

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

TRIMED, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 18-666 (MN)
	)	
ARTHREX, INC.,	)	
	)	
Defendant.	)	

**MEMORANDUM OPINION**

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March 29, 2021  
Wilmington, Delaware

*Maryellen Noreika*  
NOREIKA, U.S. DISTRICT JUDGE:

In this patent-infringement action, Plaintiff TriMed, Inc. (“Plaintiff” or “TriMed”) alleges that Defendant Arthrex, Inc. (“Defendant” or “Arthrex”) infringes U.S. Patent No. 8,177,822 (“the ’822 Patent”), a patent directed to certain hook plates for fixing bone fractures. The Court presided over a three-day bench trial on September 14, 15 and 16, 2020. (D.I. 195, 196 & 197). After trial, the parties submitted proposed findings of fact and post-trial briefs. (*See* D.I. 179, 180, 182, 183, 185, 186 & 187). This opinion revises the Court’s previous construction of a disputed claim term in the ’822 Patent, which obviates the need for a post-trial opinion under Rule 52(a) of the Federal Rules of Civil Procedure.<sup>1</sup>

## **I. BACKGROUND**

TriMed is in the business of orthopedic implants and fixation devices. TriMed owns a number of patents directed to bone fixation technology, including the ’822 Patent asserted here, and TriMed markets various plates designed for fixing fractures of different bones. One such plate designed and offered by TriMed is a volar hook plate for fixing specific fractures of the radius that involve small fragments at the distal end of the radius (*i.e.*, near the base of hand). Below is an image showing TriMed’s volar hook plate before and after installation onto the distal radius:

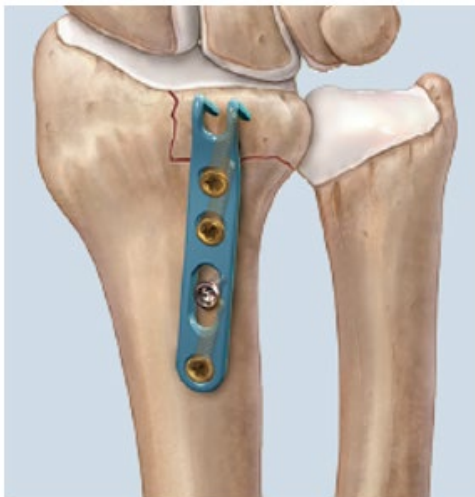
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<sup>1</sup> During a teleconference on March 9, 2021, the Court discussed revising its construction in a way that tracked Arthrex’s proposed revised construction and sought the parties’ positions on how the revised construction affected the issues tried in this case. (D.I. 193). TriMed agreed that, under the proposed revised construction, it did not present evidence at trial to satisfy its burden of proof on infringement. (*Id.* at 6:23-7:3 & 8:10-16). Arthrex agreed that, if the Court were to revise its construction as proposed and a finding of non-infringement followed, it would be appropriate to dismiss Arthrex’s invalidity counterclaim as moot. (D.I. 194; *see also* D.I. 193 at 4:15-21 (Arthrex agreeing that its prior art invalidity defenses were predicated upon a different construction)).



(PTX-002 (left); DTX-008 at 0:07 (top right) and 1:11 (bottom right)). As shown above on the right, after installation on the distal radius, screws hold the outer surface of TriMed's hook plate against the bone and the tines of the hook plate reside within the small fragment beyond the fracture. (See DTX-008 (TriMed instructional video on installation of volar hook plate)).

Arthrex also markets its own volar hook plate for fixing distal radius fractures, which is shown below both before and after installation:



(PTX-008 (left); JTX-005 at pg. 11 of 18 (right)). As seen above on the right, after installation on the distal radius, screws hold the outer surface of Arthrex's hook plate against the bone and the tines of the hook plate reside within the small bone fragment beyond the fracture.

On May 2, 2018, TriMed filed the present action, alleging that Arthrex's "Wrist Plating System" infringes one or more claims of the '822 Patent and one or more claims of the related U.S. Patent No. 9,283,010 ("the '010 Patent"). (*See generally* D.I. 1; *see also* D.I. 7 & 11 (first and second amended complaints adding further details regarding Arthrex's purported infringement)). As to the '822 Patent,<sup>2</sup> TriMed asserts that Arthrex has directly infringed and continues to directly infringe claims 1 and 2 by selling and offering to sell in the United States the Arthrex 4-hole Volar Hook Plate (AR-8916VH-04) and 6-hole Volar Hook Plate (AR-8916VH-06), along with an accompanying drill guide. (*See, e.g.*, D.I. 11 ¶¶ 31-37; *see also* D.I. 180 at 1 (limiting accused activities under § 271(a) to sales and offers for sale)). On August 27, 2018, Arthrex answered and filed declaratory judgment counterclaims for non-infringement and invalidity of the '822 Patent. (*See generally* D.I. 12). Discovery proceeded and the Court's typical claim construction process ensued.

At the outset of the claim construction process, there were three disputed terms from the '822 Patent proposed for construction. (*See* D.I. 41). The disputed terms, which all appear in claim 1, were: (1) "wrap around a terminal endpoint of the bone," (2) "offset" and (3) "fractures of a bone." (*Id.* at 1-2). By the time the joint claim construction brief was filed, the parties had agreed that "fractures of a bone," which only appears in the preamble of claim 1, should be construed to mean "a fracture or break of any bone." (D.I. 45 at 12-13). As to the disputed term

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<sup>2</sup> TriMed ultimately dropped its claims of infringement of the '010 Patent. (*See* D.I. 21 (dismissing '010 Patent claims with prejudice)).

“wrap around a terminal endpoint of the bone,”<sup>3</sup> TriMed proposed the construction “extending around a point on the terminal end of the bone.” (D.I. 41 at 1; *see also* D.I. 45 at 13-14). That is, in TriMed’s view, the “wrap around” term only required the claimed second region to be configured to extend around any point that resided on the terminal end. (*See* D.I. 45 at 13-14; *see also id.* at 20 (“The terminal end is the entire region that begins where the bone flares out and continues around the perimeter of the bone. . . . ‘A terminal endpoint’ therefore, is any point on the terminal end.”); *id.* at 23 (“[T]he claim language simply requires the hook plate to have a second portion to extend around a point on the terminal end region of the bone.”)). Arthrex, on the other hand, proposed that “wrap around a terminal endpoint of the bone” be construed as “curving or extending [around / onto] the end surface of the bone.” (D.I. 41 at 1; *see also* D.I. 45 at 14-18). In the briefing, Arthrex argued that the “wrap around” term required “not just extending to or near the end of the bone but actually curving around the very tip (i.e., the endpoint) of the bone.” (D.I. 45 at 15). At oral argument, Arthrex backed away from the argument that the second region wrap around the “very tip” of the bone, instead asserting that it must curve onto the end surface of the bone – *i.e.*, “where the bone and corresponding bone plate is actually changing angle from where it’s curving upward to curving downward,” according to Arthrex. (D.I. 50 at 14:15-15:17).

After briefing and hearing argument, on July 31, 2019, the Court issued its claim construction order, which construed “wrap around a terminal endpoint of the bone” to mean “curving or extending onto the end surface of the bone.” (D.I. 49 at 1 & 4-6). This construction

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<sup>3</sup> The Court also construed the disputed “offset” term to mean “the difference in length between the apex of the first hook and the end of the plate opposite the hook compared to the apex of another hook and that end” and clarified that the difference in length may be zero. (D.I. 49 at 1). This term did not form the basis for any non-infringement or invalidity defense raised at trial and, as such, it is not addressed in this opinion.

was essentially the proposed construction offered by Arthrex as further explained at the claim construction hearing (*i.e.*, without the “very tip” requirement). (*See* D.I. 45 at 13). At no time during claim construction proceedings – including oral argument – did Arthrex suggest that the “wrap around” term requires a specific geometric relationship between the hook-shaped projections and a longitudinal axis of the bone (or bone plate). Moreover, neither party indicated to the Court there could be meaningful differences in bone morphology that are relevant to the invention disclosed in the ’822 Patent.

On April 3, 2020, Arthrex filed a motion for summary judgment of non-infringement of the asserted claims of the ’822 Patent. (*See* D.I. 111, 112, 113 & 114). Arthrex argued that its accused volar hook plate does not “wrap around a terminal endpoint of the bone” because the plate’s tines enter a surface that stops short of the distal radius’s end surface.<sup>4</sup> (D.I. 112 at 10-19). According to Arthrex, under the Court’s construction of the “wrap around” term, the “end surface of the bone” for the distal radius is the articular surface (which contains cartilage and forms the wrist joint). (*See, e.g.*, D.I. 112 at 12). Arthrex’s volar hook plate is designed for insertion of the plate’s tines into the volar surface – the surface of the distal radius short of (but leading into) the articular surface. (*Id.* at 10-12). In response, TriMed argued that Arthrex’s volar hook plate satisfies the “wrap around” term as construed because the hook plate is designed to wrap around or extend to the end surface of the radius as defined by where the bone changes curvature from upward to downward. (D.I. 124 at 6-14). From the briefing, there appeared to be a lingering (or perhaps newly discovered) dispute over the meaning of the “wrap around” term from claim 1.

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<sup>4</sup> Arthrex also argued that its volar hook plate does not infringe because the accompanying drill guide does not have an “elongated positioning member extending from the body” as required by claim 1. (*See* D.I. 112 at 20-26). This alternative non-infringement position is not relevant to the “wrap around” term dispute and is therefore not addressed here.

Moreover, in Arthrex’s summary judgment motion, it became apparent that the morphology of bones was important – *i.e.*, bones can have different morphology at their ends and this impacts where the claimed invention (or the accused product) is to be placed.

Recognizing that the end of the distal radius is of a different morphology than the bones visually depicted in the ’822 Patent, the Court attempted to create a demonstrative to assess whether the “wrap around” issues raised in connection with Arthrex’s summary judgment motion were purely infringement issues or instead an unresolved claim construction dispute. The Court docketed this demonstrative prior to hearing argument on Arthrex’s motion for summary judgment and directed the parties to review it and be prepared to discuss.<sup>5</sup> (*See* D.I. 162; *see also id.*, Ex. A). At the hearing, the parties agreed with how the “wrap around” term as construed applied to a bone with a convex-type end, such as the ankle bone depicted in the ’822 Patent. (*See* D.I. 167 at 2:24-6:2; *see also* D.I. 162, Ex. A at 1 (boxes A1, A2 and A3)). But the parties disagreed with how the “wrap around” term as construed applied to a bone with a concave-type end, such as the distal radius. (*See* D.I. 167 at 6:3-7:10; *see also* D.I. 162, Ex. A at 1 (boxes B1, B2 and B3)). During oral argument, the Court struggled to understand the parties’ interpretations of the Court’s construction and its application to the issue of infringement, an issue complicated by Arthrex’s use of terms not present in the ’822 Patent but apparently critical to the accused product – *e.g.*, volar surface, articular surface, distal rim, etc. (*See* D.I. 167 at 2:24-3:9 & 7:8-21). Further confounding the matter, Arthrex’s counsel asserted that the “end surface” of a bone “is not defined by curvature,” a departure from its earlier position. (*Id.* at 10:16-11:13; *see also id.* at 11:8-13).

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<sup>5</sup> Use of this demonstrative was also an effort to guide and focus a discussion that was being held remotely during the COVID-19 pandemic.

Unable to determine whether there was an underlying dispute as to the meaning of the “wrap around” term or a factual dispute as to whether Arthrex’s volar hook plate met that limitation as previously construed, the Court denied the motion for summary judgment in an oral ruling. In denying Arthrex’s motion, the Court emphasized its concern that a claim construction dispute still remained over the “wrap around” term in the ’822 Patent:

. . . I’m going to deny the motion for summary judgement [sic]. As to infringement on the first issue, wrapping around, I can’t tell if this is a claim construction or an infringement issue. I take to heart Defendant’s arguments that their plates may not work the same ways as the ones depicted in the patent because the patent is depicting different bones there than are at issue here, but there are arguments made today that were different from those made at the claim construction and they were largely just that, attorney arguments. And I think I would benefit from hearing more from the parties, and particularly the experts on this, and to be able to deal with it in context.

(D.I. 167 at 48:20-49:7).

The parties submitted their proposed Pretrial Order on August 24, 2020. (*See* D.I. 166; *see also* D.I. 174 (order adopting Pretrial Order with modification)). In the proposed Pretrial Order, Arthrex addressed construction of the “wrap around” term, arguing that the term requires “the second region being specifically designed to curve back upon a bottom surface of the bone plate such that the hooks extending therefrom are substantially parallel to the longitudinal axis of the bone.” (D.I. 166 at 16; *see also generally id.* § XIII.B (setting forth the parties’ positions on the need for additional claim construction)). At the final pretrial conference on August 31, 2020, the Court reiterated its concern that there was still a dispute over the meaning of the “wrap around” term in claim 1:

I do still have concerns about whether there are unresolved claim construction issues. And I’m going to warn the parties right now that you need to make a clear record on the disputes from the vantage point of both claim construction and infringement. And when the experts are up on the stand, if I have claim construction questions,



I'm going to feel free to jump in and ask questions related to their understanding of the claim terms as well as the infringement issues. . . . [S]ometimes I look at it I think it's an issue of infringement, sometimes I'm not sure, sometimes I think it might be one of claim construction, so we need to figure that out. And if I need to ask questions of the expert, I will.

(D.I. 173 at 12:20-13:8).

A bench trial proceeded on September 14, 15 and 16, 2020. (D.I. 195, 196 & 197). TriMed attempted to prove that Arthrex directly infringes claims 1 and 2 of the '822 Patent by selling and offering to sell its 4-hole Volar Hook Plate (AR-8916VH-04) and 6-hole Volar Hook Plate (AR-8916VH-06), along with an accompanying drill guide (AR-8916-26). Arthrex offered evidence that it does not infringe and, further, attempted to prove that claims 1 and 2 are invalid as lacking adequate written description and as anticipated or obvious over U.S. Patent No. 6,755,831. As trial progressed, there was some expert testimony<sup>6</sup> elicited on the meaning of the claims to a person of ordinary skill in the art ("POSA"). (*See, e.g.*, Tr. at 136:2-141:9 (cross-examination of TriMed's expert); Tr. at 482:19-485:4, 490:2-15, 491:23-493:10 & 508:5-20 (Arthrex's expert)). After closing arguments, in commenting on Arthrex's anticipated fee motion under 35 U.S.C. § 285, the Court reiterated its concern about the dispute over the "wrap around" term. (*See* Tr. at 767:16-21 ("I would suggest that you tell your client to the extent exceptional case is based on Plaintiff continuing to pursue it after claim construction, I'm still struggling with that issue, so if it's only based on that, the exceptional case, I would suggest they think carefully about bringing that. I'm struggling with that.")).

After trial, the parties submitted proposed findings of fact and briefing on the claims and defenses raised at trial. (*See* D.I. 179, 180, 182, 183, 185, 186 & 187). In the post-trial

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<sup>6</sup> TriMed's infringement and invalidity expert, Dr. Robert Medoff, is the sole inventor of the '822 Patent and one of the founders of TriMed. (Tr. at 39:24-40:23 & 63:7-24; *see also* Tr. at 91:16-92:5).

submissions, both parties also briefed the still-lingering dispute over the meaning of “wrap around a terminal endpoint of the bone” as recited in claim 1. Arthrex argued that, if further construction is necessary to resolve the parties’ dispute, the term should be construed to require “that the second region is specifically designed to curve back upon a bottom surface of the bone plate such that the hooks extending therefrom are substantially parallel to the longitudinal axis of the bone.” (D.I. 182 at 3; *see also id.* at 3-7). Arthrex also cited record evidence to support its argument in favor of a finding of non-infringement without further claim construction and under TriMed’s interpretation of the “wrap around” term. (D.I. 182 at 7-8 & 12-17). In response, TriMed argued that the intrinsic evidence does not support a construction that requires any particular configuration of the hooks relative to the rest of the bone plate. (*See* D.I. 186 at 4-7). TriMed did not cite any evidence to show infringement under Arthrex’s proposed revised construction.

As became evident from trial and post-trial briefing, there remains an unresolved dispute over the meaning of “wrap around a terminal endpoint of the bone” in claim 1 of the ’822 Patent and not simply a factual dispute regarding whether the accused devices infringe. As such, before addressing the merits of any claim or defense tried in this action, the Court will revisit the construction of the “wrap around” term.

## **II. LEGAL STANDARD**

“[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.*, 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 banc) (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 banc), *aff’d*, 517 U.S. 370 (1996). The prosecution history, which is “intrinsic evidence, . . . consists of the complete record of the proceedings before the [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).

### **III. DISCUSSION**

As noted previously, the Court finds it necessary to revisit the construction of the “wrap around” term. “[Courts] may engage in a rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves. This is particularly true where issues involved are complex, either due to the nature of the technology or because the meaning of the claims is unclear from the intrinsic evidence.” *Jack Guttman, Inc. v. Kopykake Enterprises, Inc.*, 302 F.3d 1352, 1361 (Fed. Cir. 2002) (citation omitted). Indeed,

the Federal Circuit has repeatedly upheld a district court's decision to revisit claim construction as the case progresses, including at trial. *See, e.g., Pressure Prod. Med. Supplies, Inc. v. Greatbatch Ltd.*, 599 F.3d 1308, 1315-16 (Fed. Cir. 2010) (not improper for district court to supplement claim construction in the midst of a jury trial where parties were given opportunity to consider new construction and present arguments accordingly); *CytoLogix Corp. v. Ventana Med. Sys., Inc.*, 424 F.3d 1168, 1172 (Fed. Cir. 2005) (as long as conflicting constructions are not presented to the jury, not erroneous for district court to resolve claim construction disputes at the close of evidence because "the district court has considerable latitude in determining when to resolve issues of claim construction"). Regarding revisions during trial, the Federal Circuit has noted that "a trial judge may learn more about the technology during the trial that necessitates some clarification of claim terms before the jury deliberates." *Pressure Prod.*, 599 F.3d at 1315.

The same situation obviously may arise in cases tried to the bench – *i.e.*, a court may gain a more fulsome understanding of the technology and invention at issue during trial but before the court renders its decision. When this happens, it may be appropriate (and necessary) to revisit claim construction in a post-trial opinion following a bench trial. *See, e.g., UCB, Inc. et al. v. Watson Laboratories, Inc. et al.*, No. 14-1083-LPS, slip op. at 44-47 (D. Del. Nov. 14, 2017) (after parties previously agreed to a construction for "polymer adhesive system," the court further construing term in post-trial opinion after bench trial because trial and post-trial briefing revealed a dispute remained as to the term's meaning). Here, although the Court construed the disputed term, as the case progressed – and the Court gained a better understanding of the technology – it became clear that the Court's construction did not resolve the parties' dispute. *See GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1310 (Fed. Cir. 2014) ("[P]arties in patent cases frequently stipulate to a construction or the court construes a term, only to have their dispute evolve

to a point where they realize that a further construction is necessary.”). The parties were on notice that the Court may need to revisit its construction. (*See* D.I. 167 at 48:20-49:7 (summary judgment hearing); D.I. 173 at 12:20-13:8 (final pretrial conference)). Indeed, the parties were told that the Court may question their experts at trial about the term’s meaning and, further, that the parties should be prepared to create a record from the vantage points of claim construction and infringement. (D.I. 173 at 12:20-13:8).<sup>7</sup> Moreover, the claim construction issue was briefed in post-trial submissions. (*See, e.g.*, D.I. 182 at 3-7; D.I. 186 at 4-7). Therefore, under the unique circumstances here, the Court finds it appropriate to revisit (and revise) the construction of “wrap around a terminal endpoint of the bone.”<sup>8</sup>

As noted above, the Court previously construed the term “wrap around a terminal endpoint of the bone” to mean “curving or extending onto the end surface of the bone.” (D.I. 49 at 1). The parties now dispute whether the term requires the hook-shaped projections in claim 1 to be in a particular configuration relative to the bone (or bone plate). (*Compare* D.I. 182 at 3 (Arthrex proposing revised construction requiring the second region to be “specifically designed to curve back upon a bottom surface of the bone plate such that the hooks extending therefrom are substantially parallel to the longitudinal axis of the bone”), *with* D.I. 186 at 4-7 (TriMed arguing

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<sup>7</sup> Arthrex offered evidence of non-infringement under competing constructions. (*See* D.I. 182 at 7-8 & 12-17). TriMed did not, instead arguing only that Arthrex’s construction was incorrect.

<sup>8</sup> Parties are expected to abide by claim constructions rendered by the Court. Although claim construction may sometimes be a rolling process, it is the Court that decides when to resolve issues of claim construction and, of course, there is a point when it is too late to revisit claim construction. The Court believes, however, that revisiting the construction of the “wrap around” term is necessary and appropriate here because the parties did not adequately present the technology at issue during the initial claim construction process, the parties were repeatedly warned before trial that the Court was concerned that its construction did not resolve the parties’ dispute and this case did not involve jury concerns.

there is no required configuration of the hooks relative to the rest of the bone plate)). To resolve this dispute, the Court turns to the intrinsic evidence, starting with the claim language itself.

The disputed term appears in claim 1 of the '822 Patent:

1. A combination of a bone plate for fixing fractures of a bone having a small terminal fragment and drill guide facilitating implantation of the bone plate, the combination comprising:

a bone plate having a first region configured for placement adjacent an outer surface of a bone and a second region configured to ***wrap around a terminal endpoint of the bone***, the second region having at least two hook shaped projections for insertion into holes in the terminal endpoint of the bone;

a multiple barreled drill guide facilitating drilling of at least two parallel holes at a distal end of the bone, the multiple barreled drill guide comprising;

a body;

at least two sleeves coupled to the body in substantially parallel orientation relative to each other, each sleeve having a first longitudinal axis and a distal tip; and

an elongated positioning member extending from the body and having a second longitudinal axis;

wherein a distance between each distal tip of the at least two sleeves and the positioning member has a predetermined value such that insertion of the projections of the bone plate into the parallel holes results in coaptation of the first region of the bone plate on the outer surface of the bone wherein the projections are offset by a predetermined length; wherein the parallel holes are offset by the predetermined length; wherein the sleeves are offset by the predetermined length.

('822 Patent at Claim 1 (disputed term emphasized)). There is no special definition given to the disputed phrase in the specification – indeed, this phrase does not appear anywhere in the specification, nor do the individual terms “wrap around” or “terminal endpoint.” Starting with the plain meaning of the words “wrap around,” the term connotes curvature and, more specifically, curving onto a terminal endpoint and then back to some degree (to achieve wrapping “around”). (See, e.g., D.I. 46 at JA067, JA070 & JA073; see also D.I. 49 at 5). Although the ordinary meaning

of “wrap around” provides some insight as to what it means to “wrap around a terminal endpoint of the bone,” the term does not itself resolve the parties’ dispute.

Beyond the meaning of the claim words at issue, it is also helpful to view the disputed term in the context of surrounding claim language. *See Phillips*, 415 F.3d at 1314 (“[T]he context in which a term is used in the asserted claim can be highly instructive.”); *see also ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003) (“While certain terms may be at the center of the claim construction debate, the context of the surrounding words of the claim also must be considered in determining the ordinary and customary meaning of those terms.”). The language preceding the “wrap around” term merely indicates that the claimed bone plate has a second region configured to wrap around a terminal endpoint of the bone. Yet the language that follows is elucidating: “the second region having at least two hook shaped projections for insertion into holes in the terminal endpoint of the bone.” (’822 Patent at Claim 1). The plain meaning of “hook shaped” is having the shape of a hook – *i.e.*, a shape with curvature to allow for holding something. Read in the context of claim 1, a POSA would understand that the recited “hook shaped projections” have a curvature that allows them to hold onto something (*i.e.*, a small terminal fragment) once inserted into the holes in a terminal endpoint of the bone. A POSA would thus understand that the second region of the bone plate is configured to wrap around a terminal endpoint because it has “hook shaped projections” that curve around a terminal endpoint of the bone. In the Court’s view, the outstanding question underlying the parties’ dispute now is whether the “hook shaped projections” must curve around a terminal endpoint and back towards something in particular to achieve wrapping “around.” The Court turns to the specification in search of an answer to this question. *See Phillips*, 415 F.3d at 1313 (“[A POSA] is deemed to read the claim



term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.”); *see also Vitronics*, 90 F.3d at 1582.

The specification begins with a discussion of the shortcomings of the prior art. The '822 Patent explains that plates and screws were well known for fracture fixation, with the “standard bone plate” being a planar plate that spans a fracture and is installed using screws that thread through holes in the plate into the bone underneath. ('822 Patent at 1:13-19). To span the fracture for fixation, the bone plate has holes to receive screws on both sides of the fracture. (*Id.* at 1:17-19). The specification goes on to explain that “[d]ifficulties in using bone plates may arise in certain fractures occurring relatively close to the end of the bone, creating a relatively small end fragment.” (*Id.* at 1:26-28). In situations where a small fragment is fractured off the end of the bone (*e.g.*, the lateral malleolus), there may not be enough bone material in the small fragment to receive an adequate number of screws for fixation, which can lead to poor post-operative outcomes. (*Id.* at 1:26-33). One solution to this problem was to cut the planar bone plate completely across the body through the last screw hole and bend the resultant projections around the terminal bone fragment. (*Id.* at 1:46-56). Although this technique provided some fixation, it did not always result in the terminal bone fragment being secured well. (*Id.*). Another solution was the design of a flat plate with “pre-contoured” hooks at one end that were parallel to the body of the plate, and the hooks would be manually inserted into the terminal end of a bone (*e.g.*, olecranon) with screws holding the plate’s body against the outer surface of the bone. (*Id.* at 1:57-67). Yet this solution was inadequate for bones having a flare at the terminal end because, *inter alia*, the planar plate would “come to lie in a position that sits off the bone.” (*Id.* at 1:67-2:7).

In view of these prior art shortcomings, the '822 Patent provides a bone plate that secures a small fragment at a terminal end of a bone and, further, “a bone plate that can be seated flush

against a bone characterized by a flare at the terminal segment.” (’822 Patent at 2:22-27). Using pilot holes in the terminal fragment created by the accompanying drill guide, the bone plate will “advance both longitudinally as well as drop down against the surface of the bone as it is seated” when the hooks of the plate are inserted into pilot holes in the terminal fragment. (*Id.* at 2:29-35; *see also id.* at 2:41-43 (another object is to provide accompanying drill guide)). The invention also provides “a design that has a contour that approximates the flare of the terminal segment of a bone as well as provides one or more hooks that are angled along an axis that approximates the best linear fit approximation of such flare.” (*Id.* at 2:36-40). Although not dispositive, it is noteworthy that many of the recited objects of the invention focus on a bone plate that can accommodate a flare at the terminal end, doing so by using hooks angled in a way to secure the small terminal fragment while also accommodating the flare. (*See id.* at 2:22-43).

Before describing the embodiments, the ’822 Patent sets forth a summary of the claimed invention. Critically, the following summary of the invention is presented in language without limitation or reference to any preferred embodiment:

The present invention comprises a bone plate for fixing fractures having a small terminal fragment. The bone plate has an elongated body having a first end, a second end, a top surface, a bottom surface, and an angled or curved flared region disposed between the first end and the second end that can be described by a best fit first longitudinal axis. ***At least one hook member is provided proximate the first end and has a prong region having a second longitudinal axis. Moreover, the first longitudinal axis and the second longitudinal axis are substantially parallel to each other.***

(’822 Patent at 2:50-59 (emphasis added)). This general description of the invention, ostensibly directed to the invention as a whole, teaches a POSA that the claimed bone plate has hook members with prongs that run substantially parallel to a best fit axis of the angled or flared region of the plate. “Statements that describe the invention as a whole, rather than statements that describe only preferred embodiments, are more likely to support a limiting definition of a claim term.” *C.R.*

*Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 864 (Fed. Cir. 2004); *see also Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1308 (Fed. Cir. 2007) (“When a patent thus describes the features of the ‘present invention’ as a whole, this description limits the scope of the invention.”).

Mirroring this general summary of the invention, the Abstract of the ’822 Patent emphasizes the conformational relationship between the hook members and the elongated body of the bone plate:

A bone fixation plate for fixation of fractures having a small terminal bone fragment, such as fractures of the lateral malleolus. The bone fixation plate includes an elongated body, and two hook members extending from a first end of the elongated body. ***Each hook member curves back upon a bottom surface of the elongated body, back towards a second end of the elongated body***, and terminating in a pointed prong region. The elongated body includes a first region, a second region, and an angled region disposed between the first and second region. ***The prong region has a longitudinal axis that is substantially parallel to a longitudinal axis of the angled region of the elongated body of the bone plate.***

(’822 Patent at Abstract (emphases added)). This language conveys to a POSA that there is, indeed, a specific (and limiting) configuration of the bone plates claimed in the ’822 Patent – *i.e.*, one where the hooks curve back towards the opposite end of the plate and run substantially parallel to a portion of the plate. *See, e.g., Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1349 (Fed. Cir. 2012) (description of invention in Abstract offered additional intrinsic evidence for limiting the term “adapted to” to something narrower than “capable of”); *Hill-Rom Co. v. Kinetic Concepts, Inc.*, 209 F.3d 1337, 1341 (Fed. Cir. 2000) (relying in part on emphasized features of the invention described in Abstract to affirm a claim construction of “cushion” that requires “basic support and comfort”).

Moving to the detailed description of the invention in the ’822 Patent, the disclosure is focused on an embodiment for fixing small fragments in fractures of the lateral malleolus, an outer

bone of the ankle. (*See* '822 Patent at 5:4-7:51). To secure the fragment, the longitudinal axes of the hooks are substantially parallel to the longitudinal axis of an angled region of the bone plate, which approximates the flare of the bone. (*See id.* at 7:11-22 & FIG. 2C; *see also id.* at 5:41-47 & 10:62-11:1). Indeed, the specification describes this parallel relationship as “critical to allow hook plate 40 to seat congruently against the curved profile of the lateral malleolus as the hook members are impacted into a terminal fragment.” (*Id.* at 7:19-22; *see also id.* at 10:57-60 (“anatomic fit of the plate against the bone is the result of designing the longitudinal axis 55 of the hooks to be parallel to the longitudinal axis 63 of the intermediate region 47”). There is no description of an embodiment applied to other anatomical sites, nor is there a description of a configuration where the hooks do not run substantially parallel to a flared region of the bone plate (and thus the flare of the bone at the terminal end).

Similarly, every drawing in the '822 Patent depicting the hook-shaped projections of the claimed bone plate shows hooks that run substantially parallel to a flared or angled region of the plate (and thus substantially parallel to the flare of the bone). (*See* '822 Patent at FIGs. 2A, 2B, 2C, 3B, 10, 11 & 12). There is no figure that depicts a bone plate with hooks in a different configuration. *See, e.g., Advanced Steel Recovery, LLC v. X-Body Equip., Inc.*, 808 F.3d 1313, 1317 (Fed. Cir. 2015) (where specification did not define “proximate end,” relying in part on figures to support narrow construction when “every figure that depicts the disputed connection shows the container packer piston-and-cylinder unit connected to the container packer at the container packer’s extreme edge.” (emphasis in original)); *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1348 (Fed. Cir. 2012) (relying largely on figures to construe “free end” to mean extending rearwardly and unattached to part of frame). This further supports that

the claimed bone plate's "hook shaped projections" curve onto a terminal endpoint and back around towards the opposite end of the plate and running parallel to the flare of the bone.

Although the detailed description focuses on an ankle fracture, the claimed invention of the '822 Patent is not limited to applications on the ankle. The specification explicitly provides that the invention has broader applicability: "Other embodiments contemplated by the present invention may be formed with the angled region designed to conform to the contour of other sites of application in which the bone surface flares superficially at the terminal end, such as the olecranon, proximal ulna, proximal or distal humerus, medial malleolus, or similar bones." ('822 Patent at 3:11-16; *see also id.* at 5:56-61 (discussing contemplated manufacturing modifications "to create a hooked bone plate specifically tailored for other sites of application having a bone surface flare superficially proximate the terminal end, such as the medial malleolus, olecranon, proximal ulna, proximal femur, proximal fifth metatarsal, proximal or distal humerus, or other such sites of application")). That being said, although fixation of other bones is contemplated by the '822 Patent, as previously noted, there is no depiction or description of a bone plate where the hook-shaped projections are *not* substantially parallel to the longitudinal axis of the bone at the terminal end.

TriMed points out that the specification provides that certain angles of the bone plate may be modified during the manufacturing process. (D.I. 186 at 5). Referring to Figure 2C and the description of the embodiment depicted in that figure, TriMed asserts that "[a]ngle 49 is the angle of the flare of the plate and angle 69 is the angle of the hook." (*Id.* (discussing '822 Patent at 5:52-58)). But the specification does not support the assertion that angle 69 is the angle of the hook. Still referring to Figure 2C, the specification indicates that "angle 69" is the angle at the juncture between the bottom surface of angled region 47 of the bone plate and the bottom surface of first

region 48 of the bone plate. ('822 Patent at 6:21-23; *see also id.* at FIG. 2C). To the extent that TriMed is arguing that there is a disclosure of changing the angle formed at the apex of the hook (*i.e.*, the angle at curved region 58), that is not supported. The specification never discusses changing the curvature of the hook members, which stands in contrast to the specification teaching that “sharper bends, rather than more gentle curves” can be used to modify angle 49 and angle 69. (*Id.* at 6:29-32). This is significant because, although different configurations of the contoured region of the bone plate are contemplated, there is no teaching to modify the shape of the hook-shaped projections to do something other than curve around and back towards the opposite end of the plate. This further suggests that the disclosed configuration of the hooks is not just a preferred embodiment, but a requirement of the claimed invention itself. *See, e.g., Regents of Univ. of Minnesota v. AGA Med. Corp.*, 717 F.3d 929, 936 (Fed. Cir. 2013) (“conjoint disk” must be comprised of two separate structures because, *inter alia*, every embodiment required two separate pieces and the specification did not teach other embodiments).

TriMed also argues that the limiting language in the Abstract and elsewhere is not relevant because the “substantially parallel” language related to claims that were originally present but withdrawn in response to a restriction requirement. (*See* D.I. 186 at 3-6). The Court is unpersuaded, particularly because the claims before the Examiner differ from the ones that ultimately issued. As originally filed, the application that issued as the '822 Patent had effectively three sets of claims. The first set, original claims 1-25 and 36-37, were claims that explicitly required a substantially parallel relationship between the hooks and a flared region of the bone plate, but the claims did not contain the “wrap around” language and no drill guide was required.

(DTX-106 at pgs. 151-54 & 157-58 of 181).<sup>9</sup> The second set, original claims 26-33, recited a bone plate in combination with a drill guide, but there were no “hook shaped projections” required by the claims. (*Id.* at pgs. 154-157 of 181). The third set, original claims 34-35, were directed to a method of bone fixation. (*Id.* at pgs. 157-58 of 181). The Examiner issued a restriction requirement, asserting that, although related as subcombination (first set) and combination (second set), the first and second set of claims were distinct inventions because the combination did not require the particulars of the subcombination and because the subcombination had its own utility. (*Id.* at pgs. 92-93 of 181). More specifically, the Examiner stated that the combination (second set of claims) did “not require a prong region and a flared portion” like the subcombination (first set of claims) and that the subcombination had separate utility because the prong and flared regions could be bent with pliers to achieve a particular configuration. (*Id.*).

The '822 Patent Applicant elected to proceed with the second set of claims – *i.e.*, original claims 26-33. (*See* DTX-106 at pgs. 86-87 of 181). Claim 26 would ultimately issue as claim 1 of the '822 Patent, but at the time of election, the portion of the claim containing the disputed language read as follows: “a bone plate having . . . a second portion configured to wrap around a terminal end of the bone, the second portion having at least two projections for insertion into holes in the terminal end of the bone.” (*Id.* at pgs. 154-55 of 181). It was not until later, in response to a prior art rejection, that Applicant amended the claim to require that the projections be “hook shaped” (and to change “terminal end” to “terminal endpoint”). (*Id.* at pg. 36 of 181). This is significant because the phrase “hook shaped” connotes a curved configuration, the addition of which seems to moot the Examiner’s comments about the specific configuration of the non-elected

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<sup>9</sup> The prosecution history appears in reverse chronological order and has no bates numbering. Citations are therefore to page numbers of the PDF file provided to the Court as DTX-106.

vs. elected claims. Stated differently, the restriction requirement does not show that the issued claims have no particular configuration because the claims that issued differ from the claims subject to the restriction requirement in a way that relates specifically to configuration. Moreover, as support for adding the “hook shaped” requirement, Applicant cited Figures 2A through 2F and what would become column 5 lines 12 through 17. (*Id.* at pg. 43 of 181). Those figures all depict “hook shaped projections” that run substantially parallel to the flared region of the bone plate (and thus the flare of the bone at the terminal end).

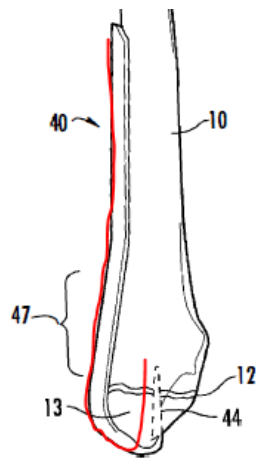
Based on the foregoing, the Court concludes that a POSA reading claim 1 in view of the specification would understand that the claimed bone plate requires a particular configuration. More specifically, a POSA would understand that the “hook shaped projections” recited in claim 1 must curve onto a terminal endpoint of the bone and back around towards the opposite end of the plate and run substantially parallel to the longitudinal axis of the bone at the terminal end. Where the bone is characterized by a flare at the terminal end, the longitudinal axis of the bone at the terminal end approximates that flare. To a POSA, this substantially parallel relationship between the “hook shaped projections” and the longitudinal axis of the terminal end of the bone is what makes the second region “configured to wrap around a terminal endpoint of the bone.”<sup>10</sup>

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<sup>10</sup> Arthrex also relies on the related '010 Patent to argue that the '822 Patent requires a specific configuration of the hooks. (D.I. 182 at 7). The Court agrees that the disclosure of the '010 Patent and the omission of the “wrap around” term in the claims there tend to suggest there is a critical difference in the configuration of plates used to fix distal radius fractures compared to those depicted in the '822 Patent, a difference that may very well be captured by the “wrap around” term. (*See, e.g.*, '010 Patent at 2:33, 4:28-45, 6:48-60 & Claims 1, 12). But claim construction seeks a term’s meaning to a POSA at the time of invention (*i.e.*, effective filing date). *Phillips*, 415 F.3d at 1312-13. The '010 Patent – a continuation-in-part of a divisional of the '822 Patent application – seems of marginal utility in showing a POSA’s understanding of the “wrap around” term as of the '822 Patent’s filing date.



Finally, contrary to TriMed’s suggestion, the Court’s revised construction does not require the second region to wrap around the most terminal point on the end of the bone. (*See* D.I. 186 at 2 (TriMed arguing that Arthrex’s proposal would “result in the hooks wrapping around the very tip of the bone”). Indeed, under the revised construction, the claimed bone plate can wrap around a terminal endpoint of the bone short of the *most* terminal endpoint. Such a configuration is shown below in red on an annotated version of Figure 11 of the ’822 Patent:



(’822 Patent at FIG. 11 (with the Court’s annotation in red)). The Court’s construction also does not read in a requirement that the claimed bone plate have a distinct flared or angled region. (*See* ’822 Patent at Claim 8 (adding a flared region to the bone plate of claim 1, as well as limitations related to the drill guide)). In the situation where the fractured bone has minimal to no flare at the terminal end, no flared or angled region on the plate would be necessary to accommodate a flare. In that situation, because there is no flare, the longitudinal axes of the hook-shaped projections would run substantially parallel to the longitudinal axis of the non-flared terminal end.

In sum, after re-examining the intrinsic evidence with a more fulsome understanding of the technology, the Court revises its construction of “wrap around a terminal endpoint of the bone” to require that the second region is configured to curve onto a terminal endpoint and back around such that the hook shaped projections are substantially parallel to the longitudinal axis of the bone

at the terminal end. The parties having agreed that this requires a finding of non-infringement and that Arthrex's invalidity counterclaim may be dismissed as moot, there are no further issues that require the Court's resolution.

#### **IV. CONCLUSION**

For the reasons set forth above, "wrap around a terminal endpoint of the bone" requires that the second region is configured to curve onto a terminal endpoint and back around such that the hook shaped projections are substantially parallel to the longitudinal axis of the bone at the terminal end. An appropriate order will follow.