IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CONFLUENT SURGICAL, INC., INTEGRA LIFESCIENCES CORPORATION AND INTEGRA LIFESCIENCES SALES LLC,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 17-688-LPS-CJB
HYPERBRANCH MEDICAL TECHNOLOGY, INC.,	)	
Defendant.	)	

REPORT AND RECOMMENDATION

In this action filed by Plaintiff Confluent Surgical, Inc., Integra Lifesciences Corporation and Integra Lifesciences Sales LLC ("Plaintiffs") against Defendant HyperBranch Medical Technology, Inc. ("Defendant" or "HyperBranch"), Plaintiffs allege infringement of United States Patent Nos. 9,517,478 (the "'478 patent"), 8,210,453 (the "'453 patent"), 8,876,021 (the "'021 patent"), 8,033,483 (the "'483 patent"), 8,616,468 (the "'468 patent"), 9,101,946 (the "'946 patent"), and 9,700,290 (the "'290 patent") (collectively, "the asserted patents" or "the patents-in-suit"). Presently before the Court is the matter of claim construction. The Court recommends that the District Court adopt the constructions as set forth below.

I. BACKGROUND AND STANDARD OF REVIEW

The Court hereby incorporates by reference the summary of the background of this matter set out in its March 7, 2019 Report and Recommendation ("March 7 R&R"). (D.I. 177 at 1-2) It additionally incorporates by reference the legal principles regarding claim construction set out in the March 7 R&R. (*Id.* at 2-4)

II. DISCUSSION

The parties had disputes regarding 15 terms or sets of terms (hereafter, "terms"). The

March 7 R&R addressed the first two terms. The Court addresses terms 3, 4 and 5 herein. The remaining terms will be addressed in a forthcoming Report and Recommendation(s).

A. "vent lumen"

The claim term "vent lumen" appears in the asserted claims of the '946 and the '468 patents.[1] (*See* D.I. 81 at 3) The use of the disputed term in claim 1 of the '946 patent and claim 1 of the '468 patent is representative. Claim 1 of the '946 patent is reproduced below, with the disputed term highlighted:

> **1.** A spray assembly for dispensing a mixture, the spray assembly comprising:
>
> a connector portion configured for operable engagement with a first source of component, a second source of component, and a source of pressurized air;
>
> an elongated portion extending distally from the connector portion, the elongated portion including an inner shaft and an outer sleeve, the inner shaft and the outer sleeve defining a *vent lumen* therebetween, the inner shaft defining a first lumen configured for fluid communication with the first source of component, a second lumen configured for fluid communication with the second source of component, and a third lumen configured for fluid communication with the source of pressurized air;
>
> a tip assembly operably connected to the elongated portion, the tip assembly defining an opening and a mixing chamber between a distal end of the elongated portion and the opening of the tip assembly; and
>
> an insert member received in the mixing chamber, a distal end of the insert member defining an annular recess and at least one radially extending slot, the annular recess and the at least one radially extending slot operating to mix first and second

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[1] The asserted patents make up two patent families. (*See* D.I. 98 at 4 n.2; Plaintiffs' Markman Presentation, Slide 2) The '483 patent and the '021 patent share a common specification and are referred to as "Family 1." (D.I. 98 at 4 n.2) The remaining five patents (the '453, '468, '946, '478 and '290 patents) share a different common specification and will be referred to as "Family 2." (*Id.*)

components prior to a combination of first and second components exiting the opening in the tip assembly.

('946 patent, col. 6:27-51 (emphasis added)) Claim 1 of the '468 patent is reproduced next, again with the disputed term highlighted:

> **1.** A spray assembly for dispensing a mixture, the assembly comprising:
>
> a connector configured for operable engagement with a first source of component and a second source of component;
>
> an elongated member operably connected to and extending distally from the connector, the elongated member including an inner shaft and an outer sleeve, and defining a *vent lumen* between the inner shaft and outer sleeve, the inner shaft defines at least a first lumen configured for fluid communication with the first source of component and a second lumen configured for fluid communication with the second source of component;
>
> a tip operably connected to the connector, the tip including an opening and defining a mixing chamber between a distal end of the elongated member and the opening of the tip; and
>
> an insert member configured to be received in the mixing chamber, the insert member defining at least one radially extending slot on a first end of the insert member and at least one radially extending slot on a second end of the insert member, each of the radially extending slots being configured to mix the first and second components prior to the combination exiting the opening in the tip.

('468 patent, col. 6:25-48 (emphasis added))

The parties' competing proposed constructions for the term are set out in the chart below:

Term	**Plaintiffs' Proposed Construction**	**Defendant's Proposed Construction**
"vent lumen"	"a passageway for air or fluid extending along the elongated portion between the inner shaft and outer sleeve"	"a passageway or cavity within a hollow body designed to release or discharge excess gas pressure at a surgical site to the open atmosphere by providing fluid communication between

		at least two external openings. An 'air lumen' is not a 'vent lumen.'"

(*See, e.g.*, D.I. 81 at 3) The Court will first explain why Plaintiffs' proposal does not appropriately define "vent lumen," and will then assess HyperBranch's proposal.

1. Plaintiffs' Proposed Construction

As an initial matter, the Court easily concludes that the second portion of Plaintiffs' proposed construction—"extending along the elongated portion between the inner shaft and outer sleeve"—is unnecessary, because it is redundant of other language contained in the claims. That is, other portions of the claims already tell us that the "vent lumen" extends along the elongated portion between the inner shaft and outer sleeve, and there is no need to repeat these details in the construction for "vent lumen" itself. (*See, e.g.*, D.I. 98 at 2; Tr. at 32-33; Plaintiffs' Markman Presentation, Slides 10-11) With this language stripped away, we are left with: "a passageway for air or fluid[.]"

HyperBranch argues that if "vent lumen" were construed to mean "a passageway for air or fluid[,]" that would give no meaning to the modifier *vent* in the term. (D.I. 98 at 2-3; *see also, e.g.*, D.I. 101 at 3 (Plaintiffs suggesting that "any lumen through which air flows" could be a "vent lumen")) That construction, HyperBranch asserts, is one that would apply to *any* lumen—but here, the term that the patentees chose for their claims, and the term that needs to be construed, is "*vent* lumen[.]" (Tr. at 33; *see also* D.I. 79 at 5) The Court agrees that the construction for "vent lumen" must give meaning to all of the words in that term, including the word "vent"; therefore, the term must mean more than merely "a passageway for air or fluid." *Cf. Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) ("Allowing a patentee to argue that physical structures and characteristics specifically described in a claim are merely

superfluous would render the scope of the patent ambiguous, leaving examiners and the public to guess about which claim language the drafter deems necessary to his claimed invention and which language is merely superfluous, nonlimiting elaboration. For that reason, claims are interpreted with an eye toward giving effect to all terms in the claim.").

Plaintiffs respond by arguing that their proposal does not ignore "vent"—instead, they claim that their proposal "recognizes that a 'vent lumen' is simply a passageway that allows air or fluid *to flow to equalize pressure*." (D.I. 101 at 2 (emphasis added); *see also* Tr. at 73 ("All that you need for a vent lumen is [a] passageway for . . . where [fluid] will be able to . . . go to equalize."); *id.* ("The vent lumen has to be one which is going to allow fluid or air to go through it, to be able to equalize it."); *id.* at 74; *id.* at 76 ("[A vent] just allows the pressure to dissipate as you go along one side."); *id.* at 81 ("[W]hat it means to vent is to allow [the air/fluid] to move from the high pressure down to the lower pressure by the fluid flow[.]") Yet there are at least two problems with Plaintiffs' position.

One problem is that there is nothing in the actual language of Plaintiffs' proposed construction that reflects this notion of "equalizing pressure." (*See* Tr. at 97-98) When pressed about this during the *Markman* hearing, Plaintiffs' counsel argued that it was unnecessary to include language getting to what "vent" means in their proposed construction, because "[i]n the law of physics, that's the way it's going to work . . . . [the air/fluid is] going to flow through, and a person of ordinary skill in the art would know that." (*Id.* at 77) In light of this, Plaintiffs contend, "[a]ny passageway for air or fluid would amount to [one that equalizes pressure in this way]." (*Id.*) But this does not seem particularly persuasive. The patents describe different lumens that each constitute passageways for air or fluid. For example, claim 1 of the '946 patent recites, in addition to the "vent lumen[,]" "a first lumen configured for fluid communication with

the first source of component, a second lumen configured for fluid communication with the second source of component, and a third lumen configured for fluid communication with the source of pressurized air[.]" ('946 patent, col. 6:36-40; *see also id.* at col. 3:35-51 (the specification discussing an embodiment that contains, in addition to the "vent lumen," the "first and second component lumen" as well as an "air lumen")) According to Plaintiffs' explanation, all of these lumens would constitute vent lumens. Yet that does not seem like the correct outcome, in light of the fact that there is a separately claimed lumen called a "*vent lumen*" that is also part of the invention. (*See* HyperBranch's Markman Presentation, Slides 222-23)

Second, there is no real support for Plaintiffs' "equalizing pressure" rationale in the record. In support of this argument, Plaintiffs cite to three paragraphs from the declaration of their expert, Dr. Bruce Kent Gale. (D.I. 101 at 2 (citing D.I. 102 at ¶¶ 3-5)) The key paragraph seems to be paragraph 5 (as paragraph 3 does not mention anything about pressure, and paragraph 4 asserts Dr. Gale's opinion as to why HyperBranch's construction is wrong). In Paragraph 5, Dr. Gale asserts that an "air lumen" can be a "vent lumen[,]"[2] opining that:

> I disagree with HyperBranch's and [its expert] Dr. Hattan's contention that an "air lumen" cannot be a "vent lumen." In my opinion, a POSITA understands that a lumen would allow air or fluid to flow therein in either direction in the spray assembly depending on whether the pressure was higher on the supply side or on the tip end. This concept is illustrated in the . . . figure below. If the pressure is higher at the supply side than at the tip end, then air would flow through the lumen to the tip. If the pressure is higher at the tip end than at the supply side, then air would flow back through the lumen from the tip and thus vent.

(D.I. 102 at ¶ 5) The figure referenced in this paragraph is below:

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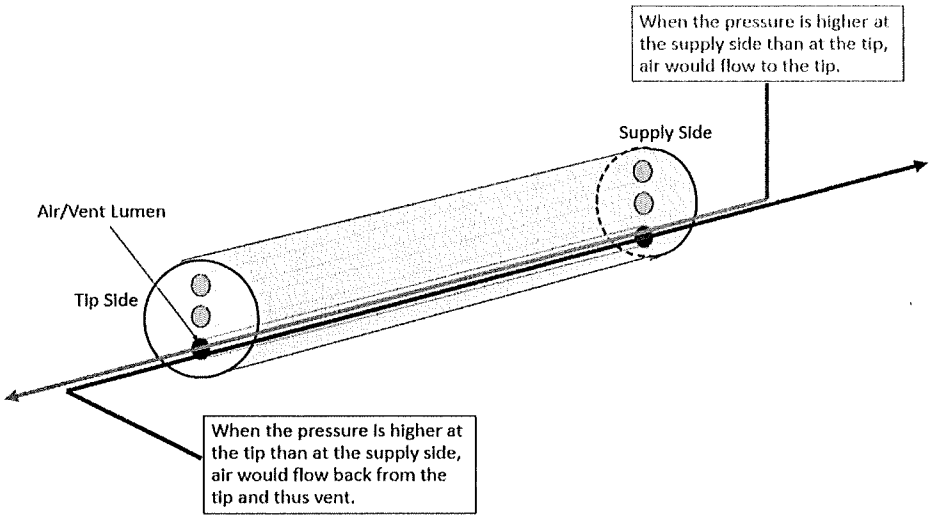
[2] This particular dispute between the parties will be addressed in further detail shortly.



Yet Dr. Gale's explanation here is not robust, and in it, he never uses the phrase "equalizing pressure"—i.e., he does not, for instance, explicitly opine that a "vent lumen" is "a passageway that allows air or fluid to flow to equalize pressure." Rather, instead of giving meaning to the term "vent" in "vent lumen," Dr. Gale's opinion seems to suggest that any lumen is a vent lumen—merely a passageway that allows fluids or air to flow in either direction.

In a later paragraph in his report (one regarding a prior art reference known as Maslanka that will be discussed further below), Dr. Gale also suggests that a "vent lumen" is something found only in an "air assist sprayer[,]" though he does not provide further explanation as to why this is so. (*Id.* at ¶ 7) During the *Markman* hearing, Plaintiffs' counsel argued that "in order to have a vent lumen, you have to have either an air [or] fluid assisted sprayer. . . . a vent lumen is necessary in an air assisted sprayer to vent the air that's being provided to dispense the combination of the components." (Tr. at 80-82; *id.* at 89 (Plaintiffs' counsel reiterating their view that Maslanka lacks a vent lumen because "Maslanka was not [an] air assisted [sprayer] . . . and [accordingly] there was no reason to be able to vent the air to equalize the pressure"); *id.* at 92) From Plaintiffs' evolving arguments, then, a "vent lumen" seems to be any lumen in an air-

assisted sprayer in which fluid or air flows through, thus "equaliz[ing] pressure" and "vent[ing] the air that's being provided to dispense the combination of the components." But again, Plaintiffs point to little in the record to support such a proposal. And that lack of record support renders Plaintiffs' proposal a black hole—one that injects uncertainty into the claim construction process. (*See, e.g.*, Tr. at 93, 95 (HyperBranch's counsel asserting that he "really do[es not] know what [Plaintiff] means [by equalizing pressure]. . . . When they are talking about equalizing pressure, I have no idea what that means because equalizing what? . . . [E]qualize has a connotation of you're going to allow the pressure in one thing to come to the same pressure."))

For all of these reasons, the Court is not persuaded that the first portion of Plaintiffs' proposed construction for "vent lumen"—"a passageway for air or fluid"—sufficiently conveys what a vent lumen actually is. And so it will adopt no part of Plaintiffs' proposed construction for this term.

2. HyperBranch's Proposed Construction

The question remains, then: "What does it mean to be a *vent* lumen?" The patent does not provide an explicit definition of the term. HyperBranch's expert, Mr. Paul Hattan, explains that the phrase "'vent lumen' is not a specialized term of art with an accepted, well-understood meaning and definition unto itself." (D.I. 80 at ¶ 23) Thus, to discern the meaning of "vent lumen[,]" the person of ordinary skill in the art would need to turn to other aspects of the intrinsic evidence. *See, e.g.*, *Sealant Sys. Int'l, Inc. v. Tek Global, S.R.L.*, 616 F. App'x 987, 993 (Fed. Cir. 2015) (explaining that where the meaning of a claim term is not clear and well-defined, recourse to the specification is necessary); *Astellas Pharma Inc. v. Actavis Elizabeth LLC*, Civil Action No. 16-905-JFB-CJB, 2018 WL 4776372, at *11 (D. Del. June 18, 2018). Below, the Court will assess each part of HyperBranch's proposed construction—"[A]

passageway or cavity within a hollow body designed to release or discharge excess gas pressure at a surgical site to the open atmosphere by providing fluid communication between at least two external openings. An 'air lumen' is not a 'vent lumen.'"—in light of that evidence and the parties' arguments.

There is no dispute that a lumen is a "passageway[,]" as Plaintiffs' proposed construction utilizes that same word. (*See* D.I. 79 at 3 (HyperBranch noting that "[t]he parties generally agree that a 'lumen' is a passageway within which air or fluids are permitted to flow"); Tr. at 36)[3] As for the next portion of HyperBranch's proposal—the "within a hollow body" language—the Court is not persuaded that it is necessary. In its briefing, HyperBranch did not expressly address why this language should be part of the construction for "vent lumen." (D.I. 79 at 3-6; D.I. 98 at 2-4)[4] With the plain language of the claims already specifying that the vent lumen is included in the elongated member/portion element of the spray assembly between the inner shaft and outer sleeve (as explained above), it is not clear why this language is needed. (*See* D.I. 81 at 4; D.I. 101 at 1; Tr. at 69)

The Court next turns to the portion of HyperBranch's proposal that reads: "by providing fluid communication between at least two external openings." This portion provides meaning to the modifier "vent" in the term "vent lumen." As HyperBranch explains it:

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[3] It is not clear what the "or cavity" portion of HyperBranch's proposal adds or why it is necessary, and therefore the Court omits it from the Court's recommended construction.

[4] During the *Markman* hearing, HyperBranch's counsel explained that the "within a hollow body" language was added to make clear that the vent lumen must be "on the inside of whatever the hollow body is." (Tr. at 36) HyperBranch's counsel asserted that Plaintiffs had previously argued in opposition to a motion to dismiss that a lumen could be a passageway located outside of the hollow body. (*Id.*; *see also* D.I. 16 at 10-11) But with surrounding claim language specifying just where the vent lumen is, the Court is not sure that there is a need for this language in the final construction.

> [F]or a lumen to be a "vent lumen," it must facilitate venting by the claimed spray assembly . . . . To enable this venting functionality, the vent lumen must connect at least two separated vent openings on the spray assembly[.]

(D.I. 79 at 3; *see also* D.I. 98 at 4; Tr. at 37)

This portion of HyperBranch's construction is also supported by the specification. To that end, the specification of the Family 2 patents explains that:

> [E]longated body portion **30** of spray assembly **10** includes an inner multi-lumen shaft **40**, an outer sleeve **50** . . . surrounding inner shaft **40** . . . . Inner shaft **40** and outer sleeve **50** are securely affixed to Y-connector **20** and include a *vent lumen* **46** . . . therebetween. Outer sleeve **50** includes a proximal vent or opening **52a** . . . and a plurality of distal vents or openings **52b** . . . . Proximal and distal vents **52a**, **52b** may be of any number, size, configuration and arrangement. *Distal vents **52b** are in fluid communication with proximal vent **52a** via vent lumen **46.***

('946 patent, col. 3:35-48 (emphasis added); *see also* FIGS. 3, 4, 6) As HyperBranch notes, "it is this connection between two or more separated vent openings that makes a lumen a vent lumen." (D.I. 79 at 3; *see also* D.I. 98 at 4; Tr. at 37-38 ("We look at the intrinsic record and we [see] that the vent lumen is connecting external openings or vents so that it can perform a venting function, and that's exactly what we have from the specification."); HyperBranch's Markman Presentation, Slide 31)

Moreover, HyperBranch points out that this characteristic of the vent lumen is supported by the commonly understood meaning of "vent. The verb "vent" means "[t]o release or discharge (steam, for example) through an opening" and the noun "vent" means "[a]n opening permitting the escape of fumes, a liquid, a gas, or steam." (D.I. 80 at ¶ 25 (citing *id.*, ex. 2 at 1981); Tr. at 36-37)

Plaintiffs retort that it would be error to require a vent lumen to provide fluid communication between two external openings since the claims do not explicitly recite such external openings. (D.I. 101 at 1 ("[T]hese extra openings, *i.e.*, vents 52a and 52b, are *not* recited in the claims—they are truly 'extra.'") (emphasis in original); Tr. at 71 (Plaintiffs' counsel arguing that if the patentees "wanted to claim the vent lumen as having openings, . . . they could have done that. [But] [t]hey claimed it more broadly and just claimed vent lumen itself requiring only that passageway that goes through there."); Tr. at 78) It is of course true that, while claim terms are to be interpreted in light of the specification, "it does not follow that limitations from the specification may be read into the claims." *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998) (internal quotation marks and citations omitted). The Federal Circuit has recognized that there is "sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification." *Id.*

Here, in concluding that the construction for "vent lumen" requires that it provide fluid communication between external openings, the Court believes that it is firmly on the former side of the line. After all, the construction must give meaning to the term "vent" in "vent lumen." And the little guidance that the specification offers regarding the meaning thereof indicates that the "vent lumen" amounts to a passageway that provides fluid communication between at least two external openings. *See E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988) ("It is entirely proper to use the specification to interpret what the patentee meant by a word or phrase in the claim.").[5] Thus, the

[5] The Court recognizes that certain dependent claims of the '468 patent recite certain types of such external openings. (*See, e.g.*, '468 patent, col. 6:59-61 (dependent claim 6

Court agrees with HyperBranch that the intrinsic record supports the inclusion of this part of HyperBranch's construction.[6]

Next, the Court turns to the portion of HyperBranch's proposed construction that reads: "designed to release or discharge excess gas pressure at a surgical site to the open atmosphere." HyperBranch argues that based on the specification's description of the "vent lumen," "a person of ordinary skill would recognize that in use, pressurized gas in the patient's body cavity would flow through the vent openings on the distal end of the applicator, through the vent lumen, and be released to the atmosphere through the proximal vent opening." (D.I. 79 at 3-4)

In support, HyperBranch cites first to the declaration of its expert, Mr. Hattan. Mr. Hattan, in turn, cites to a prior art United States Patent Application Publication (No. US 2006/0189944 A1) ("Campbell"), which discloses "a sprayer . . . for applying a biocompatible coating in situ[.]" (D.I. 80 at ¶ 27 & ex. 3) Mr. Hattan explains that the Campbell reference

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reciting "[t]he spray assembly of claim **1**, wherein the outer sleeve includes at least one lateral opening in a proximal end thereof and at least one lateral opening in a distal end thereof"); *see also id.*, col. 7:16-18) Plaintiffs did not point to these claims in support of their arguments regarding this term. And in the Court's view, these dependent claims do not render the construction here incorrect, because they specify a "lateral" opening whereas HyperBranch's construction here does not speak to the form of the opening.

[6] HyperBranch also relied on portions of the prosecution history in order to support its construction. During prosecution of the '468 patent, the applicants made certain arguments to distinguish their claims from a German patent, Maslanka. (*See* D.I. 79 at 4) HyperBranch contends that certain statements made by the applicants help demonstrate that its construction for "vent lumen" is the correct one; it argues that the applicants confirmed to the Examiner that Maslanka did not include a "vent lumen" and, in doing so, stated that a vent lumen as claimed by the asserted patents must "provid[e] fluid communication between at least two external openings." However, the Court is not relying on this line of argument here. This is because while it is clear from this portion of the prosecution history that the applicants did not view Maslanka as disclosing a "vent lumen," it is not clear enough to the Court *why* the applicants thought that. (*See* Tr. at 57-58 (HyperBranch's counsel acknowledging that the applicant's statement distinguishing Maslanka from the claimed vent opening is "a naked statement"))

supports a POSITA's understanding of "vent lumen," as the reference explains that because the sprayer employed a pressurized gas to atomize and deposit the crosslinkable solution, "'a vent system must be provided to prevent excessive distension of the tissue cavity.'" (D.I. 80 at ¶ 27 (quoting *id.*, ex. 3 at [0058])) The Campbell sprayer thus described "distal vent holes 86 that were in fluid communication with proximal vent holes 88 through the bore 87 of the elongated barrel, which 'permitted excess gas pressure to be vented from the tissue cavity through the sprayer.'" (*Id.* (quoting *id.*, ex. 3 at [0058])) From there, Mr. Hattan opines that the "vent lumen" disclosed in the Family 2 patents similarly transports pressurized gas from the distal end of the sprayer towards the proximal end. (*Id.* at ¶ 28; *see also* HyperBranch's Markman Presentation, Slide 32; Tr. at 39 (HyperBranch's counsel noting that "[Campbell] is a primary reference one of ordinary skill in the art would look at and say, okay. That's what a vent is in the context of these types of inventions"))

HyperBranch also appears to draw this language from the patent's description of another type of lumen disclosed in certain of the asserted patents: the "air lumen." The air lumen and the vent lumen are depicted separately in the Figures of the patent, as demonstrated in Figure 6 of the '453 patent below (with item 46 representing the vent lumen and item 47 representing the air lumen):

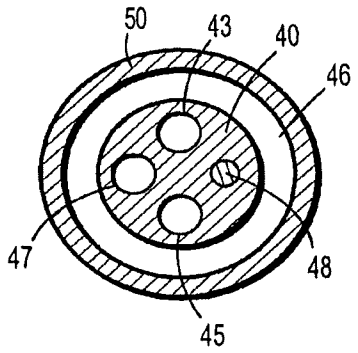

FIG. 6

('453 patent, FIG. 6) HyperBranch argues that an air lumen and a vent lumen are "two different things. They [have] two different purposes and they're described differently." (Tr. at 35; *see also* D.I. 79 at 4) In support, HyperBranch notes that the '453 patent describes, on the one hand, the air lumen as transporting pressurized gas from the proximal end of the applicator to the distal tip opening into a patient's body cavity. (D.I. 79 at 4; D.I. 98 at 4; '453 patent, col. 5:10-14 & FIGS. 3-8)[7] According to HyperBranch, a "vent lumen," on the other hand, must therefore be designed to transport gas in the opposite direction, (D.I. 79 at 4)—from the surgical site (the distal end) to the open atmosphere (the proximal end).

Plaintiffs respond that it would be error to improperly add the functional requirement that the vent lumen must be "designed to release or discharge excess gas pressure at a surgical site to

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[7] Specifically with respect to the "air lumen," the '453 patent explains that:

> The air flows into air channel **27** and through air lumen **47** formed in inner shaft **47**. The first and second components and the air provided through Y-connector **20** exit first and second lumen **43**, **45**, and air lumen **47**, respectively, at distal end **40***b* (FIG. **3**) of inner shaft **40.**

('453 patent, col. 5:10-14)

the open atmosphere." (D.I. 81 at 4; D.I. 101 at 2) They note that the claims do not recite such a function, or explicitly require any fluid connection to the open atmosphere. (D.I. 101 at 2)

In the end, the Court is not persuaded that HyperBranch's proposal here should be included in the construction. The intrinsic record itself does not expressly describe the vent lumen's purpose in a way that is related to this limitation; thus, it would be improper to make this language a claim requirement. *See, e.g.*, *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1367 (Fed. Cir. 2001) ("Where the function is not recited in the claim itself by the patentee, we do not import such a limitation."); *W.L. Gore & Assoc., Inc. v. Medtronic, Inc.*, 834 F. Supp. 2d 465, 472 (E.D. Va. 2011) ("Because the claim language, the specification, and the prosecution history make no mention of one particular function for the 'stent' used in the intraluminal stent graft, this Court will not import a functional limitation into its construction of the term."). Moreover, the Court is hesitant to define "vent lumen" based in significant part on how *another type of lumen* (an air lumen) is described by the patent. For all of these reasons, the Court will reject this portion of HyperBranch's proposed construction.

Lastly, with respect to the language in HyperBranch's construction noting that "[a]n 'air lumen' is not a 'vent lumen[,]'" the Court understands that there is a dispute between the parties as to whether an air lumen can ever be a vent lumen. (*See, e.g.*, D.I. 101 at 3 ("Finally, HyperBranch's proposed negative definition that an 'air lumen' is not a 'vent lumen' is simply wrong.")) And the Court agrees that, as discussed above, the patents suggest that these two types of lumens are not identical. With that said, the Court declines to include in the construction of one term ("vent lumen") a statement about what that term is not (an "air lumen"). As a general matter, that is not good claim construction practice. *See Meds. Co. v. Mylan, Inc.*, 853 F.3d 1296, 1308 (Fed. Cir. 2017) (noting that there is no per se rule against negative constructions but

agreeing that the patentee's argument "carrie[d] some force" when the patentee criticized a lower court's construction, which had defined "efficient mixing" as what the term is not).

For the reasons discussed above, the Court recommends that "vent lumen" be construed to mean "a passageway for air or fluid that provides fluid communication between at least two external openings."

B. "inner shaft defines/defining . . ."

The asserted claims of the '468 patent recite "'the inner shaft defines at least a first lumen configured for fluid communication with the first source of component and a second lumen configured for fluid communication with the second source of component.'" (*See* D.I. 81 at 5) The asserted claims of the '946 patent recite "'the inner shaft defining a first lumen configured for fluid communication with the first source of component, a second lumen configured for fluid communication with the second source of component, and a third lumen configured for fluid communication with the source of pressurized air[.]'" (*Id.*) The use of these disputed terms in claim 1 of the '468 patent and claim 1 of the '946 patent, respectively, is representative. For ease of reference, these claims are reproduced again below, with the disputed terms highlighted:

> **1.** A spray assembly for dispensing a mixture, the assembly comprising:
>
> a connector configured for operable engagement with a first source of component and a second source of component;
>
> an elongated member operably connected to and extending distally from the connector, the elongated member including an inner shaft and an outer sleeve, and defining a vent lumen between the inner shaft and outer sleeve, *the inner shaft defines at least a first lumen configured for fluid communication with the first source of component and a second lumen configured for fluid communication with the second source of component*;

a tip operably connected to the connector, the tip including an opening and defining a mixing chamber between a distal end of the elongated member and the opening of the tip; and

an insert member configured to be received in the mixing chamber, the insert member defining at least one radially extending slot on a first end of the insert member and at least one radially extending slot on a second end of the insert member, each of the radially extending slots being configured to mix the first and second components prior to the combination exiting the opening in the tip.

('468 patent, col. 6:25-48 (emphasis added))

1. A spray assembly for dispensing a mixture, the spray assembly comprising:

a connector portion configured for operable engagement with a first source of component, a second source of component, and a source of pressurized air;

an elongated portion extending distally from the connector portion, the elongated portion including an inner shaft and an outer sleeve, the inner shaft and the outer sleeve defining a vent lumen therebetween, *the inner shaft defining a first lumen configured for fluid communication with the first source of component, a second lumen configured for fluid communication with the second source of component, and a third lumen configured for fluid communication with the source of pressurized air*;

a tip assembly operably connected to the elongated portion, the tip assembly defining an opening and a mixing chamber between a distal end of the elongated portion and the opening of the tip assembly; and

an insert member received in the mixing chamber, a distal end of the insert member defining an annular recess and at least one radially extending slot, the annular recess and the at least one radially extending slot operating to mix first and second components prior to a combination of first and second components exiting the opening in the tip assembly.

('946 patent, col. 6:27-51 (emphasis added))

The parties' competing proposed constructions for these terms are set out in the chart below:

Term	**Plaintiffs' Proposed Construction**	**Defendant's Proposed Construction**
"the inner shaft defines at least a first lumen configured for fluid communication with the first source of component and a second lumen configured for fluid communication with the second source of component" ('468 patent)	"structure containing lumens within an outer surface of the elongated body wherein one lumen is designed to permit flow of a first component from one portion of the spray assembly to another portion of the spray assembly and a second lumen is designed to permit flow of a second component from one portion of the spray assembly to another portion of the spray assembly"	"a single long, narrow body that defines at least two distinct passageways or cavities that are designed to be in fluid communication with a first and second source of component, respectively. A pair of conduits is not an inner shaft defining a first lumen and a second lumen."
"the inner shaft defining a first lumen configured for fluid communication with the first source of component, a second lumen configured for fluid communication with the second source of component, and a third lumen configured for fluid communication with the source of pressurized air" ('946 patent)	"structure containing lumens within an outer surface of the elongated body wherein one lumen is designed to permit flow of a first component from a first source of component to another portion of the spray assembly and a second lumen is designed to permit flow of a second component from a second source of component to another portion of the spray assembly and a third lumen is designed to permit flow of air from a source of pressurized air to another portion of the spray assembly"	"a single long, narrow body that defines at least three separate passageways or cavities that are designed to be in fluid communication with a first and second source of component and a source of pressurized air, respectively. A pair of conduits is not an inner shaft defining a first lumen, a second lumen and a third lumen."

(*See, e.g.*, D.I. 81 at 5-6)

The parties' primary dispute with respect to the "inner shaft defines/defining" terms is over the type of structure that satisfies these limitations. While HyperBranch asserts that these limitations require the claimed "inner shaft [to] be a single, multi-lumen shaft" (such as, for instance, one singular body with two lumens running down that body), (D.I. 98 at 5-6), Plaintiffs argue that a group of independent component and/or air lumens (such as, for example, a pair of separate conduits) could constitute the claimed "inner shaft" for the "inner shaft defines/defining" limitations, (D.I. 81 at 6-8; *see also* Tr. at 83).[8]

The below figures help to illustrate the parties' dispute. HyperBranch asserts that "inner shaft defines/defining" terms must resemble the first figure below (with the inner shaft 40 defining first and second lumens 43 and 45 and air lumen 47). ('468 patent, FIG. 6 & cols. 3:24-32) Plaintiffs, on the other hand, contend that these terms could more broadly encompass the second figure below, which is derived from the prior art reference Maslanka and which includes notations made by HyperBranch's expert (with the component conduits 14 and 16 themselves constituting an inner shaft for the "inner shaft defines/defining" limitations). (D.I. 80 at ¶ 30; *id.*, ex. 5 at FIG. 2)

[8] As reflected in the parties' proposed constructions, they also dispute whether an "inner shaft" is most appropriately defined as a "structure containing lumens" or a "single long, narrow body." The Court agrees with HyperBranch that the latter is most appropriate, and will explain why in more detail in connection with the next term to be addressed, "inner shaft."

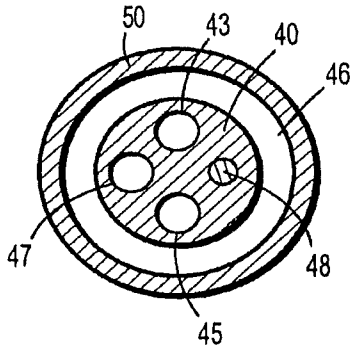
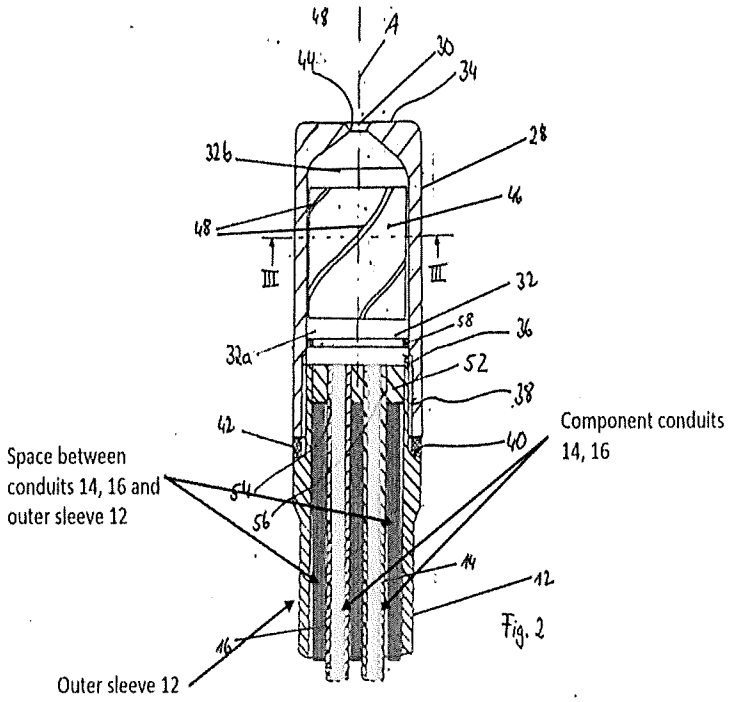


FIG. 6



The Court agrees with HyperBranch's position, which is fully supported by the intrinsic record. It so concludes for a number of reasons.

First, the claim language itself expressly tells us that "it is the inner shaft—not some other structural element or combination of elements—that *defines*" (1) "at least" two lumens configured for fluid communication with the first and second source of components in the '468 patent; or (2) three lumens configured for fluid communication with the first and second sources of components and a source of pressurized air, respectively, in the '946 patent. (D.I. 79 at 7 (emphasis in original)) A singular body (i.e., an inner shaft) with three lumens running through it (as depicted above in Figure 6) clearly constitutes an inner shaft defining those three lumens.

Plaintiffs retort that the claims do not say that the inner shaft "'*solely*' defines" or "'completely encloses'" the lumens, thus leaving open an embodiment whereby a pair of conduits each containing first and second components could together be the "inner shaft"

defining the lumens. (D.I. 101 at 4 (emphasis added); *see also* D.I. 81 at 6-7) However, as HyperBranch points out, the applicants knew how to claim lumens that were not defined solely by the inner shaft; they did so with regard to the "vent lumen," with the claims providing that the vent lumen is defined by the inner shaft and outer sleeve. (D.I. 79 at 7; HyperBranch's Markman Presentation, Slide 72) In contrast, the claim language "the inner shaft defines"/"the inner shaft defining," respectively, connotes a singular inner shaft that itself defines those lumens. (Tr. at 65 (HyperBranch's counsel explaining that these terms do not encompass "a pair of conduits. They [recite] *an inner shaft. That's not two separate things.* . . . It's one thing with two [or three] lumens inside of it"))

Second, the specification supports HyperBranch's proposed construction. As even Plaintiffs acknowledge, the only embodiment of the inner shaft described in the specification is a "singular solid structure having multiple lumens[.]" (D.I. 81 at 6; *see also* D.I. 101 at 4; D.I. 79 at 7) To that end, the specification discloses that "elongated body portion **30** of spray assembly **10** includes an *inner multi-lumen shaft **40***, an outer sleeve **50** (FIG. 6) surrounding inner shaft **40**." ('468 patent, col. 3:33-34 (certain emphasis added)) The specification further notes the "first and second component lumen **43**, **45** and an air lumen **47** (FIG. 6), respectively, *formed in inner multi-lumen shaft **40*** of elongated body portion **30**." (*Id.*, col. 3:29-32 (certain emphasis added)) And the figures of the patent, including the cross-sectional view of the outer sleeve shown in Figure 6 above, likewise depict an inner multi-lumen shaft 40 as a singular shaft contained within the outer sleeve, and which "defines and completely encloses several lumens,

including separate lumens for the first and second components and for pressurized air, respectively." (*See* D.I. 79 at 8)[9]

It is true that, as Plaintiffs point out, (D.I. 101 at 4), claims are generally not limited in scope to a preferred embodiment, *see, e.g.*, *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1370 (Fed. Cir. 2003). Nevertheless, claim terms must be construed in accordance with their ordinary meaning, unless the patentee demonstrated an intent to deviate from that meaning, such as by surrendering claim scope during prosecution. *Id.* at 1370-71. Here, as explained above, the claim language reciting *an* inner shaft that "defines" at least two component lumens directly contradicts Plaintiffs' notion that such an inner shaft "could actually consist of two or more separate, single-lumen conduits." (D.I. 98 at 6) And the content of the specification further supports the conclusion that Plaintiffs' construction cannot be correct.

Third, the Court agrees with HyperBranch that the applicants' statements during the prosecution history of the '468 patent "unequivocally establish[] that such separate conduits do not fall within the scope of these limitations." (*Id.*; *see also* D.I. 79 at 8-9) To that end, the original claims of the '468 patent did not include the "inner shaft defines/defining" language. Instead, the proposed independent claim recited, *inter alia*, "an elongated member operably connected to and extending distally from the connector, the elongated member including at least a first lumen configured for fluid communication with the first source of component and a

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[9] Plaintiffs retort that, nevertheless, persons of ordinary skill in the art would know that there are other embodiments of the invention in which a "group of independent component and/or air lumens is the 'inner shaft.'" (D.I. 81 at 6) In support, they cite to the boilerplate statement at the end of the patent specification stating that "the disclosure is not limited to [the] precise embodiments, and [] various other changes and modifications may be effected therein by one skilled in the art without departing from the scope or spirit of the disclosure." ('453 patent, col. 6:15-21 (cited in D.I. 81 at 6)) However, this statement alone cannot overcome all of the evidence supporting HyperBranch's position described herein.

second lumen configured for fluid communication with the second source of component[,]" and a proposed dependent claim further recited "wherein the elongated member includes an inner shaft and an outer shaft." (D.I. 99, ex. 1 at INT20000510-11) The Examiner rejected those claims over Maslanka, asserting that Maslanka "further shows the elongated member including an inner shaft (either of the tubes '14' or '16' defining the first and second lumens; see Figure 2) and an outer shaft (the outer shaft portion of '12'; see again, Figure 2)." (*Id.* at INT20000599)[10]

Subsequently, the applicants amended their claims to require that the "inner shaft defines at least" a first and second component lumen. (*Id.* at INT20000644 (certain emphasis omitted)) The applicants then distinguished Maslanka from the amended claims:

> [1] Clearly, the applicator of Maslanka does not include an elongated body having an inner shaft and outer sleeve and defining a vent lumen therebetween. [2] *Further, the applicator of Maslanka does not disclose an inner shaft defining first and second lumen.* [3] *Instead, as noted above, the applicator of Maslanka includes a pair of conduits.* [4] Further, despite the Examiner's assertion, the space between conduits 16 and the outer sleeve 12 does not define a vent lumen as claimed.

(*Id.* at INT20000651 (emphasis added)) With these statements, the applicants made it clear that an applicator with "a pair of conduits" does not constitute an applicator with "an inner shaft defining a first and second lumen." *See, e.g.*, *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1330 (Fed. Cir. 2007) ("Prosecution arguments . . . which draw distinctions between the patented invention and the prior art are useful for determining whether the patentee intended to surrender territory, since they indicate in the inventor's own words what the invention is not."). Thus, even were the Court wrong in its conclusion that the patent claims and

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[10] Earlier in this subsection, the Court inserted for reference a depiction of the relevant figure from Maslanka, with notations that were added by HyperBranch's expert. *See infra* at 20.

specification support HyperBranch's proposed construction, the prosecution history would demonstrate that the applicants disclaimed the claim scope that Plaintiffs are now trying to capture here.

Plaintiffs' attempt to downplay the import of this prosecution history is not persuasive. Their explanation is that when the applicants stated that the Maslanka applicator "does not disclose an inner shaft defining first and second lumen[,]" this related to the applicants' assertion that Maslanka did not teach the longer claim phrase referred to in the first sentence of argument reproduced above (i.e., "the applicator of Maslanka does not include an elongated body having an inner shaft and outer sleeve and defining a vent lumen therebetween"). (Tr. at 84-89) That is, according to Plaintiffs (and their expert Dr. Gale), applicants were here arguing that because Maslanka did not recite a "vent lumen[,]" "it couldn't have the inner shaft as claimed." (*Id.* at 85; *see also id.* at 87 ("If [Maslanka] didn't have a vent lumen, they are saying it didn't meet that . . . whole claim limitation"); *id.* at 89; D.I. 101 at 5; D.I. 102 at ¶ 12) But this is not a reasonable interpretation of the prosecution history. The second sentence of the applicants' argument (excerpted above), is saying something *different* than the first sentence (which does not refer to an "inner shaft defining" first and second lumens). This is clearly indicated by the sentence's use of the word "[f]urther": "*Further*, the applicator of Maslanka does not disclose an inner shaft defining first and second lumen." (D.I. 99, ex. 1 at INT20000651 (emphasis added)) And in the very next sentence (the third sentence of the excerpt), the applicants tell us *why* Maslanka does not disclose this additional limitation—because "[i]nstead . . . the applicator of Maslanka includes a pair of conduits." (*See* Tr. at 54) It is thus "plain as day" that in light of these statements, an applicator with a pair of conduits does not fall within the scope of an "inner shaft defining first and second lumen." (*Id.* at 58, 62)

For these reasons, the Court recommends that the "inner shaft defines/defining" terms be construed in a manner that is basically in line with HyperBranch's proposal, except that: (1) the Court omits the phrase "or cavities" from the construction, as the Court is unsure why this language is necessary or what it adds (as noted above in the Court's discussion of "vent lumen"); and (2) the Court declines to include the "A pair of conduits is not . . ." sentence—not because the sentence is inaccurate, but instead because (as noted above in the Court's discussion of "vent lumen") the Court does not wish to construe a term by describing what it is not. Accordingly, the Court recommends that "the inner shaft defines at least a first lumen configured for fluid communication with the first source of component and a second lumen configured for fluid communication with the second source of component" (as recited in the claims of the '468 patent) be construed to mean "a single long, narrow body that defines at least two distinct passageways that are designed to be in fluid communication with a first and second source of component, respectively." The Court recommends that "the inner shaft defining a first lumen configured for fluid communication with the first source of component, a second lumen configured for fluid communication with the second source of component, and a third lumen configured for fluid communication with the source of pressurized air" (as recited in the '946 patent) be construed to mean "a single long, narrow body that defines at least three separate passageways that are designed to be in fluid communication with a first and second source of component and a source of pressurized air, respectively."

C. "inner shaft"

The term "inner shaft" appears, *inter alia*, in claim 5 of the '478 patent and claim 5 of the '290 patent. Both claims recite the following:

> **5.** The spray assembly of claim **1**, wherein the elongated portion includes an inner shaft and an outer sleeve.

('478 patent, col. 6:64-65; '290 patent, col. 6:58-59) The parties' competing proposed constructions for the term are set out in the chart below:

Term	**Plaintiffs' Proposed Construction**	**Defendant's Proposed Construction**
"inner shaft"	"structure containing lumens within the outer sleeve"	"a long, narrow body contained within another distinct structure"

(*See* D.I. 81 at 5)

The parties have two disputes with respect to the construction of "inner shaft." First, their key dispute is over the meaning of the word "shaft": must it be a "long, narrow body" as HyperBranch proposes, or can it be any "structure containing lumens" as Plaintiffs propose? (D.I. 79 at 27; D.I. 81 at 7-8) Second, the parties also dispute how to define "inner," with HyperBranch interpreting it to mean "within another distinct structure" and Plaintiffs interpreting it to mean "within the outer sleeve." (D.I. 98 at 18 n.10; D.I. 101 at 3-4)

With respect to the meaning of "shaft," HyperBranch's proposed language ("a long, narrow body") reflects the plain and ordinary meaning of the word and is supported by the intrinsic record. The "inner shaft" is included in the elongated portion of the spray assembly, and HyperBranch's expert Mr. Hattan opines that in this context, the ordinary meaning of "shaft" is "a long, narrow body." (D.I. 80 at ¶ 100 (internal quotation marks and citation omitted); *see also* Tr. at 100)[11] In support, Mr. Hattan cites to a dictionary definition in which "shaft" is

[11] Indeed, several courts have found that the plain and ordinary meaning of "shaft" is similar. *See, e.g.*, *Neonatal Prod. Grp., Inc. v. Shields*, 276 F. Supp. 3d 1120, 1145 (D. Kan. 2017) (plain and ordinary meaning of "shaft" is something that is long, slender, and cylindrical); *CD3, Inc. v. Westminster, Inc.*, Civil Action No. 1:07-CV-013-LY, 2008 WL 11410040, at *9 (W.D. Tex. Sept. 25, 2008) ("'shaft'" is a "'slender' part"); *Traffix Devices, Inc. v. Bent Mfg.*

defined as "[t]he long, narrow stem or body of a spear or an arrow[.]" (D.I. 80 at ¶ 100 (citing *id.*, ex. 2 at 1656)) This definition is consistent with the specification, which depicts the inner shaft as a long, narrow body within the outer sleeve. (*See* '453 patent, FIGS. 3-8; D.I. 79 at 27; D.I. 98 at 18)

Plaintiffs' arguments to the contrary are not persuasive. In their opening brief, Plaintiffs assert that HyperBranch's "long or narrow" language would "import[] limitations into the construction *that are found nowhere in the specification or claims*[.]" (D.I. 81 at 7 (emphasis added)) Plaintiffs take a different course in their responsive brief, there acknowledging that the intrinsic record depicts the "inner shaft" as a long, narrow body, but asserting that the claims cannot be limited to such an embodiment. (D.I. 101 at 4 ("HyperBranch attempts to limit the claims to preferred embodiments by requiring the 'inner shaft' to be long, narrow, and a single body."); *see also* Plaintiffs' Markman Presentation, Slide 31) Tellingly, Plaintiffs never dispute that the ordinary meaning of shaft is "a long, narrow body[,]" nor do Plaintiffs attempt to argue that the ordinary meaning of "shaft" is, instead, "structure." HyperBranch, meanwhile, persuasively points out that using "structure" to define "shaft" would encompass objects such as spheres, cubes, thin disks, tetrahedra, etc. that would fall outside of the ordinary meaning of "shaft" and would thus effectively render the term "shaft" meaningless. (D.I. 79 at 27-28; D.I. 98 at 18; D.I. 80 at ¶ 103) In sum, HyperBranch's proposed construction for "shaft" reflects the

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Co., No. SACV 03-1569 JVS(ANx), 2005 WL 6287774, at *7 (C.D. Cal. Aug. 24, 2005) (shaft is a "long thin object or part") (internal quotation marks and citation omitted); *Knopik v. Amoco Corp.*, 96 F. Supp. 2d 892, 897-98 (D. Minn. 2000) (ordinary meaning of shaft is "generally a long hollow structure").

ordinary meaning of "shaft" in light of the intrinsic evidence from the perspective of a person of ordinary skill in the art.[12]

With respect to the parties' dispute over how the construction should convey that the shaft is an "*inner* shaft[,]" the Court finds that Plaintiffs' proposed language seems to most accurately capture the meaning of "inner shaft" in the context of these claims. It is undisputed that the "another distinct structure" that contains the inner shaft is the outer sleeve. (D.I. 101 at 3-4; D.I. 79 at 27 (HyperBranch explaining that "[t]he inner shaft (element 40) is depicted as a long narrow body within another distinct structure (*the outer sleeve*)" (emphasis added); Tr. at 90-91) In its briefing, HyperBranch simply asserts that its "within another distinct structure" language is superior because it "avoids a circularity problem in defining both the 'inner shaft' and 'outer sleeve' by reference to the other element." (D.I. 98 at 18 n.10) Yet HyperBranch's proposed construction for "outer sleeve" refers to the "inner shaft." (*Id.* at 19) During the *Markman* hearing, HyperBranch came forward with a different explanation for its proposal here, asserting that it takes issue with referring to "outer sleeve" in the construction of "inner shaft" because it has a problem with Plaintiffs' "construction of outer sleeve." (Tr. at 64) But the construction for "inner shaft" does not recite Plaintiffs' *construction* of "outer sleeve"—it simply refers to "outer sleeve."[13]

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[12] The Court also agrees with HyperBranch that there is no need to define "shaft" as "containing lumens[,]" because "other express language in the claims reciting an 'inner shaft' [already] provide[] which lumens need to be defined in whole or in part by the inner shaft, and adding 'containing lumens' to the definition of 'inner shaft' alone is unnecessary, redundant, and creates the potential for confusion." (D.I. 79 at 27)

[13] During the *Markman* hearing, HyperBranch also suggested that it would be "redundant[]" to include the "within the outer sleeve" language in the construction for "inner shaft," (Tr. at 64), but the Court does not agree. While it is undisputed that the "inner shaft" is contained "within the outer sleeve," the claim language itself does not explicitly state this. (*See,*

For the above reasons, the Court recommends that "inner shaft" be construed to mean "a long, narrow body contained within the outer sleeve."

III. CONCLUSION

For the foregoing reasons, the Court recommends that the District Court adopt the following constructions:

1. "vent lumen" should be construed to mean "a passageway for air or fluid that provides fluid communication between at least two external openings."

2. "the inner shaft defines at least a first lumen configured for fluid communication with the first source of component and a second lumen configured for fluid communication with the second source of component" (as recited in the claims of the '468 patent) should be construed to mean "a single long, narrow body that defines at least two distinct passageways that are designed to be in fluid communication with a first and second source of component, respectively" and "the inner shaft defining a first lumen configured for fluid communication with the first source of component, a second lumen configured for fluid communication with the second source of component, and a third lumen configured for fluid communication with the source of pressurized air" (as recited in the '946 patent) should be construed to mean "a single long, narrow body that defines at least three separate passageways that are designed to be in fluid communication with a first and second source of component and a source of pressurized air, respectively"

3. "inner shaft" should be construed to mean "a long, narrow body contained within the outer sleeve"

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e.g., '290 patent, col. 6:58-59 (dependent claim 5 reciting "[t]he spray assembly of claim **1**, wherein the elongated portion *includes an inner shaft and an outer sleeve*") (emphasis added))

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Dated: May 21, 2019

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE