

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

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| 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 construction set forth below for the single term 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 fourth group (i.e., Group D). On July 27, 2017, August 4, 2017, and August 18, 2017, the Court issued Reports and Recommendations regarding claim construction for the first three groups of terms (which included 13 terms/term sets). (D.I. 307, 310, 316) 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 set out in the July 27, 2017 Report and Recommendation. (*Id.* at 5-7)

III. DISCUSSION

The single disputed term at issue here is "precursor[.]" which is found in certain claims of the '3705 patent and the '5705 patent. Plaintiffs propose that the term be construed to mean "[a] compound that leads to another compound in a series of chemical reactions[.]" and Defendant proposes that it be construed to mean "[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. 230 at 21) The term's usage in claim 4 of the '3705 patent is representative:

4. A kit comprising:
a first biocompatible *precursor* having at least two electrophilic functional groups, and a second biocompatible *precursor* comprising at least two primary amine functional groups, a third biocompatible *precursor* comprising at least two primary amine functional groups and, an applicator;
wherein the first biocompatible *precursor*, the second biocompatible *precursor*, and the third biocompatible *precursor* are reactable with each other to form a crosslinked hydrogel, are resistant to enzymatic degradation, and at least one of the first, second, or third biocompatible *precursors* comprises at least one isolated hydrolytically degradable ester group;
wherein the applicator is configured to mix at least the first *precursor*, the second *precursor*, and the third *precursor* to form a crosslinked hydrogel in situ comprising covalent bonds formed by reaction of the functional groups of the *precursors* and further comprising the at least one isolated hydrolytically degradable ester group;
wherein the hydrogel comprises a sufficient number of the at least one isolated hydrolytically degradable ester groups in the crosslinked hydrogel so that the crosslinked hydrogel is degradable in less than about 180 days, is resistant to enzymatic degradation, and is degradable by hydrolysis of the at least one isolated hydrolytically degradable ester group; and
wherein the kit further comprises instructions that comprise directions for making a hydrogel that is degradable in an amount of time, with the amount of time being less than about 180 days.

('3705 patent, cols. 42:41-43:4 (emphasis added))

For its part, Defendant asserts that its definition is drawn “verbatim” from the patents.

(D.I. 231 at 6 (emphasis omitted)) Indeed, while the '3705 patent, for example, does not recite an explicit definition for the term “precursor,” it does set out a definition for the term “reactive precursor species” as follows:

The term “reactive precursor species” means a polymer, functional polymer, macromolecule, small molecule, or crosslinker that can take part in a reaction to form a network of crosslinked molecules, e.g., a hydrogel.

(‘3705 patent, col. 24:7-10) According to Defendant, the patents use the terms “reactive precursor species” and “precursor” interchangeably, and thus, this definition of “reactive precursor species” should be the construction for the term “precursor.” (D.I. 231 at 6; Tr. at 171) In support of this assertion, Defendant points to the declaration of its expert, Dr. Anthony Lowman, who opines that “[i]n the context of the Asserted Patents . . . there is no substantive difference between the inventors’ use of ‘reactive precursor species’ and ‘precursor’” and that the person of ordinary skill in the art (the “POSITA”) reading the asserted patents “would consider them to be directed to the exact same thing: the types of materials that can be used to form a hydrogel.” (D.I. 232 at ¶ 47; *see also* D.I. 244 at ¶ 10)

Plaintiffs, on the other hand, argue that Defendant’s proposed construction for “precursor” is incorrect. They claim that Defendant’s construction is the inventors’ express definition for a completely different term (i.e., “reactive precursor species”) that is “broader” than the claim term at issue. (D.I. 230 at 22; D.I. 241 at 11-12) Plaintiffs’ proposed construction, on the other hand, is derived verbatim from the *Oxford Dictionary of Chemistry*. (See D.I. 233, ex. 12 at 446) Plaintiffs argue that the intrinsic record supports this construction. (D.I. 241 at 12)

The United States Court of Appeals for the Federal Circuit has explained that while the use of two different terms in a patent implies that they have different meanings, “that implication is overcome where . . . the evidence indicates that the patentee used the two terms interchangeably.” *Baran v. Med. Device Techs., Inc.*, 616 F.3d 1309,1316 (Fed. Cir. 2010). The Court finds that here, the patentees did indeed use the terms “precursor” and “reactive precursor species” interchangeably.

Particularly instructive on this question are two paragraphs in the '3705 patent specification—the latter of which is the paragraph that concludes with the above-referenced definition for “reactive precursor species.” The first of these two paragraphs describes how, *inter alia*, an embodiment of the invention may have “reactive precursor species” with a certain number of nucleophilic functional groups each and “reactive precursor species” with a certain number of electrophilic functional groups each. (3705 patent, col. 23:45-49) Then, the second paragraph begins by explaining that “[a]n embodiment uses biocompatible crosslinked polymers formed from the reaction of *precursors* having electrophilic functional group[s] and nucleophilic functional groups”; it goes on to provide examples of such precursors. (*Id.*, cols. 23:50-24:10 (emphasis added)) This second paragraph notes, for example, that at least one of the “precursors” may be a “small molecule” that may be referred to as a “crosslinker.” (*Id.*, col. 23:54-56) The paragraph next explains that at least one of the other “precursors” may be a “macromolecule” that may be referred to as a “functional polymer.” (*Id.*, col. 23:60-62) And the paragraph ends by setting out the definition of “reactive precursor species” as encompassing each of the things (“a polymer, functional polymer, macromolecule, small molecule, or crosslinker”) that have just been identified as “precursors,” and that can each react to form a network of crosslinked molecules. (*Id.*, col. 24:7-10) This description, then, conveys that in the context of the patents, a “precursor” is the same thing as a “reactive precursor species.”

Other portions of the specification bolster this conclusion. For instance, the introductory portion of the “Detailed Description [of the Invention]” section of the specification (i.e., those first few columns in this section before the patentees break the discussion into specific headers) states that:

The Examples herein describe a variety of *reactive precursor species* and methods of making *reactive precursor species* that may be mixed to provide crosslinked networks that crosslink quickly after mixing such that one skilled in these arts will understand how to make the required materials after reading this disclosure.

(*Id.*, col. 9:32-37 (emphasis added)) Immediately thereafter, the specification goes on to describe “precursor[s]” that can be used to make the claimed hydrogels. (*See, e.g., id.*, col. 9:39-40 (explaining that “[e]ach precursor is multifunctional, meaning that it comprises two or more electrophilic or nucleophilic functional groups”); *id.*, cols. 9:61-10:31 (describing low molecular weight amine “[p]recursors” that can be used to “achieve a cross-linked hydrogel”))

Similarly, the section of the specification titled “EXAMPLES” begins by explaining that “[t]he following non-limiting examples are intended to illustrate the synthesis of new biocompatible crosslinked polymers and their *precursors*, and their use in making several medical products.” (*Id.*, col. 29:12-15 (emphasis added)) And while the remainder of that “EXAMPLES” section uses the term “precursor” instead of “reactive precursor species,”² we know from the portion of the specification described in the above paragraph (that found in the “Detailed Description” section of the patent) that these “*Examples herein describe a variety of reactive precursor species[.]*” (*Id.*, col. 9:32-33 (emphasis added))

These exemplary portions of the specification make it very clear, then, that the terms

² (*See, e.g.,* '3705 patent, cols. 34:46-47, 38:57-59 (Examples 13 and 19 referring to “[l]ow [m]olecular [w]eight [p]recursors”); *id.*, col. 35:21-23 (Example 14 referring to a hydrogel made from a “four armed 20,000 MW PEG-SG-NHS precursor and a trilycine precursor”); *id.*, col. 37:30 (Example 17 referring to hydrogels made with “small molecule precursors”))

“reactive precursor species” and “precursor” are being used by the inventors interchangeably.³

This indicates that Defendant’s proposed construction is the correct one.

In their briefing on this term, the parties also spent time laying out their respective views as to how the dispute over the meaning of “precursor” relates to the arguments the parties will later make regarding patent infringement/non-infringement. (D.I. 231 at 6-7; D.I. 241 at 11-12) The Court, however, believes that the intrinsic record with respect to “reactive precursor species” and “precursor” suffices to resolve the particular claim construction dispute presented to it. (*See, e.g.*, D.I. 232 at ¶ 49) To the extent that what remains is a dispute about infringement, now is not the appropriate time to decide that question.

For these reasons, the Court recommends that the term “precursor” be construed to mean “a polymer, functional polymer, macromolecule, small molecule, or crosslinker that can take part

³ The Court notes that the terms also seem to be used interchangeably in other asserted patents. For example, claim 1 of the '034 patent recites a method of preparing a composition suitable to coat a tissue of a patient that entails “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[.]” ('034 patent, col. 39:56-63 (emphasis added)) Meanwhile, the Abstract of the patent describes the teaching of the patent as “[b]iocompatible crosslinked polymers, and methods for their preparation . . . are disclosed in which the biocompatible crosslinked polymers are formed from water soluble *precursors* having electrophilic and nucleophilic functional groups capable of reacting and crosslinking in situ. . . . Visualization agents may be included with the crosslinked polymers.” (*Id.* at Abstract (emphasis added); *see also id.*, col. 5:56-58 (“It is preferable to provide color by adding a colored visualization agent to the hydrogel *precursors* before crosslinking.”) (emphasis added)) Likewise, claim 12 of the '566 patent teaches mixing “reactive precursor species” comprising nucleophilic functional groups, “reactive precursor species” comprising electrophilic functional groups, and a visualization agent, ('566 patent, col. 39:50-55), while the Abstract, identical to that of the '034 patent, simply uses the term “precursors[.]” (*id.* at Abstract).

in a reaction to form a network of crosslinked molecules.”⁴

IV. CONCLUSION

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

1. “precursor” should be construed to mean “a polymer, functional polymer, macromolecule, small molecule, or crosslinker that can take part in a reaction to form a network of crosslinked molecules”

⁴ As the Court explained in its July 27, 2017 Report and Recommendation regarding claim construction for the Group A terms, the parties have a lingering dispute with respect to the term “polymer composition” that they assert to be related to the parties’ disputes with respect to the term “precursor.” (D.I. 307 at 41 n.20; *see also* Tr. at 35-36) The Court recommended that the term “polymer composition” be construed to mean “the combined materials including a polymer that crosslinks. A polymer is a molecule formed of at least three repeating groups[,]” (D.I. 307 at 55), but left open the issue of whether the phrase “via polymerization” should be added to the end of the construction, as Defendant proposed, (*id.* at 41 & n.20). Defendant asserts that this requirement should be included “to properly distinguish polymers from other ‘small molecules’ that are not made by polymerization.” (D.I. 231 at 26) It points in support to the declaration of Dr. Lowman, who opines that the POSITA “recognizes that a hallmark of a polymer is that it is made by the process of polymerization”—in contrast to “other non-polymerization techniques that can be used to make non-polymeric materials.” (D.I. 232 at ¶ 149) The ‘406 patent distinguishes between materials that are polymers and ones that are not polymers, (*see* ‘406 patent, col. 3:38-41 (explaining that “small molecule refers to a molecule that is not a polymer and is typically of a molecular weight less than 2000 Daltons, or else is a polymer and is of a molecular weight of less than 1000 Daltons”)), and according to Dr. Lowman, the POSITA would understand this as drawing a distinction between materials that are made via polymerization (i.e., a polymer) and those that are not (i.e., not a polymer), (D.I. 232 at ¶ 149). 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. (D.I. 230 at 23; D.I. 241 at 19; *see also* D.I. 243 at 17) Thus, Dr. Lowman’s opinions in this regard stand un rebutted. It is clear from the patents that a small molecule could either be a polymer or not, and with the definition of “polymer” implicating the term “molecule,” the Court can see how Defendant’s clarification would clear up any ambiguity. Therefore, the Court recommends that the construction for the term “polymer composition” make clear that a polymer is formed via polymerization.

2. “polymer composition” should be further construed to mean “the combined materials including a polymer that crosslinks. A polymer is a molecule formed of at least three repeating groups via polymerization”

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