at the Hearing

My Report and Recommendation regarding several of the disputed claim terms was announced from the bench at the conclusion of the hearing as follows:

> I'm going to let you know the rulings I'm prepared to give you today. I'll just say at the outset, and I don't think I need to, but there was a lot here. We had 13 terms, most of which had multiple sub-disputes. There was 135 pages of briefing.
>
> All seven of the asserted patents are continuations or continuations in part of the same original application. With one exception, the seven patents share a common specification. We did our best to go through all of this, but the patents are lengthy. I'm fairly certain that I heard certain positions and arguments today that [I haven't] heard before. To the extent I understand the disputes, we're going to do our best to resolve them in accordance with the legal principles governing claim construction.
>
> So, let me start with what I think is off the table for now. With respect to terms 12 and 13, which are rendering and extracting, the parties have agreed that Defendants may raise their indefiniteness arguments at the summary judgment stage, and if they do so, Plaintiff reserves the right to respond to indefiniteness and to propose constructions at that stage.
>
> With respect to [term] 2, normative shape, and term 9, fits the patient's target tissue of interest, the parties are going to go back and meet and confer and see if they can come up with agreed-upon constructions that are both, one, helpful to the jury and not more confusing than the claim language and, two, resolve the parties' issues with the competing constructions. My recollection based on what was said on the record today suggests this might be able to be done. I'm also not adverse to the parties adding clarifying sentences to whatever construction turns out to resolve any of their sub-disputes. . . .

[Term 1: "template"]

So let's turn to term 1, which is template. The parties proposed competing constructions that demonstrate that there are [several] sub-disputes about what the term template means. But the parties [agree] that template does not have an ordinary and customary meaning in the field of the invention, and this isn't a situation where there is an express definition of template in the specification. The parties are also in agreement that the Court should look to the intrinsic evidence to determine how the inventor understood the term template.

The first sub-dispute is whether template must have a wire frame pattern. On this sub-dispute, I side with Defendants. The provisional application to which the patents claim priority contained a glossary, and that glossary contained a definition of a "deformable template." It expressly defined "deformable template" as a "wire frame pattern assigned to a shape" that approximates its topology. (D.I. 81, Ex. 17 at 30, Ex. 19 at 39.) Some, but not all, of the patents-in-suit expressly incorporate the provisional application by reference. And no party has argued that template should have a different meaning in the patents that do not incorporate the provisional application by reference. Rather, everyone agrees that template should be given the same meaning across all the patents.

Even if the patents did not incorporate the provisional by reference, under the circumstances here, where the parties agree that there is no ordinary and customary meaning in the field of the invention, I would consider the provisional application's definition highly relevant to the question of what the inventor understood the term to mean.

Plaintiff cites the Federal Circuit's decision in *MPHJ*, but that decision is distinguishable for multiple reasons, not the least of which is it didn't involve a provisional application's express definition of a term that was later used in the patent.[2] Moreover, the Federal Circuit reaffirmed in that case that a provisional "can contribute to understanding the claims."[3]

Plaintiff also points out that the provisional definition actually refers to a deformable template, but the claims require only a template. I don't think that matters for at least these reasons. One,

[2] *MPHJ Tech. Invs., LLC v. Ricoh Ams. Corp.*, 847 F.3d 1363, 1369 (Fed. Cir. 2017).

[3] *Id.*

whether the template is deformable has nothing to do with whether it has a wire frame structure, which is the dispute that I'm resolving. Two, the claims of all the patents except for the '756 patent separately recite that the template is deformed, confirming that in those claims, the template must be deformable. And three, no one is suggesting that the claimed template doesn't have to be deformable.

The understanding of template to refer to a wire frame pattern is consistent with all references to template in the specification and in the prosecution history, including, for example, the inventor declarations at Exhibits 21 and 22 (D.I. 81, Ex. 21 at 7, Ex. 22 at 7) and Figure 21-A of the patents.

Plaintiff argues that a wire frame construction would exclude other embodiments in the specification, but I agree with Defendants that there are no embodiments described in the specification where the template has anything other than a wire frame structure. The portions of the specification cited by Plaintiff at ['557 Patent] 41:60-67 and 21:61-63 do not, as Plaintiff suggests, indicate that a wire frame structure is optional. Rather, as Defendants point out, the optional aspect is which parts of the wire frame can be used in another step.

Plaintiff also points out that the specification describes that a template can be derived from various sources of data and have various shapes, but I agree with Defendants that Plaintiff's argument conflates two issues: the structure of the template, which I agree has to be a wire frame, with the shape that the template represents, which can include various shapes and be derived from various sources.

To be clear, I understand that it's improper to import limitations into claims from examples or embodiments in the specification. But that is not what I'm doing. Again, the circumstances here are that the parties agree that the word template does not have a customary meaning in the art and can only be understood with reference to intrinsic evidence. The provisional application sets forth the definition of template, and that definition is consistent with every embodiment described in the specification. Under those circumstances, I am not importing a limitation into the term, I'm construing the term in accordance with the intrinsic evidence.

The second sub-dispute is whether the template must represent a normative shape. On this sub-dispute, I agree with Plaintiff. Starting with the claims, some of the claims have a separate requirement that the template represent a normative shape, which

suggests that the term template does not necessarily include only templates that have a normative shape. Moreover, the provisional definitions pointed to by Defendants do not include the requirement that the template have a normative shape. They just require that the template represent a shape.

The third sub-dispute is whether the template has to span both the defective and non-defective portions. On this sub-dispute, I agree with Defendants. As Defendants point out, many of the claims separately specify what the template must span, suggesting that the term template does not necessarily include only templates that span both the defective and the non-defective portions. Moreover, as Defendants point out, in many of the claims, the template is only expressly required to span the defective portion, for example, the '920 patent, the '617 patent, the '302 patent, and the '191 patent.

Putting my rulings on those sub-disputes together, the construction should be "wire frame pattern representing a shape of patient tissue."

[Term 3: "superimposing . . ."]

Moving on to the superimposing term. The parties are at least in general agreement that the general definition of superimposing does not properly reflect the term's meaning in the context of the claim language. There is no express definition of superimposing in the specification. Both sides point to the intrinsic evidence to support their construction of superimposing. Accordingly, I will look at the intrinsic evidence as informing the meaning of superimposing.

The parties' competing constructions suggest three sub-disputes. The first is whether the construction should use the phrase correlating or matching. Having considered all the arguments made by the parties, I think matching is more accurate and will be clearer to the jury. The patent specification refers to matching, and I don't think injecting the term correlating into this litigation will clarify anything for the jury. [Plaintiff] says that correlating is better because the process involves computer data, but I don't think that computer data cannot be matched, and I'm not persuaded by Plaintiff to the contrary.

The second sub-dispute is whether it is anatomical features or anatomical landmarks that are correlated or matched in the superimposing step. Again, the parties agree that something has to

be correlated or matched, and they want me to rule on whether it's features that are matched or correlated or whether it's limited to landmarks. I agree with Defendants that it is anatomical landmarks that are matched. Plaintiff points to a portion of the specification that references ridge curves and geodesics as evidence that the term features is more appropriate [than landmarks]. ('557 Patent, 41:55-42:7.) In other words, Plaintiff is saying that Defendants' proposed construction reads out in the embodiment that matches ridge curves and geodesics, but that section only says that ridge curves and geodesics are used as time permits.

With respect to both of these first two sub-disputes, Plaintiff at various points has suggested that the Court should not construe the term as proposed by Defendants because Defendants have to show some sort of a clear intent in the specification to limit that term as Defendants had proposed. Plaintiff has phrased that argument in various ways, but that's the general assertion. However, there is no ordinary or customary meaning that can be applied to understand the term superimposing in the context of the patents. Under those circumstances, it is appropriate to look to the specification to determine how superimposing is used. And Plaintiff can't argue both that the term lacks a customary meaning and then hold Defendants to the standard for lexicography in order to support Defendants' construction.

The third sub-dispute has to do with whether correlating or matching of the landmarks proceeds automatically using only a [computer] algorithm. There was a lot of discussion today during the argument about this sub-dispute. I agree with Defendants' counsel that the real dispute here seems to be this: When the matching of landmarks is going on, what is doing it? Is there an algorithm that is matching landmarks in the templates to the landmarks in the patient's image?

To resolve that dispute, let me make clear what I think is not in dispute. There's no dispute that the identification of a landmark on the patient image can be done manually and should not be excluded by the construction; there's no dispute that there can be a manual correction after the superimposing step and that that manual correction should not be excluded by the construction; there's no dispute that when identification of landmarks is done manually or when corrections are done manually, both of those things are on the computer and that computer algorithms are involved.

But that doesn't really answer the question of whether there must be an algorithm to match the landmarks on the image to the

landmarks on the template. And on that dispute, I agree with Defendants that there has to be some sort of automatic matching that occurs. Again, the parties are in agreement that the superimposing term means the same thing in the patents in which it is used. And in the prosecution history, in particular the portion located at D.I. 81, Exhibit 23 [at pp. 11], the patentee distinguished a prior art reference on the basis that the superimposing step could not be performed manually in the claimed invention, notwithstanding the prior art's ability to manipulate an image on a computer. And I'll point the parties to the discussion we had during the oral argument today.

As for the specification, it is consistent with the understanding that the [matching] of the landmarks proceeds with a computer algorithm. There are no embodiments proposed in the specification that are being read out by requiring that the [matching] of the landmarks proceeds using a computer algorithm.[4] And while I don't base any of this decision on Plaintiff's prior representations to the Court in the § 101 briefing, I do not think that my ruling is inconsistent with those representations.

All of that said, I would be amenable to adding some language to the construction of this term to clarify that it doesn't exclude manual identification of landmarks and/or manual correction, in addition to computer matching. So, the parties should meet and confer within 14 days and submit a proposal as to the additional language that the Court could consider on this term.[5]

[Term 4: "deforming . . ."]

Now I'll turn to term 4, which is deforming. Defendants say that the deforming term fails to inform with reasonable certainty those skilled in the art about the scope of the invention. One issue with deforming, to the extent I can understand it, is that a person reading the patent can't tell where the superimposing ends and where the deforming begins. Another issue, according to Defendants, is that they say they don't even know what the deforming step is.

[4] Plaintiff's Opening Brief cited '557 Patent, 3:4-7, but there appears to be no dispute that the cited language refers to the prior art NYU Toolkit.

[5] The parties' Joint Submission Regarding Claim Construction Pursuant to Court's Oral Order sets forth competing proposals for additional language. (D.I. 85 at 2-8.) Defendants' proposal is more consistent with the Court's ruling at the hearing, and I recommend that the Court adopt most of it, as set forth in the chart above.

The situation here is that there's a disagreement about whether deforming has a customary meaning. The patent doesn't use the term deforming, and Plaintiff relies on the same portions of the specification to support its constructions of both superimposing and deforming. I have real concerns regarding indefiniteness, but the record is not sufficient for me to conclude that the term is indefinite at this time, because I'm not convinced at this stage that the clear and convincing evidentiary burden has been met.

I'm going to decline to make a ruling at this point on indefiniteness. Defendants can raise their indefiniteness arguments at the summary judgment stage to Judge Noreika. And I note for the record that my practice in this situation is consistent with how many of the judges, including Judge Noreika, do this.

I want to be clear. I understand that I can rule on indefiniteness at this stage. [But] I'm not going to do it. . . .

[Term 5: "matching . . ."]

Turning to matching, Defendants say that the matching term in the '756 Patent fails to inform with reasonable certainty those skilled in the art about the scope of the invention because the intrinsic record contains no guidance about what constitutes tissue surrounding the target tissue of interest or how it could be matched. Here again, the record is not sufficient for me to conclude that [the] "tissue surrounding the patient's target tissue of interest" [phrase] makes the term indefinite. Defendants can raise the indefiniteness argument at the summary judgment stage. To the extent that the term is not indefinite, my rulings as to the sub-disputes on the superimposing step also apply to the matching step.[6]

[Term 6: "medical device"]

I'll now turn to medical device. Starting with the claims. Some of the claims use the term medical device while others use the term implant. That suggests that medical device is not necessarily coextensive with implant.

[6] The parties' Joint Submission Regarding Claim Construction Pursuant to Court's Oral Order sets forth competing proposals for clarifying language should the Court determine that the matching term is not indefinite. (D.I. 85 at 2-8.) Defendants' proposal is more consistent with the Court's ruling at the hearing, and I recommend that the Court adopt most of it, as set forth in the chart above.

Moving to the specification, there are two things that are clear to me. The first thing that is clear is that the only embodiments in the specification are implants. Although the patent mentions that the invention is amenable to other like applications, there are no other applications or embodiments described in the patent.

The second thing that is clear to me from the specification is that it uses both the terms medical device and implant, suggesting that medical device is broader than implant. For example, in the '557 Patent at 41:10-13, it says, "As will be described below, the STL process is used for building a physical model of the medical device 30 (e.g., an implant) . . . ." It doesn't say, "i.e., an implant." That suggests to me that the patentee did not understand the term medical device to be the same thing as an implant.

Where does that leave us? Defendants point out that if the claims were construed to cover medical devices that are not implants, they would be invalid for lack of written description and enablement. That may be so, but I'm not ruling on that. What I can say is that validity analysis is not a regular component of claim construction, nor has Plaintiff argued that medical device should be construed more narrowly as to preserve validity.

I cannot conclude that a person of ordinary skill in the art reading these patents would understand the term medical device to mean device that replaces defective tissue as proposed by DePuy or device to be implanted into the subject as proposed by ConforMIS. Accordingly, I adopt Plaintiff's proposal to give medical device its plain and ordinary meaning.

[Term 10: "obtaining . . ."]

Turning to obtaining, term 10. Plaintiff says that the term should have its plain and ordinary meaning. DePuy wants it to be construed to make clear that the entity performing the method actually has to be the entity that is responsible for capturing the scan data from the patients, and ConforMIS today represented it is going to join DePuy's argument.

Having reviewed the portions of the specification and prosecution history cited by the parties, including, for example, the '557 Patent at 36:61-37:29 and 10:18-27, I side with Plaintiff. I disagree with Defendants that a person of skill in the art would understand that the entity performing the obtaining steps of the claimed methods must be the entity responsible for capturing the scan from the patient. The word obtaining is not a term of art, and

> while it's used in the patent in the context of describing the process of capturing the scan of the patient, I do not think that a person of skill in the art would understand it to be limited to that.
>
> As there's no other dispute regarding that term, I will adopt Plaintiff's proposal and rule that the term should be given its plain and ordinary meaning.
>
> **[Term 11: "optimal adjacency"]**
>
> Finally, turning to optimal adjacency, the parties agree that it's a term of degree. Defendants say that the term fails to provide an objective boundary to a person of skill in the art. Defendants also say that the portions of the specification cited by Plaintiff don't relate to the meaning of optimal adjacency. I've reviewed the portions of the specification cited by Plaintiff, and I can't say on this record that they aren't relevant to the meaning of optimal adjacency. So, on this record, I can't say that Defendants have met their burden to demonstrate by clear and convincing evidence that optimal adjacency fails to inform with reasonable certainty those skilled in the art about the scope of the invention. My ruling is without prejudice for Defendants to renew their indefiniteness argument at the summary judgment stage.

B. Reserved Constructions

I reserved ruling on the construction of two terms. Additionally, I asked the parties to meet and confer regarding two other terms. The parties reported to the Court that they were unable to resolve their dispute regarding one of those two terms. My rulings on the three remaining terms are set out below.

Term 7: "anatomical landmarks"

The parties dispute the construction of "anatomical landmarks." The parties appear to agree that the construction should make clear that "anatomical landmarks" are "locations" or "points," that they must be locations or points "of reference," and that they exist on images of

anatomy.[7] As I understand the dispute, it is essentially this: Plaintiff argues that "anatomical landmarks" is broad enough to include landmarks that are defined by the user during performance of the claimed methods. Defendants disagree and argue that "anatomical landmarks" must be *landmarks*—specific points, such as the tip of the nose, the molar, etc.—a subset of which can be identified by the user during performance of the claimed method, but are pre-defined.[8] To that end, Defendants' proposed construction requires that the "anatomical landmarks" be "specific points of reference" and that those points be "consistent across the same species."

I agree with Defendants that "anatomical landmarks" must be "specific points of reference," although I disagree with Defendants that adding the language "consistent across the same species" will resolve any dispute between the parties or clarify anything for the jury.

The claim language does not aid in resolving this dispute. Turning to the specification, it supports Defendants' construction. The specification refers to "Type II landmarks,"[9] which are "display[ed]" in Figures 19A and 19B. (*See, e.g.*, '557 Patent, 21:59-67.) Figures 19A and 19B show specific points of reference on the soft tissue of a face and the bony surface of a skull, respectively. Those visual depictions are consistent with the specification's consistent description

[7] (*See* Tr. at 202:3–23 ("[PLAINTIFF'S COUNSEL]: I think the parties agree that anatomical landmarks can be locations or points of reference, and they're on or within the images of the anatomy. . . . So the dispute here really goes to whether the anatomical landmarks must be specific, which Defendants say must be defined . . . .").)

[8] (*See* Tr. at 212:1–6 ("[DEFENDANTS' COUNSEL]: And what we're saying is what the patent teaches and what it discloses is that you are choosing from a finite set of landmarks such as the tip of the nose, the chin, a molar, an eye, something like that."); *see also id.* at 218:18-24 ("THE COURT: So the user is not defining his own landmarks, he's defining which one of the predetermined landmarks that should be used? Is that your position? [DEFENDANTS' COUNSEL]: Yes, Your Honor.").)

[9] No one argues that the claimed "anatomical landmarks" are limited to "Type II landmarks."

of anatomical landmarks as specific, predefined points of reference. (*See, e.g.*, *id.* at 19:26-27 (referring to "manually located, highly reliable, single point anatomical landmarks").)

Plaintiff suggests that the specification contemplates manual definition of landmarks by the user. But the specification appears to contemplate the manual *location* or *identification* of landmarks, rather than the manual definition of landmarks themselves. (*See, e.g., id.* at 22:28-32 ("The first step in the Simulated Annealing-based Surface Extraction (SASE) process is the operator's manual location of the Type II landmarks on the graphical manifold surface. These landmarks attach the ridge curve-based deformable template to the graphical manifold surface via a thin plate spline warp."), 41:55-57 ("The anaplast manually identifies and labels anatomical landmarks. It is expected that later techniques will use computer-assisted landmark labeling.").)

Plaintiff also contends that "preferred embodiments" disclosed by the specification show that "the relevant landmarks for the claimed methods may change based on the location of the defective anatomy (*e.g.*, the specific 'defect margin')." (D.I. 79 at 95.) But the cited portion of the specification doesn't say that. (*See* '557 Patent, 41:60-42:24 ("An implant shape is defined by finding a defect margin in a skull surface and transferring the defect margin to the warped skull surface. The warped skull surface is pinned down at the defect margin and all points exterior to the defect region. The warped skull surface tangents are also pinned down at the defect margin.").) Moreover, while the specification contemplates that a user performing the claimed method might identify different landmarks depending on the nature and location of the defect, it does not contemplate that a user would employ anything other than specific, pre-defined landmarks.

Plaintiff further contends that the specification "states that some features of the anatomy will result in 'more easily, and more repeatedly, detected anatomical landmark coordinates,' which means that ***some*** anatomical landmarks may be characterized [as specific points of reference], but

others may not." (D.I. 79 at 91 (quoting '557 Patent, 19:30-32).) I disagree. The passage Plaintiff quotes from reads in full:

> The last measure [(superimposition of manually located, highly reliable, single point anatomical landmarks)] is similar to a qualitative visual determination of the completeness of anatomical features seen on the segmented surface. Clearer features will result in more easily, and more repeatably, detected anatomical landmark coordinates by trained workers.

('557 Patent, 19:26-32.) That passage does not imply that only some anatomical landmarks should be easily and repeatably detected. It says that some conditions (*e.g.*, clearer features) will *lead* to better manual detection of anatomical landmarks.

The prosecution history also supports Defendants' construction. As discussed at the hearing, the '277 Provisional Application was incorporated by reference in several of the patents and provides relevant evidence as to how the inventors understood the term "anatomical landmark." That application contains a glossary, which defines "landmark" as: "[a] specific point on a biological form, or image of a form, located according to a geometric or textural rule and underlying developmental constraints." (D.I. 81, Ex. 19 at 40.)

I don't think that Defendants' inclusion of the phrase "consistent across the same species" will resolve any dispute between the parties or clarify anything for the jury. Accordingly, I recommend that the Court adopt the construction: "specific points of reference on the anatomy or images of anatomy."

Term 8: "to determine . . ."/"determining . . ."

The claims of six of the patents-in-suit require a step "to determine" or of "determining" the three-dimensional shape of the medical device/implant. At the hearing, it appeared that the parties might be able to make progress toward an agreed-upon construction, so I ordered them to meet and confer on this term. The parties' recent submission indicates that Defendants would drop

the phrase "external shape" from their proposed construction. (D.I. 85 at 2.) But the parties were unable to fully resolve their dispute. (*Id*.)

The remaining difference between their constructions appears to be this: Plaintiff says that the disputed phrase encompasses any use of the template to determine the shape of the medical device, without any restriction on method or function.[10] Defendants say that the disputed phrase should be construed to make clear that the shape of the medical device is determined "as a function of the difference between the respective shapes of the defective portion of the patient image and the template." There is no dispute that the shape of the device must be determined based on the template.

Beginning with the claim language, Plaintiff points out that some of the dependent claims specify that the determining function is accomplished "as a function of respective shapes of the defective portion and the template." (*See, e.g.*, '191 Patent, claims 11, 13; *see also* '920 Patent, claims 4, 6.) Plaintiff argues that, because the dependent claims set forth additional restrictions about how the determining is performed, it would be improper to include those additional restrictions into the construction of determining. The doctrine of claim differentiation can, as Plaintiff argues, assist in claim interpretation. But the doctrine of claim differentiation does not require claims to be construed broader than would otherwise be appropriate in light of the

[10] Tr. at 228:10–229:14 ("[PLAINTIFF'S COUNSEL]: The applicants chose to claim broadly. We say that the shape is based on the template. Full stop. We don't say exactly how it's done and the applicant has the right to build the claim that way. . . . THE COURT: Let's make sure I understand. So what does it mean to determine something based on something? So your view is this limitation is met if the 3D shape of the template is used in any way, with any function or any algorithm to determine the shape of the medical device, but there's no restriction on how that can be done. Basically, this step covers the function of using data about a template to [determine the] shape of implants, regardless of how that's done? [PLAINTIFF'S COUNSEL]: This particular limitation, right. That's the claim. Use the template to determine the shape. I mean, there's additional words in here.") (emphasis added).)

specification. Here, the specification suggests a narrower construction than the one Plaintiff proposes.

The specification consistently provides that the shape of the medical device is determined "as a function of respective shapes" of the template and the defective portion. (*See, e.g.*, '557 Patent, Abstract, 4:66-5:2 ("Summary of the Invention"), 5:35-37.) Some of those portions of the specification are statements of general applicability and, contrary to Plaintiff's suggestion, no other way of determining the three-dimensional shape of the medical device is even hinted at in the specification. Moreover, contrary to Plaintiff's argument, construing the determining phrase as Defendants propose would not exclude embodiments that include warping, as the specification describes performing the determining step after warping. (*See, e.g.*, '557 Patent, 10:58-11:4, 41:60-42:24.)

Turning to the prosecution history, Defendants point out that the inventors discussed the process for determining the shape of the medical device during prosecution of the '557 Patent. The inventors explained that "[w]ithout comparison to the patient's missing or defective portions of tissue the natural asymmetry as well as the actual dimensions of the region to receive an implant must be accounted for, there is a high degree of likelihood that the implant will not fit well." (D.I. 81, Ex. 30 at 8-9.) While that passage might not satisfy the high standard required for a disavowal of claim scope, it does shed light on how the inventors understood the process of determining the shape of the medical device. My recommendation is consistent with that understanding.

Accordingly, I agree with Defendants that the construction of the determining phrase should specify that the shape of the medical device/implant is determined as a function of the respective shapes of the defective portion and the template. Defendants also seek to add the additional language that the shape be determined "as a function of *the difference between* the

respective shapes of the defective portion of the patient image and the template." I'm not persuaded that including that language is appropriate. The specification describes determining the shape of an implant "as a function of a difference between the mapped points on the external surface of the target tissue and the external surface of the template" (*e.g.*, '557 Patent, 11:1-14), but it's not clear to me that that's necessarily the same thing as determining the shape as a function of the difference between the "defective portions" and the template (as Defendants propose), or even if the latter makes sense.

Accordingly, I recommend that the Court adopt the construction: "[to determine]/[determining] the three-dimensional shape of [a medical device]/[an implant] as a function of the respective shapes of the defective portion of the patient image and the template."

Term 9: "fits the patient's target tissue of interest"

The final phrase is "fits the patient's target tissue of interest," which appears only in claim 1 of the '756 Patent. Plaintiff argues that the phrase should be given its plain and ordinary meaning. Defendants propose that it be construed as "precisely fits the contours of the existing patient anatomy." I disagree with Defendants' proposed construction; accordingly, I conclude that the phrase should be given its plain and ordinary meaning.

The briefing focused on Defendants' inclusion of the word "precisely." Defendants point to the specification, which describes the "present invention" as relating "to a system and methodology for fabricating a 'drop in' replacement for a particular segment of missing bony structure, in which the implant fits precisely within the contours of the missing segment . . . ." (D.I. 79 at 111-12 (quoting '756 Patent, 1:18-25).) According to Defendants, the specification repeatedly refers to the goal of the invention as creating a "drop in" device and uses "drop in" synonymously with "precisely fits," suggesting that "fits" should be construed to require a precise

fit. (D.I. 79 at 114; *see also* '557 Patent, 1:19-28, 4:11-21.) Defendants further point out that the inventors thought it was "a critical disadvantage of [the] prior art systems and methods that they [did] not provide the ability to ensure a custom fit, 'drop in' replacement for the missing body segment." ('557 Patent, 4:50-53; *see also* D.I. 81, Ex. 25 at 7 (discussing inability of prior art method to produce a template that fit precisely to the patient).)

I do not think that adding "precisely" will clarify anything for the jury or conclusively resolve any dispute between the parties regarding the proper construction of this phrase. Defendants say that Plaintiff is trying to capture devices that require substantial cutting away of material by the surgeon before the device can be implanted.[11] But I don't think a medical device that requires significant cutting away of tissue could be said to "fit" the target tissue of interest or how the addition of the word "precisely" in the construction is helpful to resolve the dispute (as opposed to introducing more ambiguity).

To the extent there is a remaining dispute about whether it is sufficient to say that the device must "fit the patient's target tissue of interest" (as set forth in the claim) or, alternatively, "fit[] the contours of the existing patient anatomy" (as Defendants propose), I note that there was less said in the briefing and at argument about that subpart of the dispute. I suspect that there is little daylight between those two phrases, and I don't think that Defendants' proposal will clarify much for the jury.

[11] (Tr. at 242:9–23 ("[DEFENDANTS' COUNSEL]: So the precisely is meant to fill in that intellectual gap, which is if you don't use precisely, it just says it fits, plaintiffs are going to try to argue, as they currently are, that fitting means you use a device that requires substantial cutting away of tissue during surgery. And we give an example in our slides, ConforMIS's accused products are exactly that, they require substantial cutting away in order to attach and fit the medical device.").)

My recommendation at this stage is to reject Defendants' proposed construction and give the disputed phrase its plain and ordinary meaning. However, I would leave open the possibility that additional language might be added to the construction before sending the case to the jury—if the additional language is appropriate and helpful—to address Defendants' concern about cutting away tissue.

II. CONCLUSION

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), (C), Federal Rule of Civil Procedure 72(b)(1), and District of Delaware Local Rule 72.1. Any objections to the Report and Recommendation shall be filed within fourteen days and limited to ten pages. Any response shall be filed within fourteen days thereafter and limited to ten pages. The failure of a party to object to legal conclusions may result in the loss of the right to *de novo* review in the district court.

The parties are directed to the Court's "Standing Order for Objections Filed Under Fed. R. Civ. P. 72," dated October 9, 2013, a copy of which can be found on the Court's website.

Dated: September 29, 2021

The Honorable Jennifer L. Hall
United States Magistrate Judge