

IN THE UNITED STATES DISTRICT COURT  
 FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

NAZIR KHAN and IFTIKHAR KHAN,  <p style="text-align: center;">Plaintiffs,</p> v.  MERIT MEDICAL SYSTEMS,  <p style="text-align: center;">Defendant.</p>	REPORT AND RECOMMENDATION  Case No. 2:21-cv-00337-HCN-CMR  District Judge Howard C. Nielson, Jr.  Magistrate Judge Cecilia M. Romero
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This matter is referred to the undersigned pursuant to 28 U.S.C. § 636(b)(1)(B) (ECF 23). Before the court is Defendant Merit Medical Systems, Inc.’s (Defendant) Motion for Summary Judgment (Motion) (ECF 40) on the patent infringement claims set forth in Plaintiffs Nazir Khan and Iftikhar Khan’s (Plaintiffs) Amended Complaint (ECF 15). Having carefully considered the relevant filings, the court finds that oral argument is not necessary and will decide this matter on the basis of written memoranda. *See* DUCivR 7-1(g). For the reasons set forth below, the undersigned RECOMMENDS that the court GRANT Defendant’s Motion (ECF 40) and dismiss Plaintiffs’ Amended Complaint with prejudice.

**I. PROCEDURAL BACKGROUND**

Plaintiffs initiated this patent infringement action against Defendant on June 1, 2021 (ECF 2). Plaintiffs thereafter filed an Amended Complaint (ECF 15) with leave of court (ECF 14) asserting the following claims against Defendant for making, using and/or selling the HeRO® Graft : (1) Claim 1 for literal infringement, under the doctrine of equivalents, and under 35 U.S.C.

§ 112(f)<sup>1</sup> of Claim 13 of U.S. Patent No. 8,747,344 (the ‘344 patent) for a hemodialysis device; (2) Claim II for damages for direct infringement under 35 U.S.C. § 271; (3) Claim III for damages for induced infringement under 35 U.S.C. § 271; (4) Claim IV for intentional copying and willful infringement (ECF 15 at 14-15). Plaintiffs also filed a Motion for Summary Judgment (ECF 22), which the court denied as procedurally deficient (ECF 54; ECF 59).

On November 1, 2021, Defendant filed the instant Motion (ECF 40) and Appendix of Exhibits (ECF 41). In the Motion, Defendant seeks summary judgment on Plaintiffs’ claims and requests dismissal of the Amended Complaint arguing that there is no infringement (ECF 40 at 9).<sup>2</sup> Plaintiffs filed a timely Opposition with an Appendix of Evidence consisting of Exhibits F through J (ECF 45), an Errata (ECF 46), and a document entitled “Exhibit K” (ECF 49), all of which the court has considered. Defendant then filed its Reply (ECF 50) and a second Appendix of Evidence (ECF 52). Plaintiffs have made several attempts to correct their summary judgment motion (ECF 56, 60, 62, 65, 66) in violation of the court’s filing restrictions (ECF 30) pending resolution of Defendant’s Motion. The court did not review the lodged documents relating to Plaintiffs’ motion and limited its review to the filings as set forth herein.

## II. UNDISPUTED FACTS

The court agrees with Defendant that Plaintiffs’ Opposition neither disputes any of Defendant’s undisputed facts nor cites to evidence disputing the facts recited by Defendant. The court therefore deems the facts recited in Defendant’s Statement of Undisputed Facts as undisputed

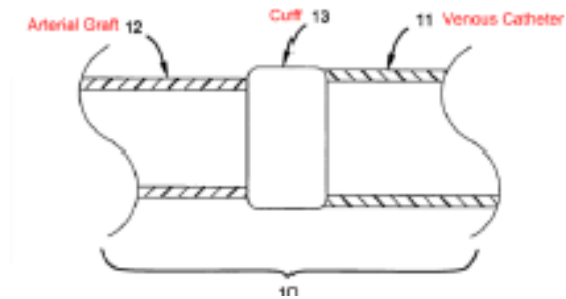
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<sup>1</sup> In the Amended Complaint, Plaintiffs refer to the statute as 35 U.S.C. § 112(6). Congress changed the naming convention for this statute as part of the American Invents Act (AIA), changing the name to 35 U.S.C. § 112(f). The court will refer to the statute herein as 35 U.S.C. § 112(f).

<sup>2</sup> Defendant does not seek summary judgment on its counterclaims for declaratory judgment of non-infringement, declaratory judgment of invalidity, and interference with economic relations (ECF 17 at 30-32). The court therefore limits its analysis herein to Plaintiffs’ claims. The court directs Defendant to submit a status report about its intentions to proceed with its counterclaims within fourteen (14) days of the district judge’s order on this Report and Recommendation.



4. The focus at issue in the Amended Complaint is limited to the claim language in section 13(iii)(1)-(2) of the '344 patent (Claim 13), in particular the limitation that “said cuff is disposed about.” The “disposed about” limitation requires a “cuff” that is wrapped around, encircles, and covers the *outside* of the outlet end of an arterial graft and the inlet end of a venous outflow catheter as shown below in Defendant’s labeled Figure 1 of the '344 patent (Defendant’s Motion (Def. Mot.), ECF 40, at 14):



#### Prosecution history of the '591 and '344 patents

5. While the '591 patent is not at issue, its prosecution history is helpful in understanding the prior art for both the '591 and '344 patents. The '591 patent initially explained a cuff “connected to” the affects ends of the graft and catheter; hence the claims did not have the “disposed about” language. The Examiner at the United States Patent and Trademark Office (PTO) (PTO Examiner) of the '591 patent rejected the claims as anticipated in or obvious in light of the prior art, including Squitieri and Twardowski.<sup>3</sup> Specifically, the PTO Examiner rejected the claims because the Squitieri reference discloses a graft whose terminal end is “connected to” the inlet of a cuff/connector and a catheter whose intake end is “connected to” the outlet of the cuff...). In response to the rejection based on Squitieri, Plaintiffs amended the '591 application to require the

<sup>3</sup> This court either refers to these two patents specifically or in general as “prior art.” By way of explanation, as set out in the Patent Trial and Appeal Board’s (the Board) Decision on Appeal (Def. Ex. 12, ECF 41-12), Claim 13 (among other claims) was rejected as being unpatentable over Squitieri and Twardowski, among others. Squitieri is patent 6,102,884, invented by Rafael Squitieri, which is comprised of a “hemodialysis and vascular access system ...” which can be found at (Def. Ex. 9, ECF 41-9). Twardowski is another patent, namely 5,509,897 (Def. Ex. 12, ECF 41-12), which the Board looked to as other prior art.



the claimed cuff was *outside* the affected ends of the graft and catheter, while the Squitieri connector was disposed *inside* the affected ends of the graft and catheter. As shown below, Plaintiffs repeatedly attempted to obtain claims that eliminated the “disposed about” limitation, but the PTO Examiner rejected each such attempt (Def. Mot. at 9–10):

Prosecution History	Statement
'591	“The cylindrical cuff (13) made of biocompatible material which <b>encircles the venous outflow catheter</b> and is surgically anastomosed to the arterial inflow graft(1).”
'591 on appeal to BPAI	“The cuff which connects the arterial graft to the venous outflow catheter <b>covers the outside of the venous outflow catheter</b> as shown in Fig. 1.”
'591 on appeal to BPAI	“The cuff of claim 1, 13 and 17 has a flat surface which is 1mm in thickness, <b>wraps around the venous outflow catheter at the inlet end</b> and is surgically anastomosed In [sic] an end to end fashion to the arterial graft.”

'591 on appeal to BPAI	“In the applicants [sic] claimed invention, the cuff is structurally different [than Squitieri] because it will be made of biocompatible material and <b>will cover the venous outflow catheter only.</b> ”
'591 on second appeal to BPAI	“In Claimed Invention [sic] the cuff connects the graft and venous outflow catheter. The cuff is made of biocompatible material. <b>It encircles the inlet end of the venous outflow catheter</b> and it is sutured to the outlet end of the graft by an anastomosis.”
Reissue	“In patent number US8,282,591 B2 date on Oct. 9, 2012 the cuff connector was shown as disposed over the venous outflow catheter to distinguish from the prior art of Squitieri which use the connector in none [sic] disposable way connecting the metal connector inside the outflow catheter and the graft.”
Reissue, argument on appeal	“The Board said that Squitieri connects the graft and the catheter which goes inside the graft and the catheter. Whereas, in my case, the cuff connects the graft and the catheter outside. So the Board made this as a distinguishing point between the Twardowski’s [sic] between the Squitieri and my invention that my cuff [sic].”

<p>Reissue</p>	<p>“A cuff by definition is wrapped around or ‘disposed about’ something. For example, a shirt cuff is disposed about a wrist, and a sphygmometer [sic] is disposed about an arm when measuring blood pressure. The term may also refer to an anatomical structure shaped like a cuff:</p> <p>Medical Definition of CUFF</p> <p><b><i>An inflatable band that is wrapped around an extremity</i></b> to constrict the flow of blood through the part when recording blood pressure with a sphygmomanometer</p> <p>An anatomical structure shaped like a cuff: especially: rotator cuff &lt;repair of complete should cuff</p> <p><a href="http://www.merriam-webster.com/dictionary/cuff">http://www.merriam-webster.com/dictionary/cuff</a></p> <p>A person of skill in the art would readily appreciate from the specification that a cuff would be disposed about the respective ends of the graft and catheter.”</p>
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Defendant’s HeRO® Graft



9. The HeRO® Graft is a hemodialysis device, which includes an arterial graft, a titanium connector, and a venous outflow catheter.<sup>4</sup> As shown in the image above, the titanium connector of the HeRO® Graft is placed *inside* the lumens of the outlet end of an arterial graft and the inlet end of a venous outflow catheter (Def. Mot. at 12).

10. On September 29, 2015, as set forth above, Plaintiffs filed a reissue application seeking to broaden the claims of the ‘591 patent by eliminating the “disposed about” limitation from the claims.

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<sup>4</sup> Plaintiffs assert that the HeRO® Graft is an “unpatented device.” Plaintiffs then accuse Defendant’s counsel of lying about the fact that it is unpatented and insist that counsel should be sanctioned for that alleged infraction (Pl. Opp. at 6, 7, 8). Plaintiffs’ have failed to establish this information is relevant. The issue in every infringement action is whether the accused device satisfies the limitations of the asserted claims. Whether it is covered by patents owned by Defendant has no bearing on whether it satisfies or does not satisfy the limitations of Claim 13.

11. As part of that reissue process, Plaintiffs made statements regarding the HeRO® Graft. Specifically, Plaintiffs argued in the prosecution of the reissue application that the connector of the titanium connector of the HeRO® Graft is placed inside the lumens of the graft and catheter in a “non-disposed way” and because of that difference, Plaintiffs could not sue for literal and equivalents infringement. Plaintiffs also asked the PTO Examiner to allow them to delete the “disposed about” limitation because that was the only way they could assert the HeRO® Graft infringed, either literally or under the doctrine of equivalents.

12. Plaintiffs abandoned the reissue application without obtaining any issued claims.

### III. LEGAL STANDARDS

#### A. Summary Judgment Standard

“Summary judgment is appropriate in a patent case, as in other cases.” *Nike, Inc. v. Wolverine World Wide, Inc.*, 43 F.3d 644, 646 (Fed. Cir. 1994). A “court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). In making this determination, courts “examine the record and all reasonable inferences that might be drawn from it in the light most favorable to the non-moving party.” *Barber ex rel. Barber v. Colorado Dept. of Revenue*, 562 F.3d 1222, 1228 (10th Cir. 2009) (quoting *T-Mobile Cent., LLC v. Unified Gov’t of Wyandotte County*, 546 F.3d 1299, 1306 (10th Cir. 2008)).

Summary judgment is only appropriate if “no reasonable jury could find infringement.” *Ishida Co., Ltd. v. Taylor*, 221 F.3d 1310, 1315 (Fed. Cir. 2000). This standard is not only applicable for literal infringement, but also for infringement under the “doctrine of equivalents” where “no reasonable jury could determine two elements to be equivalent.” See *CAE Screenplates, Inc. v. Heinrich Fiedler GmbH & Co.*, 224 F.3d 1308, 1312 (Fed. Cir. 2000) (quoting *Hilton Davis*



*Chem. Co. v. Warner-Jenkinson Co.*, 520 U.S. 17, 39 n.8, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997)). To prove infringement, the patentee must show that the accused device meets each element of the asserted claims either under literal infringement or the doctrine of equivalents. *See Deering Precision Instruments, LLC v. Vector Distr. Sys., Inc.*, 347 F.3d 1314, 1324 (Fed. Cir. 2003). Summary judgment of noninfringement is thus proper where there is no genuine issue as to whether the accused device lacks a single claim element or its equivalent. *See Lockheed Martin Corp. v. Space Sys./Loral, Inc.*, 324 F.3d 1308, 1321 (Fed. Cir. 2003).

## **B. Infringement**

Infringement requires a two-step analysis. *Lava Trading, Inc. v. Sonic Trading Management, LLC*, 445 F.3d 1348, 1352 (Fed. Cir. 2006). The required steps are as follows: “(1) claim construction to determine the scope and meaning of the claims asserted to be infringed, and then (2) a determination of whether the properly construed claims encompass the accused device.” *Zelinski v. Brunswick Corp.*, 185 F.3d 1311, 1315 (Fed. Cir. 1999).

Defendant argues that Plaintiffs do not challenge or refute Defendant’s analysis of the legal authority rejecting Plaintiff’s arguments. While the court generally agrees, the court will nonetheless consider the merits of the arguments set forth in Plaintiffs’ Opposition. In undertaking this analysis, the court is mindful that Plaintiffs are acting pro se and that “[a] pro se litigant’s pleadings are to be construed liberally and held to a less stringent standard than formal pleadings drafted by lawyers.” *Hall v. Bellmon*, 935 F.2d 1106, 1110 (10th Cir. 1991). However, it is not “the proper function of the district court to assume the role of advocate for the pro se litigant,” *id.*, and it “will not supply additional facts, nor will [it] construct a legal theory for [a pro se] plaintiff,” *Dunn v. White*, 880 F.2d 1188, 1197 (10th Cir. 1989) (per curiam).

## IV. DISCUSSION

### A. Claim Construction

Under the first step of the infringement analysis, the patented invention, as set forth in the language of the patent claims, must be construed. Claim construction is the process of determining the scope of a claim and requires a court to determine the meaning of claim limitations as a matter of law. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996). Proper claim construction requires analysis of the claim language, the specification, and the prosecution history to determine the meaning of disputed claim terms. *See Hormone Research Foundation, Inc. v. Genentech, Inc.*, 904 F.2d 1558, 1562 (Fed. Cir. 1990). “Claim construction analysis begins with the claim language itself.” *Hockerson-Halberstadt, Inc. v. Avia Group Intern., Inc.*, 222 F.3d 951, 955 (Fed. Cir. 2000). To start, “the court gives claim terms their ordinary and accustomed meaning as understood by one of ordinary skill in the art.” *Id.* Where the patentee “ascribe[s] a different, or modified, meaning to the term,” the court must “examine a patent’s specification and prosecution history to determine whether the patentee has given the term an unconventional meaning.” *See id.* “If the patentee has not done so, the term’s ordinary and accustomed meaning controls.” *Id.*

Here, it is undisputed the only claim at issue in the ‘344 patent is Claim 13, and within that claim, the only relevant language to examine within Claim 13 is the “disposed about” language, which states in total: “a cuff means comprising an inlet and an outlet, wherein: said cuff is disposed about said terminal end of said subcutaneous graft; and said cuff is disposed about said intake end of said venous outflow catheter” (Def. Ex. 4). Thus, the court’s analysis focuses on the “disposed about” limitation of Claim 13. According to Defendant’s claim construction argument, the “disposed about” limitation requires that the cuff encircle, wrap around, and cover the exterior of the affected ends of the graft and catheter. The court agrees. The undisputed language states a cuff

“disposed about” the “terminal end” of the graft and intake end of the venous outflow catheter. The common meaning of the explanation of the cuff in relation to the graft and catheter is that it must wrap around, encircle, and cover the outside of the affected ends of the graft and catheter. This is also consistent with Figure 1 in the ‘344 patent. Moreover, the prosecution history supports this conclusion whereby Plaintiffs, to get the patent to issue made amendments to Claim 13 to distinguish the prior art that had a connector that was not disposed about the graft. Plaintiffs have failed to dispute Defendant’s claim construction, either by disputing the plain language of relevant language within Claim 13 or the prosecution history. Moreover, it does not appear that Plaintiffs ascribe a different or modified meaning to the “disposed about” limitation and instead seem to focus their arguments on whether the HeRO® Graft infringes on Claim 13 regardless of this limitation. Accordingly, for purposes of Defendant’s Motion, the court concludes that as a matter of law the “disposed about” limitation requires that the cuff encircle, wrap around, and cover the exterior of the affected ends of the graft and catheter, and is therefore structurally external to both.

## **B. Infringement**

Under the second step of the analysis, the trier of fact must determine whether the limitations of the claims, properly construed, are found in the accused device. *See Hormone Research Foundation*, 904 F.2d at 1562. As explained below, the undisputed facts show that under the “disposed about” limitation, the HeRO® Graft does not as a matter of law infringe Claim 13 of the ‘344 patent, literally, under the doctrine of equivalents, or under 35 U.S.C. § 112(f).

### 1. Defendant is entitled to summary judgment on literal infringement.

Literal infringement requires that the accused device contain every limitation of the asserted claim. *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1105 (Fed. Cir. 1996). “It is . . . well settled that each element of a claim is material and essential[.]” *Perkin-Elmer Corp. v.*

*Westinghouse Blee. Corp.*, 822 F.2d 1528, 1533 (Fed. Cir. 1987) (quoting *Lemelson v. United States*, 752 F.2d 1538, 1551 (Fed. Cir. 1985)). “The absence of even a single limitation ... precludes a finding of literal infringement.” *Kahn v. General Motors Corp.*, 135 F.3d 1472, 1477 (Fed. Cir. 1998). Here, the undisputed facts show that Claim 13 requires a cuff “disposed about” the “terminal end” of the graft and intake end of the venous outflow catheter. The common meaning of the cuff in relation to the graft and catheter is that the cuff must wrap around, encircle, and cover the *outside* of the affected ends of the graft and catheter, which is consistent with Figure 1 in the ‘344 patent. It is undisputed Defendant’s HeRO<sup>®</sup> Graft is *inside* the lumens of the graft and catheter. Accordingly, because the HeRO<sup>®</sup> Graft does not satisfy the “disposed about” limitation, there is no literal infringement of Claim 13 as a matter of law.

2. Claim 13 does not invoke 35 U.S.C. § 112(f).

Plaintiffs argue that Claim 13 is a means-plus function claim under 35 U.S.C. § 112(f). The proper question is whether the “cuff means” language in Claim 13 of the ‘344 patent is a means-plus-function limitation, not whether Claim 13 is a means-plus-function claim. Means-plus-function limitations are governed by 35 U.S.C. § 112(f). Section 112(f) provides that “an element” in a claim may be expressed as a means or step for performing a specified function without the recital of structure. *See* 35 U.S.C. § 112(f). Only claim limitations that meet the strict requirements of 35 U.S.C. § 112(f) are entitled to means-plus-function treatment. Whether claim language invokes 35 U.S.C. § 112(f) is an exercise in claim construction and is therefore a question of law. *Personalized Media Communications, LLC v. Int’l Trade Comm’n*, 161 F.3d 696, 702 (Fed. Cir. 1998). A claim limitation that contains the word “means” and recites a function is presumed to be drafted in means-plus-function format under 35 U.S.C. § 112(f). *Id.* at 703. “Merely because a named element of a patent claim is followed by the word ‘means,’ however, does not automatically

make that element a ‘means-plus-function’ element under 35 U.S.C. § 112 ¶ 6.” *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 531 (Fed. Cir. 1996). Conversely, a claim limitation that does not include the word “means” gives rise to a rebuttable presumption that the limitation is not a means-plus-function limitation. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015). In other words, section 112(f) authorizes means-plus-function claims only where the claim language claims (1) a function and (2) a means for performing that function that does not recite structure.

Here, the “disposed about” language in Claim 13 does not use the term “means” and does not identify any function. This gives rise to a rebuttable presumption that the “disposed about” limitation is not a means-plus-function limitation. Notwithstanding, Plaintiffs have failed to rebut this presumption. The “disposed about” limitation does not identify a function without recitation of structure to perform the function. Rather, the “disposed about” limitation identifies the structural relationship between the terminal end of the graft, the intake end of the catheter, and the cuff. Claim 13 therefore does not invoke Section 112(f). Moreover, as discussed below, Plaintiffs’ Section 112(f) arguments fail because (1) the HeRO<sup>®</sup> Graft does not satisfy the “disposed about” limitation of Claim 13 regardless of whether the “cuff means” invokes § 112(f); (2) the titanium connector of the HeRO<sup>®</sup> Graft is not structurally equivalent to the “cuff means” of Claim 13; (3) prosecution history disclaimer bars Plaintiffs’ structural equivalency argument; and (4) Plaintiffs misconstrue the law and the facts relating to means-plus-function analysis.

- a. The HeRO<sup>®</sup> Graft does not satisfy Claim 13’s “disposed about” limitation regardless of whether the “cuff means” invokes § 112(f).*

While Plaintiffs’ sole argument relates to the “cuff means” limitation, Defendant’s Motion is based on the absence in the HeRO<sup>®</sup> Graft of the “disposed about” limitation. As

explained above, “[t]he absence of even a single limitation . . . precludes a finding of literal infringement.” *Khan*, 135 F.3d at 1477. Because the HeRO<sup>®</sup> Graft does not satisfy the “disposed about” limitation, whether it satisfies the “cuff means” limitation is irrelevant to the outcome of Defendant’s Motion.

Claim 13 not only includes the “cuff means” language, but it also requires that “said cuff” be “disposed about” the ends of the graft and catheter. Patentees are prohibited from ignoring limitations specifically described in a claim, and “claims are interpreted with an eye toward giving effect to all terms in the claim.” *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006). Plaintiffs’ Opposition violates this principle because it seems to ignore the “disposed about” limitation. Plaintiffs’ focus on the “cuff means” limitation overlooks the fact that the “disposed about” language of the claim requires that the “cuff means,” regardless of what it is, must be “disposed about,” *i.e.*, wrap around and encircle the ends of the graft and catheter.

Plaintiffs offer no response to the holding in *Asyst Technologies, Inc. v. Emtrak, Inc.*, 402 F.3d 1188, 1196 (Fed. Cir. 2005), that limitations requiring a particular structural relationship between a “means” limitation and other claim limitations cannot be ignored. Instead, they appear to ignore the existence of the “disposed about” limitation, which is impermissible. Like the claim in *Asyst*, Claim 13 requires a particular structural relationship between the “cuff means” and other structure in the claim, *viz.*, the affected ends of the graft and catheter. The “cuff means” must be structurally *disposed about* the ends of the graft and catheter, and the claim language will not allow Plaintiffs to ignore that requirement. Plaintiffs’ failure to explain how the HeRO<sup>®</sup> Graft meets the “disposed about” limitation requires summary judgment in favor of Defendant.

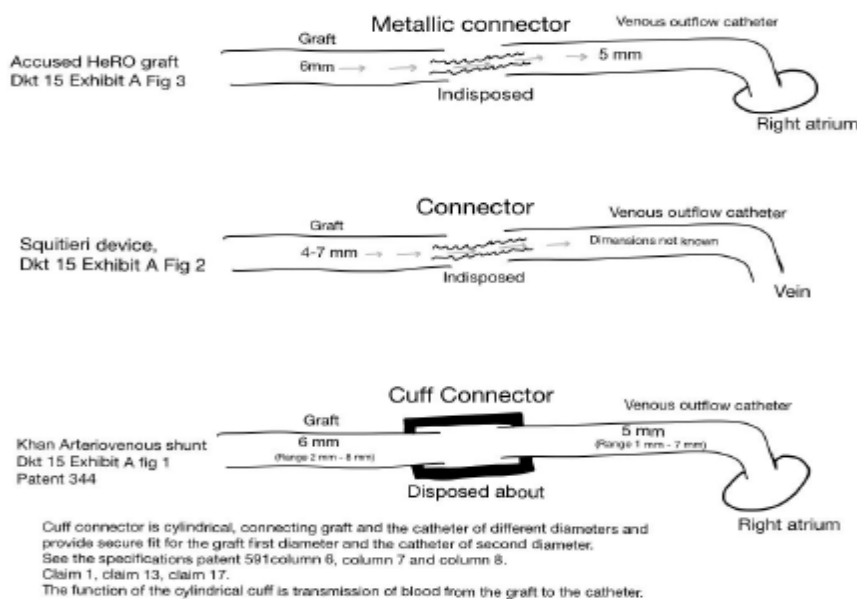
The parties agree that the titanium connector of the HeRO<sup>®</sup> Graft is “indisposed,” *i.e.*, *not* “disposed about” the graft and catheter (Plaintiff’s Opposition (Pl. Opp.), ECF 45 at 6, 7, 9, 10, 14, 16). Even if the titanium connector were somehow construed to be a “cuff means,” because the critical “disposed about” structural relationship between the “cuff means” and the ends of the graft and catheter is not present in the HeRO<sup>®</sup> Graft, whether the “cuff means” is or is not a means-plus-function limitation is irrelevant.

*b. The titanium connector of the HeRO<sup>®</sup> Graft is not structurally equivalent to the “cuff means” of Claim 13.*

Whether structure in an accused device is equivalent to a claimed “means” depends on whether the structure in the accused device is the same as or equivalent to the structure disclosed in the specification as performing the claimed function. *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934 (Fed. Cir. 1987) (en banc), *disapproved of on other grounds by Cardinal Chemical Co. v. Morton Intern., Inc.*, 508 U.S. 83 (1993). “In the context of section 112 . . . an equivalent results from an insubstantial change which adds nothing of significance to the structure, material or acts disclosed in the patent specification.” *Valmont Industries, Inc. v. Reinke Mfg. Co.*, 983 F.2d 1039, 1043 (Fed. Cir. 1993). As with the permissible range of equivalents under the doctrine of equivalents, the range of § 112(f) equivalents cannot be so broad that the claim as a whole reads on, or is obvious in light of, the prior art. *Sofamor Danek Group, Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1222 (Fed. Cir. 1996).

If, as Plaintiffs argue, an “indisposed” connector like the titanium connector of the HeRO<sup>®</sup> Graft is equivalent to the claimed “cuff means” in Claim 13, the resulting claim would have been obvious in light of the prior art, which is exactly what the PTO Examiner found during prosecution. This is consistent with the figure on page 14 of Plaintiffs’ Opposition shown below:

## Comparison of different devices



Both the Squitieri reference and the HeRO<sup>®</sup> Graft include connectors “indisposed,” *i.e.*, internal to the lumens of the graft and catheter. The PTO Examiner initially rejected Claim 13 because of the prior art references. If Plaintiffs’ argument for equivalents prevails, Claim 13 is either not infringed or it is invalid for the reasons stated by the PTO Examiner

Common sense and the law agree that opposites are not equivalent to one another. *See Moore U.S.A., Inc. v. Standard Register Co.*, 229 F.3d 1091, 1108–09 (Fed. Cir. 2000) (holding that because the claim limitation required business form where strips of adhesive extended the *majority* of the length of the form, strips in the accused device that extended over a *minority* of the length of the form were the opposite of the claim limitation, and the structure in the accused device was the antithesis of the claim limitation, and there could be no equivalents as a matter of law); *see also Abbott Laboratories v. Novopharm Ltd.*, 323 F.3d 1324, 1331 (Fed. Cir. 2003) (holding that a *dissolved* surfactant could not be equivalent to a *solid* surfactant as a matter of law). Plaintiffs concede that the claimed cuff means is “disposed about,” *i.e.*, it wraps around



the ends of the graft and catheter and is therefore structurally *external* to both. Plaintiffs likewise concede that the titanium connector of the HeRO<sup>®</sup> Graft is “indisposed,” *i.e.*, structurally *internal* to the ends of the graft and catheter. In other words, the structural relation between the titanium connector of the HeRO<sup>®</sup> Graft and the ends of the graft and catheter is the opposite of the structural relationship between the claimed cuff means and those same ends. Because opposites cannot be equivalent, there is no infringement under the doctrine of equivalents.

Plaintiffs nonetheless argue that the differences between the titanium connector of the HeRO<sup>®</sup> Graft and the “cuff means” are insubstantial. The court disagrees. The difference is so substantial that the PTO refused to allow Claim 13 until Plaintiffs amended it to distinguish between cuffs “disposed about” the graft and catheter and the prior art connector of Squitieri that is “indisposed.” In the Plaintiffs’ own words, the differences between “indisposed” connectors like the connector of the HeRO<sup>®</sup> Graft and the claimed “disposed about” connector are so significant that those differences are what made the claimed invention “patentability [sic] distinct from the prior art . . .” (Pl. Opp. at 10). The titanium connector of the HeRO<sup>®</sup> Graft and the “cuff means” are not structurally equivalent as a matter of law.

*c. Prosecution history disclaimer bars Plaintiffs from arguing that the titanium connector is structurally equivalent to the claimed “cuff means.”*

The law imposes strict limits on how far the claim language can be stretched to accommodate arguments of equivalency. If a patent owner attempts, under the guise of equivalence, to recapture claim scope surrendered by amendment or argument, estoppel bars the effort. *See Spectrum International, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1379–80 (Fed. Cir. 1998). For that reason, amendments during prosecution create a presumption that there can be no equivalents infringement with respect to the limitation not literally present. *Festo Corp. v. Shoketsu*

*Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 735–37 (2002). A patentee’s decision to submit an amended claim in response to an Examiner’s rejection “is taken as a concession that the invention as patented does not reach as far as the original claim.” *Id.* at 734. The patentee bears the burden of overcoming this presumption by showing that “at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent.” *Id.* at 741. This showing may be made by demonstrating that (1) the alleged equivalent was “unforeseeable at the time of the [amendment]”; (2) “the rationale underlying the amendment [bears] no more than a tangential relation to the equivalent in question”; or (3) there is “some other reason that the patentee could not reasonably be expected to have described the insubstantial substitute in question.” *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1360–70 (Fed. Cir. 2003) (quoting *Festo*, 535 U.S. at 740–41).

Plaintiffs argue that “[b]ecause 35 USC sections [sic] 112 para 6 equivalent analysis is performed under the mantle of literal infringement, restriction on the doctrine of equivalents by *Festo* will not apply” (Pl. Opp. at 12). Defendant does not argue that *Festo* amendment-based estoppel precludes Plaintiffs from arguing for equivalents under § 112(f). Instead, Defendant’s position is that Plaintiffs’ equivalents argument under § 112(f) is barred by prosecution history disclaimer, not by *Festo* amendment-based estoppel. Prosecution histories are a record of the patent owner’s representations concerning the scope and meaning of claim terms, and the public, including competitors like Defendant, are entitled to rely on those representations in order to design around the claimed invention. *See Hockerson-Halberstadt*, 222 F.3d at 957. Stated otherwise, the doctrine of prosecution history disclaimer means that a patent owner who represents that particular structures are outside the scope of the invention in order to obtain allowance of claims cannot later reverse course and argue that those same structures are within the scope of the claimed invention. The Federal Circuit has held that prosecution history

disclaimer applies to means-plus-function claim limitations. *Hueft Systemtechnik GMBH v. Industrial Dynamics Co., Ltd.*, 282 F. App'x 836, 842–43 (2008).

Plaintiffs offer no response to the prosecution history disclaimer arguments made at pages 29 to 32 of Defendant's Motion. Plaintiffs fail to distinguish the facts of this case from the facts in *Hueft*. In *Hueft*, the patentee, like Plaintiffs, repeatedly argued that the claimed invention was distinct from the prior art, and ultimately amended the claims to distinguish the prior art. In subsequent litigation, the patentee argued for a construction of a means-plus-function limitation that was contrary to the representations he made during prosecution. Like Plaintiffs, the patentee in *Hueft* argued that prosecution history disclaimer did not apply to means-plus-function limitations. The Federal Circuit disagreed, holding that prosecution disclaimer "operates to prevent a patentee from capturing subject matter disavowed during prosecution, and applies with equal force to means-plus-function" limitations. 282 F. App'x at 842–43 (citing *Ballard Med. Prods. v. Allegiance Healthcare Corp.*, 268 F.3d 1352, 1359 (Fed. Cir. 2001)).

Here, the PTO Examiner refused to allow Claim 13 unless and until it was amended to include the "disposed about" limitation. Plaintiffs represented to the PTO Examiner that the claimed invention does not include connectors disposed within the lumens of the graft and the catheter, going so far as to represent that the titanium connector of the HeRO® Graft is "a metallic one connecting inside lumen of graft and the catheter *in a non-disposed way*, where as [sic] in patent # 591 the connector is a cuff attaching *outside the catheter and to the flexible graft in a disposed way*." Plaintiffs' disclaimers of "indisposed" connectors precludes them from asserting that the "indisposed" titanium connector of the HeRO® Graft is equivalent to the claimed "cuff means" as a matter of law.

d. *Plaintiffs mischaracterize the facts and the law related to equivalents analysis under § 112(f).*

Plaintiffs appear to argue that the fact that the titanium connector in the HeRO<sup>®</sup> Graft and the claimed “cuff means” perform the same function makes them equivalent. Whether an accused structure is structurally equivalent to a claimed “means” for purposes of § 112(f) depends on whether the accused structure performs the identical function recited for the “means” in substantially the same way, with substantially the same result. *Odetics v. Storage Tech. Corp.*, 185 F.3d 1259, 1267 (Fed. Cir. 1999). The fact that an accused device performs the claimed *function* does not, however, mean that it does so in the same way. *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533 (Fed. Cir. 1991) (“[D]ifferent structures are not *ipso facto* equivalent merely because they perform the same function. To so hold would effectively eliminate the statutory restriction of section 112(6).”). Plaintiffs’ analysis of equivalency under § 112(f) improperly conflates the “function” element of that analysis with the “way” element. Specifically, Plaintiffs argue that the titanium connector functions in the same way as the claimed “cuff means” solely because they perform the same *function*:

. . . the structural equivalency between the disposed about cuff connector and the indisposed titanium connector of the HeRO graft is insubstantial because both performed the same function of transmitting the blood from the arterial graft to the venous outflow catheter to be deposited in the right atrium of the heart.

(Pl. Opp. at 12). As the Federal Circuit held in *Odetics*, the “function” and “way” prongs of the equivalents analysis under § 112(f) equivalents analysis are distinct, and it is improper to assume equivalents simply because the accused structure performs the same function as the claimed means. Plaintiffs offer no proper analysis of the “way” element of equivalents analysis under § 112(f), and as a result their claim fails.

Plaintiffs variously assert that the function of the “cuff means” is “transmitting blood from the arterial graft to the venous outflow catheter,” (Pl. Opp. at 6), “hemodialysis,” (Pl. Opp.

at 6, 17), and “removing of toxins from the blood of kidney-failure patients and returning back the purified blood to the body of the patient” (Pl. Opp. at 11). Plaintiffs then argue that the HeRO<sup>®</sup> Graft performs all of these functions and therefore infringes. These arguments are unsupported by both the law and the facts.

The only relevant function for purposes of § 112(f) is the function explicitly recited in the claim; it is improper to import functions from a working device or from unclaimed functions derived from embodiments disclosed in the specification. *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 2303 (Fed. Cir. 1999). Similarly, “[a] court errs when it improperly imports unclaimed functions into a means-plus-function claim limitation.” *Applied Medical Resources Corp. v. US Surgical Corp.*, 448 F.3d 1324, 1334 (Fed. Cir. 2006). Plaintiffs’ assertion that the HeRO<sup>®</sup> Graft functions to remove toxins from the blood (hemodialysis) and/or transmits blood from the graft to the catheter improperly focuses on the function of the device of Claim 13 as a whole, not on any function recited in the claim and not on any function Claim 13 claims for the “cuff means.” As noted above, equivalents analysis under § 112(f) requires a determination of equivalents on a limitation-by-limitation basis, not equivalents to the claim as a whole. *Endress + Hauser, Inc. v. Hawk Measurement Sys. Pty. Ltd.*, 122 F.3d 1040, 1043 (Fed. Cir. 1997). Neither of the functions identified by Plaintiffs (transmitting blood from the graft to the catheter and hemodialysis) is recited in Claim 13.

For the foregoing reasons, Plaintiffs’ “identical function” arguments misstate the law and lack evidentiary support. Whether the titanium connector of the HeRO<sup>®</sup> Graft performs one or more of the functions identified by Plaintiffs is irrelevant and does not prevent summary judgment of non-infringement in favor of Defendant.

3. Defendant is entitled to summary judgment of non-infringement under the doctrine of equivalents due to prosecution history estoppel.

When an applicant makes arguments to the PTO about the meaning of claim terms or the scope of the claims, the applicant cannot later argue for a different meaning after the patent issues. “If sufficient to evince a clear and unmistakable surrender of subject matter, arguments made during prosecution may . . . estop an applicant from recapturing that surrendered matter under the doctrine of equivalents.” *Augustine Medical, Inc. v. Gaymar Indus., Inc.*, 181 F.3d 1291, 1299 (Fed. Cir. 1999) (quoting *Litton Systems, Inc. v. Honeywell, Inc.*, 140 F.3d 1449 (Fed. Cir. 1998), *abrogated on other grounds by Festo*, 234 F.3d 558 (Fed. Cir. 2000)). To determine what subject matter has been relinquished, an objective test is applied, inquiring whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter. *See id.* at 1298. When this standard is met, estoppel arises regardless of whether the statement was made to overcome a rejection by an examiner. *See Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1303–1304 (Fed. Cir. 1997). When a patent owner distinguishes the claimed invention from the prior art, the applicant indicates what the claims do not cover, and by implication surrenders the distinguished feature. *See id.*

As set forth at pages 17 to 23 of Defendant’s Motion, prosecution history estoppel by amendment bars a patent owner from attempting to reclaim claim scope surrendered in order to obtain allowance of the issued claims. Plaintiffs argue that the doctrine of prosecution history estoppel does not bar claims for infringement under the doctrine of equivalents because “the plaintiffs did not make any amended claim” and as a result, “surrender of subject matter did not occur, and therefore there is no estoppel under the doctrine of equivalents” (Plaintiffs’ Errata (Pl. Errata), ECF 46 at 10, 11). Plaintiffs’ Opposition and the undisputed facts demonstrate that this argument is frivolous.

a. *Plaintiffs' arguments are unsupported by the facts.*

Plaintiffs assert that they “did not make any amended claim” during prosecution and further argue that they “did not make any new amendment to overcome the indisposed metallic connector in the prior art of Squitieri’s [sic] patent 6,582,409 . . .” (Pl. Errata at 10). Specifically, they allege that no amendment was made because the “cylindrical cuff with the cuff disposed about the venous outflow catheter was intrinsically present in the specifications [sic] of patent application No. 10/812,830 (*id.*). However, in the very next sentence Plaintiffs admit that they relied on the “disposed about” limitation to distinguish the Squitieri reference:

The plaintiff used the cylindrical cuff disposition of disposed about to differentiate the prior art of Squitieri where the metallic connector was indisposed between the arterial graft and the venous outflow catheter.

(*id.*). Plaintiffs’ claim that they did not amend Claim 13 to overcome Squitieri by adding the “disposed about” limitation is false.

It is indisputable that Claim 13 was amended to add the “disposed about” limitation to overcome the prior art. As originally filed, all of the claims of the application for the ’344 patent required only that the ends of the graft and catheter be “connected to” each other by a cuff. Plaintiffs amended Claim 13 to add the word “means” to the “cuff,” so as to require a “cuff means” that is “connected to” the ends of the graft and catheter. In response to the amendment, the PTO Examiner rejected Claim 13 as obvious in light of the prior art. Plaintiffs therefore amended Claim 13 to require that “said cuff” be “disposed about” the end of the graft and the catheter. Only then were Plaintiffs’ claims allowed.

The importance of adding the “disposed about” limitation to Claim 13 is graphically demonstrated by the illustration on page 14 of Plaintiffs’ Opposition (*Supra* at 16). According to this illustration, prepared by Plaintiffs, the connectors of Squitieri and the HeRO<sup>®</sup> Graft are both

“indisposed,” *i.e.*, inside the lumens of the graft and catheter. Also according to Plaintiffs’ illustration, the cuff of Claim 13 is “disposed about,” *i.e.*, external to the lumens of the graft and catheter. That is why Claim 13 was allowed. The assertion that Plaintiffs did not amend Claim 13 by adding the “disposed about” limitation in order to overcome the Squitieri reference is false.

*b. Plaintiffs’ arguments are unsupported by the law.*

From a legal point of view, Plaintiffs’ assertion that they did not amend Claim 13 because the *specification* already disclosed a cuff “disposed about” the graft and catheter is irrelevant. It is the amendments to the *claims* that give rise to prosecution history estoppel by amendment. As the undisputed facts establish, Claim 13 was in fact amended to add the “disposed about” limitation so as to overcome Squitieri.

The classic case of prosecution history estoppel occurs when a patent owner attempts, under the guise of equivalents, to recapture claim scope surrendered by amendment or argument. *See Spectrum*, 164 F.3d at 1379–80; *Festo*, 535 U.S. at 735–37. Here, Plaintiffs amended Claim 13 to require the “disposed about” limitation and thereby obtained allowance. The amendment created a presumption that Plaintiffs surrendered claim scope covering “indisposed” connectors like that of Squitieri and the HeRO® Graft. Plaintiffs have not rebutted that presumption.

Plaintiffs argue that because the Board allowed the claims over Squitieri based on the “disposed about” limitation, there was no surrender and prosecution history estoppel does not apply (Pl. Opp. at 11). The opposite is true. The Board allowed Claim 13 over Squitieri *because* Plaintiffs amended it to include the “disposed about” limitation. *Because* Plaintiffs were forced to amend Claim 13 to add the “disposed about” limitation to distinguish the “indisposed” connector of Squitieri, estoppel precludes them from recapturing an “indisposed” connector like the titanium connector of the HeRO® Graft.



Prosecution history estoppel by argument and disclaimer also arise because of the arguments and disclaimers Plaintiffs made during prosecution and their statements that they could not assert equivalents infringement unless the “disposed about” limitation was removed from the claims. Plaintiff’s Opposition makes no attempt to analyze or distinguish the many examples Defendant has identified of prosecution history estoppel by amendment, argument, and disclaimer. Accordingly, the court concludes that Defendant is entitled to summary judgment of no infringement on Plaintiffs’ claim under the doctrine of equivalents.

**C. Plaintiffs’ remaining claims and arguments are unavailing.**

1. Squitieri

Plaintiffs argue in their Opposition that during prosecution of the reissue application they overcame the PTO Examiner’s anticipation rejection based on Squitieri because Squitieri does not disclose depositing blood in the right atrium (Pl. Opp. at 6). The court disagrees for three reasons. First, this assertion is not true. There were two office actions in the reissue prosecution history. The first office action can be found at Defendant’s Exhibit 32, at 1637–1658. That office action rejected the claims for obviousness (not anticipation) based on Squitieri and Twardowski. *Id.* The second office action can be found at Defendant’s Exhibit 18, at 1698–1726. The second office action likewise rejected the claims based on the obviousness combination of Squitieri and Twardowski. *Id.* Because the rejections were based on obviousness, the assertion that Plaintiffs overcame anticipation rejections based on Squitieri is incorrect.

Second, it is undisputed that *no* new claims were allowed in the reissue application and all claims in that application were ultimately abandoned. The original claims (the same claims issued in the ’591 patent) were allowed, but all of the claims in which Plaintiffs tried to eliminate the “disposed about” limitation were rejected and not allowed. Plaintiffs’ assertion that they somehow overcame anticipation rejections based on the limitation requiring blood to be

deposited in the right atrium is meritless. There were no anticipation rejections in the reissue prosecution and all claims containing the “right atrium” limitation were rejected as unpatentable.

Third, even if Plaintiffs’ assertion that they overcame anticipation by Squitieri based on the right atrium limitation were true, it would be irrelevant. The record reflects that the claims were rejected based on obviousness, and it is clear that Plaintiffs were required to amend to add the “disposed about” limitation to overcome the obviousness rejection based on Squitieri and Twardowski.

2. Claims II and III for Damages

Plaintiffs assert that they are entitled to \$6,000,000 in damages for direct and induced infringement under 35 U.S.C. § 271. Given the court’s recommendation of no infringement, Plaintiffs are not entitled to this relief.

3. Claim IV for Copying and Willfulness

Plaintiffs assert they are entitled to judgment that Defendant has copied the claimed invention, is a willful infringer, and they are entitled to trebling of their damages (Pl. Opp. at 1, 2, 7, 8, and 17). Willfulness is a question of fact. *Polara Eng’g Inc. v. Campbell, Co.*, 894 F.3d 1339, 1353 (Fed. Cir. 2018). Plaintiffs produced no evidence of willfulness or copying in their Opposition, much less submitted undisputed admissible evidence entitling them to summary judgment. The undersigned therefore recommends that Plaintiffs’ Claim IV for copying and willfulness be dismissed as baseless.

4. Injunctive Relief

Plaintiffs assert they are entitled to permanent injunctive relief. An injunction requires a showing of likelihood of success on the merits and irreparable harm. *Planned Parenthood of Kansas v. Andersen*, 882 F.3d 1205, 1223 (10th Cir. 2018). Defendant’s Motion demonstrates

Plaintiffs have no likelihood of success on the merits. The undersigned recommends that Plaintiffs' demand for injunctive relief be denied.

#### V. CONCLUSION

In summary, Defendant has established that the undisputed facts show that it is entitled to judgment as a matter of law on Plaintiffs' claims for literal infringement, under the doctrine of equivalents, and under § 112(f). Defendant has also established that Plaintiffs' claims for direct and induced infringement, copying and willful infringement, and injunctive relief are subject to dismissal. Plaintiffs' Opposition fails to dispute any material facts, and their analysis of law is incorrect and unavailing.

#### RECOMMENDATION

For the foregoing reasons, IT IS HEREBY RECOMMENDED that:

1. Defendant's Motion for Summary Judgment (ECF 40) be GRANTED; and
2. Plaintiffs' Amended Complaint (ECF 15) be dismissed with prejudice.

#### NOTICE

Copies of the foregoing Report and Recommendation are being sent to all parties who are hereby notified of their right to object. Within fourteen (14) days of being served with a copy, any party may serve and file written objections. *See* 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b). Failure to object may constitute a waiver of objections upon subsequent review.

DATED this 17 August 2022.



Magistrate Judge Cecilia M. Romero  
United States District Court for the District of Utah

# EXHIBIT 6

DOCKET TEXT ORDER. On August 17, 2022, Magistrate Judge Romero entered 67 Report and Recommendation recommending that the court grant Defendant's motion for summary judgment. On August 29, 2022, Plaintiffs filed objections. Having carefully reviewed the Report and Recommendation and the objections, the court concludes that Plaintiffs' objections are not well taken. The court agrees with Judge Romero that all of Plaintiffs' claims necessary fail because, as a matter of law, Plaintiffs cannot establish infringement. First, Plaintiffs concede that they cannot establish literal infringement. See Dkt. No. 68 at 9. Second, Plaintiffs' attempt to establish infringement under 35 USC § 112(f) fails as a matter of law because the relevant limitation is not a means plus function limitation. To be sure, the limitation does refer to a cuff "means," but on the one hand, it does not identify any function, and on the other hand, it does identify a specific structure. Finally, Plaintiffs' attempt to establish infringement under the doctrine of equivalents fails as a matter of law because of prosecution history estoppel. The court agrees with Judge Romero that Plaintiffs clearly surrendered the scope that they are trying to reclaim through their infringement by equivalents argument. The court recognizes that in *Khan v. Cryolife Inc.*, No. 1:21-CV-2291-SCJ (N.D. Ga. August 04, 2022), the court held that Plaintiffs had sufficiently pleaded infringement to survive a motion to dismiss. It does not follow, however, that summary judgment is inappropriate. To the contrary, it is well settled that "a party opposing a properly supported motion for summary judgment may not rest upon the mere allegations or denials of his pleading, but must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986) (cleaned up). Plaintiffs have failed to do so here. The court accordingly OVERRULES 68 Objection to Report and Recommendation and ADOPTS 67 Report and Recommendation. 40 Motion for Summary Judgment is GRANTED. SO ORDERED. Signed by Judge Howard C. Nielson, Jr., on 09/26/2022. Signed by Judge Howard C. Nielson, Jr on 9/26/2022. (jp) (Entered: 09/26/2022)

As of September 27, 2022, PACER did not contain a publicly available document associated with this docket entry. The text of the docket entry is shown above.

*Khan et al v. Merit Medical Systems, Inc.*  
2-21-cv-00337 (DUT), 9/26/2022, docket entry 72

# EXHIBIT 7

AO 450 (Rev.5/85) Judgment in a Civil Case

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# United States District Court

District of Utah

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Nazir Khan and Iftikhar Khan,

Plaintiffs,

v.

Merit Medical Systems Inc.,

Defendant.

## JUDGMENT IN A CIVIL CASE

Case Number: 2:21-cv-00337-HCN-CMR

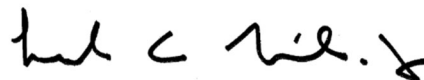
IT IS ORDERED AND ADJUDGED

That summary judgment is granted in favor of Defendant and against Plaintiffs on all of Plaintiffs' claims.

September 27, 2022

*Date*

BY THE COURT:



Howard C. Nielson, Jr.  
United States District Judge