

**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

In this action filed by Plaintiffs Integra LifeSciences Corp. (“Integra”), Integra LifeSciences Sales LLC (“Integra Sales”), Confluent Surgical, Inc. (“Confluent”) and Incept LLC (“Incept”) (collectively, “Plaintiffs”) against Defendant HyperBranch Medical Technology, Inc. (“HyperBranch” or “Defendant”), Plaintiffs allege infringement of United States Patent Nos. 6,566,406 (the “406 patent”), 7,009,034 (the “034 patent”), 7,332,566 (the “566 patent”), 7,592,418 (the “418 patent”), 8,003,705 (the “3705 patent”) and 8,535,705 (the “5705 patent”) (collectively, the “patents-in-suit” or “asserted patents”). Presently before the Court is the matter of claim construction. The Court recommends that the District Court adopt the constructions set forth below for the three terms discussed in this Report and Recommendation.¹

¹ The parties submitted 18 terms or sets of terms for claim construction. (D.I. 248 at 2). The parties grouped the 18 terms/term sets into seven groups for purposes of the *Markman* hearing. (*Id.* at 1-2) This Report and Recommendation addresses the third group of terms (i.e., Group C). On July 27, 2017 and August 4, 2017, the Court issued Reports and Recommendations regarding claim construction for the first two groups of terms (which included 10 terms/term sets), (D.I. 307, 310), and the Court will address the remaining groups in separate, forthcoming Report and Recommendations.

I. BACKGROUND

The Court incorporates by reference herein the factual and procedural background about this case and the patents-in-suit that was set out in the Court's July 27, 2017 Report and Recommendation regarding claim construction. (D.I. 307 at 2-5)

II. STANDARD OF REVIEW

The Court also incorporates by reference herein the discussion of general principles of claim construction, as well as the legal standard relating to the definiteness requirement, which were also set out in its July 27, 2017 Report and Recommendation. (*Id.* at 5-7, 30-32)

III. DISCUSSION

The Court takes up the three disputed terms addressed herein in the order in which the parties addressed them at the *Markman* hearing.

A. “chemical groups that are prone to aqueous hydrolysis”

The term “chemical groups that are prone to aqueous hydrolysis” is found in the independent claims of the '566 patent and the '418 patent. Plaintiffs propose that the term be construed to mean “[c]hemical groups susceptible to reaction with water to break chemical bonds and to degrade[.]” (D.I. 230 at 24) Defendant proposes that it be construed to mean “[c]hemical linkages that are susceptible to degradation through reaction with water to break chemical bonds, such as an ester, carbonate, or amide linkage[.]” (D.I. 231 at 8) The term's usage in claim 1 of the '566 patent is representative:

1. A polymeric coating for a substrate comprising:
water, a biocompatible visualization agent, and a biodegradable hydrogel, that is essentially completely degradable in vivo by hydrolytic degradation, with the hydrogel having an interior and an exterior, with the exterior having a substrate coating surface, and

the visualization agent being at least partially disposed within the interior,
wherein the hydrogel comprises *chemical groups that are prone to aqueous hydrolysis* and is thereby degradable in vitro by exposure to aqueous solution, and
wherein the visualization agent has a predetermined concentration that indicates a predetermined thickness of the hydrogel as deposited on the substrate.

('566 patent, col. 39:2-15 (emphasis added))

The most significant dispute between the parties is whether it is proper for the construction of this term to include the language “such as an ester, carbonate, or amide linkage.” (See D.I. 230 at 25; D.I. 241 at 13) For its part, Defendant asserts that the patents expressly identify these as exemplary linkages that are susceptible to degradation by reaction with water to break their chemical bonds. (D.I. 231 at 8-9) For support, it points to a portion of the '566 patent specification, which describes an embodiment of the invention as a hydrogel that has “water, a biocompatible visualization agent, and crosslinked hydrophilic polymers that form a hydrogel after contact with the [patient’s] tissue. . . . The polymers preferably also have a *hydrolytically biodegradable portion or linkage, for example an ester, carbonate, or an amide linkage.*” ('566 patent, col. 6:22-25, 44-47 (emphasis added))² Defendant contends that inclusion of these examples in the construction ensures that Plaintiffs will not “exclude them from the scope of the claims[.]” (D.I. 231 at 9)

Plaintiffs raise a few different concerns with Defendant’s proposal. The Court will address them in turn.

² Plaintiffs suggest that this reference is “found in . . . later continuation in part applications.” (D.I. 230 at 25; *see also* D.I. 252 (“Tr.”) at 135) To the extent they suggest that this reference is not found in the '566 patent (or the '418 patent), they are mistaken. (*See* Tr. at 153; *see also* '418 patent, col. 6:42-44)

First, Plaintiffs assert that Defendant's construction improperly seeks to "limit this term to 3 specific chemical species: (1) esters; (2) carbonates and (3) amides." (D.I. 230 at 25) And Plaintiffs then point to the specification as describing "a number of chemical species that can be used without limitation to only the three named by Defendant[.]" (*Id.*) The portion of the specification that Plaintiffs cite here is entitled "Biodegradable Linkages[.]" and it teaches that:

If it is desired that the biocompatible crosslinked polymer be biodegradable or absorbable, one or more precursors having biodegradable linkages present in between the functional groups may be used. The biodegradable linkage optionally also may serve as the water soluble core of one or more of the precursors. In the alternative, or in addition, the functional groups of the precursors may be chosen such that the product of the reaction between them results in a biodegradable linkage. For each approach, biodegradable linkages may be chosen such that the resulting biodegradable biocompatible crosslinked polymer will degrade or be absorbed in a desired period of time. Preferably, biodegradable linkages are selected that degrade under physiological conditions into non-toxic products.

The biodegradable linkage may be chemically or enzymatically hydrolyzable or absorbable. Illustrative chemically hydrolyzable biodegradable linkages include polymers, copolymers and oligomers of glycolide, dl-lactide, l-lactide, caprolactone, dioxanone, and tritethylene carbonate. Illustrative enzymatically hydrolyzable biodegradable linkages include peptidic linkages cleavable by metalloproteinases and collagenases. Additional illustrative biodegradable linkages include polymers and copolymers of poly(hydroxy acid)s, poly(orthocarbonate)s, poly(anhydride)s, poly(lactone)s, poly(amino acid)s, poly(carbonate)s, and poly(phosphonate)s.

('566 patent, col. 10:19-44 (*cited in* D.I. 230 at 25)) In light of this teaching, Plaintiffs assert, Defendant's proposal would improperly exclude these exemplary embodiments of the limitation. (D.I. 241 at 13; *see also* D.I. 230 at 26 ("[Because] there is no expression of manifest exclusion[,] there is no basis to limit this claim limitation to certain embodiments advanced by

the Defendant[.]”))

Defendant’s proposal would do no such thing. The proposal recites “chemical linkages . . . *such as* an ester, carbonate, or amide linkage.” The plain import of that construction, then, is not to *limit* the term to *only* encompassing an ester, carbonate or amide linkage, but instead to provide these three chemical species as *exemplary* chemical groups that would fall within the scope of the claim term. (D.I. 243 at 7; D.I. 244 at ¶ 11; Tr. at 155) The other examples listed in the patent would not be excluded by this language.

Plaintiffs next argue that it is especially improper to import these embodiments into the construction because they relate to a different concept—i.e., “hydrolytically degradable”—rather than to “chemical groups that are prone to aqueous hydrolysis” (the claim term at issue). (D.I. 241 at 13) But it is clear from the claims that the claim language at issue here has a direct relation to the concept of “hydrolytic degradation.” Claim 1 of the '566 patent, set out above, recites a hydrogel “that is essentially completely *degradable in vivo by hydrolytic degradation . . . wherein the hydrogel comprises chemical groups that are prone to aqueous hydrolysis and is thereby degradable in vitro by exposure to aqueous solution[.]*” ('566 patent, col. 39:4-12 (emphasis added)) And thus, polymers with a “hydrolytically biodegradable portion or linkage” such as an ester, carbonate or an amide linkage, would be “susceptible to [aqueous] hydrolysis[.]” which Defendant’s expert states means the same thing as “hydrolytic degradation.” (D.I. 232 at ¶ 83)³

³ Indeed, as Defendant’s counsel pointed out during the *Markman* hearing, Plaintiffs’ own expert Dr. Mays explained in an earlier declaration (issued in conjunction with the preliminary injunction proceedings) that “[t]he hydrogel may be hydrolytically biodegradable which means that the hydrogel biodegrades by reacting with water. One such way this can happen is that the hydrogel includes ‘a hydrolytically biodegradable portion or linkage, for

During the *Markman* hearing, Plaintiffs' counsel additionally asserted that Defendant's construction is improper because it utilizes the term "linkages" instead of "groups." (Tr. at 138) That is, the claim language recites "chemical *groups* that are prone to aqueous hydrolysis" whereas Defendant's construction (and the portion of the specification that the construction relies upon) refers to "linkage[s]." According to Plaintiffs, the linkage that is formed is "part of a group"—"the group encompasses more than just the linkage." (*Id.* at 139-40) Defendant retorted that "the patent uses these terms [']linkages['] and [']groups['] synonymously." (*Id.* at 156) Dr. Lowman likewise appears to view them as synonymous in this context, opining that "the Asserted Patents define ester, carbonate and amide *linkages* as exemplary *groups* that are susceptible to hydrolysis." (D.I. 232 at ¶ 84 (emphasis added))

The Court is not persuaded by this particular criticism, as it is undercut by the patent and by Plaintiffs' own arguments. For example, in their briefing, Plaintiffs themselves pointed to the section of the patent entitled "biodegradable linkages" as describing "a number of chemical species that can be used" with respect to this claim term. (D.I. 230 at 25) As was noted above, this discussion of the specification teaches a few ways to achieve a biocompatible crosslinked polymer that will "degrade or be absorbed in a desired period of time[,]" including that: (1) one or more precursors having biodegradable linkages present in between the functional groups may be used, or (2) functional groups of the precursors may be chosen such that the product of the reaction between them results in a biodegradable linkage. ('566 patent, col. 10:19-30) This discussion next proceeds to list "[i]llustrative . . . biodegradable linkages[,]" (*id.*, col. 10:33-44),

example an ester . . . linkage." (Defendant's Claim Construction Presentation, Slide 102 (citing D.I. 10, ex. 13 at ¶ 84); *see also* Tr. at 154)

which Plaintiffs describe as being “exemplary embodiments” of this limitation, (D.I. 241 at 13; *see also* D.I. 242, ex. 14 at ¶ 65 (Dr. Mays opining that Defendant’s proposal excludes embodiments recited in the “biodegradable linkages” discussion of the specification and improperly limits the term to “three chemical species” when the patents describe “several other chemical species that can be used” such as the aforementioned biodegradable linkage examples)) Moreover, in another portion of their briefing, Plaintiffs again seemed to treat chemical “groups” and “linkages” as synonyms in this context. (*See, e.g.*, D.I. 230 at 11 (asserting that claim 17 of the '5705 patent ““does not exclude the presence of other *biodegradable groups*, but at physiological conditions *in vivo*, the claim requires that the *biodegradable groups* responsible for degradation in less than about 90 days only be *ester groups*. Accordingly, the hydrogel of claim 17 can include *amide linkages*, but the *biodegradable linkages* can only be *ester groups*””) (citing D.I. 10, ex. 13 at ¶ 167) (certain emphasis omitted)) And so, with the patent (and the Plaintiffs) appearing to use the two terms interchangeably in this context, the Court is not persuaded that Defendant has improperly inserted “linkages” in place of “groups” in its proposed construction.

One final argument from Plaintiffs also became clear during the *Markman* hearing: that Plaintiffs “disagree that the amide linkage [included in Defendant’s proposal] falls within [a chemical] group [that] is prone to aqueous hydrolysis.” (Tr. at 136-37) This particular argument was not made clear in Plaintiffs’ briefing, where Plaintiffs mostly (incorrectly) argued that Defendant’s construction is wrong because it excludes other examples. The only support that Plaintiffs provided for this late-made argument at the *Markman* hearing was that “there’s a real fight over whether [an amide linkage is] biodegradable in other physiological conditions.” (*Id.* at

141) This bare assertion is not enough to persuade the Court that the phrase should not be included in the construction, especially where: (1) the patent defines an “amide linkage” as an exemplary group that is susceptible to hydrolysis, (D.I. 232 at ¶ 84); and (2) Defendant suspects that Plaintiffs may attempt to later exclude amide linkages from the scope of the claim, (Tr. at 152).

For these reasons, the Court recommends that “chemical groups that are prone to aqueous hydrolysis” be construed to mean “chemical linkages that are susceptible to degradation through reaction with water to break chemical bonds, such as an ester, carbonate, or amide linkage.”

B. “the biodegradable groups of the hydrogel consist of the esters”

Plaintiffs propose that this next term be construed to mean “the esters are the only biodegradable group responsible for degradation in a patient in less than about 180 days[,]” while Defendant proposes that it be construed to mean “the hydrogel does not contain any biodegradable linkages other than ester linkages[.]” (D.I. 231 at 9) The term is found in claim 1 of the '5705 patent, as shown below:

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 (emphasis added)) Claim 17 depends from claim 1 and requires that “the hydrogel is essentially fully degradable in a patient in less than about 90 days.” (*Id.*, col. 32:16-17) The crux of the dispute with respect to this term is whether its effect is that (1) the claimed hydrogel must not contain any biodegradable linkages other than ester linkages (as Defendant argues), or (2) whether the hydrogel can include other biodegradable linkages, but that those linkages that are biodegradable linkages under the conditions specified in the claims (i.e., in a patient in less than about 180 (or 90) days) must be ester groups (as Plaintiffs contend).
(See D.I. 230 at 11-12)

The Court looks first to the claim language itself, which supports Defendant’s position. As an initial matter, the claim language does *not* say something like: the “biodegradable groups of the hydrogel responsible for degradation consist of the esters.” Instead, it reads: “the biodegradable groups *of the hydrogel* consist of the esters.”⁴

⁴ Plaintiffs assert that antecedent basis for the term “the biodegradable groups of the hydrogel consist of the esters” is found only in the term “one or two chemically hydrolytically degradable ester bonds per every electrophilic functional group on the first precursor.” (D.I. 241 at 14; D.I. 159 at 69-70) According to Plaintiffs, the person of ordinary skill in the art (or

Beyond this, the Court agrees with Defendant that the effect of the “consist of” language in the phrase is to strictly limit the biodegradable groups of the claimed hydrogel to only ester groups. (D.I. 231 at 9; Tr. at 156-57) The United States Court of Appeals for the Federal Circuit has explained that ““consisting of” is a term of art in patent law “[that] signifies restriction and exclusion of unrecited steps or components.” *Conoco, Inc. v. Energy & Envtl. Int’l, L.C.*, 460 F.3d 1349, 1360 (Fed. Cir. 2006); *see also Vehicular Techs. Corp. v. Titan Wheel Int’l, Inc.*, 212 F.3d 1377, 1383 (Fed. Cir. 2000) (“[A] drafter uses the phrase ‘consisting of’ to mean ‘I claim what follows and nothing else.’”) (citation omitted).

Plaintiffs assert that the law with respect to “consisting of” does not support Defendant’s “overly exclusionary” position, because the Federal Circuit has held that “consisting of” “does not exclude elements outside of the context of said element.” (D.I. 230 at 14) The two cases that Plaintiffs cite in support of this proposition—*Norian Corp. v. Stryker Corp.*, 363 F.3d 1321 (Fed. Cir. 2004) and *Conoco, Inc. v. Energy & Envtl. Int’l, L.C.*, 460 F.3d 1349 (Fed. Cir. 2006)—set out two narrow exceptions to the above-referenced rule. First, the Federal Circuit has explained

“POSITA”) would thus understand this portion of the claim to mean that the “one or two chemically hydrolytically degradable ester bonds” or groups “consist of the esters”—in other words, this language is said to make clear that the ester groups are what is responsible for the degradation of the hydrogel within 180 days. (D.I. 241 at 14; D.I. 159 at 69-70) This explanation, however, essentially renders the term at issue redundant. That is, it would reaffirm what has already been said in the claim—that the ester bonds are hydrolytically degradable. Accepting Defendant’s position instead gives this term actual meaning—Defendant asserts that the “one or two chemically hydrolytically degradable ester bonds” language sets out a structural requirement for the precursor, while the term at issue sets out a structural requirement for the hydrogel. (D.I. 159 at 199) This is consistent with the claim’s later reference to ester bonds as structures in the hydrogel—the claim recites “mixing the first and the second synthetic hydrophilic polymer precursors forms crosslinking covalent bonds that are reaction products of the electrophilic and 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. 30:59-65; *see also* D.I. 231 at 10)

that “consisting of” “does not limit aspects *unrelated* to the invention.” *Norian Corp.*, 363 F.3d at 1331-32 (emphasis added) (concluding that claims directed to a kit “consisting of” specified chemicals did not permit any other chemicals in the kit, but finding that the presence of a spatula in the accused kit containing the same claimed chemicals did not help the defendant avoid infringement, for the spatula “has no interaction with the chemicals, and is irrelevant to the invention”). The Federal Circuit has recently emphasized that this is a “rare exception” that is not often implicated. *Shire Dev., LLC v. Watson Pharms., Inc.*, 848 F.3d 981, 984 (Fed. Cir. 2017). Second, the Federal Circuit has also noted that “impurities that a person of ordinary skill in the relevant art would ordinarily associate with a component on the ‘consisting of’ list do not exclude the accused product or process from infringement.” *Conoco, Inc.*, 460 F.3d at 1360.

Neither of these exceptions apply here. Under Plaintiffs’ view, the claims permit other biodegradable groups, aside from esters, to exist in the hydrogel. But the Court cannot understand how inclusion of other biodegradable groups in the hydrogel would not be an aspect related to this invention (nor have Plaintiffs made any attempt to shed light on that issue). And no one is asserting that other such groups would be akin to the “impurities” at issue in *Conoco, Inc.* Thus, the plain import of the term “the biodegradable groups of the hydrogel consist of the esters” is that the claimed hydrogel does not contain any biodegradable groups other than the esters (and that if it does, it does not meet the limitations of the claims).

The Court also agrees with Defendant that the prosecution history supports its proposal. The Court will now set out the relevant portion of this prosecution history in some detail. To provide context for this discussion, the Court notes that Dr. Lowman has opined that a “‘biodegradable group’ is a chemical structure that is susceptible to degradation, *either hydrolytic*

or enzymatic.” (D.I. 232 at ¶ 86 (emphasis added); *see also* Tr. at 157)

Originally, the forerunner to the claim that ultimately issued as claim 1 of the '5705 patent did not include a limitation regarding the types of biodegradable groups present in the claimed hydrogel. (D.I. 232, ex. 7 at HBMT0405076-82) To overcome rejections, the patentees next added the limitation “wherein the hydrogel as placed in situ in the patient *has no enzymatically degradable peptidic linkages* and is essentially fully degradable in a patient in less than about 180 days[.]” (*Id.* at HBMT0405456 (certain emphasis added, certain emphasis omitted), *see also id.* at HBMT0405461 (“The amended claims are amended to recite that the hydrogel as placed in situ in the patient has no enzymatically degradable peptide linkages.”)) This limitation narrowed the pending claim by excluding hydrogels with enzymatically degradable peptide linkages (and thus covered hydrogels with hydrolytically degradable linkages). (*See id.* at HBMT0405501 (“The claim language that the hydrogel as placed in situ in the patient has no enzymatically degradable peptidic linkages is directed to claiming *one* of these alternatives, namely chemically degradable via a hydrolytically degradable ester and not the other alternative, namely enzymatically biodegradable linkages.”); D.I. 232 at ¶ 88) The Examiner continued to reject the claims, however, and the patentee ultimately abandoned the application. (D.I. 232, ex. 7 at HBMT0405547-50, HBMT0405570-72, HBMT0405577)

The applicants then re-filed a new continuation application that became the '5705 patent, in which they resubmitted the claims reciting the “no enzymatically degradable peptidic linkages” limitation. (*Id.*, ex. 6 at HBMT0408834) The Examiner rejected the claims as unpatentable in view of U.S. Patent No. 5,874,500, a prior art reference referred to as “Rhee '500.” (*Id.* at HBMT0409300) According to the Examiner, Rhee '500 teaches a method of

making a hydrogel that, *inter alia*, as placed in situ “has no enzymatically degradable peptidic linkages[,]” and “[i]t would have been obvious to [the POSITA] at the time the instant invention was made to prepare a hydrogel according to the method of [Rhee '500] containing hydrolytically degradable linkages.” (*Id.* at HBMT0409300-01)

Because excluding hydrogels with enzymatically degradable peptidic linkages did not suffice to gain allowance of the claims, the patentees then deleted the “has no enzymatically degradable peptidic linkages” limitation and replaced it with the current phraseology—i.e., “wherein the biodegradable groups of the hydrogel consist of the esters[.]” (*Id.* at HBMT0409335) With respect to this amendment, the applicants explained that “[c]laim 1 is amended to clarify that *the biodegradable groups are the isolated esters[.]*” (*Id.* at HBMT0409338 (emphasis added))

As for the rejection over Rhee '500, the applicants argued that Rhee '500 taught the artisan to add certain enzymatically degradable peptides or certain biodegradable materials such as lactide, glycolide, E-caprolactone, poly(a-hydroxy acid), poly(amino acids) or poly(anhydride) to make a composition that was easily degraded. (*Id.* at HBMT0409344) None of these materials were ester groups. (*Id.*) The applicants then explained that “the present claims do not read on any of these materials. For instance, *adding a polyanhydride places the precursor outside of the claims.*” (*Id.* (emphasis added); *see also id.* at HBMT0409377) Dr. Lowman points out that the '5705 patent lists some of these same biodegradable materials as examples of biodegradable linkages, (D.I. 232 at ¶ 92):

The biodegradable linkage may be chemically or enzymatically hydrolyzable or absorbable. Illustrative chemically hydrolyzable biodegradable linkages include polymers, copolymers and

oligomers of *glycolide*, *dl-lactide*, *l-lactide*, *caprolactone*, dioxanone, and trimethylene carbonate. . . . Additional illustrative biodegradable linkages include polymers and copolymers of *poly(hydroxy acid)s*, poly(orthocarbonate)s, *poly(anhydride)s*, poly(lactone)s, *poly(aminoacid)s*, poly(carbonate)s, and poly(phosphonate)s.

('5705 patent, cols. 6:61-7:5 (emphasis added))

The clear import of the prosecution history, then, is that the claim covers only those hydrogels that do not contain biodegradable groups other than esters. (See D.I. 232 at ¶¶ 88, 91) Indeed, the applicants explicitly *said* that they added the language at issue to clarify that the biodegradable groups are the esters, and they also explained how adding a degradable material to the precursor that was *not* an ester (i.e., a polyanhydride) would remove it from the scope of the claimed invention.

Plaintiffs' responses to Defendant's arguments relating to the prosecution history are not persuasive. Plaintiffs first attempt to dispute the relevance of Defendant's citations by asserting that the claim term at issue "is neither mentioned nor discussed in the portions of the prosecution history cited by" Defendant. (D.I. 241 at 15) This is true at least for the first portion of the prosecution history discussed above, because the phrase at issue was not even a limitation in the claim at that point. Rather, that discussion is relevant here because it shows how this term *originated*; the applicants replaced the earlier "no enzymatically degradable peptidic linkages" language with the phrase at issue.

Plaintiffs also argue that "[w]hat the prosecution history actually shows is that applicants did not limit claims to hydrogels only having ester linkages, but rather distinguished the claims from SG-PEG hydrogels having esters that were persistent, not biodegradable in a patient, unless

specifically modified with other biodegradable groups[.]” (Plaintiffs’ Claim Construction Presentation, Slide 53; *see also* D.I. 241 at 15; Tr. at 147-48) And it is correct that the applicants did further explain that Rhee '500 “does not teach that the esters in the SG-PEG are biodegradable and, to the contrary, repeatedly and explicitly states that the materials of the [Rhee] '500 patent are persistent unless specifically modified with other biodegradable groups”—all to provide one reason why the prior art reference taught away from what is claimed. (D.I. 232, ex. 6 at HBMT0409344 (emphasis in original)) But this was not the only reason the applicants gave as to why Rhee '500 should not stand in the way of their claims. Right before giving that reason, the applicants had made the previously-referenced statement that “the present claims *do not read* on any of these [other biodegradable] materials [that are not esters]” and asserted that adding one such (non-ester) material to the precursor *would place it outside of the claims*. (*Id.* (emphasis added)) Plaintiffs never directly address *these* statements in the prosecution history. Their failure to do so is a tacit admission of the impact of those statements.

The Court agrees with Defendant that these prosecution history statements are “unequivocal”—i.e., that other biodegradable materials are “out” for the purposes of this claim and the patentees “limited it strictly down to the esters.” (Tr. at 158-59; *see also* D.I. 231 at 12)⁵ For these reasons, the Court recommends that the term “the biodegradable groups of the hydrogel consist of the esters” be construed to mean “the hydrogel does not contain any biodegradable

⁵ As Defendant points out, Plaintiffs’ contrary position “would permit [them] to assert that a hydrogel with a polyanhydride group fell within the scope of the claims[.]” when they clearly told the United States Patent and Trademark Office that inclusion of such a material in a precursor making up the hydrogel would *not* fall within the claims. (D.I. 231 at 13)

linkages other than ester linkages.”⁶

C. “essentially completely degradable”

The term “essentially completely degradable” appears in claims 1 and 25 of the '566 patent and claim 1 of the '418 patent in the following context: “a biodegradable hydrogel[] that is *essentially completely degradable* in vivo by hydrolytic degradation[.]” ('566 patent, cols. 39:2-15, 40:41-58; '418 patent, cols. 38:66-39:9 (emphasis added)) Plaintiffs propose that the term be construed to mean “[d]egradation is nearly, though not entirely complete[.]” (D.I. 230 at 15) Defendant asserts that the term is indefinite as the language “essentially completely” is a subjective phrase, and no guidance can be found in the intrinsic record with regard to the term’s boundaries. (D.I. 231 at 26)

Defendant first notes that, in the context of the claims, the term “essentially completely degradable” relates to the degree of degradation achieved by means of hydrolytic degradation. (*Id.*) Defendant then asserts that the intrinsic record sheds no light on what degree of degradation would satisfy the “essentially completely” limitation. (*Id.* at 26-27) It argues that Plaintiffs’ proposal improperly connotes measuring degradation at a specific point in time (i.e., before complete degradation but after the majority of degradation has occurred), but that this is not supported by the intrinsic record. (*Id.* at 27) Additionally, Defendant contends that Plaintiffs’

⁶ Plaintiffs assert in their answering brief as to this term that “[t]here is no support for [Defendant’s] improper attempt to swap ‘biodegradable groups’ with ‘biodegradable linkages[.]’” (D.I. 241 at 14), but as discussed above, it is clear that “groups” and “linkages” are at times used synonymously with each other. Indeed, Plaintiffs themselves used the terms synonymously while arguing about this term in their opening brief. (*See, e.g.*, D.I. 230 at 11-12 (“[T]he hydrogel of claim 17 can include amide linkages, but the biodegradable linkages can only be ester groups.”) (citing D.I. 234, ex. 13 at ¶ 167); (“This phrase does not mean that the claimed hydrogel does not contain any biodegradable linkage other than ester linkages[.]”); *see also* Tr. at 156)

proposal does not give any guidance on when degradation should be measured or how much degradation is “nearly, though not entirely, complete.” (*Id.*) Finally, Defendant argues that the prosecution history demonstrates that Plaintiffs’ proposal is wrong because the inventors intended degradation to occur “essentially completely” by means of chemical (hydrolytic) degradation as opposed to enzymatic degradation. (*Id.*)

It is clear that it is the word “essentially” that is causing the problem for Defendant here, as “[c]ompletely degradable” would be clear and would not implicate a term of approximation. (See Tr. at 149-50); *see also, e.g., Ruckus Wireless, Inc. v. Netgear, Inc.*, No. C 08-2310 PJH, 2013 WL 6627737, at *4 (N.D. Cal. Dec. 16, 2013) (identifying “essentially” as a term of approximation); *Shell Global Solutions (US) Inc. v. RMS Eng’g, Inc.*, 782 F. Supp. 2d 317, 343 (S.D. Tex. 2011) (same). The Federal Circuit has explained that “words of approximation, such as ‘generally’ and ‘substantially,’ are descriptive terms ‘commonly used in patent claims to avoid a strict numerical boundary to the specified parameter.’” *Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1310-11 (Fed. Cir. 2003) (citations omitted).

This issue is a difficult one. The Court is not in a position to resolve every issue raised by the parties with respect to this term at this time. However, the Court has come to a few conclusions.

First, the Court is convinced that Plaintiffs’ proposal does not move the ball in terms of what the term “essentially completely degradable” actually means. Their proposal unhelpfully swaps out “essentially” for “nearly, though not entirely” without providing a persuasive explanation as to how this proposal eliminates any uncertainties raised by the claim language. Nor, for purposes of claim construction, does their briefing explain where the patent utilizes the

term “nearly” to mean “essentially.”

Second, the Court agrees with Defendant’s assertion that Plaintiffs’ proposal is wrongly directed to the timing of the process of degradation. The language “degradation is nearly, though not entirely, complete” suggests that the claim is directed to a hydrogel that has already been applied to the patient, with time having passed. Yet the claims at issue are directed to a hydrogel having certain features and to methods of making such hydrogels—not necessarily to hydrogels that have already been applied to a patient, with enough time having passed to allow for an almost finalized degradation process.

Third, the Court does find that the term at issue can be construed.⁷ Although the term “essentially completely degradable” does not appear in the specifications, the Court gleans from the patents that a biodegradable hydrogel “that is essentially completely degradable in vivo by hydrolytic degradation” is one that may almost completely degrade (in vivo by hydrolytic degradation), with the word “essentially” allowing for a “small” amount of hydrogel to remain. As Plaintiffs point out, the specification explains that if it is desired that the biocompatible crosslinked polymer be biodegradable, “biodegradable linkages may be chosen such that the resulting biodegradable biocompatible crosslinked polymer *will degrade* . . . in a desired period

⁷ In a footnote in their opening brief, Plaintiffs “noted” that the claim term only appears in the preamble of claim 1 of the '418 patent and claim 25 of the '566 patent and is therefore “presumptively [] not a limitation of the claim that requires construction by the Court.” (D.I. 230 at 15) Defendant did not respond to this “note” and Plaintiffs did not further press the issue. Generally, a preamble is not limiting unless it recites an “essential structure or steps” or 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). A preamble will also be deemed to be limiting where the patent applicants clearly relied on the benefits or features recited therein as patentably significant. *Id.* at 808-09. With virtually no argument from the parties on the issue, the Court will assume, without deciding, that the phrase is a claim limitation in all three claims in which it appears.

of time.” (’566 patent, col. 10:19-30 (emphasis added)) Example 21 of the specification, in turn, describes experiments whereby satisfactory results (“[n]o adhesions”) were achieved even with a “[s]mall amount of gel present on cecum[.]” (*Id.*, col. 37:20-45 (emphasis added)) The Examples are of course intended to illustrate aspects of the patentee’s inventions, (*see, e.g., id.*, col. 28:15-18), and the experiments described in Example 21 depict a hydrogel that prevented adhesions even where it did not completely degrade but instead left a small amount of gel. The Court’s understanding of the term “essentially” in this context also comports with the specification’s other usages of the term “essentially.” (*See, e.g., id.*, col. 5:27-32 (“A substrate coating surface is a surface of a hydrogel that contacts a substrate and, in the region of contact, is *essentially* in continuous contact with that substrate. Although some *small portions* of the coating or substrate may not be in contact, the contact is intimate.”) (emphasis added)) Thus, in line with the specification, the Court believes that the import of the “essentially completely degradable” language is to describe a hydrogel of a kind such that it will degrade so that no more than a small amount remains.

Fourth, while the Court can understand what “essentially” is intended to get at with respect to the claimed hydrogel, it remains unclear to the Court on this record whether the claim term is indefinite. The Court has adopted a construction different from that proposed by Plaintiffs, and could use a better record and more focused argument as to whether the now-construed claim term fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention.⁸ Accordingly, the Court’s decision here is without prejudice to

⁸ For example, even after the Supreme Court of the United States’ decision in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2125 (2014), claim terms utilizing terms of degree have been found definite where they provide “enough certainty to one of skill in

Defendant's ability to challenge the validity of the claims containing this term as indefinite at the summary judgment stage if it believes there is a basis to do so. *See Spectrum Pharms., Inc. v. InnoPharma, Inc.*, Civil Action No. 12-260-RGA-CJB, 2014 WL 3365684, at *9 (D. Del. July 3, 2014) (citing cases).

For these reasons, the Court recommends that the term "essentially completely degradable" be construed to mean "degradable to the extent that no more than a small amount of the hydrogel remains."

IV. CONCLUSION

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

1. "chemical groups that are prone to aqueous hydrolysis" should be construed to mean "chemical linkages that are susceptible to degradation through reaction with water to break chemical bonds, such as an ester, carbonate, or amide linkage"
2. "the biodegradable groups of the hydrogel consist of the esters" should be

the art when read in the context of the invention." *Sonix Tech. Co., Ltd. v. Publ'ns Int'l Ltd.*, 844 F.3d 1370, 1377 (Fed. Cir. 2017) (quoting *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370 (Fed. Cir. 2014)); *see, e.g., Edgewell Personal Care Brands, LLC v. Albaad Massuot Yitzhak, Ltd.*, Civil Action No. 15-1188-RGA, 2017 WL 1900736, at *2-3 (D. Del. May 9, 2017) (rejecting the defendant's argument that the term "generally tapered" was indefinite where the patent "informs with reasonable certainty" the POSITA regarding the meaning of the term); *Saint Lawrence Commc'ns LLC v. ZTE Corp.*, Case No. 2:15-CV-349-JRG, 2016 WL 6275390, at *64-67 (E.D. Tex. Oct. 25, 2016) (finding that even though "substantially" is a word of degree that may be imprecise, the term "substantially decoupled" was not indefinite where the "intrinsic and extrinsic evidence demonstrate that 'substantially decoupled' is reasonably well-understood in the relevant art such that the claims at issue inform[s] those skilled in the art about the scope of the invention with reasonable certainty") (certain internal quotation marks and citations omitted). The Court would benefit from further argument as to why this term of degree is or is not sufficiently objective, as compared to the results in other cases like these.

construed to mean “the hydrogel does not contain any biodegradable linkages other than ester linkages”

3. “essentially completely degradable” should be construed to mean “degradable to the extent that no more than a small amount of the hydrogel remains”

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: August 18, 2017



Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE