

**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 LifeSciences Sales LLC, Confluent Surgical, Inc. and Incept LLC (collectively, “Plaintiffs” or “Integra”) against Defendant HyperBranch Medical Technology, Inc. (“Defendant” or “HyperBranch”), Plaintiffs allege infringement of United States Patent Nos. 7,009,034 (the “’034 patent”), 7,332,566 (the “’566 patent”), 7,592,418, 8,003,705 and 8,535,705 (the “’5705 patent”) (collectively, the “patents-in-suit” or “asserted patents”).¹ Presently before the Court are: (1) Plaintiffs’ Motion for Summary Judgment of Infringement of claim 10 of the ’034 patent, (D.I. 399) (“Plaintiffs’ Motion”); and (2) Defendant’s Motion for Summary Judgment of Invalidity of claim 10 of the ’034 patent for obviousness, (D.I. 393) (“Defendant’s Motion”).² The Court recommends that

¹ Plaintiffs originally also alleged infringement of United States Patent No. 6,566,406, but Plaintiffs do not appear to currently be asserting any claims from that patent. (*See, e.g.*, D.I. 402 at ix)

² The Court also addresses HyperBranch’s motion for summary judgment of non-infringement of the “mixing” limitation of claims 1, 6, 12 and 17 of the ’5705 patent, (D.I. 393), which remains pending, (*see* D.I. 508 at 7 n.4). The Court previously recommended granting HyperBranch’s motion of non-infringement regarding the asserted claims of the ’5705 patent

Plaintiffs' Motion be GRANTED-IN-PART and Defendant's Motion be DENIED for the reasons set out herein.

I. BACKGROUND

A. The Parties and the Accused Products

The Court incorporates by reference its recent discussions of the parties and of the accused products at issue (HyperBranch's Adherus Dural Sealant, Adherus Spinal Sealant, Adherus AutoSpray Dural Sealant, and Adherus AutoSpray Extended Tip (ET) Dural Sealant (the "Accused Products")), set out in the Court's February 20, 2018 and March 13, 2018 Report and Recommendations. (D.I. 508 at 2-3; D.I. 555 at 2-3)

B. The '034 Patent

The Court also incorporates by reference its recent discussion of the '034 patent, set out in the Court's Report and Recommendation dated March 13, 2018. (D.I. 555 at 4) The instant Motions relate to claim 10 of the '034 patent, which depends from claim 1. Claim 1 and claim 10 recite:

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

based on its non-infringement of another limitation of those claims. (D.I. 508 at 26) The District Court has since adopted that recommendation and granted Defendant's motion of non-infringement with respect to the '5705 patent. (D.I. 679) Therefore, the Court DENIES AS MOOT Defendant's motion as it relates to the mixing limitation in claims 1, 6, 12 and 17 of the '5705 patent. *See MicroStrategy, Inc. v. Bus. Objects, S.A.*, 429 F.3d 1344, 1352 (Fed. Cir. 2005) ("If . . . even one claim limitation is missing or not met, there is no literal infringement."); *Semitool, Inc. v. Novellus Sys., Inc.*, 44 F. App'x 949, 957-58 (Fed. Cir. 2002).

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.

10. The method of claim 1, wherein the hydrogel forms within 5 seconds after contact with the substrate.

('034 patent, cols. 39:56-40:2, 40:23-24)

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)

Briefing on the instant Motions was completed on December 21, 2017, (D.I. 463, 465), and the Court heard oral argument on the Motions (and various other summary judgment and *Daubert* motions filed in the case) on January 5, 2018, (D.I. 482 (hereinafter, "Tr.")). A 7-day trial is set to begin on May 29, 2018. (D.I. 660)

II. STANDARD OF REVIEW

The Court incorporates by reference its prior discussion of the legal standards for resolving summary judgment motions and for establishing patent infringement, which was found in its February 20, 2018 Report and Recommendation. (D.I. 508 at 4-7)

HyperBranch's invalidity defense based on obviousness is also at presently at issue. A patent granted by the United States Patent and Trademark Office (the "PTO") is presumed to be valid. 35 U.S.C. § 282(a); *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 102 (2011). The rationale underlying this presumption of validity is that "the PTO, in its expertise, has approved

the claim[.]” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007). The burden of proving invalidity rests with the patent challenger at all times, who, when disputed questions of fact arise, must establish a patent’s invalidity by clear and convincing evidence in order to prevail.

Microsoft Corp., 564 U.S. at 98-99, 114; *see also id.* at 114-15 (Breyer, J., concurring). Clear and convincing evidence places within the mind of the fact finder “an abiding conviction that the truth of [the] factual contentions are highly probable.” *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009) (quoting *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984)).

A patent claim is invalid as obvious under 35 U.S.C. § 103 “if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.” 35 U.S.C. § 103; *see also KSR Int’l*, 550 U.S. at 406-07. “Obviousness is a question of law based on underlying factual findings: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the art; and (4) objective indicia of nonobviousness.” *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1360 (Fed. Cir. 2012) (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). A party seeking to invalidate a patent on the basis of obviousness must establish (by clear and convincing evidence) that a person of ordinary skill in the art (“POSITA”) would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the POSITA would have had a reasonable expectation of success in doing so. *Id.*

Objective considerations of nonobviousness constitute “independent evidence” which

“may often be the most probative and cogent evidence of nonobviousness in the record.” *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1378 (Fed. Cir. 2012) (internal quotation marks and citations omitted). The objective considerations, which include unexpected results, expert skepticism, copying, commercial success, praise by others, and long-felt need, “help inoculate the obviousness analysis against hindsight.” *Id.* at 1378-79. The United States Court of Appeals for the Federal Circuit has explained that:

These objective criteria thus help turn back the clock and place the claims in the context that led to their invention. Technical advance, like much of human endeavor, often occurs through incremental steps toward greater goals. These marginal advances in retrospect may seem deceptively simple, particularly when retracing the path already blazed by the inventor. For these reasons, this court requires consideration of these objective indicia because they provide objective evidence of how the patented device is viewed in the marketplace, by those directly interested in the product.

Id. at 1378 (internal quotation marks and citation omitted). The proponent of the evidence of objective considerations bears the burden of showing that a nexus exists between the claimed features of the invention and the objective evidence offered to show non-obviousness. *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1068 (Fed. Cir. 2016). The existence of a nexus is a question of fact. *Id.*

III. DISCUSSION

A. Plaintiffs’ Motion

Plaintiffs move for summary judgment that Defendant and its customers have directly infringed claim 10 of the '034 patent. (D.I. 400 at 1, 5) They also move for summary judgment that HyperBranch is liable for induced infringement and contributory infringement of claim 10.

(*Id.* at 1)

Claim 10 is directed to a method of preparing a composition, and “[a] method claim is *directly* infringed only by one practicing the patented method.” *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 775 (Fed. Cir. 1993) (emphasis in original); *see also Mirror Worlds, LLC v. Apple Inc.*, 692 F.3d 1351, 1359 (Fed. Cir. 2012) (explaining that to establish direct infringement of a method claim, the plaintiff “has to show that [the defendant] performed all of the steps in the claimed method[.]”). Here, Plaintiffs assert that HyperBranch itself has performed each step of claim 10 by formulating and manufacturing the Accused Products, and then using them to make hydrogels in the course of demonstrating the Accused Products to customers and potential customers. (D.I. 400 at 5; D.I. 465 at 1) Moreover, Plaintiffs contend that HyperBranch’s customers have performed every step of claim 10 by using the Accused Products for dural repair. (D.I. 400 at 5; D.I. 465 at 1)³ Defendant makes several different arguments in response, which

³ Although Plaintiffs did not make this expressly clear in their briefing, Plaintiffs’ infringement claims pursuant to 35 U.S.C. §§ 271(a), 271(b) and 271(c) do not appear to relate to those of the Accused Products that are not approved for use (and that are thus not used within) the United States (i.e., Adherus Dural Sealant and Spinal Sealant). (*See* D.I. 441 at 4) Instead, these claims appear to relate to the Adherus AutoSpray Dural Sealant and Adherus AutoSpray Extended Tip (ET) Dural Sealant products; thus, those are the products at issue in the Court’s discussion of infringement below.

Indeed, in its answering brief, HyperBranch asserted that Plaintiffs’ infringement allegations regarding claim 10 fail to the extent that they relate to Adherus Dural Sealant and Spinal Sealant, because patent infringement cannot be predicated on acts wholly done in a foreign country. (*Id.* (citing *Dowagiac Mfg. Co. v. Minnesota Moline Plow Co.*, 235 U.S. 641, 650 (1915))). In response, Plaintiffs noted that any use of such products outside the United States to make hydrogels supports Plaintiffs’ infringement claims under 35 U.S.C. § 271(f)(1) and 35 U.S.C. § 271(f)(2). (D.I. 465 at 1 n.2) However, Plaintiffs only moved for summary judgment regarding 35 U.S.C. §§ 271(f)(1)-(2) with respect to *claim 4 of the '566 patent*. (D.I. 400 at 1-2; D.I. 465 at 21-22) And the Court has addressed that motion in a prior Report and Recommendation. (D.I. 555 at 32) For these reasons, the Court does not assess herein whether Plaintiffs have established export infringement with respect to claim 10 of the '034 patent.

the Court will take up in turn.

1. Direct Infringement By HyperBranch

In Plaintiffs' opening brief, they argue that HyperBranch itself has performed every step of claim 10 "by formulating and manufacturing the Adherus products and using the Adherus products to make hydrogels while demonstrating the accused products to customers and potential customers." (D.I. 400 at 5) Plaintiffs then cite to evidence establishing that HyperBranch employees and distributors were present in operating rooms and related locations, instructing physicians and staff on how to set up the products and on how to use the products. (*Id.* at 5-6 (citing D.I. 429, ex. 3 at 184-85; *id.*, ex. 4 at 39-40; *id.*, ex. 5 at 15-16, 20-25, 38-43, 52; *id.*, ex. 6 at HyperBranch's Responses and Objections Nos. 25, 27-28, 33; *id.*, ex. 7 at 53-57, 60-61, 91-92, 115-16)) Plaintiffs further note that that the Instructions for Use included with the Accused Products teach end users to assemble and use the products to make hydrogels, and HyperBranch prepares videos showing how to prepare and apply the Accused Products. (*Id.* (citing D.I. 429, ex. 3 at 156, 168; *id.*, exs. 8, 11-15, 17-19, 44))

In response, Defendant asserts that claim 10 requires "mixing . . . *after contact with the tissue* to form a hydrogel[,]" and that Plaintiffs have failed to establish that "anyone *employed by HyperBranch* (or one of its distributors)" has ever used an Accused Product and applied it to "the tissue" of a patient. (D.I. 441 at 3 (certain emphasis in original, certain emphasis added)) While it is true that Defendant's employees and/or its distributors perform demonstrations to surgeons in which they spray the product onto a surface, Defendant argues that this fact does not prove direct infringement, in that it does not meet the requirement that the product be applied to "the tissue." (*Id.*) And Defendant further retorts (in a footnote) that the mere fact that

HyperBranch employees and/or its distributors might be present in an operating room when *hospital personnel* use the Accused products to form a sealant on the tissue of a patient is not sufficient proof of Defendant's infringement, because those hospital employees do not work for Defendant. (*Id.* at 3 n.3)

In their reply brief, Plaintiffs respond that Defendant should be held "vicariously liable" for the actions of surgeons who actually apply the Accused Products to the tissue of patients. (D.I. 465 at 2) They argue that this is appropriate under the current legal framework for direct infringement of a method claim. (*Id.*)

Plaintiffs are correct that the Federal Circuit has held—in cases including *Travel Sentry, Inc. v. Tropp*, 877 F.3d 1370, 1378 (Fed. Cir. 2017) and *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1364-65 (Fed. Cir. 2017)—that an entity can be held responsible for others' performance of a patented method under 35 U.S.C. § 271(a) where, *inter alia*, that entity directs or controls the performance of others. A two-pronged test is utilized to determine whether liability can be found: the alleged infringer must (1) condition participation in an activity or receipt of a benefit upon others' performance of one or more steps of a patented method; and (2) establish the manner or timing of that performance. *Eli Lilly*, 845 F.3d at 1365; *see also Travel Sentry*, 877 F.3d at 1378. Whether a single actor has directed or controlled the acts of one or more third parties is a question of fact. *Travel Sentry*, 877 F.3d at 1378.

Under the circumstances here, it would not be equitable for the Court to grant Plaintiffs' summary judgment based on this theory. For one thing, Plaintiffs raised the vicarious liability argument for the first time in their reply brief. (Tr. at 144; Defendant's Summary Judgment Presentation, Slide 131) In Plaintiffs' opening brief, Plaintiffs never clearly identified their

reliance on a vicarious liability theory. In that brief, they did not, for example: (1) use the words “vicarious liability”; (2) note the above-referenced two-part test for vicarious liability; or (3) cite to any supporting caselaw (like the decision in *Eli Lilly*).⁴ At best, Plaintiffs vaguely foreshadowed their future reliance on this theory by citing to evidence that Defendant’s employees/distributors instructed their customers on how to use the Accused Products. (D.I. 400 at 6) A party really should be clear in its opening brief as to the bases on which it is entitled to relief—so that, among other things, the responding party is fairly put on notice of which fights it has to fight (and which it does not).

Moreover, the Court does not have before it some other important information about this claim. That is, the Court does not know: (1) what Plaintiffs’ theory was during the course of this litigation as to direct infringement of claim 10 (and whether, as Defendant alleges, Plaintiff did not earlier disclose the vicarious liability theory), or (2) whether Defendant had ever contended, prior to its opposition brief, that it does not infringe claim 10 because it does not directly apply hydrogel to the tissue of a patient (and if it had not, whether it *should* have fairly made this assertion earlier in the case).

In sum, Plaintiffs have not shown that Defendant’s employees or distributors apply the Accused Products to the tissue of a patient. And for the reasons set out above, the Court is not prepared to find that Plaintiffs should prevail on their vicarious liability theory of direct infringement. Thus, the Court recommends that Plaintiffs’ motion for summary judgment of HyperBranch’s direct infringement of claim 10 be denied.

⁴ While the *Travel Sentry* decision issued just a few days before Plaintiffs’ reply brief was filed, *Eli Lilly* issued almost a year before.

2. Direct Infringement By HyperBranch's Customers

With respect to direct infringement by Defendant's customers, Defendant challenges Plaintiffs' infringement position in two primary ways (relating to two different claim limitations). The Court addresses these two arguments in turn below.

a. The "Forms Within 5 Seconds" Limitation

Defendant first argues that Plaintiffs have failed to demonstrate that use of the Accused Products meets claim 10's limitation requiring that "the hydrogel forms within 5 seconds after contact with the substrate" (the "forms within 5 seconds" limitation). (D.I. 441 at 5) With regard to this limitation, Defendant explains that: (1) the process of hydrogel formation begins immediately upon mixing the nucleophilic and electrophilic functional groups as they begin to crosslink; (2) the formation process continues through "gel time"; and (3) crosslinking continues thereafter, until there is a fully "cured" hydrogel in which all of the functional groups that can react have reacted. (*Id.* at 6; D.I. 429, ex. 42 at ¶ 106) Plaintiffs' technical expert, Dr. Mays, similarly explained that at the point of gelation, a three-dimensional network begins to form but the material at issue would not "necessarily be [a] visible solid aggregate" at that point. (D.I. 466, ex. 5 at 354-59)

It is Plaintiffs' contention that the forms within 5 seconds limitation is met at the point when the material has cured and a "visible solid aggregate has been formed[;]" Plaintiffs explain that a POSITA can determine that this has occurred by way of a visual inspection. (Tr. at 131, 133-34; *see also* D.I. 465 at 4; D.I. 466, ex. 5 at 353-63 (Dr. Mays opining that in the context of claim 10, a hydrogel meets this limitation when there is "a fully cured hydrogel within five seconds after contact with the substrate"); D.I. 429, ex. 56 at ¶ 183 (Dr. Mays noting that a

hydrogel has been formed when a POSITA can assess that the “hydrogel materials form visible and solid aggregate that swells in water”)) Defendant appears to agree that this is how the forms within 5 seconds limitation should be interpreted. (D.I. 429, ex. 39 at 53 (Defendant’s technical expert, Dr. Anthony Lowman, explaining that when he made hydrogels for the purpose of this case, he was able to assess by visual observation whether a sufficient amount of crosslinking between functional groups had occurred, such that a hydrogel formed); D.I. 441 at 7 (arguing that, to avoid indefiniteness concerns, this claim term must be interpreted to require that the hydrogel be fully cured within five seconds after contact with the substrate); Tr. at 149) The Court concurs.⁵

⁵ This standard for assessing whether a hydrogel has formed is consistent with the teachings of the '034 patent, which explains that:

An embodiment of the invention involves a mixture or a process of mixing hydrophilic reactive precursor species having nucleophilic functional groups with hydrophilic reactive precursor species having electrophilic functional groups such that they form a mixture that crosslinks quickly after contact with the tissue of a patient to form a biodegradable hydrogel that coats and adheres to a tissue. . . . [I]t is believed that reactive precursor species [] that crosslink appropriately quickly after contacting a tissue surface *will form a three dimensional structure that is mechanically interlocked with the coated tissue*. This interlocking contributes to adherence, intimate contact, and essentially continuous coverage of the coated region of the tissue.

('034 patent, col. 8:13-37 (emphasis added); *see also id.*, col. 36:61-66 (“When this spray was directed to a piece of tissue . . . a hydrogel coating was observed to form on the surface of the tissue. This hydrogel coating was rinsed with saline (the hydrogel coating is resistant to rinsing) and was observed to be well adherent to the tissue surface.”); *id.*, col. 38:49-52 (“The mixture formed a gel in about 3-6 seconds on the surfaces. The sprayed gel was observed through a 10 mm laparoscope and videotaped[.]”)) It is also in accord with the teachings of United States Patent No. 7,964,217, a patent cited by the parties’ experts, (*see, e.g.*, D.I. 403, ex. A at ¶ 163; D.I. 429, ex. 56 at ¶ 183), which states that “[t]he PEG hydrogel that is formed is a visible and solid aggregate that swells in water in which, in theory, all available crosslinks are formed.”

Plaintiffs next argue that there can be no dispute that the Accused Products meet this limitation. They assert that this is confirmed by HyperBranch's own documents and its expert's testimony. (D.I. 400 at 14; D.I. 465 at 3-4; Tr. at 129-30, 132) Specifically, Plaintiffs point to:

- (1) A HyperBranch Adherus AutoSpray ET Dural Sealant brochure indicating that the “[s]et [t]ime” for the product is 1 second. (D.I. 466, ex. 3 at ARM0004883 (“The Adherus hydrogel sets in approximately one second. It remains where it is applied.” (emphasis added)))
- (2) A HyperBranch presentation regarding Adherus AutoSpray Dural Sealant explaining that “[w]hen the surgeon applies the Adherus hydrogel to the patient, it will be delivered equally and will then set to form an effective hydrogel.” (*Id.*, ex. 2 at SWS0003929)
- (3) A Risk Management Report for Adherus AutoSpray Dural Sealant explaining that the device “delivers a small amount of polymerizing liquid which becomes an adherent hydrogel within about 3 seconds of application.” (*Id.*, ex. 12 at HBMT0351714)
- (4) Instructions for Use for the Adherus AutoSpray Dural Sealant that provide a table of tests demonstrating the “[i]mmediate polymerization time of novel PEG-based hydrogel” with times ranging from 0.96 to 1.47 seconds, and also notes that “the formulation of the novel PEG-based hydrogel allows for such rapid self-polymerization that a watertight barrier is formed within 1 s.” (*Id.*, ex. 1 at 114, 118-19)
- (5) A HyperBranch patent application stating that the Adherus AutoSpray Dural Sealant “is simple to prepare and, once applied to the dural surface, quickly cures to form a watertight seal.” (D.I. 429, ex. 38 at ¶ 36)
- (6) A prior declaration from Dr. Lowman in which he noted that the Accused Products “have been designed to result in gel formation through the formation of amide linkages in []

(D.I. 466, ex. 6 at 4:27-29; *see also* D.I. 465 at 5)

approximately 1 second or less.” (D.I. 466, ex. 4 at ¶ 39)

Defendant counters that, even in light of this evidence, there is a genuine issue of material fact as to whether its customers perform the forms within 5 seconds limitation. (D.I. 441 at 7) Defendant argues, for example, that certain of Plaintiffs’ evidence does not establish whether the hydrogels of the AutoSpray Accused Products are “fully cured within five seconds” because they “only describe gel time” or “set time[.]” (*Id.* at 7-8 (internal quotation marks omitted); Tr. at 150) But plenty of the above evidence is clearly referring to a hydrogel that is fully cured (and fully formed) within the applicable time period. Dr. Lowman’s own prior declaration, for example, described gel *formation* in 1 second. The Instructions for Use for the Adherus AutoSpray Dural Sealant product indicates that a *watertight barrier* is formed within 1 second. And the Risk Management Report describes the accused products as forming an *adherent hydrogel* within 3 seconds. Defendant has not pointed to any persuasive evidence of record suggesting that the Accused Products at issue do *not* form a fully cured hydrogel (that is, one where a “visible solid aggregate has been formed”) within five seconds of contacting a substrate. In light of this, there can be no genuine dispute that the Accused Products at issue meet the forms within 5 seconds limitation.⁶

⁶ Defendant asserts that Plaintiffs did not provide any proof of infringement by the Adherus AutoSpray Extended Tip (ET) Dural Sealant (“the ET product”) with respect to this limitation. (D.I. 441 at 4-5) To that end, Defendant notes that it is undisputed that the ET product has a unique applicator that is not used with the other Accused Products. (*See* D.I. 403, ex. A at ¶¶ 173-76) It suggests that Plaintiffs have not done enough to establish an inference (or negate a genuine dispute of fact) that the different applicator does not have an impact on an assessment of infringement of claim 10. (D.I. 441 at 5)

The Court does not agree. To be sure, a significant number of Defendant’s records cited above (i.e., as providing support for Plaintiffs’ Motion) are associated with the Adherus AutoSpray Dural Sealant product (and not the ET product). But Defendant’s Rule 30(b)(6)

b. The “Crosslink After Contact” Limitation

Defendant’s other challenge here relates to the requirement in claim 10 (pursuant to its dependence on claim 1) of “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” (the “crosslink after contact” limitation).

Resolving this dispute requires, as a starting point, that the Court construe the crosslink after contact limitation.⁷

Defendant asserts that this limitation should be construed to mean that the functional groups of the reactive precursor species must be mixed such that *all* of the functional groups on the precursors crosslink after (not before) contact with the tissue. (D.I. 441 at 13 (“In the context of the full claim language, the antecedent basis for ‘*the nucleophilic functional groups and electrophilic functional groups*’ refers to *all* of the functional groups on the reactive precursor species, because *all* of the functional groups that crosslink are what ‘form a hydrogel’”) (certain emphasis in original); Defendant’s Summary Judgment Presentation, Slide 144) Therefore, according to Defendant, the claim requires that the mixing step occur directly on the tissue,

witness, Mr. Jeffrey Clark, testified that the chemistry for the gel is the same in the ET product as it is in the Adherus AutoSpray Dural Sealant product, and that testing demonstrated that the ET product “delivered the dural sealant gel equivalently [to the Adherus AutoSpray Dural Sealant product.]” (D.I. 465 at 3 (citing D.I. 429, ex. 2 at 11-12, 23, 29)) And Dr. Lowman’s testimony, cited above, was in reference to all Accused Products (including the ET product). The evidence is more than sufficient to find that the ET product also meets this limitation. And there is no contrary evidence cited by Defendant to suggest it does not.

⁷ In assessing a disputed issue of claim construction, the Court is guided by the familiar legal standards for such review, which were set out in its July 27, 2017 Report and Recommendation. (D.I. 307 at 5-7)

because if the reactive precursor species were mixed prior to contact with the tissue (i.e., if they were “pre-mixed”), this would cause reactive functional groups of those precursors to begin to crosslink before the mixture ever made contact with the tissue. (D.I. 429, ex. 42 at ¶ 107; Tr. at 152)⁸

Plaintiffs respond that claim 1 (and thus claim 10) only requires that the functional groups of the reactive precursor species are mixed so that *some, but not necessarily all*, crosslinking occurs after contact with the tissue (leading to hydrogel formation). (D.I. 465 at 10) The claim is broad enough, according to Plaintiffs, to encompass hydrogels with functional groups that are mixed and that start to crosslink prior to tissue contact. (D.I. 400 at 11; Plaintiffs’ Motion for Partial Summary Judgment Presentation, Slide 4)

Both sides’ positions have merit and, in the Court’s view, the claim language could allow for either interpretation. But ultimately, the Court finds Plaintiffs’ view of the “crosslink after contact” limitation to be most persuasive.

The Federal Circuit has counseled that when determining the ordinary meaning of a claim term, a court must not extract and isolate that term from the context of the patent, but rather should endeavor to reflect the term’s “meaning to the ordinary artisan after reading the entire patent.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1321 (Fed. Cir. 2005); *see also Eon Corp. IP Holdings LLC v. Silver Spring Networks, Inc.*, 815 F.3d 1314, 1320 (Fed. Cir. 2016). With that in mind, the Court finds that the '034 patent’s specification supports Plaintiffs’ view of the limitation. (D.I. 400 at 11-12; D.I. 465 at 10; D.I. 429, ex. 56 at ¶ 185; Plaintiffs’ Motion for

⁸ It is undisputed that the Accused Products at issue, in fact, require that the precursors be pre-mixed before they make contact with a patient’s tissue. (D.I. 429, ex. 42 at ¶¶ 112-13)

Partial Summary Judgment Presentation, Slide 5) In a section of the specification entitled “In Situ Formation[,]” the patentee explains that “[i]n many applications, the biocompatible crosslinked polymers of this invention typically will be formed ‘in situ’ at a surgical site in the body.” (’034 patent, col. 25:16-19)⁹ The specification proceeds to explain that:

Thus, in one embodiment, an aqueous solution of a freshly prepared crosslinker (e.g., SNHS-terminated oligolactide synthesized from a glycerol core in phosphate buffered saline . . .) and a functional polymer (e.g., albumin or amine terminated tetrafunctional polyethylene glycol at pH 10 in sodium borate) *are applied and mixed on the tissue* using a double barrel syringe (one syringe for each solution). The two solutions *may be applied simultaneously* or sequentially.

(*Id.*, col. 25:23-31 (emphasis added)) The patentees then note that “[o]ne may use specialized devices to apply the precursor solutions, such as those described” in various listed references, the “disclosures of which” are incorporated into the ’034 patent by reference. (*Id.*, col. 25:38-45 (emphasis added)) And Dr. Mays explains that “many” of the “specialized devices” that are being referred to there require pre-mixing of the hydrogel forming solutions *before* contact with the tissue. (D.I. 429, ex. 56 at ¶ 185; *see also* Plaintiffs’ Motion for Partial Summary Judgment Presentation, Slide 5; Tr. at 125-26)

Defendant attempts to brush off the impact of this argument by asserting that: (1) the specification discloses embodiments that appear to perform mixing directly on the tissue (i.e., those where the two solutions are applied “sequentially”); and (2) it is only these embodiments that fall within the scope of claim 1 (and thus claim 10) of the ’034 patent. (D.I. 441 at 15 n.8)

⁹ The patent earlier notes that “[m]ore preferably the crosslinking reactions occur ‘*in situ*,’ meaning they occur at local sites such as on organs or tissues in a living animal or human body.” (’034 patent, col. 11:35-38 (emphasis added))

But this seems to ignore that the above-referenced portion of the specification is all about forming the hydrogel *on the tissue*. That portion states that the two precursor solutions can be applied *at the same time* and with devices that *pre-mix* the solutions—and that this still constitutes a way to mix and to form a hydrogel *on the tissue*.¹⁰ And Dr. Mays explains that the POSITA understands that when hydrogel-forming solutions are pre-mixed in an applicator, some amount of crosslinking will begin to occur and will continue after the mixture is applied to tissue to form the hydrogel thereon. (D.I. 429, ex. 76 at ¶ 46) His explanation thus gibes with what the patent claim seems to allow for.

Accordingly, the Court finds that the patent supports Plaintiffs' interpretation of the claim limitation, which permits pre-mixing of the precursor solutions, so long as some amount of crosslinking also occurs after application onto the tissue.¹¹ The Court thus recommends that “the nucleophilic functional groups and electrophilic functional groups crosslink after contact with the tissue” be construed to mean “the functional groups of the reactive precursor species are mixed in such a way that some, but not necessarily all, crosslinking occurs after the composition makes contact with the tissue.”

¹⁰ It does not appear that Dr. Lowman, in formulating his opinion that the limitation cannot encompass a hydrogel with precursors that are pre-mixed, considered the disclosures of the patents referenced in the portion of the '034 patent specification set out above (i.e., referencing devices that require pre-mixing of hydrogel solutions). (D.I. 429, ex. 39 at 94-99)

¹¹ Plaintiffs point out that during an *inter partes review* (“IPR” proceeding) with respect to, *inter alia*, claim 10 of the '034 patent, Dr. Lowman's position seemed to be consistent with Plaintiffs' position here—that is, he asserted that a prior art reference known as Rhee '500 meets this limitation because the solutions of Rhee are premixed and then applied to tissue “before substantial cross linking has occurred between the nucleophilic groups and the electrophilic groups[, and] the reaction mixture is allowed to continue crosslinking in situ[.]” (See D.I. 429, ex. 57 at 25-26; D.I. 400 at 12-13; D.I. 465 at 10) Defendant did not respond to this point. (D.I. 441 at 12-15)

In light of this construction, the Court finds that there is no genuine dispute of material fact that the Accused Products at issue infringe this limitation of claim 10. (*See* D.I. 400 at 8-10; D.I. 465 at 9-11) Indeed, Defendant does not really attempt to argue otherwise. There is no question that the functional groups of the reactive precursor species at issue are mixed when the Accused Products at issue are used—the Instructions for Use for those products, along with other HyperBranch documents, all indicate that the precursors “mix within the applicator and quickly crosslink to form the hydrogel sealant soon after exiting the applicator tip.” (D.I. 429, ex. 8 at 4; *see also id.*, ex. 11 at 5; *id.*, ex. 77 at HBMT0011220 (Design and Development Plan for Adherus AutoSpray Dural Sealant explaining that the “delivered solution immediately crosslinks to form a hydrogel”)) And there is also no question that some crosslinking occurs after the mixed composition makes contact with a patient’s tissue. For example, a Risk Management Report for Adherus AutoSpray Dural Sealant explains that “[t]he mixed formulation comes in contact with the tissue as a low viscosity, largely monomeric solution and wets the dural surface. In doing so, the PEG[] and PEI components crosslink to form an interpenetrating network on the dural surface[.]” (*Id.*, ex. 32 at HBMT0351613) Dr. Lowman also acknowledged that the functional groups crosslink after the solution makes contact with the tissue. (*Id.*, ex. 39 at 66-69) Dr. Mays reached the same conclusion, explaining that the Adherus AutoSpray Dural Sealant propels the mist droplets onto the tissue that “mix together on the tissue surface to form the crosslinked hydrogel.” (*Id.*, ex. 56 at ¶ 298)

c. Conclusion

In light of the Court’s conclusions with respect to the forms within 5 seconds limitation and the crosslink after contact limitation, the Court finds that there is no genuine issue of

material fact regarding Defendant's customers' direct infringement of claim 10 of the '034 patent (which relates to Defendant's alleged indirect infringement of the claim).¹² It therefore recommends that summary judgment be granted in this regard.

3. HyperBranch's Indirect Infringement

Plaintiffs also move for summary judgment that HyperBranch infringes claim 10 under 35 U.S.C. §§ 271(b) and 271(c). (D.I. 400 at 1, 24-31) HyperBranch challenges only one aspect of Plaintiffs' proof with respect to indirect infringement of claim 10; it argues that Plaintiffs failed to establish the predicate act of direct infringement by one of HyperBranch's customers and thus there can be no finding of indirect infringement. (D.I. 441 at 15) However, the Court has found that there is no genuine dispute of material fact regarding Defendant's customers' direct infringement. Therefore, the Court also recommends that summary judgment be granted with respect to Plaintiffs' claims of induced and contributory infringement of claim 10.

B. Defendant's Motion

The Court now turns to Defendant's Motion. Therein, Defendant argues that claim 10 is invalid for obviousness, pursuant to 35 U.S.C. § 103. (D.I. 402 at 40-45; D.I. 463 at 20-22) Defendant's position is that the combination of two prior art references would render claim 10 invalid: United States Patent No. 5,874,500 ("Rhee '500") and United States Patent No.

¹² Defendant also argued that the Accused Products do not satisfy Plaintiffs' interpretation of the "biocompatibility" requirement in the claim. (D.I. 441 at 9-12 ("[I]f Plaintiffs are properly held to the same construction of the scope of claim 10 for purposes of infringement that they impose in the context of invalidity, they have not shown that they are entitled to summary judgment of infringement.")) The Court recently recommended that Defendant's proposed construction of the biocompatibility requirement be adopted, (D.I. 652), and therefore assumes that if the District Court agrees with that decision, then Defendant's argument here is moot.

5,292,362 (“Bass”).

In summarizing the invention of the '034 patent, the inventors explain that they “have realized that use of color in biocompatible crosslinked polymers and precursors greatly improves their performance in a surgical environment[.]” ('034 patent, col. 2:18-20) Rhee '500, which is cited on the face of the '034 patent, discloses biodegradable crosslinked hydrogels formed from electrophilic-nucleophilic reactions for various medical applications. (See D.I. 429, ex. 59 (hereinafter, “Rhee '500”) at Abstract); D.I. 403, ex. A at ¶ 92; D.I. 429, ex. 56 at ¶ 81) For its part, Bass discloses gels formed from two components—a first natural or synthetic peptide and a second “support material”—used to bond tissue together and to serve as a tissue coating. (See D.I. 409, ex. 89 (hereinafter, “Bass”) at Abstract, col. 1:9-11) Bass explains that “[t]he composition of the present invention may . . . include . . . chromophores to facilitate visualization of the material during placement into warm blooded animals.” (*Id.*, col. 11:18-21) The specification further notes that “[u]se of a chromophore will allow material which becomes displaced from the desired application site to be easily visualized” and that “[u]se of exogenous chromophores for aid in the placement of biological glues has been previously described[.]” (*Id.*, col. 11:21-25, 29-31) It then cites to a prior art reference known as “Nasaduke,” (*id.*, col. 11:31-34), which describes a “biodegradable, nontoxic sealant” to which “a minute amount of methylene blue” and a fluorescein dye were added in order to create a “green color” that “permitted accurate visualization of the sealant at the time of surgery[.]” (D.I. 409, ex. 90 at 324-25). Defendant asserts that all of the limitations of claim 10 are disclosed in Rhee '500 and Bass, and that it would have been obvious to a POSITA at the time of the invention to combine the “chromophores” disclosed in Bass with the hydrogels of Rhee '500 to enhance visualization of

polymers used as tissue sealants. (D.I. 402 at 42)

Defendant makes a strong case for invalidity. But the Court ultimately concludes that Plaintiffs have raised sufficient questions of material fact to preclude summary judgment here.¹³

For instance, genuine issues of material fact exist regarding whether a POSITA would have had a reasonable expectation of success in achieving the claimed invention.¹⁴ (D.I. 443 at 33; Tr. at 168 (Plaintiffs' counsel indicating that "one of the crux issues here . . . [is Plaintiffs' position that the POSITA will be] highly s[k]eptical about throwing things into [the reactive crosslinking components of Rhee] that interfered with that crosslinking chemistry")) Plaintiffs' expert, Dr. Mays, explains that in Bass, there is no crosslinking reaction to be concerned with upon adding a chromophore, such as there is when making the hydrogel disclosed in the '034 patent. (D.I. 429, ex. 56 at ¶ 103) Dr. Mays opines that the POSITA would have been concerned with the ability of the chromophores disclosed in Bass to interfere with the nucleophilic-

¹³ The Court notes that on April 3, 2018, the United States Patent and Trademark Office's Patent Trial and Appeal Board ("PTAB") issued a Final Written Decision in the IPR proceeding; the Final Written Decision concluded that certain claims of the '034 patent—including claim 10—are unpatentable under 35 U.S.C. § 103(a) in view of, *inter alia*, Rhee '500 and Bass. (*See* D.I. 676) There, Defendant had to demonstrate that the claims were unpatentable by a *preponderance of the evidence*. (*Id.* at ECF Page 9) Here, in contrast, Defendant must demonstrate that there is *no genuine dispute of material fact* as to whether, by *clear and convincing evidence*, it has shown that the claims are unpatentable.

¹⁴ With respect to whether the combination of Rhee '500 and Bass disclose all of the elements of claim 10, the only element that Plaintiffs disputed in their brief was that the references did not disclose a "biocompatible" composition. (D.I. 443 at 27-29) Since briefing on Defendant's Motion, the Court recommended that claim 10's requirement for a biocompatible composition be construed in line with Defendant's proposal, "a hydrogel/composition formed from crosslinked biocompatible precursors [as set out in the claim]." (D.I. 652) The Court assumes that, were the District Court to agree with the Court's construction, this would affect Plaintiffs' arguments with respect to biocompatibility. But the parties have not indicated whether that is the case, and so the Court does not focus on those arguments here.

electrophilic crosslinking reactions of Rhee '500 by either competing reactions or steric hindrance or hydrogen bonding. (*Id.* at ¶¶ 107-08) In light of the nature of the chemistry involved in creating hydrogels, Dr. Mays opined that the POSITA would have believed that every time a reactive dye reacts with a nucleophile or electrophile while forming the hydrogel, a defect in the network would be created and the crosslinking density would be reduced (thus affecting the properties of that resulting hydrogel). (*Id.* at ¶¶ 108, 144) To that end, Dr. Mays opines that “[t]he nature and extent that disrupting the stoichiometry [by adding the dyes of Bass] would have on formation of a hydrogel tissue coating . . . would at least be unpredictable[;]” thus, the POSITA could not predict that a hydrogel with sufficient crosslinking density would be formed, or that it would be formed within a reasonable gel time for use as a tissue coating. (*Id.* at ¶ 139)¹⁵

Dr. Lowman disagrees, opining that Dr. Mays’ arguments are “technically unsound and scientifically invalid.” (D.I. 403, ex. A at ¶ 542) Instead, he asserts that the POSITA would not find any technical challenge or uncertainty in adding a dye to a hydrogel—in that “[t]here is nothing unusual about a dye molecule that would render its behavior unpredictable in the context of the Rhee hydrogels.” (D.I. 403, ex. A at ¶ 542; *see also id.* at ¶¶ 541-48) He also adds that in his opinion, “Dr. Mays’ assertions fail to account for the extremely low concentrations of dye needed to render a hydrogel visibly colored.” (*Id.* at ¶ 541) But disagreements between experts on matters like these typically suggest that there is a material factual dispute that a jury needs to

¹⁵ As to this argument—that the POSITA would have been less likely to combine the teachings of the references because of the “unpredictable” impact on crosslinking—the PTAB found it to be “not without some merit[.]” (D.I. 676 at ECF Page 43) And though it ultimately did not find the argument persuasive enough to rebut HyperBranch’s position on invalidity, the PTAB repeatedly emphasized that its conclusion was based on “a preponderance of record evidence[.]” (*Id.* at ECF Page 44; *see also id.* at ECF Page 43)

resolve.¹⁶

In addition to the above-referenced issues, Plaintiffs adduce evidence of objective considerations of non-obviousness. This evidence also highlights disputed facts concerning the obviousness question.

For example, with respect to commercial success, Plaintiffs' DuraSeal product, which Dr. Mays contends is covered by claim 10 of the '034 patent, (D.I. 429, ex. 56 at ¶ 471; *id.*, ex. 90 at ¶¶ 307-09), has well exceeded \$100 million in domestic sales, (D.I. 456, ex. 20 at ¶¶ 58-60).

Commercial success is relevant “because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art.” *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005). To establish nonobviousness, there must be a nexus between the commercial success and the claimed invention. *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011); *see also Novartis AG v. Torrent Pharms., Ltd.*, 853 F.3d 1316, 1330-31 (Fed. Cir. 2017) (“Where the offered secondary consideration actually results from something other than what is

¹⁶ The Court understands that the PTAB did not find Dr. Mays' testimony regarding chemical reactivity and steric hinderance persuasive because of deposition testimony he gave in the PTAB proceeding. (D.I. 676 at ECF Page 42) This deposition transcript is in the record here (although Defendant did not refer to it in its briefing with respect to this issue). (D.I. 416, ex. 158) And it is true that in that testimony, Dr. Mays acknowledged that: (1) he did not study the concentration effects of the relative impact that low or high concentrations of dye would have on the ability of the hydrogels at issue to crosslink; and (2) a POSITA would have expected that lower concentrations of dye would have less of an effect on the crosslinking process as compared to higher concentrations of dye. (*Id.* at 49) Nevertheless, he *also* stated that even a “very low concentration” of dye could have a big effect on crosslinking. (*Id.*)

In the end, the burden of proof was different in the PTAB than it is here, and the PTAB's role was different than the Court's role here. That is why this evidence, although ultimately unpersuasive to the factfinder in the PTAB proceeding, nevertheless has had an impact on the Court's determination that genuine issues of material fact remain.

both claimed and *novel* in the claim, there is no nexus to the merits of the claimed invention.”) (internal quotation marks and citation omitted, emphasis in original). A prima facie case of nexus is made when the patentee “shows both that there is commercial success, and that the product that is commercially successful is the invention disclosed and claimed in the patent.” *Crocs, Inc. v. Int’l Trade Comm’n*, 598 F.3d 1294, 1310-11 (Fed. Cir. 2010).

Defendant argues that Plaintiffs’ arguments with respect to objective considerations of non-obviousness (like commercial success) are legally deficient because Plaintiffs have not shown how the merits of the claimed inventions are connected to any alleged objective considerations. (D.I. 402 at 44; D.I. 463 at 22) The Court, however, finds that Plaintiffs’ evidence is sufficient to raise a genuine issue of material fact on that issue.

For instance, Plaintiffs’ damages expert, Mr. John Jarosz, explains that an important feature of claim 10 of the asserted patent is the addition of a visualization agent to the hydrogel. (D.I. 456, ex. 20 at ¶ 93) Mr. Jarosz then cites to evidence demonstrating that this feature was important to the parties and to surgeons using DuraSeal (and HyperBranch’s Accused Products). (*Id.* at ¶¶ 93-97) Dr. Amarpreet Sawhney, an inventor of the '034 patent, testified that physicians had manifested a need for a product that could be easily visualized. (*Id.* at ¶ 93) Further, he explained that the visualization feature of DuraSeal indicates to the surgeon when the hydrogel has achieved adherence and a watertight closure, which are important benefits of DuraSeal; in other words, the color of the hydrogel provides neurosurgeons with valuable feedback during their application of the product. (*Id.* at ¶¶ 96-97) A Confluent Management Presentation created for Integra (prior to Integra’s acquisition of Confluent) identified DuraSeal’s blue color that “allows for visualization” as a “[k]ey [s]uccess [f]actor[.]” (*Id.* at ¶¶ 82, 94) A 2011 press

release announcing DuraSeal Exact’s approval by the United States Food and Drug Administration (“FDA”) emphasized its distinctive blue colorant. (*Id.* at ¶ 94) And a 2007 HyperBranch research report comparing DuraSeal (formally known as NuSeal) to fibrin glue indicated that NuSeal had “[g]reat visibility—[g]reen” while the fibrin glue product at issue had “[p]oor visibility—clear.” (*Id.* at ¶ 93) According to this report, surgeons stated that the colorant in DuraSeal was “useful” because it enabled a surgeon to “know where [the product] was going[;]” the report concluded that HyperBranch’s forthcoming dural sealant “[m]ust be colored.” (*Id.* at ¶¶ 83, 95)

In addition to commercial success, Plaintiffs point out that DuraSeal has received substantial industry recognition. For example, DuraSeal was recognized by the FDA as one of the ten most significant medical device approvals of 2005. (*Id.* at ¶ 72) That same year, Confluent won an award for its development of DuraSeal. (*Id.*) And in 2006 Dr. Sawhney and Confluent won several additional awards relating to their development of the product. (*Id.* at ¶ 73)

Plaintiffs also contend that DuraSeal satisfied a long-felt need for a commercial hydrogel tissue coating formulation made by reacting nucleophilic functional groups and electrophilic functional groups and including a visualization agent. Dr. Sawhney provided a declaration wherein he recounted neurosurgeon testimony regarding DuraSeal that was provided during an FDA-related hearing; while the cited testimony does not specifically call out the product’s color, certain of it noted DuraSeal’s ease of use and impact on visualization. (D.I. 456, ex. 24 at ¶¶ 19, 29 (Dr. Harry van Loveren explaining that DuraSeal “is a remarkably easy product to use when you compare it to what’s available in the market” and “is easy to apply”); *id.* at ¶ 20 (Dr. Rees

Cosgrove noting that “you can’t test [fibrin glue] in the operating room *to see if you really got everything covered* with fibrin glue”) (emphasis added))

Finally, Plaintiffs point to evidence of “unexpected results,” via the testimony of Dr. Mays. (D.I. 443 at 35; Plaintiffs’ Opposition to Defendant’s Summary Judgment of Invalidity Presentation, Slide 36) Dr. Mays opines that, at the time when the inventors worked to develop DuraSeal, a POSITA could not predict whether adding visualization agents to the claimed mixture would produce positive results. (D.I. 429, ex. 56 at ¶ 163) The inventors pushed forward anyway, and in Dr. Mays’ view, they obtained unexpectedly positive outcomes. (*Id.*)

Having said all of the above, it is clear that Defendant’s invalidity argument has real merit. The disclosures of Rhee '500 and Bass in combination do appear to cover all elements of the invention recited in claim 10. The Rhee '500 and Bass references are in the same field of endeavor, and both concern the use of materials in medical tissue coating applications. And as Defendant notes, there are portions of both Rhee '500 and Bass that seem to describe the efficacy of an imaging agent in the compositions at issue. (D.I. 402 at 42-44; Tr. at 157-58)

But the clear and convincing evidence standard is a high bar to meet. The evidence regarding objective considerations is real. And the Court is not permitted to weigh the credibility of the parties’ competing experts in resolving a summary judgment motion. In light of all of this, and because there are material issues of fact regarding the obviousness of the invention of claim 10, the Court recommends that Defendant’s motion for summary judgment of invalidity be denied.

IV. CONCLUSION

For the reasons set forth above, the Court recommends that Plaintiffs’ Motion be

GRANTED-IN-PART as set out above and Defendant's Motion be DENIED.

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 by no later than **April 30, 2018**; responses are due by no later than **May 10, 2018**. 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 Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

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 **April 25, 2018**, 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: April 20, 2018



Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE