IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OSTEOPLASTICS, LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 20-405 (MN) (JLH)
	)	
CONFORMIS, INC.,	)	
	)	
Defendant.	)	

MEMORANDUM OPINION

Martina Tyreus Hufnal, FISH & RICHARDSON P.C., Wilmington, DE; Jason M. Zucci, FISH & RICHARDSON P.C., Minneapolis, MN – Attorneys for Plaintiff.

Steven J. Balick, Andrew C. Mayo, ASHBY & GEDDES, Wilmington, DE; John R. Emerson, Charles M. Jones II, Stephanie N. Sivinski, Tiffany M. Cooke, Jamie Raju, HAYNES AND BOONE, LLP, Dallas, TX – Attorneys for ConfirMIS, Inc.

February 14, 2022
Wilmington, Delaware

NOREIKA, U.S. DISTRICT JUDGE:

On September 29, 2021, Magistrate Judge Hall issued a Report and Recommendation ("the Report") (D.I. 89)[1] recommending that the Court adopt constructions for disputed claim terms in U.S. 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"). On October 13, 2021, Plaintiff Osteoplastics, LLC ("Plaintiff" or "Osteoplastics") objected to the Report. (D.I. 92). On October 27, 2021, ConforMIS, Inc. ("ConforMIS" or "Defendant") responded to Plaintiff's objections. (D.I. 95).

The Court has reviewed the Report, the objections and the responses thereto, and has considered *de novo* the original claim construction briefing and supporting documents, as well as the transcript of the claim construction hearing regarding the objected to terms. *See, e.g.*, *St. Clair Intellectual Prop. Consultants, Inc. v. Matsushita Elec. Indus. Co.,* 691 F. Supp. 2d 538, 541-42 (D. Del. 2010); 28 U.S.C. § 636(b)(l); FED. R. CIV. P. 72(b)(3). For the reasons set forth below, the objections to the Report are OVERRULED and the recommended constructions are ADOPTED.

I. LEGAL STANDARDS

"[T]he ultimate question of the proper construction of the patent [is] a question of law," although subsidiary fact-finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.,*

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[1] The Report was issued in this matter as well as in related matter, C.A. No. 20-406 between Plaintiff and DePuy Synthes, Inc., DePuy Synthes Products, Inc., and Synthes, Inc. (collectively, "DePuy"). DePuy filed objections to the Report on October 13, 2021 (D.I. 104 in C.A. No. 20-406) and on January 21, 2022, the parties filed, and the Court granted, a Stipulation and Order for Dismissal with Prejudice (D.I. 122, 123 in C.A. No. 20-406). In light of the settlement, the Court does not address DePuy's objections.

135 S. Ct. 831, 837-38 (2015). "[T]he words of a claim are generally given their ordinary and customary meaning [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.,* 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en bane) (internal citations and quotation marks omitted). Although "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Id.* at 1314. "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted).

The patent specification "is always highly relevant to the claim construction analysis . . . [as] it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.,* 90 F.3d 1576, 1582 (Fed. Cir. 1996). It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips,* 415 F.3d at 1316. "Even when the specification describes only a single embodiment, [however,] the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.,* 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotation marks omitted) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.,* 358 F.3d 898, 906 (Fed. Cir. 2004)).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.,* 52 F.3d 967,980 (Fed. Cir. 1995) (en bane), *aff'd,* 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence, . . . consists of the complete record of the proceedings before the PTO [Patent and Trademark

Office] and includes the prior art cited during the examination of the patent." *Phillips,* 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id*.

In some cases, courts "will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva,* 135 S. Ct. at 841. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman,* 52 F.3d at 980. Expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Phillips,* 415 F.3d at 1318. Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id*. Overall, although extrinsic evidence "may be useful to the court," it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.,* 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics,* 90 F.3d at 1583).

II. DISCUSSION

Plaintiff objects to five of the ten[2] constructions adopted in the Report: "anatomical landmarks," the "superimposing" and "matching" terms, "determining" and "template." The Court addresses each in turn.

A. "Anatomical Landmarks"

The Report recommended construing "anatomical landmarks" to mean "specific points of reference on the anatomy or images of anatomy." (D.I. 89 at 4). Plaintiff objects that anatomical landmarks need not be pre-defined points. The Court has carefully reviewed the record regarding the construction of "anatomical landmarks" *de novo* as well as the Report, which states:

> 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.
>
> 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. 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.

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[2] The parties presented thirteen disputes but agreed on the meaning of one term ("normative shape") (D.I. 89 at 2) and agreed to postpone the issue of definiteness of two others ("rendering a volumetric image at least a portion of a patient from image data of the patient" and "extracting a region of interest from the volumetric image of the patient, wherein the volumetric image comprises target tissue of interest of a patient") (*id.* at 5).

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 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."

The Report carefully analyzed the intrinsic evidence and the arguments put forth by the parties. The Court agrees with the Report's reasoning and the analysis of the intrinsic evidence, as well as the ultimate recommended construction. Plaintiff's objection to the construction of "anatomical landmarks" is overruled.

B. "Superimposing" and "Matching"

The Report recommended construing the "superimposing" terms[3] to mean: "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" with the added clarification that "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." (D.I. 89 at 3). As for the "matching term,"[4] as noted above, the Report recognized that Defendant may reraise their definiteness arguments, but recommended that "[i]f 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." (D.I. 89 at 4). Plaintiff objects that the "superimposing" and "matching" terms are not limited to automatically matching anatomical landmarks. With respect to that issue, the Court has carefully reviewed the record *de novo* as well as the Report, which states:

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[3] The "superimposing terms" are "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." (D.I. 89 at 3).

[4] The complete term is "matching a computer-rendered three-dimensional template onto a computer-rendered three dimensional surface of tissue surrounding the patient's target tissue of interest." (D.I. 89 at 4).

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 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. 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.
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> * * *
>
> 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.

As with "anatomical landmarks," the Court agrees with the Report's reasoning and the analysis of the specification, as well as the ultimate recommended constructions. Plaintiff's objection to the construction of the "superimposing" and "matching" terms is overruled.

3. "Determining" Terms

The Report recommended construing the "determining" terms[5] to mean "[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." (D.I. 89 at 4). Plaintiff objects to that last part of the construction, *i.e.*, that determining should not be limited to using a function of the shape of the defective portion of the patient image and

[5] The terms are "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." (D.I. 89 at 4).

template. Once again, the Court has carefully reviewed the record *de novo* as well as the Report, which states:

> 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. 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 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."

The Report carefully analyzed the claim language, the specification and the prosecution history in making the recommended construction. The Court agrees with the Report's reasoning and the analysis of the intrinsic evidence, as well as the ultimate recommended construction. Plaintiff's objection to the construction of the "determining" terms is overruled.

4. "Template"

The Report recommended construing "template" to mean "wire frame pattern representing a shape of patient tissue." (D.I. 89 at 2). During claim construction before Judge Hall, there were multiple disputes relating to this term. Here, Plaintiff objects to the resolution of one of those disputes, arguing that "template" should not be limited to wire frame patterns and the Report improperly relied on lexicography. With respect to that issue, the Court has carefully reviewed the record *de novo* as well as the Report, which states:

> . . . [T]he 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. Moreover, the Federal Circuit reaffirmed in that case that a provisional "can contribute to understanding the claims."

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, 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 Court finds that the Report's reasoning is sound and supported by the intrinsic evidence. The Court agrees with the Report, and Plaintiff's objection to the construction of "template" is overruled.

III. CONCLUSION

For the foregoing reasons, Plaintiff's objections are OVERRULED and the Report is ADOPTED. An appropriate order will follow.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OSTEOPLASTICS, LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 20-405 (MN) (JLH)
	)	
CONFORMIS, INC.,	)	
	)	
Defendant.	)	

ORDER

At Wilmington, this 14th day of February 2022, for the reasons set forth in the Memorandum Opinion issued on this date, IT IS HEREBY ORDERED that:

1. Plaintiff Osteoplastics's Objections to the Report and Recommendation Regarding Claim Construction (D.I. 92) are OVERRULED.

2. The Report and Recommendation regarding claim construction is ADOPTED. As such, the Court adopts and construes the agreed upon and disputed claim terms as follows:

Agreed Upon Construction:

1. "Normative shape" means "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" ('557, '206, '756, and '617 Patents).

Disputed Terms:

1. "template" means "wire frame pattern representing a shape of patient tissue" ('557, '206, '920, '756, '617, '302, and '191 Patents);

2. "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" means "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" ('557, '206, '920, '617, '302, and '191 Patents);[1]

3. "medical device" shall have the parties' agreed upon[2] plain and ordinary meaning of "any health care product that is intended for the diagnosis, prevention, or treatment of disease, birth defect, or trauma, and does not primarily work by effecting a chemical change in the body." ('206, '920, '756, '617, and '302 Patents);

4. "anatomical landmarks" means "specific points of reference on the anatomy or images of anatomy" ('920, '302, and '191 Patents);

5. "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" means "[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" ('557, '206, '920, '617, '302, and '191 Patents);

6. "fits the patient's target tissue of interest" shall have its plain and ordinary meaning[3] ('756 Patent); and

7. "obtaining a computer readable image" / "obtaining computer readable image data" means "to come into possession of [a computer readable image] / [computer readable image data]; get, acquire, or procure [a computer readable image] /

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1 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.

2 In response to the Court's November 9, 2021 Oral Order (D.I. 96), the parties filed a Joint Statement (D.I. 97) regarding their agreement as to the plain and ordinary meaning of the terms "medical device," "fits the patient's target tissue of interest," and "obtaining a computer readable image" / "obtaining computer readable image data". This construction comes from that statement. (*Id*. at 1-2).

3 Pursuant to the parties' November 16, 2021 submission, they agree that this term is clear as written and that no further construction is necessary. (D.I. 97). In her Report and Recommendation, Judge Hall recommended that the Court "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." The Court will adopt this recommendation.

[computer readable image data], as through an effort or by a request." ('557, '206, '920, and '191 Patents).

IT IS FURTHER ORDERED that, for the following terms, the Court agrees with the Report and Recommendation that Defendant has not met the burden at this stage to establish indefiniteness and, therefore, Defendant may reraise indefiniteness at the summary judgment stage:

1. "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);

2. "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);[4]

3. "optimal adjacency" ('920 and '191 Patents);

IT IS FINALLY ORDERED that, for the following two terms and pursuant to the parties' agreement, Defendant may raise indefiniteness at the summary judgment stage and Plaintiff may propose constructions in response:

1. "rendering a volumetric image at least a portion of a patient from image data of the patient" ('756 Patent); and

[4] If this term is reraised during summary judgment, and the claim is not found to be indefinite, Judge Hall recommends that the Court construe the claim to require that the matching occur with respect to "landmarks" and occur "automatically . . . using only a computer algorithm." Judge Hall also notes that the Court should clarify that the 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. The Court will consider these recommendations when making its determination.

2. "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).

Maryellen Noreika

The Honorable Maryellen Noreika
United States District Judge