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,	:	C.A. No. 15-819-LPS-CJB
v.	:	
HYPERBRANCH MEDICAL TECHNOLOGY, INC.,	:	
Defendant.		

MEMORANDUM ORDER

WHEREAS, Magistrate Judge Burke issued a series of five Reports and Recommendations (D.I. 307, 310, 316, 317, 321), between July 27, 2017 and August 30, 2017, recommending that the Court adopt certain claim constructions for disputed terms in U.S. Patent Nos. 6,566,406; 7,009,034; 7,332,566; 7,592,418; 8,003,705; and 8,535,705;

WHEREAS, beginning on August 10, 2017, Plaintiffs Integra LifeSciences Corp., Integra LifeSciences Sales LLC, Confluent Surgical, Inc., and Incept LLC (collectively, "Integra") objected to the various Reports (D.I. 311, 315, 324, 325, 331), and specifically objected to the recommended constructions of the terms "visualization agent," "molecular weight," "small molecule," "precursor," "polymer composition," "the biodegradable groups consist of the esters," "chemical groups that are prone to aqueous hydrolysis," and "free of amino acid sequences of more than about four residues in number;"

WHEREAS, beginning on August 24, 2017, Defendant HyperBranch Medical

Technology, Inc. ("HyperBranch") responded to the various Integra objections (D.I. 319, 323, 335, 336, 342);

WHEREAS, the Court has considered the parties' claim construction disputes addressed by the Reports *de novo*, *see St. Clair Intellectual Prop. Consultants, Inc. v. Matsushita Elec. Indus. Co., Ltd.*, 691 F. Supp. 2d 538, 541-42 (D. Del. 2010); 28 U.S.C. § 636(b)(l); Fed. R. Civ. P. 72(b)(3);

NOW THEREFORE, IT IS HEREBY ORDERED that:

1. Integra's objections (D.I. 311, 315, 324, 325, 331) to Judge Burke's constructions of "visualization agent," "molecular weight," "small molecule," "precursor," "polymer composition," "the biodegradable groups consist of the esters," "chemical groups that are prone to aqueous hydrolysis," and "free of amino acid sequences of more than about four residues in number" are OVERRULED and the constructions set forth in Judge Burke's Reports are ADOPTED.[1]

2. Integra objects to the construction of "visualization agent,"[2] which Judge Burke recommended construing as "a substance or material that is detectable by the human eye and that imparts a color or obscures the optical clarity of the hydrogel." (D.I. 311 at 3; D.I. 307 at 23)

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[1]HyperBranch repeatedly faults Integra for recycling the same arguments it made (unsuccessfully) to Judge Burke. (*See, e.g.*, D.I. 319 at 1, 5, 8; D.I. 323 at 1, 8-9; D.I. 335 at 1-2; D.I. 336 at 1-2, 4; D.I. 342 at 1, 4) This is not a basis for overruling Integra's objections. "To the contrary, with limited (if any) exception, parties objecting to a Magistrate Judge's report or order are required to adhere to the arguments, evidence, and issues they presented first to the Magistrate Judge. Far from being inappropriate, rehashing is exactly what parties are expected to do." *Masimo Corp. v. Philips Elec. N. Am. Corp.*, 62 F. Supp. 3d 368, 377 (2014).

[2]This term appears in the following asserted claims: claims 1 and 16 of the '034 patent, claims 1, 4, 12, 15, 16, and 25 of the '566 patent, and claims 1 and 23 of the '418 patent.

Integra disputes three parts of Judge Burke's construction: (1) that a "visualization agent" must be a "substance or material;" (2) that it must "impart[] a color or obscure[] the optical clarity of the hydrogel;" and (3) that it does not encompass "air or air bubbles alone." (D.I. 311 at 1) Integra contends that the Court should instead adopt its proposed construction of "an agent that is detectable by the human eye." (*Id.*)

Integra asserts that Judge Burke erred principally by importing extraneous limitations from the preferred embodiments – the requirements that the agent be a substance or material and that it impart a color or obscure the optical clarity of the hydrogel – into his recommended construction. (*Id.* at 3) According to Integra, the term "visualization agent" is commonly understood in the industry, and should be construed to have its plain and ordinary meaning without the added limitations stemming from preferred embodiments in the specification. (*Id.* at 3-4) The Court agrees, however, with Judge Burke, who explained: "Plaintiffs do not cite anything in support of that assertion. Meanwhile, Defendant's expert, Dr. Anthony Lowman, has opined to the contrary that 'visualization agent' is 'not a technical term with an understood definition amongst those skilled in the art' but instead 'was crafted by Plaintiffs specifically for the purpose of the Asserted Patents – it has no accepted plain and ordinary meaning to one of ordinary skill in the art outside of how the term has been used with the patents.'" (D.I. 307 at 10) Therefore, Integra's reliance on *EPOS Techs., Ltd. v. Pegasus Techs. Ltd.*, 766 F.3d 1338, 1343 (Fed. Cir. 2014), is misplaced, as the disputed term does not have an accepted ordinary meaning to a person of skill in the art. *See generally Goldenberg v. Cytogen, Inc.*, 373 F.3d 1158, 1164 (Fed. Cir. 2004) ("Where a claim term has no ordinary and customary meaning, a court must resort to the remaining intrinsic evidence – the written description and the prosecution history –

to obtain the meaning of that term.").

The intrinsic evidence makes clear that the "visualization agent" is intended to impact the color or obscure the clarity of a hydrogel. *See, e.g.,* '566 patent at 2:4-10 (describing problem in prior art of "essentially colorless" hydrogels that are "difficult to visualize"); *id.* at 2:18-25 ("The present inventors have realized that use of color in biocompatible crosslinked polymers and precursors greatly improves their performance in a surgical environment . . . . Moreover, the better visibility available with the use of color also permits efficient use of materials and avoids waste."); *id.* at 7:21-25 ("The user may apply the hydrogel to a test surface with a color that resembles the surface that the user contemplates using and observe the color that results when the hydrogel reaches a desired thickness that the user has predetermined. In use the user applies the hydrogel until the desired color is reached."); *id.* at 7:28-36 ("One embodiment is to introduce a concentration of visualization agent into the hydrogel so that the user applies the hydrogel until the microvasculature is no longer visible through the hydrogel . . . . Another suitable method is to apply the hydrogel until the underlying tissue is obscured."); *id.* at 7:56-57 ("A visually observable visualization agent is an agent that has a color detectable by a human eye."). In fact, the specification contains a section titled "Visualization Agents," in which the term is described as being "especially useful when used in [minimally invasive surgical] procedures, due among other reasons to their improved visibility ***on a color monitor***." *Id.* at 10:50-53 (emphasis added); *see also id.* at 10:53-63 (describing that blue and green visualization agents are preferred over red, unless "the underlying tissue is white, for example the cornea").

Similarly, the specification refers to a "visualization agent" as a substance or material. *See, e.g.,* '566 patent at 10:53-57 ("Visualization agents may be selected from among any of the

various non-toxic colored ***substances*** suitable for use in [] implantable medical devices.") (emphasis added). Integra acknowledges that embodiments disclosed in the specification "include agents that are considered to be substances or materials." (D.I. 311 at 4) Integra's contention that Judge Burke's construction improperly limits the scope of the claims to the preferred embodiments is unavailing here, particularly given that the disputed term has no ordinary meaning to one of skill in the art. *See Indacon, Inc. v. Facebook, Inc.*, 824 F.3d 1352, 1357 (Fed. Cir. 2016) ("[T]erms [that] have no plain or established meaning to one of ordinary skill in the art . . . ordinarily cannot be construed broader than the disclosure in the specification."); *see also Irdeto Access, Inc. v. Echostar Satellite Corp.*, 383 F.3d 1295, 1300 (Fed. Cir. 2004) ("[A]bsent such an accepted meaning [in the art], we construe a claim term only as broadly as provided for by the patent itself.").

Integra also contends that the recommended construction wrongly excludes "air or air bubbles alone" from being considered "visualization agents." Integra points to a separate patent, U.S. Patent No. 6,165, 201, which the '034 patent incorporates by reference, for its position that a combination of dye and air can serve as a visualization agent. (D.I. 311 at 7-8) The '034 patent describes using "a hydrogel applicator tool such as a sprayer," as described in the '201 patent. '034 patent at 9:14-22. Integra argues that the air bubbles from the sprayer combine with the dye to form a visualization agent. (D.I. 311 at 7-8) The Court agrees with Judge Burke's rejection of this argument, as "the '034 patent is clear that: (1) the visualization agent described therein was the ***dye*** and (2) the patentees were ***not*** making reference to the presence of any air bubbles in the

hydrogel in describing what the visualization agent was." (D.I. 307 at 12)[3]

3. Integra next objects to Judge Burke's recommendation that the Court find the terms "molecular weight"[4] and "small molecule"[5] indefinite. (D.I. 315 at 2; D.I. 310 at 19-20) Instead, Integra proposes construing the terms as "the mass of a molecule which is often expressed in units of Daltons or g/mol" and "a molecule with a molecular weight of 2000 or less," respectively. (D.I. 315 at 1, 8)

Integra asserts that the issue of indefiniteness is premature at this stage and is best resolved during the summary judgment stage. (*Id.* at 2) The Court disagrees. As Judge Burke noted, not only does Integra fail to "identify how additional time would better advance the record," but "[t]he parties' experts have presented dueling opinions as to the question, the parties have fully joined the issue, and they have had a full, fair opportunity to litigate it." (D.I. 310 at 3 n.2) (internal citations omitted) While it is sometimes best to defer ruling on indefiniteness challenges until summary judgment, often this is not the case. *See, e.g., Trusted Knight Corp. v. Int'l Bus. Machines Corp.*, 2015 WL 7307134, at *6-7 (D. Del. Nov. 19, 2015) (finding multiple terms indefinite during claim construction); *Graphics Props. Holdings, Inc. v. ASUS Computer Int'l, Inc.*, 2014 WL 4929340, at *18 (D. Del. Sept. 29, 2014) (same).

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[3]Integra asserts that in finding that air alone cannot be a visualization agent, Judge Burke wrongly imposes a temporal condition, by requiring that the agent be detectable ***before*** mixing with the reactive precursor series. (D.I. 311 at 9) The Court intends no such temporal limitation in its construction. Because air is invisible, it cannot be detected by the human eye before or after mixing with a reactive precursor series. Moreover, as Judge Burke found, "Plaintiffs have not pointed to anything in the intrinsic record discussing air bubbles as constituting a visualization agent." (D.I. 307 at 13)

[4]This term appears in asserted claims 1, 12, and 23 of the '406 patent.

[5]This term appears in asserted claims 1, 6, 7, and 12 of the '406 patent.

Judge Burke found that HyperBranch demonstrated by clear and convincing evidence that the term "molecular weight," as used in the asserted claims, is indefinite because "there is no reasonable certainty as to which measure of molecular weight [(number-average molecular weight ("Mn") or weight-average molecular weight ("Mw"))] should be utilized." (D.I. 310 at 13) In addition, because the '406 patent expressly defines "small molecule" in terms of its molecular weight, "small molecule" is indefinite as well. (*Id.* at 20) Integra contends that the meaning of both terms is reasonably clear in the context of the claims. (D.I. 315 at 5-8) According to Integra, the asserted patents instruct that "when dealing with polymers the value of the molecular weight is the value of the number average molecular weight." (*Id.* at 5)

The Court agrees with Judge Burke that HyperBranch has met its heavy burden to show that the term "molecular weight," and by association the term "small molecule," is indefinite. Nowhere does the specification indicate which measure of molecular weight is intended. The Court agrees with Judge Burke's detailed explanation as to how the nine-step process described by Integra's expert (Dr. Jimmy Mays) is unsupported and, more importantly, confirms the uncertainty a person of ordinary skill in the art would have as to the meaning of "molecular weight." (*See* D.I. 310 at 12-19 (emphasizing that Dr. Mays never explains ***why*** he takes various steps, or why POSITA would think to do so); *see also generally Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015) (finding same claim term, "molecular weight" – in different patent – is invalid due to indefiniteness))

4. Integra objects to the recommended construction of "chemical groups that are

prone to aqueous hydrolysis"[6] as "chemical linkages that are susceptible to degradation through reaction with water to break chemical bonds, such as an ester, carbonate, or amide linkage." (D.I. 325 at 8; D.I. 316 at 8) Integra objects to this construction only "to the extent that it allows an amide linkage alone to be such a chemical group." (D.I. 325 at 8) Amide linkages, Integra contends, are not "degradable in vitro by exposure to aqueous solution. . . . because amide linkages are stable under such conditions." (*Id.* at 9) As Judge Burke noted, Integra did not raise this argument until the *Markman* hearing, and even then Integra provided nothing more than a bare assertion that there was an argument between the parties over whether an amide linkage is biodegradable in other physiological conditions. (D.I. 316 at 7-8) While Integra provides more than that now, it appears to the Court that Integra's proposed construction contradicts the patent's teaching. Furthermore, disputed language included in the Court's construction – "such as an ester, carbonate or amide linkage" – is taken directly from the patents-in-suit. *See, e.g.*, '566 patent at 6:44-47. The Court, therefore, agrees with Judge Burke that its construction should include amide linkages as an example of such chemical groups.

5. Integra objects to the construction of "the biodegradable groups consist of the esters,"[7] which Judge Burke recommended construing as "the hydrogel does not contain any biodegradable linkages other than ester linkages." (D.I. 325 at 2; D.I. 316 at 15-16) Integra contends that Judge Burke's recommendation improperly excludes "all non-ester groups that may be 'biodegradable' to even a small or insignificant extent and over a very long period of time

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[6]This term appears in the following asserted claims: claims 1, 12, and 25 of the '566 patent and claim 11 of the '418 patent.

[7]This term appears in asserted claim 1 of the '5,705 patent.

beyond 180 days," and proposes construing the term as "the esters are the only biodegradable group responsible for degradation in a patient in less than about 180 days." (D.I. 325 at 2)

Integra's proposal is contrary to both the claim language and prosecution history. As Hyperbranch observes, "[t]he claim language does ***not*** say something like: the "biodegradable groups of the hydrogel ***responsible for degradation*** consist of the esters,'" but rather "reads: 'the biodegradable groups ***of the hydrogel*** consist of the esters." (D.I. 316 at 9) (emphasis added) As stated in the Report, the inventors' decision to use the language "consist of" is significant – it limits the biodegradable groups of the claimed hydrogel to ester groups only. (*Id.* at 10)[8] Further, as Judge Burke explained, the prosecution history shows that "the forerunner to the claim that ultimately issued as claim 1 of the '5,705 patent did not include a limitation regarding the types of biodegradable groups present in the claimed hydrogel." (*Id.* at 12) After multiple rejections, a new continuation application, and additional rejections, the '5,705 patent eventually issued in its current form. (*Id.*) Throughout prosecution of these amendments, the patent applicants explained that (1) "[c]laim 1 is amended to clarify that the biodegradable groups are the isolated esters," (2) the prior art "taught the artisan to add certain enzymatically degradable

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[8]In the Report, Judge Burke found that "no one is asserting that other such [non-ester] groups would be akin to the 'impurities' at issue in *Conoco* [*Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1360 (Fed. Cir. 2006)]." (D.I. 316 at 11) Now, in its objections, Integra belatedly contends exactly that. (D.I. 325 at 5) ("Here, non-ester groups are akin to the 'impurities' at issue in *Conoco* . . . .") According to Integra, "one of ordinary skill knows that such groups have no effect on the invention of claim 1 of the '5,705 [patent] as it relates to the 'biodegradability' of the hydrogel under physiological conditions in less than 180 days." (*Id.*) However, as discussed above, amide linkages are considered biodegradable in the context of the asserted patents and, therefore, would have an effect on the biodegradability of the hydrogel and cannot be considered "impurities normally associated with the component." Thus, because the term states "the biodegradable groups ***consist of*** the esters," non-ester groups are excluded. '5,705 patent at cl. 1 (emphasis added); *see Conoco*, 460 F.3d at 1360 ("The phrase 'consisting of' signifies restriction and exclusion of unrecited steps or components.").

peptides or certain biodegradable materials," none of which were esters, and (3) adding one non-ester material would place the precursor outside of the applicants' claims. (*Id.* at 13-15) The Court agrees with Judge Burke that "[t]he clear import of the prosecution history, then, is that the claim covers only those hydrogels that do not contain biodegradable groups other than esters." (*Id.* at 14)

6. Integra objects to the recommended construction of "precursor"[9] as "a polymer, functional polymer, macromolecule, small molecule, or crosslinker that can take part in a reaction to form a network of crosslinked molecules." (D.I. 324 at 3; D.I. 317 at 8) Judge Burke based his construction on the '3,705 patent's express definition of the term "reactive precursor species," which he found was used interchangeably with that patent's use of the term "precursor." (D.I. 317 at 4-5) Integra asserts that the term should instead be construed according to its plain and ordinary meaning as "a compound that leads to another compound in a series of chemical reactions." (D.I. 324 at 3)

Integra contends that Judge Burke's narrower construction wrongly equated the terms "precursor" and "reactive precursor series." (*Id.* at 4-5) Instead, Integra contends, "precursor" is the "genus" and "reactive precursor series" is "a list of species, and not intended to be limiting of the genus term 'precursor.'" (*Id.*) This argument contradicts Integra's position earlier in the claim construction process, which was that "reactive precursor species" was the broader term. (D.I. 230 at 22 ("Defendant's proposed construction for 'precursor' is the definition that the inventor expressly gave to a different, broader claim term – 'reactive precursor species.'"))

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[9]This term appears in asserted claims 4, 11, and 19 of the '3,705 patent and asserted claims 1 and 9-16 of the '5,705 patent.

Moreover, contrary to Integra's current position, the patents in which the terms appear (the '3,705 and '5,705 patents) ***are*** related, as both are continuations-in-part of the '406 patent. Additionally, the '034 patent, '418 patent, and '566 patent (which are all continuations of the '406 patent) use the term "reactive precursor series" interchangeably with the term "precursor," further supporting the Court's construction. *See, e.g.,* '034 patent at 2:52-56, 3:12-18 (describing forming biodegradable hydrogel by mixing hydrophilic precursor polymers and then describing embodiment of invention having "instructions for using the visualization agent and the reactive precursor species such that the reactive precursor species may be combined to form crosslinked hydrophilic polymers that form a biodegradable hydrogel"); *see also, e.g.,* '418 patent at 2:52-56, 3:12-18 (same); *see also, e.g.,* '566 patent at 2:52-56, 3:12-18 (same).

7. Integra objects to the construction of "polymer composition,"[10] which Judge Burke recommended construing as "the combined materials including a polymer that crosslinks. A polymer is a molecule formed of at least three repeating groups via polymerization." (D.I. 324 at 9; D.I. 307 at 41 n.20, 55; D.I. 317 at 8 n.4) The parties' only dispute is whether to include the phrase "via polymerization." (D.I. 324 at 9-10; D.I. 336 at 10) Integra contends that the inventors expressly defined the term "polymer" as "a molecule formed of at least three repeating groups," and inclusion of "via polymerization" is "at odds with" that definition. (D.I. 324 at 9) Besides generally stating that the words "via polymerization" do not appear in the asserted patents, however, Integra fails to explain how their inclusion goes against the inventors' definition or is otherwise inconsistent with the intrinsic evidence. (*See id.*; *see also* D.I. 317 at 8

[10]This term appears in the following asserted claims: claims 16 and 20 of the '034 patent, claims 22 and 25 of the '566 patent, and claims 1 and 11 of the '418 patent.

n.4 ("While it is true that the '034 patent does not expressly define a polymer to include the clarification that it is made 'via polymerization,' neither of Plaintiffs' claim construction briefs asserted any argument as to why the clarification that a polymer's repeating groups are formed via polymerization is incorrect.")) By contrast, HyperBranch presented the unrebutted expert testimony of Dr. Lowman, who explained that "a hallmark of a polymer is that it is made by the process of polymerization." (D.I. 336 at 9-10) The Court agrees with the recommended construction.

8. Lastly, Integra objects to Judge Burke's finding that the term "free of amino acid sequences of more than about four residues in number"[11] is indefinite. (D.I. 331 at 2; D.I. 321 at 13) The Court again rejects Integra's contention that resolution of this indefiniteness challenge is premature. (D.I. 331 at 2) As Judge Burke noted, "this is a situation where, despite having multiple opportunities to bring further clarity to the record, Plaintiffs did not do so during the briefing process, nor during the *Markman* hearing." (D.I. 321 at 13 n.5) Integra submitted a rebuttal declaration of its expert, Dr. Mays, in response to HyperBranch's opening claim construction brief – giving Integra an opportunity (in addition to its opening brief and opportunity for opening declarations) to address the issue – but Dr. Mays' response did not address the uncertainty surrounding "about" at all. (*Id.* at 10 n.4) Integra is not unfairly prejudiced by the Court deciding this issue now. (*See generally* D.I. 342 at 5) (Defendant arguing: "Plaintiffs never purported to need additional time to better advance the record during claim construction.")

[11]This term appears in asserted claims 9, 21, and 31 of the '566 patent and asserted claim 7 of the '418 patent.

Integra contends that the term is definite because a person of ordinary skill in the art would understand that "about four residues in number" means "2, 3, or 4 residues in number, *i.e.*, an upper limit of 4 and a lower limit of 2." (D.I. 331 at 4, 5)[12] Integra contends that because the patent exemplifies the use of dilysine, trilysine, and tetralysine, which have 2, 3, and 4 residues, respectively, the patent teaches that "about 4" signifies that "the number of residues is not limited to only 4," but rather, encompasses embodiments with 2, 3, or 4 residues. (*Id.* at 6-7) As Judge Burke noted, however, these examples "do[] little to explain why the term 'about' was included in these ***claims***, which (if the presence of 'about' were not considered) would otherwise ***already*** recite a hydrogel with amino acid sequences of no more than four residues." (D.I. 321 at 12)

Integra now reasons that "about" is important to provide the "lower limit of 2" (D.I. 331 at 8), but that is contrary to what Integra argued at the *Markman* hearing, at which time its position was that "about" provided the ***upper*** limit in signifying that there were "no more than four" residues – which would effectively read "about" out of the claims (D.I. 321 at 11-12). Overall, Integra's inconsistent arguments and citations to expert opinion outside of the record do nothing to undermine the Court's finding, by clear and convincing evidence, that the term "free of amino acid sequences of more than about four residues in number" is indefinite.

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[12]Integra relies on Dr. Mays' opening expert report submitted on September 8, 2017, after the Report issued and seven months after the claim construction hearing. (D.I. 331 at 1) Even considering Dr. Mays' report, Integra still fails to point to any evidence in the specification supporting its position that "about four" means "2, 3, or 4."

9. Given the detailed reasoning provided in the Reports, the Court finds it unnecessary to address Integra's objections any further.

November 8, 2017
Wilmington, Delaware

HON. LEONARD P. STARK
UNITED STATES DISTRICT JUDGE