

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

INTEGRA LIFESCIENCES CORP.,)
 INTEGRA LIFESCIENCES SALES LLC,)
 CONFLUENT SURGICAL, INC., and)
 INCEPT LLC,)

Plaintiffs,)

v.)

Civil Action No. 15-819-LPS-CJB

HYPERBRANCH MEDICAL)
 TECHNOLOGY, INC.,)

Defendant.)

REPORT AND RECOMMENDATION

1. In this action filed by Plaintiffs Integra LifeSciences Corp., Integra LifeSciences Sales LLC, Confluent Surgical, Inc. and Incept LLC (collectively, “Plaintiffs” or “Integra”) against Defendant HyperBranch Medical Technology, Inc. (“HyperBranch” or “Defendant”), Plaintiffs allege infringement of a number of patents (collectively, the “patents-in-suit” or “asserted patents”), including United States Patent Nos. 8,535,705 (the “’5705 patent”) and 7,009,034 (the “’034 patent”). Presently before the Court is the question of whether the preambles from asserted claims 1, 6, 12 and 17 of the ’5705 patent and asserted claim 10 of the ’034 patent are limiting. (*See* D.I. 402 at 23-24; D.I. 443 at 27; D.I. 467 at 3 & n.1; D.I. 482 at 151 (hereinafter, “Tr.”))¹ For the reasons set out below, the Court recommends that the District

¹ The parties provided argument regarding this issue in the context of HyperBranch’s “Motion for Summary Judgment of Non-Infringement and Invalidity of the Patents-in-Suit,” in which HyperBranch moved for summary judgment with respect to various issues. (D.I. 393, 402) Quick disposition of this issue has been requested, as it may guide the parties as they undergo additional expert discovery and related inquiry into Plaintiffs’ “biocompatibility” theory. (*See* D.I. 467 at 3) Thus, this Report and Recommendation solely addresses the limited question of whether the preambles in these claims are limiting.

Court find that the preambles are limiting.

2. 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 claim “rely upon and derive antecedent basis from the preamble[.]” *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 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 no “litmus test” for determining whether preamble language is limiting. *Id.* 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); *see also 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).

4. Turning first to the '5705 patent, claim 1 of that patent recites:
 1. A method of making a biocompatible degradable hydrogel to treat a medical condition of a patient comprising:
identifying a medical condition for treatment by use of a hydrogel formed in situ in a patient and fully degradable in a patient in less than about 180 days; and
mixing a first precursor with a second precursor in situ in the patient to form the hydro gel for treatment of the medical condition, with the first biocompatible synthetic hydrophilic polymer precursor having a water solubility of at least 1 gram per 100 milliliters and comprising at least two electrophilic functional groups; and the second biocompatible synthetic hydrophilic polymer precursor comprising at least two nucleophilic amine functional groups; and wherein
 - (i) the first precursor is selected to have only one or two chemically hydrolytically degradable ester bonds per every electrophilic functional group on the first precursor; and
 - (ii) the second precursor comprises at least three nucleophilic functional groups;wherein the biodegradable groups of the hydrogel consist of the esters and the hydrogel as placed in situ in the patient is essentially fully degradable in a patient in less than about 180 days, and wherein mixing the first and the second synthetic hydrophilic polymer precursors forms crosslinking covalent bonds that are reaction products of the electrophilic and the nucleophilic groups, wherein essentially every ester bond in the hydrogel is separated from other ester bonds in the hydrogel by at least three covalent bonds when the hydrogel is formed.

('5705 patent, col. 30:34-65)²

5. HyperBranch argues that the preamble language of claim 1 of the '5705 patent (i.e., “[a] method of making a biocompatible degradable hydrogel to treat a medical condition of a patient comprising”) is non-limiting because it describes only an intended use, with the body of claim 1 itself defining a structurally complete invention. (D.I. 402 at 23) The claim body covers

² Claims 6, 12 and 17 of the '5705 patent depend from claim 1.

a “first precursor” and “second precursor” that are biocompatible, and according to HyperBranch, that is all that is required to satisfy the claim in terms of biocompatibility. (*Id.*) HyperBranch further asserts that the preamble is non-limiting because: (1) there is no antecedent basis in the preamble for any of the elements recited in the claim body; and (2) the preamble was not relied upon during prosecution to distinguish the invention over the prior art. (*Id.*) For its part, Integra argues that “a biocompatible hydrogel” in the preamble of claim 1 of the '5705 patent is an affirmative limitation because the references to “hydrogel” in the claim body refer back to the preamble, and because the biocompatibility of the hydrogel is a fundamental aspect of the inventions described in the patent. (*See* Integra’s Opposition to Defendant’s Summary Judgment of Invalidity Slide Presentation, Slide 11)

6. The Federal Circuit has explained that where language in the preamble recites additional structure underscored as important by the patent specification, the preamble may operate as a claim limitation. *Catalina*, 289 F.3d at 808; *see also, e.g., Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997) (explaining that to determine whether preamble language is a structural limitation, the court should “examin[e] the entire patent record to determine what invention the patentee intended to define and protect”). Here, the Court believes that the preamble’s reference to “a biocompatible . . . hydrogel” is in fact a reference to structure that the intrinsic record describes as being very important to the invention.³

7. For one, the title of the '5705 patent itself is “Biocompatible Polymers and Hydrogels and Methods of Use.” ('5705 patent at 1) Moreover, the remainder of the

³ The other language in the preamble recites aspects of the invention that are duplicative of language in the body of the claim.

specification repeatedly describes the invention as relating to “biocompatible crosslinked polymers.” For instance, the Abstract explains that “[b]iocompatible crosslinked polymers, and methods for their preparation and use, are disclosed[.]” (*Id.*) The “Field of the Invention” section of the patent notes that the invention relates to “biocompatible crosslinked polymers[.]” (*Id.*, col. 1:16-17) The “Summary of Invention” section also repeatedly notes that objects of the invention are to provide “biocompatible crosslinked polymers” and methods for their use. (*Id.*, col. 4:21-61) As yet another example, the “Detailed Description of the Invention” section of the patent begins by stating that “[t]he novel biocompatible crosslinked polymers of this invention are formed from the reaction of precursors having electrophilic and nucleophilic functional groups.” (*Id.*, col. 5:58-60)

8. In the context of this patent, biocompatible crosslinked polymers *are* biocompatible crosslinked hydrogels. HyperBranch itself confirms this. (*See, e.g.*, D.I. 94 at 5 (explaining, in opposing Integra’s motion for preliminary injunction, that the asserted patents are “directed to ‘[b]iocompatible cross-linked polymers’ (*i.e., hydrogels*) and methods for making them”) (emphasis added); *see also* D.I. 97 at ¶ 41 (HyperBranch’s expert Dr. Lowman describing the asserted patents as all disclosing “biocompatible cross-linked polymers or hydrogels and methods for making hydrogels”); D.I. 10, ex. 13 at ¶ 34 (Integra’s expert Dr. Mays explaining that the asserted patents “are directed to methods of making biocompatible polymer hydrogels”)) The specification of the related '034 patent also indicates that biocompatible crosslinked hydrogels are the same thing as biocompatible crosslinked polymers. It explains that “[s]everal *biocompatible crosslinked hydrogels* may be produced using the crosslinkers and functional polymers described in **FIGS. 1 to 5**. Preferred combinations of such polymers suitable for

producing *such biocompatible crosslinked polymers* are described in Table 2.” (’034 patent, col. 22:40-44 (emphasis added))

9. The intrinsic record makes it clear, then, that making a “biocompatible hydrogel” (by, *inter alia*, mixing a first and second biocompatible precursor) is an important feature of the invention. To hold otherwise would seem divorced from reality. The Court therefore recommends that the “biocompatible degradable hydrogel” language in the preamble of the asserted claims of the ’5705 patent be found to be a claim limitation.⁴ *See, e.g., Poly-Am., L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1310 (Fed. Cir. 2004) (concluding that “blown-film” in the preamble of a patent directed to a landfill liner was a claim limitation where the specification is replete with references to the invention as a “‘blown-film’ liner, including the title of the patent itself and the ‘Summary of the Invention[.]’ [t]he phrase is used repeatedly to describe the preferred embodiments, and the entire preamble ‘blown-film textured liner’ is restated in” every claim, thus demonstrating to the court that “the inventor considered that the ‘blown-film’ preamble language represented an important characteristic of the claimed invention”); *Rotatable Techs.*, 567 F. App’x at 943 (holding that “selectively rotating” in the preamble limited the claimed invention where, *inter alia*, the specification is replete with references to “selectively rotating,”—in the title, abstract, background of the invention, summary of the invention, description of the drawings, detailed description, and all independent claims—thereby

⁴ With respect to Integra’s suggestion that the term “biocompatible degradable hydrogel” provides antecedent basis for terms in the claim body and that this is evidence that the phrase is limiting, the Court finds this argument a bit less persuasive. The first limitation in the body of the claim recites “identifying a medical condition for treatment by use of a hydrogel[.]” and therefore “a hydrogel” in that recitation could be said to provide antecedent basis for the claim’s later recitations of “the hydrogel.” (*See, e.g., ’5705 patent*, col. 30:36-38, 40)

“underscoring the importance of the feature to the claimed invention”); *Script Sec. Sols. L.L.C. v. Amazon.com, Inc.*, No. 2:15-CV-1030-WCB, 2016 WL 3959804, at *6-7 (E.D. Tex. July 22, 2016) (holding that the reference to “portable security alarm system” in the preamble is limiting where “[p]ortability is a theme that runs throughout the [asserted] patent,” with the title and abstract referring to the system as “portable” and the specification repeatedly emphasizing the portability of the system, rendering it “evident that the patentees simply used the preamble as the vehicle for incorporating that requirement into the claims”) (Bryson, J., sitting by designation).⁵

10. Turning to the '034 patent, claim 1 of that patent, from which asserted claim 10 depends, recites:

1. A method of preparing a composition suitable to coat a tissue of a patient, the method comprising:
mixing reactive precursor species comprising nucleophilic functional groups, reactive precursor species comprising electrophilic functional groups, and a visualization agent such that the nucleophilic functional groups and electrophilic functional groups crosslink after contact with the tissue to form a hydrogel having an interior and an exterior, with the exterior having at least one substrate coating surface and the visualization agent being at least partially disposed within the interior and reflecting or emitting light at a wavelength detectable to a human eye to thereby provide a means for visualization of the coating by a human eye.

('034 patent, cols. 39:56-40:2)

⁵ It is true that Integra does not point to instances in the prosecution history where the patentees were distinguishing their invention from the prior art on the basis that it claimed biocompatible hydrogels. But that is not a prerequisite to a Court’s finding that a preamble contains a claim limitation. *See, e.g., Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1380 (Fed. Cir. 2001) (rejecting the plaintiff’s argument that the preamble phrase “correlated set” was not limiting, where the plaintiff argued that the limitation was irrelevant to patentability, and finding that the term was limiting because the specification described the invention as relating to a correlated set of irons and because the term appeared in the preamble of every claim; thus, the term did not simply refer to the prior art or to a possible use, but “describes and limits the invention being claimed”).

11. HyperBranch argues that the preamble language of this claim (i.e., “[a] method of preparing a composition suitable to coat a tissue of a patient, the method comprising”) is non-limiting because it describes only a purpose or intended use of the composition—“suitable to coat.” (D.I. 463 at 21) For its part, Integra argues that “suitable to coat a tissue of a patient” is an affirmative claim limitation describing a feature of the claimed composition, because the preamble serves as antecedent basis for at least the terms “the tissue” and “the coating.” (D.I. 443 at 27; Tr. at 135-36, 163) Furthermore, Integra asserts that in order to be “suitable to coat a tissue of a patient,” the claimed hydrogel must be biocompatible, (D.I. 443 at 27; Tr. at 136), with biocompatibility being a fundamental aspect of the invention, (*see* Integra’s Opposition to Defendant’s Summary Judgment of Invalidity Slide Presentation, Slide 19). This latter aspect of Integra’s argument (i.e., that “suitable to coat a tissue of a patient” means that the composition must be biocompatible) does not appear to be disputed by HyperBranch. (*See, e.g.*, D.I. 463 at 21-22 (arguing that even if the preamble is found to be limiting, there is no genuine issue of material fact that prior art reference Rhee teaches coating a surface of a synthetic implant and “*biocompatible* crosslinked polymers[,]” and that there is thus no dispute that the reference teaches the “preamble to claim 1” of the '034 patent) (emphasis in original))

12. The Court agrees with Integra—that the preamble of claim 1 of this patent is also limiting. It does so for two reasons.

13. First, just as with the '5705 patent above, the '034 patent makes clear that the invention disclosed therein is a *biocompatible* hydrogel and methods for its use. The title of the '034 patent is “Biocompatible Crosslinked Polymers”—i.e., biocompatible crosslinked hydrogels—and the Abstract and “Field of the Invention” section of the patent indicate that the

patent discloses “[b]iocompatible crosslinked polymers” and methods for their use. (’034 patent at 1 & col. 1:24-26) The “Background of the Invention” portion of the specification explains that “[h]ydrogels are especially useful for use in the body because they are more biocompatible than non-hydrogels and are thus better tolerated in the body.” (*Id.*, col. 1:52-54) The “Summary of the Invention” section of the specification repeatedly states that the “object” of the invention is to provide “biocompatible crosslinked polymers” and methods for their preparation and use. (*Id.*, col. 3:20-60) And the specification later explains that “[s]everal biocompatible crosslinked hydrogels may be produced using the crosslinkers and functional polymers described in **FIGS. 1 to 5**. Preferred combinations of such polymers suitable for producing such biocompatible crosslinked polymers are described in Table 2.” (*Id.*, col. 22:40-44) Thus, with it clear that the invention is indeed a method of preparing a biocompatible crosslinked hydrogel, the Court finds that “[a] composition suitable to coat a tissue of a patient”—i.e., a “biocompatible” composition—is a claim limitation.

14. Second, the Court agrees that the preamble language “suitable to coat a tissue of a patient” provides the necessary antecedent basis for the “the tissue” and “substrate coating surface” limitations in the body of the claim. This further demonstrates that the preamble language should be regarded as a claim limitation. *See, e.g., Catalina*, 289 F.3d at 808 (explaining that “dependence on a particular disputed preamble phrase for antecedent basis may limit claim scope because it indicates a reliance on both the preamble and claim body to define the claimed invention”); *see also Pacing Techs., LLC v. Garmin Int’l, Inc.*, 778 F.3d 1021, 1024 (Fed. Cir. 2015) (“Because the preamble terms ‘user’ and ‘repetitive motion pacing system’ provide antecedent basis for and are necessary to understand positive limitations in the body of

claims in the [asserted] patent, we hold that the preamble to [the claim] is limiting.”); *Proveris Sci. Corp. v. Innovasystems, Inc.*, 739 F.3d 1367, 1372-73 (Fed. Cir. 2014) (finding that the preamble, which recites an apparatus for producing image data representative of at least one sequential set of images of a spray plume, was a claim limitation, where the specification identified the invention as producing a “sequential set of images” and a phrase in the claim body clearly derived antecedent basis from the “‘image data’ that is defined in greater detail in the preamble”); *Script Sec. Sols.*, 2016 WL 3959804, at *7 n.2.

15. For the foregoing reasons, the Court recommends that the preambles of the asserted claims of the '5705 patent and the '034 patent be found to be limiting, in the manners described above.

16. 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: January 16, 2018



Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE