

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CONFLUENT SURGICAL, INC.,
INTEGRA LIFESCIENCES
CORPORATION AND INTEGRA
LIFESCIENCES SALES LLC,

Plaintiffs,

v.

HYPERBRANCH MEDICAL
TECHNOLOGY, INC.,

Defendant.

Civil Action No. 17-688-LPS-CJB

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”), presently before the Court is the matter of claim construction. The Court recommends that the District Court adopt the conclusion set forth below.

I. BACKGROUND

Plaintiffs filed the instant case on June 6, 2017. (D.I. 1) The case was thereafter referred to the Court to hear and resolve all pretrial matters, up to and including case-dispositive motions. (D.I. 8)

In the currently-operative Amended Complaint, Plaintiffs are alleging that HyperBranch’s Adherus AutoSpray Dural Sealant product and Adherus AutoSpray Extended Tip (ET) Dural Sealant product (the “accused products”) infringe claims of seven patents-in-suit. (D.I. 40) The patents-in-suit relate to applicator assemblies for mixing components of, for example, a polymer or synthetic material for use in internal and external wound closure, and for

dispensing the resulting mixture of components for application, for example as a bioadhesive or tissue sealant. (*Id.* at ¶ 22)

The parties filed simultaneous opening claim construction briefs on August 14, 2018 and simultaneous responsive briefs on September 6, 2018. (D.I. 79; D.I. 81; D.I. 98; D.I. 101) The Court held a *Markman* hearing on October 5, 2018. (D.I. 120 (hereinafter, “Tr.”))

II. STANDARD OF REVIEW

It is well-understood that “[a] claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention.” *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989). Claim construction is a generally a question of law, although subsidiary fact finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015).

The Court should typically assign claim terms their ““ordinary and customary meaning[,]”” which is “the meaning that the term[s] would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (citations omitted). However, when determining the ordinary meaning of claim terms, the Court should not extract and isolate those terms from the context of the patent; rather it should endeavor to reflect their “meaning to the ordinary artisan after reading the entire patent.” *Id.* at 1321; *see also Eon Corp. IP Holdings LLC v. Silver Spring Networks, Inc.*, 815 F.3d 1314, 1320 (Fed. Cir. 2016).

In proceeding with claim construction, the Court should look first and foremost to the language of the claims themselves, because “[i]t 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*, 415 F.3d at 1312 (internal quotation marks and citations omitted). For example, the context in which a term is used in a claim may be “highly instructive.” *Id.* at 1314. In addition, “[o]ther claims of the patent in question, both asserted and unasserted, can . . . be valuable” in discerning the meaning of a particular claim term. *Id.* This is “[b]ecause claim terms are normally used consistently throughout the patent, [and so] the usage of a term in one claim can often illuminate the meaning of the same term in other claims.” *Id.* Moreover, “[d]ifferences among claims can also be a useful guide[,]” as when “the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15.

In addition to the words of the claims, the Court should look to other intrinsic evidence. For example, the Court should analyze the patent specification, which “may reveal a special definition given to a claim term . . . that differs from the meaning [that term] would otherwise possess” or may reveal an intentional disclaimer of claim scope. *Id.* at 1316. Even if the specification does not contain such revelations, it “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.” *Id.* at 1315 (internal quotation marks and citation omitted). That said, however, the specification “is not a substitute for, nor can it be used to rewrite, the chosen claim language.” *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). And a court should also consider the patent’s prosecution history, if it is in evidence, because it “can

often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution[.]”

Phillips, 415 F.3d at 1317.

Extrinsic evidence, “including expert and inventor testimony, dictionaries, and learned treatises[.]” can also “shed useful light on the relevant art[.]” *Id.* (internal quotation marks and citations omitted). Overall, while extrinsic evidence may be useful, it is “less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Id.* (internal quotation marks and citations omitted); accord *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 981 (Fed. Cir. 1995).

In utilizing these resources during claim construction, courts should keep in mind that “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

III. DISCUSSION

The parties currently have disputes regarding 15 terms or sets of terms (hereafter, “terms”). This Report and Recommendation addresses the first two terms: “dispensing a mixture” and “a system for mixing at least a first component and second component.” The other terms will be addressed in forthcoming Report and Recommendations.

The “dispensing a mixture” term appears in the preambles of the asserted claims of six of the patents; representative is claim 1 of United States Patent No. 8,210,453 (the “453 patent”). The “system for mixing” term appears in the preamble of claim 19 of United States Patent No. 8,033,483 (the “483 patent”). Claim 1 of the ‘453 patent reads as follows:

1. A spray assembly for *dispensing a mixture*, the assembly

comprising:

a connector configured for operable engagement with a first and second source of component and a source of pressurized fluid;

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

an elongated member extending between the connector and the tip, the elongated member including at least 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 fluid; and

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

('453 patent; col. 6:28-49 (emphasis added)) Claim 19 of the '483 patent reads:

19. *A system for mixing at least a first component and a second component, the system comprising:*

at least a first source of component and a second source of component;

a manifold configured for operable engagement with the at least first and second sources of component, the manifold including at least a first component channel and a second component channel therethrough;

an elongated shaft extending distally from the manifold, the elongated shaft including at least a first component lumen and a second component lumen extending the length thereof, the at least first and second component lumens in fluid communication with the at least first and second component channels;

a tip assembly defining a first chamber, an intermediate chamber and a final chamber, wherein the first chamber is configured to receive a distal end of the elongated shaft, the second chamber is

configured to receive an insert, and the final chamber is configured to receive the at partially mixed at least first and second components prior to the mixture being ejected from an outlet defined in the distal end of the tip assembly; and,

an insert received in the second chamber, the insert including a substantially cylindrical member having a recess formed in a distal end thereof.

('483 patent, cols. 6:57-8:3 (emphasis added))

Plaintiffs assert that these preambles are limiting, and that the “dispensing a mixture” term should be construed to mean “providing a combination of at least two reactive^[1] components in addition to any pressurized air or pressurized fluid” and that the “system for mixing” term should be construed to mean “a system for combining at least two reactive components[.]” (D.I. 81 at 27, 29) Defendant counters that the preambles are not limiting and that even if they are deemed limiting, these terms require no further construction. (*Id.*)

From what the Court can discern, the reason why these terms are in dispute has to do with a disagreement about whether the asserted claims should include a limitation requiring that the claimed assemblies or systems all must utilize two *reactive components*.² (Tr. at 30) Plaintiffs

¹ Plaintiffs’ originally-proposed construction did not include the word “reactive” for the “dispensing a mixture” term. During the *Markman* hearing, the Court questioned Plaintiffs’ counsel as to why this was so, in light of the fact (as is further set out herein) that the key dispute between the parties was as to whether the claimed inventions should include a requirement that the assembly or system at issue utilizes first and second components that are reactive components. (Tr. at 28) Plaintiffs’ counsel responded by stating that the intent of their proposed construction was to make it clear that the two components at issue must be reactive, and that they had no objection to the Court adding the word “reactive” to their proposed construction to make this explicit. (*Id.*)

² Plaintiffs had proposed that the “dispensing a mixture” term also include the limitation “in addition to any pressurized air or pressurized fluid” because they were concerned that Defendant would argue that air itself could qualify as a “component.” (Tr. at 10) Defendant’s counsel confirmed during the *Markman* hearing that Defendant would be taking no

argue that they should. (*Id.* at 7-8 (Plaintiffs’ counsel arguing that “[t]his is an important fundamental characteristic[] of the invention confirming that the mixture is not simply a mixture of any two components, but of two reactive components” and that “if the components or the mixture could be non-reacting inert things, there would be no need for specific structures in the claimed invention that maintain the separation between the first and second components until they are mixed together shortly before they’re actually applied”); *id.* at 13-14; D.I. 101 at 20) Defendant disagrees. (Tr. at 20 (Defendant’s counsel arguing that “[T]here’s no requirement . . . in the body . . . [that] the first and second components are reactive.”); *id.* at 23; D.I. 98 at 20)

With that in mind, the Court turns to the threshold dispute, which is over whether the preambles are limiting. The question of whether language in a preamble constitutes a claim limitation is a question of law. *Rotatable Techs. LLC v. Motorola Mobility LLC*, 567 F. App’x 941, 943 (Fed. Cir. 2014). “While it is true that preamble language is often treated as nonlimiting in nature, it is not unusual for [the United States Court of Appeals for the Federal Circuit] to treat preamble language as limiting[.]” *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 952 (Fed. Cir. 2006). Generally, “a preamble limits the invention if it recites essential structure or steps, or if it is necessary to give life, meaning and vitality to the claim.” *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (internal quotation marks and citation omitted); *see also Intellectual Ventures I LLC v. AT & T Mobility LLC*, C.A. No. 12-193-LPS, 2015 WL 1393386, at *24 (D. Del. Mar. 24, 2015). A preamble may also be construed as limiting when the claim limitations in the body of the claim “rely upon and derive antecedent basis from the preamble[.]” *Eaton Corp. v. Rockwell Int’l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir.

such position, (*id.* at 22, 31), and so the Court does not further comment on that portion of Plaintiffs’ proposed construction.

2003). On the other hand, when the claim body recites a structurally complete invention and the preamble language is used merely to state the purpose or intended use of the invention, the preamble is generally not treated as limiting the scope of the claim. *Catalina*, 289 F.3d at 808.³

There is some initial appeal to Plaintiffs' argument. For example, Plaintiffs argue that the reason why the claimed assemblies/systems are structured the way that they are—and why they reference a “first and [] second source of component[s]” or a “source of first component [and] a source of second component”—is because the patentee understood that the inventions would be utilizing two reactive components (and, as such, would need to be configured in such a way to keep these components separate until just before they are mixed and dispensed). Plaintiffs point in support to the Background section of the '453 patent, which explains that it relates to a “spray assembly for dispensing a mixture.” ('453 patent, col. 1:42) It further describes the types of “bioadhesives” that the patented invention might dispense, explaining that:

Most bioadhesives are composed of components that have a tendency to immediately activate and in some instances, rapidly polymerize when combined with one another. Because of this immediate activation and/or rapid polymerization of the bioadhesive, the components comprising the bioadhesive may not be combined until immediately prior to application.

(*Id.*, col. 1:28-34) Additionally, Plaintiffs point to the Abstract of the '483 patent, which states that the invention relates to an applicator assembly “for mixing at least a first and a second

³ There is no “litmus test” for determining whether preamble language is limiting. *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). Rather, whether such language is limiting is assessed in regard to “the facts of each case in light of the claim as a whole and the invention described in the patent.” *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 831 (Fed. Cir. 2003); *Catalina*, 289 F.3d at 808 (“Whether to treat a preamble as a limitation is a determination resolved only on review of the entire . . . patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim.”) (internal quotation marks and citation omitted).

component.” (’483 patent at 1) The Background section of that patent goes on to describe the nature of the components that both prior art devices and the patented invention can dispense, explaining that:

Because of the reactant nature of the components used to form the bioadhesive, mixing of the components does not occur until the solution is ready to be applied. Mixing of the components too soon before application may result in premature hardening of the mixture, thereby making application of the solution impossible.

(*Id.*, col. 1:22-27)

However, the Court ultimately agrees with Defendant that the preamble phrases at issue here should not be found to be limiting.

The Court comes to this conclusion because the bodies of the two representative claims at issue seem to be describing the structure of a spray assembly/system and do not seem to be claiming the nature of the components that happen to be utilized by that assembly/system. Instead, the claim bodies appear to recite a structurally complete invention (made up of certain connectors, tips, members, slots, manifolds, shafts, lumens, tip assemblies, etc.). (Tr. at 13 (Plaintiffs’ counsel acknowledging that the body of the claims recites a structurally complete invention)) In other words, even though the specification seems to suggest that the inventions at issue are structured the way they are so that they *could handle* two reactive components, the claims do not seem to be claims to the *actual components themselves*.⁴ (See Tr. at 24-25) They

⁴ In this way, this case differs from the situation in *Poly-America, L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1310 (Fed. Cir. 2004), a case cited by Plaintiffs. (D.I. 81 at 28; Tr. at 14, 26) In that case, the patent-at-issue had claims all drawn to an apparatus—a blown-film textured liner—and the dispute was over whether the preamble phrase “blown-film” was a substantive limitation in the patent’s claims. See *Poly-America, L.P.*, 383 F.3d at 1305, 1310. The Federal Circuit found that the preamble was limiting, in light of the content of the patent, which emphasized in different ways that the blown-film nature of the liner was an “important characteristic of the claimed invention.” *Id.* But at least in that case, the claims

seem instead to be drawn to certain structure that makes use of those components. *See, e.g., Catalina*, 289 F.3d at 809 (“[P]reambles describing the use of an invention generally do not limit the claims because the patentability of apparatus . . . claims depends on the claimed structure, not on the use or purpose of that structure.”).

This conclusion also seems to be underscored by the structure of claims 1 and 2 of one of the asserted patents, United States Patent No. 9,700,290 (the “290 patent”). Claim 1 of the '290 patent is to a “spray assembly for dispensing a mixture” that has certain pieces of structure (a connector portion, an elongated portion, a tip assembly, and an insert member), while claim 2 adds that the spray assembly of claim 1 further includes “a first component and a second component.” ('290 patent, col. 6:30-52) It seems incorrect to conclude that claim 1 of the '290 patent is limited to a spray assembly that utilizes two separate reactive components when claim 2 explicitly makes two separate components a part of the structure of the assembly.

For these reasons, the Court finds the preamble phrases at issue not to be limiting.

IV. CONCLUSION

For the foregoing reasons, the Court recommends that the District Court adopt the

themselves were about the physical structure of the liner and the disputed preamble phrase (“blown-film”) was itself a component of that structure. Here, in contrast, the claims are to the structure of an assembly/system, and yet Plaintiffs want to import into that structure a requirement not about an *aspect of that structure*, but instead about the *types of components* that structure may utilize.

The facts here also differ from *Poly-America* because there, *inter alia*, the “specification [was] replete with references to the invention as a ‘blown-film’ liner[,]” the title of the patent referred to a “blown-film liner[,]” and the “phrase [was] used repeatedly to describe the preferred embodiments[.]” *Id.* at 1310. Here, the “Summary” and “Detailed Description” sections of the specification make no reference to the components being reactive, and the patents are entitled either “Spray Applicator” or “Silicon Spray Tip” without any reference to the nature of the components that may be utilized by the inventions. (D.I. 72, exs. A-G)

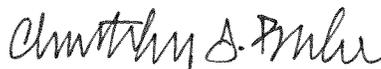
following conclusion:

1. The preamble phrases at issue are not limiting and thus no construction of the terms is necessary.

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: March 7, 2019



Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE