

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

B. BRAUN MELSUNGEN AG, B. BRAUN
MEDICAL INDUSTRIES SDN. BHD. and B.
BRAUN MEDICAL, INC.,

Plaintiffs;

v.

Civil Action No. 1:16-cv-411-RGA

BECTON, DICKINSON AND COMPANY
and BECTON, DICKINSON INFUSION
THERAPY SYSTEMS, INC.

Defendants.

MEMORANDUM OPINION

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Attorneys for Defendants

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ANDREWS, U.S. DISTRICT JUDGE:

Presently before the Court is the issue of claim construction of multiple terms in U.S. Patent Nos. 9,149,626 (“the ’626 patent”), 8,540,728 (“the ’728 patent”), 8,337,463 (“the ’463 patent”), 8,333,735 (“the ’735 patent”), 8,328,762 (“the ’762 patent”), 8,460,247 (“the ’247 patent”), 8,587,249 (“the ’249 patent”), 9,370,641 (“the ’641 patent”), 8,414,539 (“the ’539 patent”), 8,444,605 (“the ’605 patent”), and 8,545,454 (“the ’454 patent”). The Court has considered the Parties’ Joint Claim Construction Brief. (D.I. 110). The Court heard oral argument on June 8, 2017. (D.I. 130).

I. Background

Plaintiffs brought this infringement action on June 6, 2016, alleging infringement of ten patents. (D.I. 1). On July 25, 2016, Plaintiffs filed their First Amended Complaint adding an additional count alleging infringement of an eleventh patent. (D.I. 16). The parties divide the patents into three families: the Woehr/Raines patents (the ’626, ’728, ’463, ’735, and ’762 patents), the Woehr/Zerbes patents (the ’247, 249, and ’641 patents), and the Kuracina patents (the ’539, ’605, and ’454 patents). All of these patents claim catheter insertion devices with needle protection components.

II. Legal Standard

“It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). “[T]here is no magic formula or catechism for conducting claim construction.’ Instead, the court is free to attach the appropriate weight to appropriate sources ‘in light of the statutes and policies that inform patent law.’”

SoftView LLC v. Apple Inc., 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*,

415 F.3d at 1324) (alteration in original). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, “the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Phillips*, 415 F.3d at 1315 (internal quotation marks omitted).

“[T]he words of a claim are generally given their ordinary and customary meaning. . . . [Which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Id.* at 1312–13 (citations and internal quotation marks omitted). “[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted). “In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.” *Id.* at 1314.

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court’s construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Phillips*, 415 F.3d at 1317–19 (internal quotation marks omitted). Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic

evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

“A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent.” *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that “a claim interpretation that would exclude the inventor’s device is rarely the correct interpretation.” *Osram GMBH v. Int’l Trade Comm’n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (citation and internal quotation marks omitted).

III. CONSTRUCTION OF DISPUTED TERMS

A. The Patents-in-Suit

1. The Woehr/Raines Patents

The Woehr/Raines patents are directed to devices, systems, and methods for catheter insertion. The only disputed terms in the ’626 patent appear in claim 11, which reads as follows:

11. A catheter insertion device comprising:
 - a catheter hub comprising an interior cavity, an opening at a proximal end, and a catheter tube attached to a distal end;
 - a needle having a needle shaft defining a needle axis projecting distally of an end of a needle hub, said needle projecting through the catheter tube in a ready position and comprises a needle tip;
 - a valve positioned inside the interior cavity of the catheter hub and in contact with the interior cavity, said valve being sized and shaped to obstruct fluid flow and comprises a wall surface comprising a slit; said valve remaining inside the interior cavity when the needle is removed from the catheter tube and the catheter hub;
 - a valve actuating element slidably disposed in the catheter hub to actuate the valve, the valve actuating element comprising a nose section having a tapered end for pushing the valve to open the slit and a plunger end extending proximally of the nose section; the plunger end transferring a distally directed force to the nose section to push the valve to open the slit when pressed upon; and
 - a *needle protective device* spaced from the needle tip in the ready position and *movable relative to the needle tip, at least in part distally of the needle tip* to prevent unintended needle sticks.

(’626 patent, claim 11) (disputed terms italicized).

Claim 1 of the '728 patent is representative and reads as follows:

1. A catheter insertion device comprising:
 - a catheter hub comprising an interior cavity, an opening at a proximal end, and a catheter tube attached thereto and extending from a distal end;
 - a needle having a needle shaft defining a needle axis projecting distally of an end of a needle hub, said needle projecting through the catheter tube and comprising a needle tip;
 - a valve sized and shaped to obstruct fluid flow comprising a wall surface comprising a slit positioned inside the interior cavity of the catheter hub and in contact with the interior cavity; said valve remaining inside the interior cavity when the needle is removed from the catheter tube and the catheter hub and abuts a shoulder formed in the interior cavity of the catheter hub;
 - a valve actuating element slidably disposed in the catheter hub to actuate the valve, the valve actuating element comprising a nose section having a tapered end for pushing the valve to open the slit of the valve and a *plunger* end having at least two *plunger* elements extending proximally of the nose section and having a gap therebetween to permit fluid flow to flow therethrough; the two *plunger* elements being sufficiently rigid to transfer a distally directed force to the nose section to push the valve to open the slit;
 - a *needle protective device* spaced from the needle tip in a ready position and *movable relative to the needle tip to a protective position, at least in part, distally of the needle tip* to prevent unintended needle sticks.

('728 patent, claim 1) (disputed terms italicized).

Disputed terms in the '463 patent appear in claims 1 and 10. Claim 1 reads as follows:

1. A catheter insertion device comprising:
 - a catheter hub comprising an interior cavity, an opening at a proximal end, and a catheter tube attached thereto and extending from a distal end;
 - a needle having a needle shaft defining a needle axis projecting distally of an end of a needle hub, said needle projecting through the catheter tube and comprising a needle tip;
 - a valve sized and shaped to obstruct fluid flow through the catheter hub comprising a wall surface comprising a slit positioned inside the interior cavity of the catheter hub and abutting a shoulder in the interior cavity of the catheter hub; said valve remaining inside the interior cavity when the needle is removed from the catheter tube and the catheter hub;
 - a valve actuating element slidably disposed in the catheter hub to actuate the valve, the valve actuating element comprising a nose section having a tapered end for pushing the valve to open the slit of the valve and at least two *plunger* elements extending proximally of the nose section and having a gap therebetween to permit fluid flow to flow therethrough; the two *plunger* elements structured to transfer a distally directed force to the nose section to push the valve to open the slit;

a needle protective device spaced from the needle tip in a ready position and movable relative to the needle tip to a protective position, at least in part, distally of the needle tip to prevent unintended needle sticks.

(’463 patent, claim 1) (disputed terms italicized). Claim 10 of the ’463 patent reads as follows:

10. A catheter insertion device comprising:
 - a first hub comprising an interior cavity, a perimeter defining an opening at a proximal end, and a catheter tube having a distal end opening extending distally of the first hub;
 - a needle having a needle shaft defining a needle axis projecting distally of an end of a second hub, said needle projecting through the catheter tube and comprising a needle tip;
 - a valve sized and shaped to obstruct fluid flow comprising a slit positioned inside the interior cavity of the first hub and having a distal surface pushed against a shoulder in the interior cavity; said valve remaining inside the interior cavity when the needle is removed from the catheter tube and the first hub;
 - a valve actuating element slidably disposed in the first hub to actuate the valve, the valve actuating element comprising a projection, a nose section having a tapered end with an opening structured to push the valve to open the slit, and at least two *plunger* elements extending proximally of the nose section and having a gap therebetween; wherein the at least two *plunger* elements with the gap therebetween are disposed distally of the proximal end of the first hub and are slidable distally when a male implement projects into the opening of the first hub to transfer a distally directed force to the nose section to push the valve to open the slit;
 - a needle protective device positioned proximal of the valve and at least in part around the needle and distal of the proximal end of the second hub in a ready position, the needle protective device is moveable to prevent unintended needle sticks in a protective position.*

(’463 patent, claim 10) (disputed terms italicized).

Claims 1 and 18 of the ’735 patent are representative as to the disputed terms. Claim 1 reads as follows:

1. A catheter insertion device comprising:
 - a catheter hub comprising an interior cavity, an opening at a proximal end, and a catheter tube attached thereto and extending from a distal end;
 - a needle having a needle shaft defining a needle axis projecting distally of an end of a needle hub, said needle projecting through the catheter tube and comprising a needle tip;

a valve configured to obstruct fluid flow comprising a wall surface comprising a slit positioned inside the interior cavity of the catheter hub; said valve remaining inside the interior cavity when the needle is removed from the catheter tube and the catheter hub;

a valve actuating element slidably disposed in the catheter hub configured to actuate the valve, the valve actuating element comprising a nose section having a tapered end for pushing the valve to open the slit of the valve and at least two *plunger* elements extending proximally of the nose section and having a gap therebetween to permit fluid flow to flow therethrough; the two *plunger* elements configured to transfer a distally directed force to the nose section to push the valve to open the slit;

a needle protective device spaced from the needle tip in a ready position and movable relative to the needle tip to a protective position, at least in part, distally of the needle tip to prevent unintended needle sticks.

('735 patent, claim 1) (disputed terms italicized). Claim 18 reads as follows:

18. A catheter insertion device comprising:

a catheter hub comprising an interior cavity comprising a shoulder, an opening at a proximal end, and a catheter tube attached thereto and extending from a distal end;

a needle having a needle shaft defining a needle axis projecting distally of an end of a needle hub, said needle projecting through the catheter tube and comprising a needle tip;

a valve configured to obstruct fluid flow positioned inside the interior cavity of the catheter hub; said valve remaining inside the interior cavity of the catheter hub when the needle is removed from the catheter tube and the catheter hub;

a valve actuating element slidably disposed in the catheter hub for actuating the valve, the valve actuating element comprising a nose section having a tapered end configured to open the valve, a projection on the valve actuating element located proximally of the tapered nose section engaging the shoulder of the catheter hub, and a *plunger* end extending proximally of the nose section having one or more gaps to permit fluid flow to flow therebetween and to transfer a distally directed force to the nose section to open the valve;

a needle protective device positioned, at least in part, around the needle between the valve and the proximal end of the needle hub in a ready position and configured to prevent unintended needle sticks in a protective position.

('735 patent, claim 18) (disputed terms italicized).

Claim 18 of the '762 patent is representative and reads as follows:

18. A method of manufacturing a catheter insertion device comprising:

forming a catheter hub comprising a body comprising an interior cavity with an opening at a proximal end and attaching a catheter tube thereto;

positioning a valve in sealing communication with the interior cavity of the catheter hub for regulating fluid flow through the interior cavity;

positioning a valve actuating element in mechanical communication with the valve for deflecting the valve to permit fluid flow through the interior cavity of the catheter hub;

positioning a *needle protective device* at least partially inside the interior cavity of the catheter hub such that the *needle protective device* is in-line with the catheter hub and the valve actuating element;

positioning a needle hub having a needle attached thereto proximally of the catheter hub so that the needle projects through the catheter hub and the catheter tube; and

wherein the valve remains inside the interior cavity of the catheter hub when the needle is removed from the catheter tube and the catheter hub.

('762 patent, claim 18) (disputed terms italicized).

2. *The Woehr/Zerbes Patents*

The Woehr/Zerbes patents are directed to catheter assemblies with needle protection features. The disputed terms in the '247 patent appear in independent claims 12 and 23 and dependent claims 22 and 29. Claim 12 is representative of the independent claims and reads as follows:

12. A safety catheter assembly comprising:
 - a first hub comprising an interior cavity, an opening at a proximal end, and a catheter tube having a distal end opening extending distally of the first hub;
 - a needle having a needle shaft defining a needle axis projecting distally of an end of a second hub, said needle projecting through the catheter tube and comprising a needle tip;
 - a valve comprising a slit for obstructing fluid flow positioned inside the interior cavity of the first hub; said valve remaining inside the interior cavity when the needle is removed from the catheter tube and the first hub;
 - a valve actuating element slidably disposed in the first hub for actuating the valve, the valve actuating element comprising a nose section having a tapered end with an opening configured to push the valve to open the slit and at least two *leg* elements extending proximally of the nose section and having a gap therebetween; wherein the at least two *leg* elements with the gap therebetween are disposed distally of the opening at the proximal end of the first hub and are slidable distally by a male implement projecting into the opening of the first hub to transfer a distally directed force to the nose section to push the valve to open the slit;

a *needle protective device* positioned proximally of the valve and at least in part around the needle and distal of a proximal end of the second hub in a ready position and configured to prevent unintended needle sticks in a protective position;

wherein an arm extends distally of a third hub and is located at least in part in the first hub in a ready position; and

wherein a portion of the *needle protective device* springs relative to the needle to move to the protective position.

('247 patent, claim 12) (disputed terms italicized). Dependent claim 22 reads as follows:

22. The safety catheter assembly of claim 21, wherein *the valve actuating element remains engaged to the valve to open the slit* for fluid flow through the first hub.

('247 patent, claim 22) (disputed terms italicized).

The only disputed term in the '249 patent appears in claim 1, which reads as follows:

1. A catheter assembly comprising:
 - a first hub comprising an interior cavity, an opening at a proximal end, and a catheter tube having a distal end opening extending distally of the first hub;
 - a needle having a needle shaft defining a needle axis projecting distally of an end of a second hub, said needle projecting through the catheter tube and comprising a needle tip;
 - a valve comprising a slit for obstructing fluid flow and a skirt section positioned inside the interior cavity of the first hub such that the skirt section contacts the interior cavity of the first hub; said valve remaining inside the interior cavity when the needle is removed from the catheter tube and the first hub;
 - a valve opener disposed in the first hub for actuating the valve, the valve opener comprising a nose section for pushing the valve to open the slit when activated and a leg element extending proximally of the nose section; wherein the leg element is slidable distally within the interior cavity of the first hub by a male implement to transfer a distally directed force to the nose section to push the valve to open the slit;
 - a *needle protective device* spring loaded in a ready to use position and positioned proximally of the valve and at least in part around the needle to prevent unintended contact with the needle tip in a protective position; and
 - a third hub positioned substantially proximally of the first hub.

('249 patent, claim 1) (disputed terms italicized).

The disputed terms in the '641 patent appear in independent claim 15 and dependent claims 20 and 22. Claim 15 is representative and reads as follows:

15. A safety catheter assembly comprising:
 - a catheter hub comprising a housing comprising an exterior surface and an interior surface defining an interior cavity; said catheter hub having a catheter tube attached to a distal end of the catheter hub and the catheter tube comprising a distal opening;
 - a needle hub having a needle with a needle tip attached to the needle hub and projecting distally of the needle hub and into the catheter tube with the needle tip extending out the distal opening of the catheter tube;
 - a valve for limiting fluid flow and a valve opener in cooperative arrangement therewith positioned in the interior cavity of the catheter hub;
 - a *safety device* for covering the needle tip comprising a tip protector housing having a housing section positioned proximally of a proximal end of the catheter hub; and
 - wherein the valve opener comprises two proximally extending *legs* having a gap therebetween, the two proximally extending *legs* being sized and shaped to be pushed distally towards the valve to transfer a force imparted by a male Luer to the valve.

('641 patent, claim 15) (disputed terms italicized).

3. *The Kuracina Patents*

The Kuracina patents are directed to intravenous catheter assemblies with needle tip guards. The only disputed term in each of the three Kuracina patents is “needle trap.” This term appears in claims 1, 15, and 17 of the '539 patent, claims 1, 25, and 30 of the '605 patent, and claims 1, 18, 23, and 24 of the '454 patent. Claim 1 of the '539 patent is representative with respect to this disputed term and reads as follows:

1. An intravenous catheter assembly comprising:
 - a catheter hub with a catheter tube;
 - a needle having a needle shaft, a proximal end attached to a needle hub, a sharpened distal end, and a change in profile;
 - a needle guard slidably disposed about said needle shaft, said needle guard comprising a *needle trap*, the *needle trap* comprising an extending arm and a projection for releasably holding the catheter hub in a ready to use position; the needle guard further comprising an inner chamber and a slot for fixedly attaching the needle trap into the slot;

wherein the projection is free to move to allow the catheter hub to separate from the needle guard when the *needle trap* is no longer biased by the needle; and

an opening on the needle guard for interacting with the change in profile to limit distal advancement of the needle guard along the needle.

(’539 patent, claim 1) (disputed terms italicized).

B. Disputed Terms

1. “needle protective device . . . movable relative to the needle tip to a protective position, at least in part, distally of the needle tip”
 - a. *Plaintiffs’ proposed construction*: “needle protective device and needle tip are movable with respect to each other to a protective position, where a portion of the needle protective device is located distally of the needle tip”
 - b. *Defendants’ proposed construction*: “The needle protective device moves from one position to a second position that covers the needle tip and that is, at least in part, distal of the needle tip.”
 - c. *Court’s construction*: “The needle protective device moves from one position to a second position that covers the needle tip and that is, at least in part, distal of the needle tip.”

This term appears in the ’735, ’728, and ’626 patents. The only dispute is whether the needle protective device itself must be movable, or whether the needle protective device may be stationary while only the needle tip moves to the protective position. Defendants do not argue that the needle itself cannot be movable; rather, they contend that the plain language of the claim requires that the needle protective device must be movable. (Hr’g Tr. at 78:20-79:1). Plaintiffs focus on the words “relative to” as support for their argument that all this claim language requires is that either the needle protective device or the needle tip, or both, can move, as long as the two move relative to each other. (Hr’g Tr. at 71:16-72:3). I disagree. The plain language of this term supports Defendants’ construction. Movable modifies “needle protective device,” not “needle tip.” A plain reading of this indicates that the “needle protective device” must be movable. Indeed, Plaintiffs admit that the “needle protective device” is movable in every embodiment disclosed in

the specification. (Hr'g Tr. at 77:15-17). There is nothing in the patent, therefore, to indicate that the patentee intended for this claim language to mean anything other than what a plain reading of it means; that is, the "needle protective device" must be movable. Therefore, I will adopt Defendants' proposed construction.

2. "the valve actuating element remains engaged to the valve to open the slit"
 - a. *Plaintiffs' proposed construction*: "the valve actuating element causes the valve slit to remain open after the male implement is withdrawn from the catheter hub; Not indefinite under § 112"
 - b. *Defendants' proposed construction*: "element is in contact with the valve and is configured to open the slit; alternatively, indefinite under § 112"
 - c. *Court's construction*: "the valve actuating element causes the valve slit to remain open"

This term appears in the '247 patent in asserted dependent claim 22, which depends through a series of other claims from independent claim 12. Plaintiffs contend that Defendants' proposed construction limits the claim to a device in the ready position, while Plaintiffs argue the device is not necessarily in the ready position. (Hr'g Tr. at 96:14-18). Defendants argue that claim 12 is a product claim that specifically describes a safety catheter in the ready position. (D.I. 110 at 27). Plaintiffs disagree, arguing that claim 12 merely describes the "different attributes of the claimed safety catheter assembly," including when it is not in the ready position. (Hr'g Tr. at 99:8-15). I agree with Defendants that claim 12 describes the safety catheter assembly in the ready position. This is clear from the fact that the claim calls for a needle to be present "projecting through the catheter tube." Claim 12, however, does describe features of the assembly in other positions, such as after "the needle is removed." As discussed below, I find that Claim 22 describes the assembly after the needle has been removed and the valve has been opened. Therefore, I find this term is not indefinite under § 112.

The parties further disagree about which embodiment this claim is directed to. Plaintiffs argue the claim is directed to the embodiment shown in Figure 5, while Defendants contend it is the embodiment shown in Figure 9D. (Hr'g Tr. at 96:19-97:1, 105:7-10). I agree with Plaintiffs that this claim is directed to the embodiment shown in Figure 5. The specification states that the distinctive feature of the alternative safety catheter, whose embodiment is shown in Figure 9D, is "an air permeable fluid impermeable wiper . . . incorporated distal of the valve." ('247 patent at 9:48-49). This embodiment is described as being otherwise "similar" to the catheter assembly disclosed earlier in the specification, including the assembly pictured in Figure 5. (*Id.* at 9:44-47) The wiper feature that distinguishes this embodiment does not appear in claim 22 or any of the claims from which claim 22 depends. The specification's discussion of Figure 9D also does not mention the limitation found in claim 22, that "the valve actuating element remains engaged to the valve." Therefore, I do not find Figure 9D to disclose a relevant embodiment of the catheter assembly.

The specification's disclosure regarding Figure 5A, on the other hand, contains the only disclosure in the entire specification of the actuating element and valve "remain[ing] engaged." ('247 patent at 7:37-39). This portion of the specification indicates that the two elements become "engaged" only after the valve opener (the valve actuating element) has been pushed forward into the valve, "forc[ing] the cut-out to deflect," and thereby opening the valve. (*Id.* at 7:33-37). The specification further provides that, "If the IV set luer connector is subsequently withdrawn from the catheter hub, then the valve would remain open and consequently there could be blood leakage." (*Id.* at 7:44-46). I think this disclosure indicates that if the two elements are "engaged," then the valve is open. I do not think, however, that the only time the valve remains open is after the male implement, or IV set luer, is withdrawn. I see no reason to import this additional

limitation into the meaning of this claim term as neither claim 22 nor any of the claims from which it depends mention the male implement having been withdrawn. Nor does the engagement of the two elements imply or require that the male implement be withdrawn. Therefore, I will construe this term to mean “the valve actuating element causes the valve slit to remain open.”

3. “plunger”

- a. *Plaintiffs’ proposed construction*: “No construction necessary. Alternatively: structure that transfers an external force”
- b. *Defendants’ proposed construction*: “A longitudinal structure that receives an external force that moves the structure along the longitudinal axis”
- c. *Court’s construction*: “Plain and ordinary meaning.”

As discussed at oral argument, I am not convinced that this term needs to be construed as I think it has an ordinary meaning to a person of skill in the art. (Hr’g Tr. at 112:3-6). Therefore, I will provisionally construe the term “plunger” to have its plain and ordinary meaning. (Hr’g Tr. at 115:1-9). If, closer to trial, the parties determine that this term needs construction beyond plain and ordinary meaning, they should make a request with the Court for further claim construction.

4. “needle protective device positioned proximal of the valve and at least in part around the needle and distal of the proximal end of the second hub”

“a needle protective device positioned, at least in part, around the needle between the valve and the proximal end of the needle hub”

- a. *Plaintiffs’ proposed construction*: “needle protective device positioned proximal of the valve and at least in part: (i) around the needle, and (ii) distal of the proximal end of the second hub”

“needle protective device positioned, at least in part: (i) around the needle, (ii) between the valve and the proximal end of the needle hub”

- b. *Defendants’ proposed construction*: “The needle protective device (the spring clip) is positioned (i) proximal of the valve; (ii) at least in part around the needle; and (iii) distal of the proximal end of the second hub”

“The needle protective device (the spring clip) is positioned (i) proximal of the valve; (ii) at least in part around the needle; and (iii) distal of the proximal end of the needle hub”

- c. *Court’s construction*: “The needle protective device (the spring clip) is positioned (i) proximal of the valve; (ii) at least in part around the needle; and (iii) distal of the proximal end of the second hub”

“needle protective device positioned, at least in part: (i) around the needle, (ii) between the valve and the proximal end of the needle hub”

The first of these terms appears in claims in the ’463, ’735, and ’728 patents, while the second appears in different claims of the ’735 and ’728 patents. The parties frame the dispute as primarily a question of grammar.

Plaintiffs invoke the Federal Circuit’s holding in *SuperGuide* as support for their argument that the phrase “at least in part” modifies both of the phrases that follow it. (D.I. 110 at 36). I do not think *SuperGuide* is relevant to this dispute. The dispute in *SuperGuide* involved the phrase “at least one of” followed by a list of categories. *SuperGuide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 886 (Fed. Cir. 2004). The parties disagreed about whether “at least one of” indicated that only one member in the list must be included or whether at least one item from each category in the list must be included. *Id.* The Federal Circuit determined that the language at issue was a conjunctive list and the phrase “at least one of” required one item from each category in the conjunctive list. *Id.* This is not relevant to the dispute here, which does not involve a conjunctive list of items or categories. Rather, the dispute is whether “at least in part” modifies each of the phrases that follows.

As to the first term, I agree with Defendants. The term lists three limitations on the positioning of the needle protective device: 1) proximal of the valve; 2) at least in part around the needle; and 3) distal of the proximal end of the second hub. The fact that the patentee separated each of the three elements by the word “and” indicates that each of the three elements represents

an individual limitation on the positioning. The phrase “at least in part” modifies only the second element in the list. For this term, I will adopt Defendants’ proposed construction.

As to the second term, I agree with Plaintiffs. This term lists two limitations on the positioning of the needle protective device: 1) around the needle; and 2) between the valve and the proximal end of the needle hub. The phrase “at least in part” precedes both of these limitations and is set off by commas, indicating that it modifies both of the limitations. For this term, I will adopt Plaintiffs’ proposed construction.

5. “leg”

- a. *Plaintiffs’ proposed construction*: “No construction necessary. Alternatively: structure that transfers an external force”
- b. *Defendants’ proposed construction*: “A projection that is not attached to another structure at one end and that receives an external force that moves the projection”
- c. *Court’s construction*: “leg-like projection”

This term appears in asserted claims in the ’247, ’249, and ’641 patents. At the *Markman* hearing, I proposed construing it to mean “a leg-like structure, a leg-like projection . . . not attached at the ends.” (Hr’g Tr. at 123:11-12). In post-hearing letter briefing, Plaintiffs indicated their agreement with “leg-like structure” or “leg-like projection,” but argued that including the phrase “not attached at the ends” would be improper, characterizing the phrase as a “negative limitation” not supported by the intrinsic evidence. (D.I. 131 at 2). Defendants respond that all embodiments of each of the patents-in-suit have “legs” that are not attached to any other structures at their ends. (D.I. 139 at 2). Defendants contend that this is not a negative limitation, but rather a “structural description” of the term. (*Id.*). I agree with Defendants that all disclosed embodiments in all three patents include “legs” that are not attached to other structures at one end. As Plaintiffs note,

however, it is improper to limit a claim to the specific embodiments disclosed in the specification. *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985) (en banc).

Defendants cite a technical dictionary which defines “leg” to mean “any object or part that resembles a human or animal leg, either structurally or functionally.” (D.I. 110 at 42). This extrinsic evidence does not unambiguously indicate that a person of ordinary skill would understand that a “leg,” as the term is used in the patents-in-suit, cannot be attached to another structure at one end. Some “legs” on everyday objects, such as the legs on rocking chairs, are connected to other structures at both ends. I do not think there is sufficient intrinsic evidence for me to construe this term to include the structural limitation proposed by Defendants. Defendants contend that their expert’s understanding of the term comports with their proposal. (D.I. 110 at 42). Defendants’ expert’s understanding may very well be the plain and ordinary meaning to one of skill in the art in the context of the patents. It seems to me, however, that whether a person of ordinary skill would understand the structure in the accused device to include a “leg,” as that term is used in these patents, is something that can best be addressed at trial through expert testimony. Therefore, I will construe “leg” to mean “leg-like projection.”

6. “needle trap”

a. *Plaintiffs’ proposed construction*: “Not means-plus-function. A device for trapping the needle.”

b. *Defendants’ proposed construction*: “Means plus function.”

Function: releasably holding a needle guard adjacent a catheter hub prior to use, and entrapping and blocking a needle tip and releasing the catheter hub after use

Structure: a radially extending wall including a planar surface, an extending arm extending from the radially extending wall, and a projection extending from the extending arm, as described in the Kuracina patent specification at: ’605 patent, FIGS. 103-105, cols. 34:44-36:25; ’605 patent, FIGS. 114, 115, 118, 123, 124, cols. 38:28-39:19, 41:49-64; ’605 patent, FIGS. 120-121, cols. 39:26-41:45; ’605 patent, FIGS. 125-128, cols. 41:65-43:27; and structural equivalents thereof

Alternatively, “A lead in section, a wall that blocks a needle tip and that is separated from the lead in section by a first bend, an extending arm separated from the wall by a second bend, and a projection separated from the extending arm by a third bend.” *Alternatively*, indefinite under §112

c. *Court’s construction*: “Not means-plus-function.”

This term appears in asserted claims in the ’605, ’454, and ’539 patents. Defendants contend that this is a means-plus-function term. (D.I. 110 at 52). Plaintiffs agree that the term is functional, but argue that it is not means-plus-function. (*Id.* at 51). Plaintiffs initially declined to offer a construction, instead suggesting that “it would be improper to further construe needle trap in this situation, because . . . needle trap is a functional term.” (Hr’g Tr. at 48:3-6). According to Plaintiffs, “Once you determine that there’s sufficient structure in the claim for performing that function, then the analysis stops there.” (Hr’g Tr. at 48:9-11). At the Court’s request, Plaintiffs have offered the alternative construction, “A device for trapping the needle.” (D.I. 131 at 1).

I agree with Plaintiffs that this is not a means-plus-function term. When the word “means” does not appear in the claim element, there is a presumption that the element is not means-plus-function. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015). “[T]he presumption can be overcome and § 112, para. 6 will apply if the challenger demonstrates that the claim term fails to ‘recite sufficiently definite structure’ or else recites ‘function without reciting sufficient structure for performing that function.’” *Id.*

I conclude that § 112 ¶ 6 does not apply to this claim element. The word “means” does not appear in the claim element, so I begin with the presumption that § 112 ¶ 6 does not apply. Defendants have not overcome this presumption. While I do not think the term “needle trap” has an agreed upon meaning to a person of ordinary skill, the claims at issue recite sufficient structure to perform the function of trapping the needle. For example, claim 1 of the ’605 patent recites that “the needle trap compris[es] an extending arm, a first projection, a fold located between the

extending arm and the first projection such that the first projection releasably holds the catheter hub in a ready to use position and a sharp projection.” Defendants agree that this structure is sufficient for “holding the needle trap to the catheter body,” but argue it is not sufficient to perform the function of “trapping the needle.” (D.I. 110 at 53). I disagree. The specification and claims disclose that the “needle trap” is a component of the “needle guard.” (*See, e.g.*, ’605 patent at 4:28-31, claim 1). The “needle trap” is movable and “advances over the tip of the needle, entrapping the needle tip.” (*Id.* at 4:33-34). The claims each disclose sufficient structural elements of different embodiments of the “needle trap” such that the “needle trap” can perform this function. For example, the structure recited in claim 1 of the ’605 patent, quoted above, is disclosed in the embodiment pictured in Figure 118 and the corresponding description in the specification. (*Id.* at 38:63-39:19). The disclosed structure performs the function of advancing over the tip of the needle and “entrapping” or covering it. Simply because the “needle trap” does not fully enclose the needle tip does not mean that it does not perform the function of “entrapping the needle tip.” Therefore, I find that § 112, ¶6 does not apply to this term.

As to the parties’ alternative proposed constructions, I find that Plaintiffs’ proposal is not a construction at all and adds nothing helpful to an understanding of the meaning of this coined term in the context of these patents. On the other hand, it appears that Defendants’ proposal limits the meaning of “needle trap” to one or more preferred embodiments, while excluding other embodiments. Therefore, I reject both parties proposed constructions and instruct the parties to submit additional briefing for this term.

7. “safety device”

- a. *Plaintiffs’ proposed construction:* “Not means-plus-function. A device for covering the needle.”

- b. *Defendants' proposed construction:* "Means plus function." Alternatively, "a tip protector having a wall with an opening for the needle and at least one arm that covers the needle tip as the needle is withdrawn from the catheter hub."

Function: Covering the needle tip

Structure: tip protector as more completely described in the patent specification at: '641 patent at FIGS. 3, 6, 7, 8C, 9D, 13, 14; '641 patent, Col. 2:29-38; '641 patent, Col. 2:52-54; '641 patent, Col. 5:58-6:2; '641 patent, Col. 6:57-64; '641 patent, Col. 7:65-8:11; '641 patent, Col. 10:13-15; '641 patent, Col. 11:23-24; '641 patent, Col. 11:65-12:10; '641 patent at col. 5:58-62 (incorporating by reference spring clips disclosed in U.S. Patent No. 6,616,630: '630 patent, FIGS. 1-17, 21, 22; '630 patent, Col. 2:47-49; '630 patent, Col. 3:19-20; '630 patent, Col. 3:46-55; '630 patent, Col. 5:54-6:9; '630 patent, Col. 6:27-41; '630 patent, Col. 7:9-13; '630 patent, Col. 7:16-56; '630 patent, Col. 8:23-36; '630 patent, Col. 8:61-9:3; '630 patent, Col. 9:23-35; '630 patent, Col. 9:61-10:4; '630 patent, Col. 10:17-36; '630 patent, Col. 10:58-11:2; '630 patent, Col. 12:20-24); '641 patent, FIGS. 6-7, col. 6:64-7:3, col. 7:65-67 (incorporating by reference tip protectors disclosed in U.S. Appl. No. 11/496,769); '718 patent, FIGS. 1A, 1B, 2-15; '718 patent, "Tip protector," passim; '641 patent at col. 7:6-12 (incorporating by reference tip protectors with an opening that cants over to grip the needle disclosed in U.S. Patent No. 6,709,419, U.S. Appl. No. 10/677,810, and U.S. Appl. No. 10/954,041: '419 patent, FIGS. 1-5; '419 patent, Col. 1:19-28; '419 patent, Col. 1:43-58; '419 patent, Col. 2:41-47; '419 patent, Col. 3:12-30); U.S. Pub. No. 2005/0075609, FIGS. 1-8; U.S. Pub. No. 2005/0075609, "needle clip," passim; '476 patent, FIGS. 1-10; '476 patent, Col. 1:37-62; '476 patent, Col. 2:54-65; '476 patent, Col. 3:3-11; '476 patent, Col. 3:24-46; '476 patent, Col. 3:57-63; '476 patent, Col. 3:66-4:4; '476 patent, Col. 4:63-5:3; '476 patent, Col. 5:21-6:38; '476 patent, Col. 7:1-8; and structural equivalents thereof.

- c. *Court's construction:* "Not means-plus-function."

This term appears in unasserted claim 15 of the '641 patent, from which asserted claims depend. Claim 15 includes the limitation of a "safety device for covering the needle tip." As with the previous term, Defendants argue that it is a means-plus-function term and, while Plaintiffs do not dispute that this term is functional, they argue that the claims recite sufficient structure for performing the function. (Hr'g Tr. at 59:20-60:4, 61:10-13).

The phrase "safety device" does not appear in the specification of the '641 patent. Claim 15 specifies that the "safety device . . . compris[es] a tip protector housing having a housing section positioned proximally of a proximal end of the catheter hub." The only asserted dependent claim

that adds any limitations on the “safety device” is claim 20, which requires that the “safety device . . . comprises a resilient portion made from a metal material and the tip protector housing surrounding the resilient portion.” At a minimum, therefore, the “safety device” is comprised of a tip protector housing. I think this provides sufficient structure to conclude that § 112, ¶6 does not apply to this term.

As to the parties’ alternative proposed constructions, as with the previous term, I find that Plaintiffs’ proposal is not helpful to an understanding of this term and, again, Defendants’ proposal limits the meaning to one or more preferred embodiments. Therefore, I reject both parties proposed constructions and instruct the parties to submit additional briefing for this term.

8. “needle protective device”

a. *Plaintiffs’ proposed construction*: “Not means-plus-function. A device configured to prevent unintended needle sticks.”

b. *Defendants’ proposed construction*: “Means plus function.”

For the ’762, ’463, ’735, ’728, and ’626 patents:

Function: to prevent unintended needle sticks

Structure: spring clip as more completely described in the Woehr/Raines patent specification at: ’735 patent, FIGS. 1-2, 4, 5, 7a 7d, 8, 9a, 10; ’735 patent, Col. 2:31; ’735 patent, Col. 2:33-41; ’735 patent, Col. 3:15-27; ’735 patent, Col. 3:34-38; ’735 patent, Col. 3:67-4:7; ’735 patent, Col. 4:39-53; and structural equivalents thereof.

For the ’247 and ’249 patents:

Function: to prevent unintended needle sticks

Structure: tip protector as more completely described in the Woehr/Zerbes patent specification at: ’247 patent at FIGS. 3, 6, 7, 8C, 9D, 13, 14; ’247 patent, Col. 2:24-34; ’247 patent, Col. 2:48-50; ’247 patent, Col. 5:55-62; ’247 patent, Col. 6:49-56; ’247 patent, Col. 7:57-8:3; ’247 patent, Col. 10:4-6; ’247 patent, Col. 11:14-15; ’247 patent, Col. 11:58-12:3; ’247 patent, Col. 5:51-55 (incorporating by reference spring clips disclosed in U.S. Patent No. 6,616,630 at: ’630 patent, FIGS. 1-17, 21, 22; ’630 patent, Col. 2:47-49; ’630 patent, Col. 3:19-20; ’630 patent, Col. 3:46-55; ’630 patent, Col. 5:54-6:9; ’630 patent, Col. 6:27-41; ’630 patent, Col. 7:9-13; ’630 patent, Col. 7:16-56; ’630 patent, Col. 8:23-36; ’630 patent, Col. 8:61-9:3; ’630 patent, Col. 9:23-35; ’630 patent, Col. 9:61-10:4; ’630 patent, Col. 10:17-36; ’630 patent, Col. 10:58-11:2; ’630 patent, Col. 12:20-24), ’247 patent, Col. 6:56-58, Col. 7:57-59 (incorporating by reference tip protectors disclosed in U.S. Appl. No. 11/496,769); ’718 patent,

FIGS. 1A, 1B, 2-15; '718 patent, "Tip protector," passim; '247 patent at col. 6:65-7:4 (incorporating by reference tip protectors with an opening that cants over to grip the needle disclosed in U.S. Patent No. 6,709,419, U.S. Appl. No. 10/677,810, and U.S. Appl. No. 10/954,041); '419 patent, FIGS. 1-5; '419 patent, Col. 1:19-28; '419 patent, Col. 1:43-58; '419 patent, Col. 2:41-47; '419 patent, Col. 3:12-30; U.S. Pub. No. 2005/0075609, FIGS. 1-8; U.S. Pub. No. 2005/0075609, "needle clip," passim; '476 patent, FIGS. 1-10; '476 patent, Col. 1:37-62; '476 patent, Col. 2:54-65; '476 patent, Col. 3:3-11; '476 patent, Col. 3:24-46; '476 patent, Col. 3:57-63; '476 patent, Col. 3:66-4:4; '476 patent, Col. 4:63-5:3; '476 patent, Col. 5:21-6:38; '476 patent, Col. 7:1-8; and structural equivalents thereof

c. *Court's construction:* "Means plus function."

For the '762, '463, '735, '728, and '626 patents:

Function: to prevent unintended needle sticks

Structure: spring clip as more completely described in the Woehr/Raines patent specification at: '735 patent, FIGS. 1-2, 4, 5, 7a 7d, 8, 9a, 10; '735 patent, Col. 2:31; '735 patent, Col. 2:33-41; '735 patent, Col. 3:15-27; '735 patent, Col. 3:34-38; '735 patent, Col. 3:67-4:7; '735 patent, Col. 4:39-53; and structural equivalents thereof.

For the '247 and '249 patents:

Function: to prevent unintended needle sticks

Structure: tip protector as more completely described in the Woehr/Zerbes patent specification at: '247 patent at FIGS. 3, 6, 7, 8C, 9D, 13, 14; '247 patent, Col. 2:24-34; '247 patent, Col. 2:48-50; '247 patent, Col. 5:55-62; '247 patent, Col. 6:49-56; '247 patent, Col. 7:57-8:3; '247 patent, Col. 10:4-6; '247 patent, Col. 11:14-15; '247 patent, Col. 11:58-12:3; '247 patent, Col. 5:51-55 (incorporating by reference spring clips disclosed in U.S. Patent No. 6,616,630 at: '630 patent, FIGS. 1-17, 21, 22; '630 patent, Col. 2:47-49; '630 patent, Col. 3:19-20; '630 patent, Col. 3:46-55; '630 patent, Col. 5:54-6:9; '630 patent, Col. 6:27-41; '630 patent, Col. 7:9-13; '630 patent, Col. 7:16-56; '630 patent, Col. 8:23-36; '630 patent, Col. 8:61-9:3; '630 patent, Col. 9:23-35; '630 patent, Col. 9:61-10:4; '630 patent, Col. 10:17-36; '630 patent, Col. 10:58-11:2; '630 patent, Col. 12:20-24), '247 patent, Col. 6:56-58, Col. 7:57-59 (incorporating by reference tip protectors disclosed in U.S. Appl. No. 11/496,769); '718 patent, FIGS. 1A, 1B, 2-15; '718 patent, "Tip protector," passim; '247 patent at col. 6:65-7:4 (incorporating by reference tip protectors with an opening that cants over to grip the needle disclosed in U.S. Patent No. 6,709,419, U.S. Appl. No. 10/677,810, and U.S. Appl. No. 10/954,041); '419 patent, FIGS. 1-5; '419 patent, Col. 1:19-28; '419 patent, Col. 1:43-58; '419 patent, Col. 2:41-47; '419 patent, Col. 3:12-30; U.S. Pub. No. 2005/0075609, FIGS. 1-8; U.S. Pub. No. 2005/0075609, "needle clip," passim; '476 patent, FIGS. 1-10; '476 patent, Col. 1:37-62; '476 patent, Col. 2:54-65; '476 patent, Col. 3:3-11; '476 patent, Col. 3:24-46; '476 patent, Col. 3:57-63; '476 patent, Col. 3:66-4:4; '476 patent, Col. 4:63-5:3; '476 patent, Col. 5:21-6:38; '476 patent, Col. 7:1-8; and structural equivalents thereof

As with the previous two terms, this term does not include the word “means,” so there is a rebuttable presumption that it is not means-plus-function. Plaintiffs acknowledge that no structure appears in the claim or specification. (Hr’g Tr. 18:2-20). Plaintiffs instead argue that a person of ordinary skill in the art would understand “needle protective device” to refer to a class of structures whose function is “to prevent . . . unintended needle sticks.” (Hr’g Tr. at 20:6-14). Plaintiffs cite to a number of references, most of which either do not use the term “needle protective device” or post-date the filing dates of some or all of the patents at issue, as support for this contention. (D.I. 110 at 75-76; Hr’g Tr. at 22:22-28:12). The earliest of these references, and the only one that predates the priority dates of all of the patents, does not use the term “needle protective device,” however. (Hr’g Tr. 23:15-25:6). Plaintiffs cite specifically to a definition of the term “needle protective device” in a reference that post-dates the Woehr/Raines patents but pre-dates the Woehr/Zerbes patents, that Plaintiffs argue is evidence of the state of the art as of the filing date of the application. (Hr’g Tr. at 23:1-25:25).

Defendants counter that the relevant case law points to the need to look to dictionaries to determine whether the term provides structure to a person of skill in the art and note that Plaintiffs have not produced a single dictionary definition for this term. (Hr’g Tr. at 30:11-31:9; D.I. 110 at 71, 78). Defendants further note that “needle protective device” is not used anywhere in the specifications of the patents. (Hr’g Tr. at 31:10-11; D.I. 110 at 70). Defendants argue that the single reference cited by Plaintiffs that uses the term “needle protective device” defines the term as applying to the entire device, such that, under this definition, the “needle protective device” would be the entire catheter assembly, not the component of the device claimed in the patents. (Hr’g Tr. at 33:3-18; *See, e.g.*, ’762 patent, claim 18 (“positioning a needle protective device at least partially inside the interior cavity”)).

It seems to me that the definition in Plaintiffs' reference indicates that even if there were a well understood meaning for this term, a person of ordinary skill in the art would not understand "needle protective device" to refer to only the component of the device claimed in these patents as opposed to the device as a whole. I agree with Defendants that this is a means-plus-function term. I do not think a person of ordinary skill at the time the application was filed would have an understanding of what "needle protective device" means in the context of these patents. Plaintiffs have not provided any contemporary evidence of the use of this term to mean, specifically, the type of device that is claimed in these patents. The only relevant reference Plaintiffs supply only supports my conclusion as it gives a very broad definition for the term that could encompass the invention, but also encompasses many other types of devices that are not contemplated by the patent. Contrary to Plaintiffs' position, this is evidence that a person of ordinary skill in the art would not have had an understanding of what Plaintiffs refer to as a class of structures such as the ones described in the patents-in-suit. Plaintiffs agree that the function of a "needle protective device" is to prevent unintended needle sticks, but have not offered a proposed alternative structure to that offered by Defendants. Since I think Defendants' proposed structure is consistent with the "needle protective device" claimed in the patents, I will adopt Defendants' construction.

IV. Conclusion

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion suitable for submission to the jury.