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 eight terms/term sets discussed in this Report and Recommendation.[1]

I. BACKGROUND

[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 first group of terms, and the Court will address the remaining groups in separate, forthcoming Report and Recommendations.

A. The Parties

Plaintiffs Integra, Integra Sales and Confluent are Delaware corporations with their principal places of business in Plainsboro, New Jersey. (D.I. 1 at ¶¶ 2-4) Incept is a Delaware limited liability company with its principal place of business in Lexington, Massachusetts. (*Id.* at ¶ 6)

Integra is involved in the design, development and manufacturing of medical devices for orthopedics, tissue technologies and speciality surgical solutions, with an emphasis on products that help heal and/or regenerate tissue. (*Id.* at ¶ 7) Integra Sales sells and distributes Integra's medical technology products, including Integra's dural sealant products. (*Id.* at ¶¶ 8, 25) Integra and Integra Sales are affiliates of Confluent, which is a medical device company that has developed in-situ polymerized biomaterials with applications as synthetic sealants and hemostats in minimally invasive surgery, adhesion prevention and interventional procedures. (*Id.* at ¶¶ 5, 9) Incept is a medical technology company that promotes and advances technological innovation and entrepreneurship. (*Id.* at ¶ 10)

According to the Complaint, the asserted patents "relate to Integra's and Integra Sales' dural sealant products and technology, particularly those used by neurosurgeons and orthopedic spine surgeons." (*Id.* at ¶ 25) Integra, Integra Sales and Confluent are the exclusive licensees of the asserted patents, and Incept owns them by assignment. (*Id.* at ¶¶ 11-16; D.I. 35, ex. 1 at ¶ 5)

Defendant HyperBranch is a Delaware corporation, and has its headquarters in Durham, North Carolina. (D.I. 1 at ¶ 18; D.I. 25 at ¶ 2; D.I. 37 at ¶ 18) It is a medical device company that is involved in the business of designing, developing, manufacturing and selling surgical sealants. (D.I. 1 at ¶ 19; D.I. 25 at ¶ 2; D.I. 37 at ¶ 19)

In this action, Plaintiffs allege that HyperBranch directly and indirectly infringes the asserted patents by the manufacture, sale, and offers to sell of products including its Adherus Autospray Dural Sealant, Adherus Dural Sealant and Adherus Spinal Sealant. (D.I. 1 at ¶¶ 28, 35, 42, 49, 56)

B. Asserted Patents

The asserted patents all come from the same patent family. They are directed to biocompatible crosslinked polymers (i.e., hydrogels) having certain features and methods for their preparation and use. (D.I. 246, exs. A-F)[2]

The '418 patent is a continuation of the '566 patent, which is a continuation of the '034 patent. (*See* Plaintiffs' Claim Construction Presentation, Slide 2) It is entitled "Biocompatible Crosslinked Polymers with Visualization Agents" and it issued with 30 claims. ('418 patent) The '566 patent has the same title and issued with 38 claims. ('566 patent) The '034 patent is entitled "Biocompatible Crosslinked Polymers" and issued with 22 claims. ('034 patent) These three patents are directed to the following technological area:

> Biocompatible crosslinked polymers, and methods for their preparation and use, 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. Methods for making the resulting biocompatible crosslinked polymers biodegradable or not are provided, as are methods for controlling the rate of degradation. The crosslinking reactions may be carried out in situ on organs or tissues or outside the body. Applications for such biocompatible crosslinked polymers and their precursors include controlled delivery of drugs, prevention of post-operative adhesions, coating

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[2] The asserted patents appear on the docket in this action more than once. Citations to the patents will simply be to the '406 patent, the '034 patent, the '566 patent, the '418 patent, the '3705 patent and the '5705 patent.

> of medical devices such as vascular grafts, wound dressings and surgical sealants. Visualization agents may be included with the crosslinked polymers.

(*See, e.g.*, '034 patent, Abstract) All of the terms/term sets in the group addressed in this Report and Recommendation are found in claims in one or more of these three patents; they are not present in the remaining three asserted patents addressed in the next paragraph.

The '406 patent is also entitled "Biocompatible Crosslinked Polymers" and issued with 27 claims. ('406 patent) The '406 patent is directed to the same general technological area as the '418, '566, and '034 patents, although its abstract does not reference visualization agents. (*Id.*, Abstract) The '3705 patent is entitled "Biocompatible Hydrogels Made with Small Molecule Precursors" and issued with 22 claims. ('3705 patent) The '3705 patent is directed to the same general technological area as the '418, '566 and '034 patents, but also discusses hydrogel embodiments having isolated hydrolytically degradable esters and embodiments using low molecular weight amines to make the hydrogels. (*Id.*, Abstract) The '5705 patent is entitled "Biocompatible Polymers and Hydrogels and Methods of Use" and issued with 18 claims. ('5705 patent) Its Abstract is nearly identical to the Abstracts of the '418, '566 and '034 patents set out above, but it does not discuss visualization agents, and it notes that the precursors have electrophilic and nucleophilic groups (but not electrophilic and nucleophilic *functional* groups). (*Id.*, Abstract)

C. Procedural History

Plaintiffs filed the instant case on September 15, 2015. (D.I. 1) On September 25, 2015, Chief Judge Leonard P. Stark referred this case to the Court to hear and resolve all pretrial matters, up to and including the resolution of case-dispositive motions. (D.I. 15) After a lengthy

preliminary injunction stage, the Court recommended denial of Plaintiffs' request for a preliminary injunction, (D.I. 164), and a schedule for the remainder of the case issued soon after, (D.I. 173).

The parties filed simultaneous opening claim construction briefs on February 3, 2017, and simultaneous responsive briefs on February 20, 2017. (D.I. 230, 231, 241, 243) The Court held a *Markman* hearing on February 27, 2017. (D.I. 252 (hereinafter "Tr."))

II. STANDARD OF REVIEW

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

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

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

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

claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution[.]" *Phillips*, 415 F.3d at 1317.

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

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

III. DISCUSSION

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

A. "visualization agent"

Plaintiffs propose that "visualization agent" be construed to mean "'an agent that is detectable by the human eye[,]'" while Defendant proposes that it be construed to mean "'a substance or material that imparts a visually discernible color or obscures the optical clarity of the hydrogel[.]'" (D.I. 230 at 2) The parties have two real disputes with respect to this term: (1) whether the visualization agent must be a "substance or material," as Defendant argues, or instead can be more broadly defined as an "agent" (and thus could encompass trapped air alone

or a combination of air and dye); and (2) whether the term requires detection of the agent by the human eye alone (as Plaintiffs assert), or instead allows for detection by machines. (*See* D.I. 243 at 14) The Court will first provide some additional context with respect to this term, and will then explain why it agrees with Defendant's position with respect to the first dispute, and with Plaintiffs' position with respect to the second dispute.

The term "visualization agent" appears in certain claims of the '034 patent, the '566 patent and the '418 patent. The '566 patent explains that one risk of undergoing surgery is a condition known as "adhesion[,]" wherein bodily tissues exposed during the course of surgery will adhere to each other. ('566 patent, col. 1:30-32)[3] Adhesions can have the appearance of scar-like masses, and they are often painful. (*Id.*, col. 1:34-35) One treatment option for adhesions has been to coat tissues exposed during surgery with a gel before closing the surgical site. (*Id.*, col. 1:39-41) Hydrogels are useful for this treatment option, as well as for other medical purposes such as tissue augmentation, medical device coating, surgical sealing and drug delivery. (*Id.*, col. 1:52-57) The patent explains that polymeric hydrogels are "essentially colorless" and that "[t]his problem is often even more acute when the hydrogel is applied as a coating on a tissue because tissue coatings conventionally are thin." (*Id.*, col. 2:4-8) Therefore, "[t]he resulting colorless solution or film is . . . difficult to visualize, especially in the typically wet and moist surgical environment." (*Id.*, col. 2:8-10; *see also id.*, col. 5:15-19 ("Conventional polymeric hydrogels may sometimes have a faint inherent color or develop a faint color as a result of chemical activity, but their lack of color makes a layer of a hydrogel very difficult to see after it has been

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[3] The content of the specification of the '034 patent, '566 patent and '418 patent are identical. (*See* Tr. at 13) For ease of reference, the Court will cite to the '566 patent in connection with this discussion, unless otherwise indicated.

applied to a tissue.")) Visibility of the colorless hydrogel "is even more difficult" under laparoscopic conditions, when only a two-dimensional view of the surgical field is available on the monitor that is used in such procedures. (*Id.*, col. 2:10-14)

The '566 patent explains that the present invention was intended to solve this problem, as the inventors "realized that use of color in biocompatible crosslinked polymers and precursors greatly improves their performance in a surgical environment, especially under minimally invasive surgical procedures[.]" (*Id.*, col. 2:18-21; *see also id.*, col. 5:56-58) Additionally, the better visibility achieved with the use of color permits more efficient use of materials and prevents waste. (*Id.*, col. 2:22-25) Typically, applications of such materials have the best results when a predetermined amount of hydrogel is delivered to the surgical site, and the use of a visualization agent "allows the user to determine the thickness of the applied hydrogel." (*Id.*, cols. 4:65-5:10) The patent notes that "[t]he visualization agent is preferably an agent that provides a color that is visible to the human eye, e.g., a color that is detected visually by the user or detected by a video camera and relayed to a video screen observed by the user." (*Id.*, col. 5:10-14)

1. "Agent" vs. "Substance or Material"

With respect to the parties' first dispute (i.e., whether the construction for "visualization agent" should define the term as an "agent" as Plaintiffs propose, or instead as a "substance or material" as Defendant proposes), the Court will adopt Defendant's proposal. Defendant's proposal is the more helpful of the two, and it also reflects the proper scope of the term as described by the inventors in their patents.

As a starting point, the Court notes that while Plaintiffs' briefing suggests that

"visualization agent" is a term with a "commonly understood, plain and ordinary meaning[,]" (D.I. 230 at 2; *see also* D.I. 241 at 17), 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 within the patents[.]" (D.I. 244 at ¶ 28; *see also* Tr. at 94-95) Thus, to discern the meaning of the term "visualization agent," the POSITA would need to turn to the intrinsic evidence. (*See* Tr. at 95 (Defendant's counsel explaining that the term "visualization agent" is a term "solely for the purposes of these patents, and that's why we've come up with our construction from the intrinsic record")); *see also, e.g.*, *Astra Aktiebolag v. Andrx Pharms., Inc.*, 222 F. Supp. 2d 423, 451 (S.D.N.Y. 2002) (explaining that, with respect to a term that the "patentees created for use" in the asserted patents, such term "must be defined in the context of those patents" and accordingly the "court must rely on the intrinsic evidence, particularly the specification, to determine the meaning of the [term]").

Turning then to the patents, it is evident that their specifications do consistently describe a "visualization agent" as a substance or a material (in line with Defendant's proposal). (*See* D.I. 231 at 22) For instance, the specification of the '566 patent explains that "[v]isualization agents may be selected from among any of the various non-toxic colored *substances* suitable for use in [] implantable medical devices, such as FD&C BLUE dyes 3 and 6, eosin, methylene blue, indocyanine green, or colored dyes normally found in synthetic surgical sutures." ('566 patent, col. 10:53-57 (emphasis added)) And the specification also similarly conveys that the

visualization agent may be a material. (*Id.*, col. 33:35-51 (describing an example of preparation of a hydrogel wherein colored commercial sutures are cut/ground into several small pieces and mixed into a solution that is an ingredient in a crosslinked gel and these "colored suture particles entrapped in the crosslinked gel help to visualize the gel especially when under laparoscopic conditions . . . . The suture particles . . . can be replaced with biodegradable microparticles loaded with drugs or bioactive compounds") (emphasis added)) The patents further describe visualization agents in terms of specific weight/volume concentrations, (*see, e.g.*, *id.*, col. 11:1-4 ("The visualization agent may be used in small quantities, preferably less than 1% weight/volume . . . .")), which also supports the conclusion that the term is meant to describe a substance or material, whose quantity may be controlled, (D.I. 231 at 22).

Plaintiffs argue to the contrary that the claims and the specification do not restrict the visualization agent to a "substance or material" and that they therefore do not "exclude other visualization agents, such as [(1)] trapped air . . . or [(2)] a combination of visualization agents, such as a dye and air." (D.I. 230 at 3; *see also* D.I. 241 at 17) But a closer look at Plaintiffs' line of argument here shows its flaws.

With regard to Plaintiffs' assertion that *air alone* could amount to a "visualization agent," the Court agrees with Defendant's retort that, even under Plaintiffs' own construction, this could not be so. That is because air is invisible and therefore not "detectable by the human eye." (D.I. 243 at 14; D.I. 244 at ¶ 30)[4]

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[4] Plaintiffs argue that their construction of "visualization agent" is "consistent with the specifications"; in support they cite to portions of the specifications that describe embodiments in which the visualization agent "reflects or emits light at a wavelength detectable to a human eye" and "'is preferably an agent that provides a color that is visible to the human eye[.]" (Plaintiffs' Claim Construction Presentation, Slide 9 (quoting '034 patent, cols. 2:25-36,

As for Plaintiffs' arguments about the patents' references to *air in combination with dye*, those references are also not helpful to Plaintiffs. Plaintiffs assert that the '034 patent discloses that this combination (air/air bubbles plus dye) amounts to a "visualization agent." (D.I. 230 at 3; D.I. 241 at 17; Tr. at 19) In doing so, they point to where the patent states that it is preferable to use a hydrogel that crosslinks in about 2-4 seconds, in order to allow a user to make multiple passes over the tissues "with a hydrogel applicator tool such as a sprayer; see, for example commonly assigned U.S. Pat. No.[] 6,165,201 [the "'201 patent"] . . . which [is] hereby incorporated herein by reference[.]" ('034 patent, col. 9:14-22) The '201 patent, in turn, states: "As the gas, preferably air or carbon dioxide, flows through gas flow outlet **21**a, it mixes with the crosslinkable solution from syringe **13** passing through outlet nozzle **20**a, breaking the crosslinkable solution into fine droplets or a mist." (D.I. 242, ex. 14 at ex. 3, cols. 8:66-9:3) Plaintiffs' argument is that these "examples that were [] given in the specification include both the dye in combination with the air bubbles [as being the visualization agents]." (Tr. at 19)

The Court disagrees that these references suggest that "air" plays any meaningful role in the definition of a "visualization agent." For one thing, the '034 patent describes an exemplary embodiment that actually utilizes an air-assisted sprayer (like the sprayer discussed in the '201 patent). And when it does, 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. ('034 patent, col. 36:47-50 ("Solution 2 consisted of a 1.2% solution of dilysine . . . with 0.5 mg/ml methylene blue *for*

5:10-13, 6:22-29)) But air is not visible to the human eye and therefore would not be consistent with these descriptions of the claimed visualization agent.

visualization[.]") (emphasis added); *see also* D.I. 243 at 15; D.I. 244 at ¶ 32) Plaintiffs have not pointed to anything in the intrinsic record discussing air bubbles as constituting a visualization agent. (*See* D.I. 243 at 15) Rather, the patents teach that the hydrogel is made up of a "combination of everything that's in it, [but] only some of those things are visualization agents and add color . . . . or obscure[] the transparency." (Tr. at 89-90; *see, e.g.*, '034 patent, col. 2:27-29 ("[t]he hydrogel has water, a biocompatible visualization agent, and reactive hydrophilic polymers that form a crosslinked hydrogel")) To this end, in the example where the inventors used the sprayer, it was the *dye itself* that was added "for visualization." ('034 patent, col. 36:50; Tr. at 89)

For these reasons, the Court concludes that the term "visualization agent" should not be construed in such a way as to encompass air or air bubbles alone, and that Defendant's use of the phrase "substance or material" should be included in the construction.

2. "Detectable by the Human Eye"

With respect to the parties' dispute regarding whether a "visualization agent" must be "detectable by the human eye" (as Plaintiffs propose), the Court understands Plaintiffs' proposal to exclude scenarios where such an agent is detectable by the human eye only with assistance from a machine like an x-ray machine or MRI machine. (Tr. at 15-16) After careful consideration of the intrinsic evidence, the Court concludes that this limitation should be a part of the Court's construction.

The Court acknowledges that, if one looked only to the text of the patents themselves, one would come to a contrary conclusion. That is because the specification and the claims leave room for Defendant's broader proposal here.

The Court first assesses the specification. On the one hand, the specification explains that "[v]isually observable visualization agents *are preferred*." ('566 patent, col. 11:11 (emphasis added)) Indeed, the patents go on to note that the human eye observes wavelengths of light from approximately 400 to 750 nm as colors, and the color of an object depends on the predominant wavelength of light that the object reflects. (*Id.*, col. 11:12-19) Describing "[a]n embodiment of the invention"—a hydrogel for use on a patient's tissue—the patent explains that the hydrogel:

> has water, a biocompatible visualization agent, and reactive hydrophilic polymers that form a crosslinked hydrogel . . . . The visualization agent is disposed in the hydrogel and reflects or emits light at a wavelength *detectable to a human eye*. This feature lets a user applying the hydrogel observe the hydrogel and estimate its thickness and apply the hydrogel until it reaches a predetermined thickness.

(*Id.*, col. 2:25-35 (emphasis added)) But on the other hand, the specification also clearly describes circumstances where visualization agents may *not* be observable by the naked human eye alone. For example, it later describes "[a]n alternative embodiment" that is a "visualization agent that may not normally be seen by the human eye but is detectable at a different wavelength, e.g., the infrared or ultraviolet, when used in combination with a suitable imaging device, e.g., a videocamera." (*Id.*, col. 7:60-65) And it teaches that aside from dyes, "[a]dditional visualization agents may be used, such as fluorescent . . . compounds . . . , x-ray contrast agents . . . for visibility under x-ray imaging equipment, ultrasonic contrast agents, or MRI contrast agents[.]" (*Id.*, col. 11:5-10) In view of the specification alone, to construe "visualization agent" as Plaintiffs propose would seem to directly contradict these teachings in the specification.

The import of the claim language is similar. As Defendant notes, (D.I. 231 at 23), the

express requirement that the visualization agent be "detectable to a human eye" is recited in some claims. For example, claim 1 of the '034 patent claims:

> **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 (emphasis added)) For claims such as this one, adopting Plaintiffs' proposal ("[a]n agent that is detectable by the human eye") would render some of the additional language relating to the visualization agent redundant, which is disfavored. *See, e.g.*, *W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc.*, Civil Action No. 11-515-LPS-CJB, 2014 WL 3950663, at *9 (D. Del. Aug. 8, 2014) (citing cases). Moreover, construing the term as Plaintiffs propose would limit visualization agents to those detectable by the human eye for *all* claims, even those that do not contain language to that similar to the italicized language in claim 1 of the '034 patent above. This includes claim 16 of the '034 patent:

> **16.** A method for formulating a polymer composition that crosslinks to form a hydrogel, the method comprising selecting a concentration of *visualization agent* for the polymer composition such that the *visualization agent* causes a visually observable change that indicates that a crosslinked hydrogel having a predetermined thickness has been formed on the tissue of a patient wherein the polymer composition comprises electrophilic functional groups and nucleophilic functional groups that crosslink to each other.

('034 patent, col. 40:41-49 (emphasis added)) It also includes, for example, claim 1 of the '566 patent:

> **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))

Despite all this, however, Plaintiffs assert that the "detectable by the human eye" language of their proposed construction is proper because the patentees "expressly disclaimed embodiments that were not detectable by the human eye" during prosecution of the '034 patent. (D.I. 241 at 16; *see also* Tr. at 14) Prosecution history disclaimer occurs when a patentee clearly and unmistakably surrenders claim scope during the course of prosecution, either through argument or amendment. *Heuft Systemtechnik GmbH v. Indus. Dynamics Co., Ltd.*, 282 F. App'x 836, 839 (Fed. Cir. 2008). The Court has examined the prosecution history of the relevant patents, and it agrees with Plaintiffs that the patentees expressly disclaimed embodiments that were not detectable by the human eye, even in relation to those claims that recite "visualization agent" without also expressly reciting the "detectable to a human eye" language.

Turning first to the prosecution history of the '034 patent, the Court notes that original independent claim 28 presented by the patentees is similar to claim 16 recited above, in that it did

not expressly recite that the visualization agent was one that "reflect[s] or emit[s] light at a wavelength detectable to a human eye," as did other originally presented claims such as independent claim 1 and independent claim 13. (D.I. 246, ex. I at 164, 166, 169)[5] Original independent claim 28 instead recited: "[a] method for formulating a polymer composition that crosslinks to form a hydrogel, the method comprising selecting a concentration of visualization agent for the polymer composition that results in a visually observable change when the polymer composition is applied to a substrate at a predetermined thickness[,]" with original claims 29-35 depending from claim 28. (*Id.* at 169)[6]

In a May 17, 2004 Office Action, the Examiner rejected claims 13-20 and 28-35 as being unpatentable over two prior art references: "Hubbell et al." and "Rhee et al." (*Id.* at 235) Rhee et al. described crosslinked polymer compositions that could contain various imaging agents such as iodine or barium sulfate, or fluorine in order to aid visualization of the compositions after administration via x-ray or MRI. (D.I. 242, ex. 15 at 20) Critically, in their July 8, 2004 Response to this rejection, the patentees distinguished Rhee et al. from *both sets of claims* on the basis that Rhee et al. "teach the use of visualization agents for X-Ray or MRI, which are procedures that do not involve detection by a human eye"—even though one set (claims 13-20) expressly recited the "detectable by a human eye" language and the other set (claims 28-35) did

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[5] Citations to D.I. 246 and D.I. 247, which contain the prosecution histories of the relevant patents, will be to the page numbers generated by the ECF system.

[6] It is clear from the prosecution history that original claim 28 ultimately issued as claim 16. (*See, e.g.*, D.I. 246, ex. I at 388, 412-15; '034 patent, col. 40:41-49)

not. (*Id.* at 21)[7] In response, the Examiner again rejected claims 13-20 and 28-35 over Hubbell et al. and Rhee et al. (D.I. 246, ex. I at 277, 285-91)

Then, in a December 20, 2004 Response, the patentees noted that the prior Office Action argued that "Rhee et al. provide the claimed visualization agent for at least some of the claims 13-20 and 28-35[,]" and then the patentees again distinguished Rhee et al. by explaining in detail how the additives in Rhee et al. "are proposed *for visualization by x-ray and MRI* [and] are not directed to reflecting or emitting light at a wavelength detectable to a human eye." (*Id.* at 307-08 (certain emphasis in original)) The patentees then note that the agents disclosed in Rhee et al. are to be clear, in contrast to the claimed visualization agents that are intended to be detectable by the human eye, and the patentees then conclude that "[f]or all of the above reasons, the withdrawal of the rejection of claims 13-20 and 28-35 is requested." (*Id.* at 308)

Nowhere did the patentees distinguish claims 28-35 as claiming visualization agents that did not have to be detectable by the human eye; instead, these claims were lumped in with claims including the express language "detectable to the human eye" by the patentee in overcoming the rejection to these claims. The Court finds that these statements made during prosecution of the

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[7] More specifically, in this July 8, 2004 Response, the patentees: (1) began a paragraph by noting that "Claims 13-20 and 28-35 were rejected under 35 U.S.C. 103(a) in light of Hubbell et al. and Rhee et. al"; (2) next provide one sentence summaries each of original claim 13 and claim 28; (3) provide a few sentences as to why Hubbell et al. is distinguishable from these claims; and (4) then begin the very next paragraph by stating that "*[t]he claims* are directed to visualization agents detectable by a human eye[,]" and go on to distinguish Rhee et al. in the manner described above, by explaining that Rhee et al. does not teach visualization agents that are detectable by a human eye, because Rhee et al. "teach the use of visualization agents for X-Ray or MRI[.]" (*Id.*) In drawing a contrast with Rhee et al., the patentees did so with respect to "*the claims*"—that is, both sets of claims they had previously called out (claims 13-20 and claims 28-35). In other words, to overcome the rejection by Rhee et al., the patentees explained that the claimed visualization agents are detectable to a human eye, even with respect to those claims that did not recite that specific additional language.

'034 patent demonstrate that the inventors limited all of the relevant claims of that patent to "visualization agents" that are detectable to the human eye—including those claims that do not expressly contain that additional language.[8] Put differently, being detectable to the human eye is an inherent part of what it means to be a "visualization agent," according to the patentees.

The next question is whether the disclaiming statements that Plaintiffs made with respect to "visualization agent" during prosecution of the '034 patents also apply to the term as used in the claims of the '566 and '418 patents. Generally, with respect to the construction of terms across patent families, the United States Court of Appeals for the Federal Circuit has explained that "[w]e presume, unless otherwise compelled, that the same claim term in the same patent or related patents carries the same construed meaning." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1334 (Fed. Cir. 2003). Thus, if a clear and unmistakable disclaimer of claim scope is made with respect to a claim limitation in one patent, and if the same limitation is also found in later related patents, it is presumed that the prior disclaimer applies to those later-issued patents as well. *Id.* at 1333 (citing cases); *see also Pragmatus AV, LLC v. Yahoo! Inc.*, Civil Action No. 11-902-LPS-CJB, 2014 WL 1961980, at *4 (D. Del. May 15, 2014) (noting that the "Federal Circuit has held that a claim term in a particular patent may be limited by statements made during the prosecution history of a related patent application" and that where "the *same claim limitation*

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[8] As for Defendant's argument that construing "visualization agent" such that it must be "detectable by the human eye" would read out embodiments described in the specification, the United States Court of Appeals for the Federal Circuit has explained that "limitations may be construed to exclude a preferred embodiment if the prosecution history compels such a result [and that] the fact that claims do not cover certain embodiments disclosed in the patent is compelled when narrowing amendments are made in order to gain allowance over prior art." *N. Am. Container, Inc. v. Plastipak Packaging, Inc.*, 415 F.3d 1335, 1346 (Fed. Cir. 2005).

is at issue [in both patent applications], prosecution disclaimer made on the same limitation in an ancestor application will attach[to the related application]") (internal quotation marks and citations omitted; emphasis in original). And here, the Court finds that the statements Plaintiffs made with respect to "visualization agent" in the '034 patent do apply to the term as recited in the '566 and '418 patents.

Looking first to the prosecution history of the '566 patent, the Court notes that the claims did originally expressly include the "reflects or emits light at a wavelength detectable to a human eye" language, (*see, e.g.*, D.I. 247, ex. J at 75), and this language was eventually deleted from the claims, (*see, e.g.*, *id.* at 271). The Examiner had rejected certain claims as being unpatentable over a prior art reference referred to as "Russell et al.," explaining that Russell et al. disclosed a visualization agent "that reflects or emits light at a wavelength detectable to a human eye with a light reddish color resulting from the Dextran's dye." (*Id.* at 246) Though the patentee then amended the claims to omit the express "detectable to the human eye" language, (*id.* at 271-72), it did not then state that the visualization agents claimed by the '566 patent could be detectable by x-ray or MRI machines. Rather, it stated that it would explain why Russell et al. did not "clearly disclose a polymeric coating for a substrate comprising water, a biocompatible visualization agent and a biodegradable hydrogel, wherein the visualization agent that reflects or omits light at a wavelength detectable to a human eye to thereby provide a means for visualization for the intended purpose of the coating[.]" (*Id.* at 281) In view of the '034 prosecution history, which made it exceedingly clear that a "visualization agent," however used in the claims, was "detectable to a human eye[,]" here deletion of this express language, without more, does not compel the Court to conclude that the same term in the '566 patent carries a different construed

meaning.

Nor does the prosecution history with respect to the '418 patent compel a different result. There, the patentee originally presented 11 claims that recited a "visualization agent" but did not include the "detectable to a human eye" language. (*Id.*, ex. K at 388-89) The Examiner initially rejected these claims under, *inter alia*, the doctrine of obviousness-type double patenting as being unpatentable over: (1) the claims of the '406 patent (another asserted patent in this action whose claims do not recite "visualization agent") in view of Hubbell et al.; and (2) claims 1-38 of the '566 patent. (*Id.* at 438-39, 441) With respect to the first ground, the Examiner explained that while the claims of the '406 patent did not recite use of visualization agents, Hubbell et al. recited a "visualization agent [that] is disposed in the hydrogel and reflects or emits light at a wavelength detectable to a human eye." (*Id.* at 439) As for the second ground, the Examiner explained that the claims of the '566 patent were similar to original claims 1-11 as "the claims of [the '566 patent are] directed to a polymer coating for a substrate comprising water, a biocompatible visualization agent and a biodegradable hydrogel, wherein the visualization agent that reflects or emits [light] at a wavelength [detectable] to a human eye and to a method of preparing composition suitable to coat tissue of a patient thereof." (*Id.* at 441) In response, in order to gain allowance of the claims, the patentee filed terminal disclaimers with respect to, *inter alia*, the '406 and '566 patents. (*Id.* at 465)

In sum, then, the prosecution history for each of the three relevant patents here demonstrates that when the patentees recited "visualization agent" (even in claims that did not otherwise include the express "detectable to a human eye" language), they were indicating that such an agent must be "detectable to a human eye."

For these reasons, the Court will adopt Plaintiffs' proposal in this regard.

3. Final Construction

Once these primary disputes have been addressed, we know that the claimed "visualization agent" is a "substance or material" that need be "detectable to the human eye." That leaves the issue of whether the remaining language in Defendant's proposed construction (i.e., "that imparts a [] color or obscures the optical clarity of the hydrogel") should be adopted. This language is meant to convey what the visualization agent *does* in connection with the invention, (*See* D.I. 231 at 22-23; D.I. 244 at ¶ 28; Defendant's Claim Construction Presentation, Slide 51), and the Court agrees with Defendant that it finds support in the specification.

The specification explains that "visualization agents" may be included in the hydrogel to give it color. (*See* '566 patent, col. 5:10-12, 15-19, 56-58 (explaining that the "lack of color" of conventional polymeric hydrogels makes a layer of hydrogel very difficult to see after it has been applied to tissue and "[t]he visualization agent is preferably an agent that provides a color . . . . It is preferable to provide color by adding a colored visualization agent to the hydrogel precursors before crosslinking")) It also teaches that the visualization agent can be included in the hydrogel to obscure the optical clarity of the hydrogel (or to completely render what is below the hydrogel no longer visible). (*See id.*, col. 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, at which point the hydrogel is a desired thickness. Another suitable method is to apply the hydrogel until the underlying tissue is obscured. An appropriately selected concentration of visualization agent is used so that the

hydrogel obscures the tissue features when the hydrogel achieves a predetermined thickness."))[9]

Thus, the Court recommends that the term "visualization agent" be construed 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."

B. "predetermined thickness"

Plaintiffs propose that "predetermined thickness" be construed to mean "'a thickness determined in advance for a particular application[,]'" while Defendant proposes that it be construed to mean "'a particular thickness of the hydrogel determined before application of the hydrogel[.]'" (D.I. 230 at 4) The term appears in certain claims of the '034 patent, the '566 patent, and the '418 patent. The patent specification explains that "[t]he predetermined thickness

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[9] One criticism Plaintiffs offered with respect to this portion of Defendant's proposed construction is that it improperly imports functional language into the claim term. (D.I. 230 at 3) The Federal Circuit has explained that "[a]n invention claimed in purely structural terms generally resists functional limitation." *Toro Co. v. White Consol. Indus., Inc.*, 266 F.3d 1367, 1371 (Fed. Cir. 2001). Yet it has also noted that "it is 'entirely proper to consider the functions of an invention in seeking to determine the meaning of particular claim language.'" *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1374-76 (Fed. Cir. 2009) (citation omitted) (affirming district court's construction of "spike[,]" which included functional language of "'for piercing the seal[,]'" because, *inter alia*, the entire specification "never suggests that the spike can be anything other than pointed"). "A description of what a component does may add clarity and understanding to the meaning and scope of the claim[,]" and "[t]he criterion is whether the explanation aids the court and the jury in understanding the term as it is used in the claimed invention." *Funai Elec. Co., Ltd. v. Daewoo Elecs. Corp.*, 616 F.3d 1357, 1366 (Fed. Cir. 2010). The Court also notes that "[n]umerous patent cases specifically approve of functional definitions of chemicals." *Precision Fabrics Grp., Inc. v. Tietex Int'l Ltd.*, No. 1:13cv645, 1:14cv650, 2015 WL 224942, at *6-7 (M.D.N.C. Jan. 15, 2015) (construing "intumescent" to mean "'a substance that swells and chars upon exposure to heat or flame'"); *see also, e.g.*, *Lab. Skin Care, Inc. v. Ltd. Brands, Inc.*, 616 F. Supp. 2d 468, 480 (D. Del. 2009) (construing "antimicrobial lotion" to mean "'a lotion that effectively inhibits the growth of or kills microorganisms present on the skin'"); *Procter & Gamble Co. v. McNeil-PPC, Inc.*, No. 08-CV-251-BBC, 2009 WL 196826, at *8 (W.D. Wis. Jan. 26, 2009) (construing "gelling agent" to mean "an agent that has the ability to form a gel").

[of the hydrogel] is chosen to correspond to the particular application." ('034 patent, col. 7:36-38) The specification provides an example of a method of use in which the hydrogel is applied to the tissue "until the color of the hydrogel indicates that a predetermined thickness of hydrogel has been deposited on the tissue":

> 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. A typical patient's tissue has a pinkish appearance and the microvasculature can be observed as thin lines. 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, at which point the hydrogel is a desired thickness. Another suitable method is to apply the hydrogel until the underlying tissue is obscured. An appropriately selected concentration of visualization agent is used so that the hydrogel obscures the tissue features when the hydrogel achieves a *predetermined thickness*.

(*Id.*, col. 7:16-36 (emphasis added)) The parties' dispute with respect to this term boils down to whether "predetermined thickness" must constitute a single particular thickness (i.e., with one specific numerical value), as Defendant argues, or whether it can encompass ranges of predetermined thickness, as Plaintiffs argue. (*See* D.I. 243 at 9-10; Tr. at 25-26; Plaintiffs' Claim Construction Presentation, Slides 17-18; Defendant's Claim Construction Presentation, Slide 23)

In support of their proposal, Plaintiffs assert that the patents describe several ranges of predetermined thickness; thus, they say, adopting Defendant's construction would read out preferred embodiments. (D.I. 230 at 5; D.I. 241 at 10; Tr. at 28) Claim 23 of the '566 patent (which depends from claim 12), for example, claims a method of preparing a composition suitable to coat a tissue substrate of a patient, and its method includes use of a visualization agent

with "a predetermined concentration that indicates a predetermined thickness of the hydrogel as deposited on substrate" "wherein the predetermined thickness is from about 0.5 to about 10.0 mm." ('566 patent, cols. 39:50-40:3, 40:35-36) The specification of the patents at issue likewise makes references to ranges of thickness. The clearest example, in the Court's view, is found in the following description of a particular embodiment of the invention:

> [A] hydrogel . . . is coated onto a tissue and generally has at least a portion with a thickness of between 0.8 to 12.0 mm. One technique for measuring the thickness is to create a hydrogel on a test surface and use a micrometer to measure thicknesses at various points. Alternatively, a calibrated videomicroscopic image could be used. The preferred thickness depends on the medical application but *a preferred thickness* for prevention of surgical adhesions *is about 0.5 to 10 mm, and more preferably about 0.8 to 5 mm and even more preferably about 1-3 mm.*

('034 patent, col. 7:5-15 (emphasis added)) The Court will turn back to this passage momentarily.

For its part, Defendant argues that limiting the term to a singular, particular thickness is consistent with the intrinsic evidence. Looking to the plain language of the claim term itself, Defendant asserts that "predetermined thickness" refers to a singular thickness—i.e., that the term in the claims is not "predetermined thicknesses." (D.I. 243 at 10; Tr. at 76)[10] With respect to the portions of the claims and specification mentioned above, which seem on their face directed to a range of thickness, Defendant's view is that these examples are not actually directed to the entire recited ranges. (D.I. 243 at 10) According to Defendant, for example, claim 23 of the '566 patent, which requires that "the predetermined thickness is from about 0.5 to about 10.00

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[10] Defendant's expert Dr. Lowman opined that the plain and ordinary meaning of "thickness" is singular, and refers to "'the distance through an object, as distinct from width or height.'" (D.I. 244 at ¶ 16 (citation omitted))

mm[,]" would be understood by the POSITA to claim "a particular thickness that falls within the range of about 0.5 to about 10.0 mm." (*Id.*)

Defendant also contends that Plaintiffs' proposal ignores arguments made by the patentees during prosecution. (D.I. 231 at 17; D.I. 243 at 10) There, the Examiner had rejected claims of the '566 patent as being unpatenable over, *inter alia*, Hubbell et al. and a prior art reference known as "Bass et al." (*See* D.I. 232, ex. 3 at HBMT0407020)[11] To overcome the rejection, the patentees argued that Hubbell et al. and Bass et al. did not teach the claimed features of "a visualization agent in a predetermined concentration that indicates a predetermined thickness of the hydrogel[.]" (*Id.* at HBMT0407056-57) With respect to Hubbell et al., they explained that:

> Any visual change caused by the dye of Hubbell et al. will not be *correlated with any particular thickness of the hydrogel*, since the amount of unconsumed dye present can vary depending upon arbitrary polymerization conditions such as the duration of exposure to the polymerizing light source as affected by the choice of light source and its distance from the tissue, intensity of the light source, and the thickness of the precursor composition.

(*Id.* (emphasis added)) Bass et al., like Hubbell et al., used light absorbing initiator dyes to activate a reaction, (*see* Plaintiffs' Claim Construction Presentation, Slide 16; Tr. at 24), and therefore the patentees distinguished that reference on the same grounds, (Tr. at 24; D.I. 232, ex. 3 at HBMT0407057 (patentee stating that Bass et al. "does not teach or suggest the visualization

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[11] During oral argument regarding Plaintiffs' Motion for Preliminary Injunction, Plaintiffs' counsel described Hubbell et al. as claiming a hydrogel formed by a photo-initiated crosslinking reaction. Hubbell mixed a catalyst dye in the hydrogel components, and described putting an ultraviolet ("UV") light source on the material that would start a catalytic reaction which would initiate the cross-linking. (D.I. 159 at 62-63) During this process, parts of the dye were consumed, with the particular amount of consumption varying depending upon the exposure to the UV light source. (*Id.* at 63)

agent used can be *correlated with any particular thickness* of composition") (emphasis added)). Defendant contends that these prosecution history arguments clarify that the claimed predetermined thickness is a "particular thickness" which it asserts is "a *singular* thickness." (D.I. 243 at 10 (emphasis in original))

This issue is not free from doubt. Ultimately, though, the Court believes that Plaintiffs' position is correct.

Most persuasive in this regard is the portion of the specification found at column 7, lines 11-13 of the '034 patent. The patent there states that while the preferred thickness depends on the medical application, "*a* preferred thickness . . . *is* about 0.5 to 10.0 mm[.]" ('034 patent, col. 7:11-13 (emphasis added)) These words do not read that "a preferred thickness is located somewhere in the range of 0.5 to 10.0 mm" or "a preferred thickness is located at a particular point in the range of 0.5 to 10.0 mm." Rather, the plain import of the language is that *a* thickness *is* about 0.5 to 10.0 mm—i.e., it can be a range. (Tr. at 109 (Plaintiffs' counsel noting that this language demonstrates that when the inventors "talked about a thickness, they meant a range"); *see also id.* at 28)

Indeed, as to this portion of the specification, even the testimony of Defendant's expert, Dr. Lowman, can be seen as helpful to Plaintiffs. Dr. Lowman discussed a sentence found at column 7, lines 7-10 of the '034 patent—the sentence located just prior to the portion of the '034 patent specification quoted in the previous paragraph. With respect to this sentence, which explains that a technique for measuring thickness is to apply a hydrogel to a test surface "and use a micrometer to measure thicknesses at various points[,]" Dr. Lowman acknowledged that "[t]he specification expressly recognizes that, *while a hydrogel may have regions of different*

thicknesses, it will have a particular thickness at any point." (D.I. 244 at ¶ 17 (emphasis added)) Plaintiffs do not seem to dispute that *at any given point*, measurement of the hydrogel will result in a specific thickness with one numerical value. But the claims are not directed to obtaining a predetermined thickness at one particular point of the hydrogel. Rather, the "predetermined thickness" limitation is directed to a predetermined thickness of the applied hydrogel generally, which "is chosen to correspond to the particular application." ('034 patent, col. 7:36-38) Since such a hydrogel may have different regions of different thicknesses, it seems consistent that the "predetermined thickness" at issue could constitute a range of thickness, such as the range claimed in claim 23 of the '566 patent ("the predetermined thickness is from about 0.5 to about 10.0 mm") or claim 14 of the '034 patent ("choosing the predetermined thickness to be about 0.5 to about 4.0 mm"). ('566 patent, col. 40:35-36; '034 patent, col. 40:35-36; *see also* Tr. at 27-28 (Plaintiffs' counsel explaining that the inventions are directed to a "hydrogel that you're applying to a surface . . . . It's not going to be a precise[,] completely level application as you put it on. You will have some variance in what that thickness is. That's why they say measure it at different places on the hydrogel so you will get a range based on that, that would have to be within the range the person has determined in advance"))

In sum, the specification is more consistent with the notion that the user will predetermine a numeric value as to thickness that he wishes to achieve in advance, and that can be a range of thickness (not just one particular number). And thus, as Dr. Mays has opined—with respect to claim 14 of the '034 patent, for example, in which the user chooses "the predetermined thickness to be about 0.5 to about 4.0 mm"—the patent there "provides guidance of an exemplary numerical thickness range of [] hydrogel tissue coatings, i.e. between about 0.5

to about 4.0 mm[,] [and] [a]ll claim 14 requires is that the color of the hydrogel indicates that a predetermined thickness of hydrogel between about 0.5 to about 4.0 mm has been deposited on the tissue." (D.I. 122, ex. 6 at ¶ 96)[12]

With respect to Defendant's prosecution history disclaimer argument, the Court agrees with Plaintiffs that the statements made by the patentees do not *clearly* disavow a range of predetermined thickness. After all, it is not as if Hubbell et al. and Bass et al. claimed predetermined thickness ranges and the patentees distinguished their inventions by arguing that they were directed to a singular predetermined thickness. Rather, the patentees were distinguishing these prior art references by noting that the dye present in these disclosures varied each time the composition was made because the dyes were consumed during polymerization—such that there would not necessarily be a reliable correlation between any visual change in the dye and any predetermined thickness of the hydrogel. (*See* Tr. at 23-25, 109) Put differently, in the prosecution history, the patentees were clearly making a point about *lack of correlation*, and in doing so, they did not really seem to be focused on laying out a definition of "predetermined thickness." Although the patentees did use the phrase "particular thickness" in making their point, it is just not clear enough that they did so in order to infuse meaning into the "predetermined thickness" limitation.[13]

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[12] The Court notes that during the preliminary injunction proceedings, Defendant seemed to acknowledge that the claims could encompass ranges of thickness. (*See, e.g.*, D.I. 159 at 143-45, 147-48, 154 (Defendant's counsel acknowledging that the desired predetermined thickness for the accused product is between 1 to 2 millimeters and agreeing that "[i]f some aspect of the color of the hydrogel could indicate that you were within that predetermined range, then there would be infringement"))

[13] In its briefing, a second criticism that Defendant had of Plaintiffs' proposed construction here was that the "in advance" language was imprecise in failing to define a specific

For these reasons, the Court recommends that the term "predetermined thickness" be construed as "a thickness (which can be a singular thickness or a range of thickness), determined before application of the hydrogel, for a particular application."[14]

C. "observable change"

Plaintiffs propose that "observable change" be construed to mean "'a change in appearance observable to the human eye[,]'" while Defendant argues that the term is indefinite, but to the extent it should be construed, it should be construed to mean "'a visually discernible change in the color or transparency of the hydrogel[.]'" (D.I. 230 at 12; D.I. 231 at 17) The term "observable change" appears in certain claims of the '034 patent, the '566 patent, and the '418 patent.

1. Legal Standards Regarding Definiteness

35 U.S.C. § 112 ("Section 112") requires that a patent claim "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2.[15] If it does not, the claim is indefinite and therefore invalid. *Nautilus, Inc. v. Biosig*

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timeframe for determining the thickness—for instance, could it encompass a determination made during application? (D.I. 231 at 16-17) During oral argument, however, Plaintiffs' counsel confirmed that the "in advance" language in their proposal means "before application of the hydrogel[,]" (Tr. at 22), and so there is no longer a dispute with respect to this language, (*id.* at 76). For avoidance of doubt, the Court will incorporate the "before application of the hydrogel" language into its construction of the term.

[14] The Court's decision here is without prejudice to 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).

[15] Here, the Court refers to the text of Section 112 as it read prior to the passage of the Leahy-Smith America Invents Act, since the patent applications leading to the patents at issue

Instruments, Inc., 134 S. Ct. 2120, 2125 (2014) ("*Nautilus*"). In *Nautilus*, the Supreme Court of the United States set out the test to be applied in the indefiniteness inquiry: "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Id.* at 2124. Definiteness is to be evaluated from the perspective of a POSITA at the time the patent was filed. *Id.* at 2128.

Like claim construction, definiteness is a question of law for the court. *H-W Tech., L.C. v. Overstock.com, Inc.*, 758 F.3d 1329, 1332 (Fed. Cir. 2014); *Pi-Net Int'l Inc. v. JPMorgan Chase & Co.*, 42 F. Supp. 3d 579, 586 (D. Del. 2014). The Federal Circuit has stated that "[a]ny fact critical to a holding on indefiniteness . . . must be proven by the challenger by clear and convincing evidence." *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1366 (Fed. Cir. 2003); *see also Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1338 (Fed. Cir. 2008).[16]

The primary purpose of the definiteness requirement is to ensure that patent claims are written in such a way that they give notice to the public of what is claimed, thus enabling interested members of the public (e.g., competitors of the patent owner) to determine whether they infringe. *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779-80

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here were filed well before September 16, 2012. ('034 patent; '418 patent; '566 patent); *see also Q.I. Press Controls, B.V. v. Lee*, 752 F.3d 1371, 1374 n.2 (Fed. Cir. 2014).

[16] In *Nautilus*, the Supreme Court left open the question of whether factual findings subsidiary to the ultimate issue of definiteness should, in fact, trigger the application of a "clear-and-convincing-evidence standard[,]" noting that it would "leave th[is] question[] for another day." *Nautilus*, 134 S. Ct. at 2130 n.10. In the absence of Supreme Court precedent to the contrary, the Federal Circuit's caselaw (utilizing the clear-and-convincing-evidence standard) controls. *See Cal. Inst. of Tech. v. Hughes Commc'ns Inc.*, 35 F. Supp. 3d 1176, 1182 n.4 (C.D. Cal. 2014).

(Fed. Cir. 2002). Put another way, "[a] patent holder should know what he owns, and the public should know what he does not." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 731 (2002). Even so, the Supreme Court has recognized that "absolute precision is unattainable." *Nautilus*, 134 S. Ct. at 2129. Claims with language utilizing terms of degree have long been found definite, where they provide "'enough certainty to one of skill in 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)).

2. Discussion

Turning first to Defendant's indefiniteness argument, Defendant asserts that the term "observable change" is "'purely subjective'" and "there is nothing in the intrinsic record that provides an objective measure for determining whether an 'observable change' did or did not occur across different individuals, let alone that precisely defines [the] specific change the users should be observing[.]" (D.I. 231 at 18 (quoting *Interval Licensing. LLC*, 766 F.3d at 1371); *see also* D.I. 243 at 11-12; Tr. at 95) In support of its position that "observable change" is a subjective term that is indefinite, Defendant cites to, *inter alia*, *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364 (Fed. Cir. 2014) and *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1350 (Fed. Cir. 2005). (D.I. 231 at 18; Defendant's Claim Construction Presentation, Slide 62) But in the Court's view, these cases do not compel a conclusion that "observable change" is indefinite for the reasons pressed here by Defendant.

In *Interval Licensing*, the Federal Circuit found that claims related to displaying content "'in an unobtrusive manner that does not distract a user'" were invalid for indefiniteness, 766

F.3d at 1371-74, and in *Datamize*, the Court considered claims directed to an "aesthetically pleasing" look and feel for interface screens, finding that such language rendered the claims indefinite, 417 F.3d at 1350-56. Those cases, in addition to "involv[ing] terms that were subjective in the sense that they turned on a person's tastes or opinion[,]" *Sonix Tech. Co.*, 844 F.3d at 1378, also involved intrinsic records that did not provide sufficient guidance as to the scope of the claims, *Interval Licensing*, 766 F.3d at 1371-74; *Datamize*, 417 F.3d at 1352.

Here, in contrast, the term "observable change" is not purely subjective. It does not rely on a person's whimsical taste or opinion to give the term meaning; instead it relies on a user's visual observation. And as this Court has recently explained, "[a] claim is not indefinite just because a person has to make a visual judgment." *Ansell Healthcare Prods. LLC v. Reckitt Benckiser LLC*, No. 15-cv-915 (RGA), 2017 WL 1021844, at *2 n.2 (D. Del. Mar. 16, 2017); *cf. Collins & Aikman Floor Coverings, Inc. v. Interface, Inc.*, Civil Action File No.: 4:05-CV-0133-HLM, 2009 WL 10669083, at *5 (N.D. Ga. Jan. 8, 2009) (noting that "patent claims which rely on [an artisan's] visual assessment" are not inherently indefinite).

The Federal Circuit recently illustrated this principle in *Sonix Tech. Co., Ltd. v. Publ'ns Int'l Ltd.*, 844 F.3d 1370 (Fed. Cir. 2017), where it reversed a district court's finding that the claim term "visually negligible" rendered the asserted claims invalid as indefinite. 844 F.3d at 1381. The Federal Circuit explained that while "visually negligible" was indeed a "term of degree[,]" it was not "'purely subjective'" like the terms at issue in *Interval Licensing* and *Datamize*. *Sonix Tech.*, 844 F.3d at 1377-78. Rather, the Court explained that the question of whether something is "'visually negligible' . . . involves what can be seen by the normal human eye[,]" which the Court found to "provide[] an objective baseline through which to interpret the

claims." *Id.* The Court then noted that "the written description is key to determining whether a term of degree is indefinite[,]" and concluded that the written description of the asserted patent contained "statements that provide guidance on how to create visually-negligible indicators, and specific examples that provide points of comparison for the result." *Id.* at 1379.

Similar to the situation in *Sonix Tech.*, here the term "observable change" is not indefinite on this record. Turning first to the claim language, it is true that certain claims do not specify exactly what the observable change at issue is said to be. For example, claim 16 of the '034 patent claims:

> **16.** A method for formulating a polymer composition that crosslinks to form a hydrogel, the method comprising selecting a concentration of visualization agent for the polymer composition such that the visualization agent causes a visually *observable change* that indicates that a crosslinked hydrogel having a predetermined thickness has been formed on the tissue of a patient . . . .

('034 patent, col. 40:41-47 (emphasis added)) This claim language tells us only that the "observable change" *indicates* something—that a predetermined thickness has been formed.

Yet certain of the dependent claims do recite specific examples of what type of "observable change" the user must see. (*See* D.I. 230 at 13; Plaintiffs' Claim Construction Presentation, Slide 22) For instance, claim 18 of the '034 patent claims the method of claim 16, wherein "the observable change is not being able to see a substrate through the polymer composition." ('034 patent, col. 40:52-54) Claim 19 also claims the method of claim 16, wherein "the observable change is not being able to see patterns in a substrate surface through the polymer composition." (*Id.*, col. 40:55-57) And claim 25 of the '566 patent lists a number of examples of "observable change[s]"—"not being able to see the substrate tissue through the

polymer composition" or "not being able to see patterns in the substrate tissue surface through the polymer composition" or where "the features of the substrate are obscured" or "not being able to see the microvasculature on the substrate tissue[.]" ('566 patent, col. 40:53-58)

While the specification does not explicitly use the term "observable change," it too undisputedly discusses examples of what would constitute such a change. (*See* D.I. 231 at 18 (Defendant noting that the specification "mentions subjective assessments to be made by the user")) As described above, the specification teaches that a preferred method of use is to first "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." ('034 patent, col. 7:21-25) Then, in use:

> the user applies the hydrogel until the desired color is reached. A typical patient's tissue has a pinkish appearance and the microvasculature can be observed as thin lines. 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*, at which point the hydrogel is a desired thickness. Another suitable method is to apply the hydrogel *until the underlying tissue is obscured.* An appropriately selected concentration of visualization agent is used *so that the hydrogel obscures the tissue features* when the hydrogel achieves a predetermined thickness.

(*Id.*, col. 7:25-36 (emphasis added))

In light of this guidance, the Court agrees with Plaintiffs that a POSITA reading the specification would understand what to look for with respect to an "observable change."[17] All of

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[17] Defendant presents as separate claim terms for construction phrases describing the specific assessments of observable change (i.e., "[the/an] observable change [of/is] not being able to see the substrate tissue through the polymer composition, not being able to see patterns in the substrate tissue surface through the polymer composition, the features of the substrate are obscured, or not being able to see the microvasculature on the substrate tissue") that the Court

the examples of such a "change" in the patents (those listed above and otherwise) describe either (1) how the person using the hydrogel is unable to see a thing or feature (substrate tissue, or patterns in a substrate surface, or microvasculature) after the composition is applied that the viewer *could* see before the composition was applied; (2) how the person using the hydrogel is able to see a certain feature less clearly after the composition is applied; or (3) how the person using the hydrogel observes a change in color that results when the predetermined thickness is reached. These examples, then, provide the necessary objective baseline through which one can interpret the claims.

As for the proper construction of the term, the Court finds that the "observable to the human eye" portion of Plaintiffs' proposal should be adopted (over the "visually discernable" language of Defendant's proposal, which allows for detection via the help of machines). (Plaintiffs' Claim Construction Presentation, Slide 21; Tr. at 33) As described above in discussing "visualization agent" (which causes the observable change), the patentees limited the term to one that is detectable to the human eye. Therefore, the Court finds it appropriate to restrict the "change" at issue to be one that may be seen only by the human eye.

With respect to the remainder of the proposed constructions, the last few words of Defendant's proposal strike the Court as in line with the guidance provided by the patents. Plaintiffs argue that this proposal improperly limits the scope of the claimed invention, asserting that the claims do not require that the observable change be limited to a "'change in the color or transparency of the hydrogel[.]'" (D.I. 230 at 13) But Plaintiffs never clearly indicated *why* Defendant's proposal was "under inclusive in some way" or why it would fail to capture the

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will take up next.

meaning demonstrated by the examples of "observable changes" that are set out in the patents. (Tr. at 32-33) Most of those examples, as noted above, speak of a viewer being unable to see a feature or thing (or to see it less clearly) after the composition is applied. These are events that would all surely amount to a "change in the . . . transparency of the hydrogel."[18]

Therefore, the Court recommends that "observable change" be construed to mean "change in the color or transparency of the hydrogel observable to the human eye."

D. "[the/an] observable change [of/is] not being able to see the substrate tissue through the polymer composition, not being able to see patterns in the substrate tissue surface through the polymer composition, the features of the substrate are obscured, or not being able to see the microvasculature on the substrate tissue"

Claims 22 and 25 of the '566 patent and claim 11 of the '418 patent each recite that the predetermined thickness of the hydrogel is indicated by "[the/an] observable change [of/is] not being able to see the substrate tissue through the polymer composition, not being able to see patterns in the substrate tissue surface through the polymer composition, the features of the substrate are obscured, or not being able to see the microvasculature on the substrate tissue." Plaintiffs do not provide a proposed construction for these terms, asserting that the POSITA would understand what these phrases mean in the context of the claims and the patents. (D.I. 230 at 13-14; D.I. 241 at 9) Defendant asserts that these terms are indefinite because the recited changes include the phrase "'the features of the substrate are obscured[,]'" and because "any measure of an 'observable change' based on an assessment of the substrate being 'obscured' is inherently ambiguous and subjective." (D.I. 231 at 20)

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[18] Indeed, Defendant, in its responsive brief, indicated its view that Plaintiffs "do not identify *any* 'observable change' caused by a visualization agent in a hydrogel that would not be captured by [Defendant's] construction." (D.I. 243 at 12 n.1 (emphasis in original))

Alternatively, if the Court construes these terms, Defendant proposes that these terms be construed to mean "'the/a visually discernible change in the transparency of the hydrogel caused by the visualization agent of/is not being able to see the substrate tissue through the polymer composition, not being able to see patterns in the substrate tissue surface through the polymer composition, the features of the substrate are no longer clearly visible, or not being able to see the microvasculature on the substrate tissue." (*Id.*) Defendant's proposal highlights two basic disputes between the parties with respect to these terms: (1) whether the word "obscured" renders the term indefinite (or whether it should be further defined); and (2) whether the construction should specify the requirement that it is the recited "visualization agent" that causes the observable change. (*Id.* at 20-21)

With respect to the parties' first dispute, Defendant's argument is that "obscure" does not have one unambiguous meaning. Therefore, according to Defendant, whether a POSITA discerns an observable change of the features of the substrate being obscured will be subjective, since different people will assess whether the features are "obscured" differently. (*Id.* at 20) Defendant points to Plaintiffs' own expert's infringement analysis as demonstrating that the term "obscured" can be used to describe varying degrees of "obscured." (D.I. 243 at 13) For example, Dr. Mays opined that after the first application of Defendant's hydrogel, he observed that it "*obscures* features of the tissue substrate below including the color and grain of the tissue. . . . With additional applications making the hydrogel thicker, the dye hydrogel *obscures features of the tissue substrate to a greater degree*, making observation of the tissue substrate below and the suture more difficult." (D.I. 122, ex. 6 at ¶ 44 (emphasis added)) Dr. Mays then observed (with respect to an experiment that Dr. Lowman performed) that "the green color hydrogels in

column B *completely obscure* the white substrate below compared to the colorless hydrogels in column D[.]" (*Id.* at ¶ 47 (emphasis added)) Defendant asserts that if an "observable change" simply implicates situations where a feature is said to be "obscured," then "different users would come to different subjective conclusions as to what connotes 'the features of the substrate are obscured' because it could be *any* obscuring, *more* obscuring, and *complete* obscuring." (D.I. 243 at 13 (emphasis in original))

In the context of these claims, however, the Court does not find that these terms are indefinite, nor that it should limit the terms to "the first appearance of any obscuring of an otherwise clear hydrogel—i.e., the first point at which the features of the substrate are no longer clearly visible through the hydrogel." (D.I. 231 at 21) As to definiteness, Defendant itself utilizes the term "obscures" in its proposal for "visualization agent." This suggests that the word has a clear enough meaning to the POSITA. And as to the correct construction, while it is obvious from Dr. Mays' analysis that there can be varying degrees of "obscuring," the type of observable change that occurs when "the features of the substrate are obscured" (and thus indicates that the predetermined thickness of hydrogel has been reached) would depend on the predetermined thickness that the user wanted to reach. (*See, e.g.*, '418 patent, col. 5:48-51 ("A visualization agent in the hydrogel makes the hydrogel change in its appearance until the user determines that the thickness of the hydrogel is sufficient."); *see also* D.I. 122, ex. 6 at ¶ 108 ("One of skill will readily understand that when the hydrogel is applied onto a substrate to reach an average predetermined thickness of the hydrogel, an observable change occurs *indicating the predetermined thickness of hydrogel has been deposited on the substrate.*") (emphasis added); *cf. id.* at ¶ 57 ("[T]he application of the hydrogel is an active process and [] the user is an

experienced surgeon who wants to achieve a continuous coating of suitable thickness with no gaps to provide a dural sealant. The surgeon continually observes the applied hydrogel from start to finish and based on the color of the applied hydrogel, makes a decision whether to apply more hydrogel to achieve a greater thickness or stop applying more hydrogel[.]"))[19]

With respect to the second dispute implicated by Defendant's proposed construction, Plaintiffs never specifically respond to Defendant's argument that any observable change covered by the claims must be caused by the visualization agent. Therefore, it is not entirely clear whether there is a dispute here. To the extent there is one, the Court agrees with Defendant. The plain language of the claims makes it clear that it is the visualization agent that causes the observable change. For example, claim 1 of the '418 patent recites a method comprising "*selecting a concentration of visualization agent . . . so that* when the hydrogel is applied onto a substrate to reach an average predetermined thickness of the hydrogel, *an observable change occurs*[.]" ('418 patent, col. 39:2-5 (emphasis added)) And claim 12 of the '566 patent states that the "visualization agent *has a predetermined concentration that indicates a predetermined thickness of the hydrogel*" with dependent claim 22 then reciting that "the predetermined thickness [indicated by the visualization agent's predetermined concentration] of the hydrogel is indicated by an observable change[.]" ('566 patent, col. 40:1-3, 29-31 (emphasis added))

For these reasons, the Court recommends that the term "[the/an] observable change [of/is] not being able to see the substrate tissue through the polymer composition, not being able to see

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[19] On this point, while the Court is sure what the appropriate construction is, the Court is less sure whether the construction renders the claim indefinite. Again, if Defendant wishes to make such an indefiniteness argument at summary judgment, it may do so with the benefit of a more focused record.

patterns in the substrate tissue surface through the polymer composition, the features of the substrate are obscured, or not being able to see the microvasculature on the substrate tissue" be construed to mean "[the/a] observable change in the transparency of the hydrogel caused by the visualization agent [of/is] not being able to see the substrate tissue through the polymer composition, not being able to see patterns in the substrate tissue surface through the polymer composition, the features of the substrate are obscured, or not being able to see the microvasculature on the substrate tissue."

E. "polymer composition"

Plaintiffs propose that "polymer composition" be construed to mean "'[a] composition including a polymer that crosslinks. A polymer is a molecule formed of at least three repeating groups[.]'" (D.I. 230 at 23) Defendant asserts that it be construed to mean "'[t]he combined materials used to form a hydrogel before they are crosslinked. A polymer is a molecule formed of at least three repeating units *via* polymerization[.]'" (*Id.* (emphasis in original)) The term "polymer composition" appears in certain claims of the '034 patent, the '566 patent, and the '418 patent. The parties' main dispute is whether the term refers to the combination of materials used to form a hydrogel *before* crosslinking has occurred (i.e., to the pre-crosslinked materials), as Defendant asserts, or whether the term refers to both the ingredients prior to cross-linking as well as what remains following the cross-linking, as Plaintiffs argue. (*Id.*; D.I. 231 at 25; D.I. 241 at 19; Tr. at 37, 101-03)[20]

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[20] The parties also dispute whether this term's construction should recite that a polymer is formed "via polymerization." 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) During oral argument, it became clear that this particular dispute is related to the parties' disputes with respect to the term "precursor." (*See* Tr. at 35-36)

The Court agrees with Plaintiffs that the patent does not limit "polymer composition" to the pre-crosslinked materials. It is true that, as Defendant notes, (D.I. 231 at 25; D.I. 243 at 17), certain claim language recites a "polymer composition that crosslinks to form a hydrogel"—thus seeming to distinguish the polymer composition from the hydrogel, (*see, e.g.*, '034 patent, col. 40:41-42; *see also id.*, col. 40:58-60; '566 patent, col. 40:41-42). But it is also true that in other instances, the patent specification and claim language use the term "polymer composition" in a way that references more than just the combination of materials before crosslinking has occurred. (D.I. 230 at 23; D.I. 241 at 19) For example, the specification explains that:

> Methods for using the *polymeric compositions to coat a tissue* include mixing hydrophilic precursor polymers with chemically distinct reactive functional groups *such that they form crosslinks via nucleophilic-electrophilic reaction after mixing and contact with the tissue.* The polymers crosslink to form a biodegradable hydrogel. A preferred application is to prevent surgical adhesions by applying the hydrogel as a coating on a tissue substrate and maintaining another surface of the hydrogel as a free surface.

('034 patent, col. 2:52-60 (emphasis added)) Relatedly, claim 12 of the '566 patent recites a "method of preparing *a composition* suitable to coat a tissue substrate of a patient[,]" ('566 patent, col. 39:50-51 (emphasis added)), and claim 22, which depends from claim 12, adds that the "predetermined thickness of the hydrogel is indicated by an observable change of not being able to see the substrate tissue *through the polymer composition* [or] not being able to see patterns in the substrate tissue surface *through the polymer composition*[,]" (*id.*, col. 40:28-34 (emphasis added)). In light of these references, the Court agrees with Plaintiffs that the intrinsic

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This Report and Recommendation does not address that particular term, and so the Court will address the substance of this issue when it later takes up the proper construction for the term "precursor."

evidence at times equates the polymer composition with the hydrogel that is coated onto the tissue (i.e., after the crosslinking process has begun). (*See, e.g.*, Tr. at 37-38, 112-13) Thus, the construction should therefore not be limited to a specific time frame as Defendant proposes.

As for other aspects of Plaintiffs' proposed construction, the first portion ("[a] composition . . .") simply parrots back the word "composition" that is found in the very term at issue. That is unhelpful. (*See* D.I. 231 at 25) The "combined materials" portion of Defendant's proposal, in contrast, better describes what a composition actually is. It also comports with Plaintiffs' contention that the dictionary definition of "composition" is "'[a] thing composed of various elements[,]'" (D.I. 230 at 23 (citing D.I. 233, ex. 6 at 2)), and so the Court will utilize Defendant's phraseology here.

The remainder of Plaintiffs' construction mimics the explicit definition of "polymer" taught in the specification: "[t]he term polymer, as used herein, means a molecule formed of at least three repeating groups." ('034 patent, col. 6:15-17) And so the Court will adopt it.

For these reasons, the Court recommends 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."

F. "predetermined concentration"

Plaintiffs propose that "predetermined concentration" be construed to mean "'[a] concentration determined in advance to indicate a thickness determined in advance[,]'" while Defendant argues that the term be construed to mean "'[t]he amount of a particular component in a particular volume determined in advance[.]'" (D.I. 230 at 27) This term is found in claims 1 and 12 of the '566 patent, which are directed to a hydrogel and visualization agent "wherein the

visualization agent has a *predetermined concentration* that indicates a predetermined thickness of the hydrogel as deposited on the substrate." ('566 patent, cols. 39:13-15, 40:1-3 (emphasis added))

The crux of the dispute here relates to the word "concentration." There is no dispute that "predetermined" means "determined in advance," as that language is included in both proposals. It is also clear that the "to indicate a thickness determined in advance" language in Plaintiffs' proposal is unnecessary, as the claim language immediately following the term "predetermined concentration" already expresses this concept—that the visualization agent has a predetermined concentration "that indicates a predetermined thickness of the hydrogel." (*See* D.I. 231 at 24; D.I. 243 at 16; Tr. at 42-43) And so the Court is left with the issue of whether to construe "concentration" to mean "the amount of a particular component in a particular volume" in accordance with Defendant's proposal, or whether that word need not be construed. (*See* D.I. 231 at 24 (Defendant noting that its construction "clarifies what [the patents] mean[] by 'concentration'"))

Plaintiffs' briefing does not express why they believe that Defendant's proposal for "concentration" is incorrect. During the *Markman* hearing, the only problem that Plaintiffs raised with respect thereto is that Defendant's proposal uses the phrase "particular component"; according to Plaintiffs, "[t]here's nothing that limits the visualization agent to a particular component. . . . it could be [made up of] multiple different types of dye . . . . So it wouldn't necessarily be *a* component." (Tr. at 42 (emphasis added); *see also* Plaintiffs' Claim Construction Presentation, Slide 27 (noting that the patent does not limit "'visualization agent'" to "'a particular component'" and instead encompasses a "'visualization agent'" that contains

one or more "'components'")) Otherwise, Plaintiffs noted that there was "no dispute as to [the] definition" of "concentration." (Plaintiffs' Claim Construction Presentation, Slide 27)

Plaintiffs' point is well-taken. As was previously discussed, the Court agrees with Defendant that a visualization agent is a substance or material, and in addressing the term "predetermined concentration" in its briefing, Defendant stated that "[a] concentration is an amount of *material* in a particular volume." (D.I. 231 at 24 (emphasis added)) Therefore, rather than utilize the "particular component" language of Defendant's construction, it makes more sense to define "predetermined concentration" as "amount of the substance or material in a particular volume determined in advance." This comports with the specification's teaching that, for instance, 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 . . . . a concentration that is too low will result in a hydrogel that is too thick and a concentration that is too high will result in a hydrogel that is too thin." ('566 patent, col. 7:28-41) This construction is further supported by the specification's explanation that "[t]he visualization agent may be used in small quantities, preferably less than 1% weight/volume, more preferably less that 0.01% weight/volume and most preferably less than 0.001% weight/volume *concentration*." (*Id.*, col. 11:1-4 (emphasis added); *see also* Defendant's Claim Construction Presentation, Slide 43)

For these reasons, the Court recommends that the term "predetermined concentration" be construed to mean "amount of the substance or material in a particular volume determined in advance."

G. Phrases Related to "predetermined thickness"

Claims 16 of the '034 patent, claims 1, 12, 22 and 25 of the '566 patent, and claim 1 of the '418 patent each recite similar claim limitations requiring the use of a "visualization agent" to cause a visual change that indicates that a "predetermined thickness" of the "polymer composition" or hydrogel has been reached. The primary dispute between the parties with respect to these claims is "whether the disputed phrases require that the visual change caused by the 'visualization' agents be correlated with a particular thickness of the hydrogel." (D.I. 231 at 14)[21] Plaintiffs argue that these full phrases do not need to be construed. (Tr. at 43) Rather, Plaintiffs assert that once the other individual disputed terms contained in these phrases are construed, those meanings can simply be plugged in where appropriate, and there is no need to do anything further. (*Id.*) The phrases at issue and Defendant's proposed constructions are set out in the chart below, along with an identification of the asserted claims that contain the terms:

Term	**Defendant's Construction**
"the visualization agent causes a visually observable change that indicates that a crosslinked hydrogel having a predetermined thickness has been formed" ('034 patent, claim 16)	"the visualization agent causes a visually discernable change in the color or transparency of the hydrogel that is correlated with a particular thickness of hydrogel, such that the change can be used to indicate that a crosslinked hydrogel of a particular thickness determined before application has been formed"

[21] Defendant has also argued that because all of the phrases at issue here recite or necessarily require an assessment of an "observable change," they are indefinite. But as discussed previously, the Court has not found the term "observable change" to be indefinite on this record. Therefore, it will proceed to address the parties' claim construction dispute with regard to these phrases.

"visualization agent for the polymer composition that results in a visually observable change when the polymer composition is applied to a substrate tissue at a predetermined thickness" ('566 patent, claim 25)	"visualization agent for the polymer composition that results in a visually discernable change in the color or transparency of the polymer composition that is correlated with a particular thickness of the polymer composition, such that the change indicates that the polymer composition has been applied to a substrate at a particular thickness determined before application"
"visualization agent for the polymer composition so that when the hydrogel is applied onto a substrate to reach an average predetermined thickness of the hydrogel, an observable change occurs indicating the predetermined thickness of hydrogel has been deposited on the substrate" ('418 patent, claim 1)	"visualization agent for the polymer composition so that, when the hydrogel is applied onto a substrate to reach a particular average thickness of hydrogel determined before application, there is a visually discernable change in the color or transparency of the hydrogel that is correlated with a particular average thickness of the hydrogel, such that the change indicates that the hydrogel has been deposited on the substrate at the particular thickness determined before application"
"the predetermined thickness of the hydrogel is indicated by an observable change" ('566 patent, claim 22)	"the particular thickness of the hydrogel determined before application is indicated by a visually discernable change in the color or transparency of the hydrogel that is correlated with that particular thickness of hydrogel"
"the visualization agent has a predetermined concentration that indicates a predetermined thickness of the hydrogel as deposited on the substrate" ('566 patent, claim 1)	"the visualization agent is at a concentration in the materials used to form the hydrogel before they are crosslinked, where the visualization agent at said concentration causes a visually discernable change in the color or transparency of the hydrogel that is correlated with a particular thickness of hydrogel, such that the change can be used to indicate that a hydrogel of a particular thickness determined before application has been deposited on the substrate"

(D.I. 231, Appendix A (internal quotation marks omitted))

Portions of Defendant's proposed constructions for these terms implicate disputes

regarding "observable change" and "predetermined thickness" that the Court has already resolved. Thus, here the Court will simply focus on the "correlation" issue.

The Court finds that the claims do require a correlation between the visual change caused by the visualization agent and the predetermined thickness.[22] Looking to the plain language of the claims, in requiring the use of a "visualization agent" to cause a change that indicates that a "predetermined thickness" has been reached, "the user [must] know, prior to application, what will be the visual change caused by the visualization agent once the 'predetermined thickness' is reached." (D.I. 232 at ¶ 109) Dr. Lowman explained that this "necessarily requires that the visual change caused by the visualization agent be *correlated with a particular thickness of hydrogel*." (*Id.* (emphasis in original)) Put another way, as Defendant's attorney asked during the oral argument regarding Plaintiffs' Motion for Preliminary Injunction ("Preliminary Injunction oral argument"), "[i]f there's no correlation, how can I use [the visual change] as an indication of a predetermined thickness?" (D.I. 159 at 138; *see also id.* at 141-42; Tr. at 75 (Defendant's counsel reiterating that you need to have a correlation between the visual change and the predetermined thickness "or else [the user] cannot use the visual change that's happening to indicate what the thickness is"))

Indeed, from what the Court can tell, Plaintiffs do not seriously dispute that, if "predetermined thickness" is properly construed to encompass a range, then a correlation is required. During the Preliminary Injunction oral argument, for example, Plaintiffs' counsel explained that "[w]hat we're saying is required is that you'll see an observable change *which will*

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[22] The Court reiterates that it has already found that the "predetermined thickness" is not limited to a singular thickness and instead may encompass a range of thickness.

correlate or correspond to a range, just like it says in the patent, the predetermined thickness can be a range." (D.I. 159 at 230 (emphasis added); *see also id.* at 58 (Plaintiffs' counsel explaining that the user will do a test application and will measure to see if he is in the range that he wants, and then will be able to see the observable change at that thickness and will then "know exactly what to look for when [the user goes] out to actually do it in [] a neurosurgical operation"))

Finally, requiring a correlation also comports with the patentees' arguments distinguishing Hubbell et al. from the present inventions during the prosecution history, as was detailed above. To review, the patentees relied on the phrases at issue to overcome prior art gels containing dyes. (*See* D.I. 231 at 15) For example, to overcome a rejection of claims of the '034 patent based on Hubbell et al., the patentees explained that "[a]ny visual change caused by the dye of Hubbell et al. will not be correlated with any particular thickness of the hydrogel," and "[i]n contrast, Applicants' invention . . . is directed to a composition, wherein the visualization means causes a visually observable change when the composition at a predetermined thickness is applied to the tissue of patient to form a hydrogel." (D.I. 232, ex. 2 at HBMT0406702) And patentees made the same argument with respect to Hubbell et al. during prosecution of the '566 patent. (*Id.*, ex. 3 at HBMT0407056 (explaining that the claims recited various features not taught or suggested by Hubbell et al., such as "a visualization agent in a predetermined concentration that indicates a predetermined thickness of the hydrogel as deposited on a substrate . . . or a concentration of visualization agent for the polymer composition that results in a specific visually observable change . . . . Any visual change caused by the dye of Hubbell et al. will not be correlated with any particular thickness of the hydrogel"))

For these reasons, the Court recommends the following constructions with respect to the

phrases relating to predetermined thickness:

Term	Defendant's Construction	Court's Construction
"the visualization agent causes a visually observable change that indicates that a crosslinked hydrogel having a predetermined thickness has been formed" ('034 patent, claim 16)	"the visualization agent causes a visually discernable change in the color or transparency of the hydrogel that is correlated with a particular thickness of hydrogel, such that the change can be used to indicate that a crosslinked hydrogel of a particular thickness determined before application has been formed"	"the visualization agent causes a visually observable change that is correlated with a thickness of hydrogel, such that the change can be used to indicate that a crosslinked hydrogel having a predetermined thickness has been formed"
"visualization agent for the polymer composition that results in a visually observable change when the polymer composition is applied to a substrate tissue at a predetermined thickness" ('566 patent, claim 25)	"visualization agent for the polymer composition that results in a visually discernable change in the color or transparency of the polymer composition that is correlated with a particular thickness of the polymer composition, such that the change indicates that the polymer composition has been applied to a substrate at a particular thickness determined before application"	"visualization agent for the polymer composition that results in a visually observable change that is correlated with a thickness of the polymer composition, such that the change indicates that the polymer composition has been applied to a substrate at a predetermined thickness"

"visualization agent for the polymer composition so that when the hydrogel is applied onto a substrate to reach an average predetermined thickness of the hydrogel, an observable change occurs indicating the predetermined thickness of hydrogel has been deposited on the substrate" ('418 patent, claim 1)	"visualization agent for the polymer composition so that, when the hydrogel is applied onto a substrate to reach a particular average thickness of hydrogel determined before application, there is a visually discernable change in the color or transparency of the hydrogel that is correlated with a particular average thickness of the hydrogel, such that the change indicates that the hydrogel has been deposited on the substrate at the particular thickness determined before application"	"visualization agent for the polymer composition so that, when the hydrogel is applied onto a substrate to reach an average predetermined thickness of the hydrogel, there is an observable change that is correlated with an average thickness of the hydrogel, such that the change indicates that the predetermined thickness of hydrogel has been deposited on the substrate"
"the predetermined thickness of the hydrogel is indicated by an observable change" ('566 patent, claim 22)	"the particular thickness of the hydrogel determined before application is indicated by a visually discernable change in the color or transparency of the hydrogel that is correlated with that particular thickness of hydrogel"	"the predetermined thickness of the hydrogel is indicated by an observable change that is correlated with that thickness of hydrogel"

"the visualization agent has a predetermined concentration that indicates a predetermined thickness of the hydrogel as deposited on the substrate" ('566 patent, claim 1)	"the visualization agent is at a concentration in the materials used to form the hydrogel before they are crosslinked, where the visualization agent at said concentration causes a visually discernable change in the color or transparency of the hydrogel that is correlated with a particular thickness of hydrogel, such that the change can be used to indicate that a hydrogel of a particular thickness determined before application has been deposited on the substrate"	"the visualization agent has a predetermined concentration, where the visualization agent at said concentration causes an observable change that is correlated with a thickness of hydrogel, such that the change can be used to indicate that a predetermined thickness of the hydrogel has been deposited on the substrate"

H. "the visualization agent being at least partially disposed within the interior"

Plaintiffs propose that the term "the visualization agent being at least partially disposed within the interior" be construed to mean "'the visualization agent is at least within the internal portion of the hydrogel[,]'" while Defendant argues that it should be construed to mean "'the visualization agent is at least partially included within the water[-]containing interior of the hydrogel[.]'" (D.I. 230 at 14) Claims 4, 5 and 10 of the '034 patent (which are dependent on claim 1) are directed to a method of forming a hydrogel that has "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[.]" ('034 patent, cols. 39:63-67, 40:8-11, 23-24)

According to Defendant, its proposal provides clarity to the term by spelling out what constitutes the interior of the hydrogel, thereby differentiating the interior of the hydrogel from the surface thereof. Defendant's position is that "[i]t is the water within the interior of the hydrogel that distinguishes the interior from the surface of the hydrogel, such as the interface

between the hydrogel and air." (D.I. 243 at 16; *see also* D.I. 231 at 25) Defendant cites in support to Dr. Lowman's declaration, wherein he explains that a hydrogel is "made up of a network of crosslinked polymers with pores that are filled with water" and asserts that the surfaces of the hydrogel (those portions attached to a substrate or forming an interface with air) are not part of the interior. (D.I. 232 at ¶ 141)

In response, Plaintiffs contend that Defendant's proposal improperly imports an extraneous limitation into the claim in restricting the visualization agent to being "within the water-containing interior" of the hydrogel. (D.I. 230 at 14-15; D.I. 241 at 18-19; Tr. at 47) During oral argument, Plaintiffs' position crystallized. Their counsel explained that the interior of the hydrogel is the area between (1) the surface of the hydrogel that is on the tissue and (2) the upper surface of the hydrogel, and that, in Plaintiffs' view, this "interior" area "[i]sn't just water." (Tr. at 48) The claims at issue teach that the hydrogel is formed by mixing reactive precursor species that crosslink after contact with the tissue to form the hydrogel, and Plaintiffs' counsel asserted that "within [the three-dimensional crosslink], there are voids and the [visualization agent could] get[] into those voids that may not have water in there." (*Id.* at 48-49)

The Court is in a difficult spot here, because—as to what turned out to be the key area of dispute between the parties—it does not have a lot to go on. Plaintiffs do not cite to any expert testimony that specifically supports their categorization of what makes up a hydrogel's interior (i.e., that explains that there will be voids in the interior of the hydrogel that do not contain water). Nevertheless, Plaintiffs argue that the construction for the term should not include the term "water-containing" because the claims do not exclude a scenario wherein the visualization agent can be included exclusively within the non-water-containing voids found in the interior of

the hydrogel. (*Id.*) As for Defendant, even Dr. Lowman's declaration (which indicates that interior of the hydrogel amounts to "pores that are filled with water"), (D.I. 232 at ¶ 141), does not categorically state that the hydrogel's interior is *exclusively* filled with water, either.

In the end, the Court must most strongly rely on the intrinsic evidence. First and foremost, the claim term at issue is a broad one, in that the visualization agent must only be partially disclosed "within the interior" of the hydrogel. That phraseology, in and of itself, is expansive enough to allow for a scenario in which the visualization agent is disposed in a portion of the interior that does not necessarily contain water. As for the specification, at one point, it notes that "[a]n embodiment of the invention is a hydrogel for use on . . . a patient's tissue. The hydrogel has water, a biocompatible visualization agent, and reactive hydrophilic polymers that form a crosslinked hydrogel after contact with the tissue." ('034 patent, col. 2:25-29) That portion of the written description could have stated that the hydrogel "has water and a biocompatible visualization agent found in the water-containing portion of the hydrogel," but it does not. (*Cf.* D.I. 241 at 18; Tr. at 51) And so it too allows room for Plaintiffs' proposed construction.

With nothing in the claims or the specification restricting the visualization agent to being, in all cases, at least partially disposed within the *water-containing* interior of the hydrogel, the Court will not read such a limitation into the claims. Therefore, the Court recommends that the term "the visualization agent being at least partially disposed within the interior" be construed to mean "the visualization agent is at least within the internal portion of the hydrogel."

IV. CONCLUSION

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

following constructions:

1. "visualization agent" should be construed to mean "a substance or material that is detectable by the human eye and that imparts a color or obscures the optical clarity of the hydrogel"

2. "predetermined thickness" should be construed to mean "a thickness (which can be a singular thickness or a range of thickness), determined before application of the hydrogel, for a particular application"

3. "observable change" should be construed to mean "change in the color or transparency of the hydrogel observable to the human eye"

4. "[the/an] observable change [of/is] not being able to see the substrate tissue through the polymer composition, not being able to see patterns in the substrate tissue surface through the polymer composition, the features of the substrate are obscured, or not being able to see the microvasculature on the substrate tissue" should be construed to mean "[the/a] observable change in the transparency of the hydrogel caused by the visualization agent [of/is] not being able to see the substrate tissue through the polymer composition, not being able to see patterns in the substrate tissue surface through the polymer composition, the features of the substrate are obscured, or not being able to see the microvasculature on the substrate tissue"

5. "polymer composition" should be construed to mean "the combined materials including a polymer that crosslinks. A polymer is a molecule formed of at least three repeating groups"

6. "predetermined concentration" should be construed to mean "amount of the substance or material in a particular volume determined in advance"

7a. "the visualization agent causes a visually observable change that indicates that a crosslinked hydrogel having a predetermined thickness has been formed" should be construed to mean "the visualization agent causes a visually observable change that is correlated with a thickness of hydrogel, such that the change can be used to indicate that a crosslinked hydrogel having a predetermined thickness has been formed"

7b. "visualization agent for the polymer composition that results in a visually observable change when the polymer composition is applied to a substrate tissue at a predetermined thickness" should be construed to mean "visualization agent for the polymer composition that results in a visually observable change that is correlated with a thickness of the polymer composition, such that the change indicates that the polymer composition has been applied to a substrate at a predetermined thickness"

7c. "visualization agent for the polymer composition so that when the hydrogel is applied onto a substrate to reach an average predetermined thickness of the hydrogel, an observable change occurs indicating the predetermined thickness of hydrogel has been deposited on the substrate" should be construed to mean "visualization agent for the polymer composition so that, when the hydrogel is applied onto a substrate to reach an average predetermined thickness of the hydrogel, there is an observable change that is correlated with an average thickness of the hydrogel, such that the change indicates that the predetermined thickness of hydrogel has been deposited on the substrate"

7d. "the predetermined thickness of the hydrogel is indicated by an observable change" should be construed to mean "the predetermined thickness of the hydrogel is indicated by an observable change that is correlated with that thickness of hydrogel"

7e. "the visualization agent has a predetermined concentration that indicates a predetermined thickness of the hydrogel as deposited on the substrate" should be construed to mean "the visualization agent has a predetermined concentration, where the visualization agent at said concentration causes an observable change that is correlated with a thickness of hydrogel, such that the change can be used to indicate that a predetermined thickness of the hydrogel has been deposited on the substrate"

8. "the visualization agent being at least partially disposed within the interior" should be construed to mean "the visualization agent is at least within the internal portion of the hydrogel"

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.

Because this Report and Recommendation may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Report and Recommendation. Any such redacted version shall be submitted no later than **August 3, 2017** for review by the Court, along with a

clear, factually detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Report and Recommendation.

Dated: July 27, 2017

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE