

INTEGRA LIFESCIENCES CORP.,
INTEGRA LIFESCIENCES SALES LLC,
CONFLUENT SURGICAL, INC., and
INCEPT LLC,

Plaintiffs,

v.

HYPERBRANCH MEDICAL
TECHNOLOGY, INC.,

Defendant.

WHEREAS, Magistrate Judge Burke issued a 34-page Report and Recommendation (“Report”) (D.I. 555), dated March 13, 2018, recommending the Court: (1) deny Defendant HyperBranch Medical Technology, Inc.’s (“Defendant” or “HyperBranch”) motion for summary judgment of non-infringement of claim 20 of the ’034 patent, claim 4 of the ’566 patent, and claims 8 and 23 of the ’418 patent (the “Predetermined Thickness” claims) (D.I. 393); and (2) deny Plaintiffs Integra LifeSciences Corp., Integra LifeSciences Sales LLC, Confluent Surgical, Inc., and Incept LLC’s (collectively, “Plaintiffs” or “Integra”) motion for summary judgment of infringement of the Predetermined Thickness claims (D.I. 399);

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summary judgment of non-infringement under the doctrine of equivalents;

WHEREAS, on April 2, 2018, Integra responded to HyperBranch's Objections (D.I. 665) ("Response" or "Resp."), contending the Report properly interpreted and construed claim 20 and the prosecution history surrounding "visualization agent;"

WHEREAS, the Court has considered the parties' objections and responses *de novo*, see *St. Clair Intellectual Prop. Consultants, Inc. v. Matsushita Elec. Indus. Co., Ltd.*, 691 F. Supp. 2d 538, 541-42 (D. Del. 2010); 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b);

NOW THEREFORE, IT IS HEREBY ORDERED that:

1. HyperBranch's Objections (D.I. 641) are OVERRULED, Judge Burke's Report (D.I. 555) is ADOPTED, and the parties' motions (D.I. 393, 399)¹ are DENIED.²
2. HyperBranch contends that the Report (1) wrongly construes claim 20 of the '034 patent and (2) erroneously finds the tangential exception to prosecution history estoppel applies. (Objs. at 2, 7) The Court disagrees with HyperBranch.
3. The Report properly found that "in order to infringe the method of claim 20, one has to (1) formulate a polymer composition that comprises electrophilic functional groups and nucleophilic functional groups and (2) 'select[] a visualization agent for the polymer

¹The underlying Report, and accordingly, this Order, solely addresses the portions of the parties' motions (D.I. 393, 399) related to infringement of the Predetermined Thickness claims. (See Report at 1 n.2, 2 n.3)

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

composition’ that, when deposited on the tissue of a patient, can cause a visually observable change that indicates that a crosslinked hydrogel having a predetermined thickness has been formed.” (Report at 23-24 n.14) In addition, the Report properly found that “there is no requirement in the claim that, for Defendant’s infringement to be complete, a user must actually apply the hydrogel to a patient’s tissue and look for the observable change in doing so.” (*Id.* at 15 n.11) HyperBranch contends the Report’s conclusion “reads several limitations out of the claim” (Objs. at 3), but HyperBranch’s interpretation – requiring the alleged infringer to apply the hydrogel to a patient’s tissue to be liable – reads limitations *into* the claim where none exist.

4. Claim 20 depends from claim 16. Both claims are reproduced below:

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.

20. The method of claim **16**, wherein the polymer composition crosslinks to form a hydrogel within about 60 seconds after being applied to a substrate.

5. The only method step of claim 16 (and of claim 20) is “selecting” the visualization agent. The other limitations – i.e., that the visualization agent “causes a visually observable change” and that the visually observable change “indicates that a crosslinked hydrogel having a predetermined thickness has been formed on the tissue of a patient” – are not steps in the asserted method but, instead, are characteristics of the visualization agent that is selected. *See Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1290-91 (Fed Cir. 2015) (finding claim limitation was “not a step in the claimed method,” but was instead only “a phrase that

characterizes the claimed pre-processing parameters,” as limitation was “not used as a verb . . . , but instead is a part of a phrase that conveys information about” claimed method parameters); *see also SimpleAir, Inc. v. Google, Inc.*, 2015 WL 5883129, at *2 (E.D. Tex. Oct. 6, 2015) (“[N]ot every term in a claim limitation identifies a separate component that must be present in the claimed system.”). For one to infringe the method of claim 16 (or claim 20), the alleged infringer need “select[] a concentration of visualization agent” that has the above listed characteristics. Contrary to HyperBranch’s contentions, the alleged infringer need not actually apply the hydrogel to a patient’s tissue and look for an observable change. *See SiRF Tech., Inc. v. Int’l Trade Comm’n*, 601 F.3d 1319, 1331 (Fed. Cir. 2010) (finding certain actions, though necessary to claim performance, were not required by claims and, therefore, “the fact that other parties perform these actions does not preclude a finding of direct infringement”).³

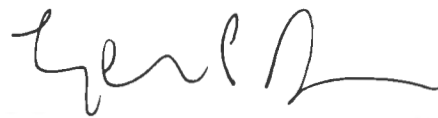
6. The Report also properly found the tangential exception to prosecution history estoppel applies here. The Court agrees with HyperBranch that it is the **visualization agent** that must cause the visually observable change (Objs. at 10), but the narrowing amendment HyperBranch points to bears no relation to what constitutes a visualization agent or whether that

³HyperBranch also contends it “had no meaningful opportunity to respond” to Integra’s argument that there is no requirement in claim 20 that, for one to infringe, one must affirmatively apply the hydrogel to tissue or use the color or transparency to assess thickness. (Objs. at 2-3) However, Integra’s expert, Dr. Jimmy Mays, opined in September 2015 that “all that is required is ‘selecting a concentration of a visualization agent’ to achieve an intended use or effect along with the other characteristics of the polymer composition.” (D.I. 10 Ex. 13 ¶ 129) Moreover, Integra’s contention was made in response to HyperBranch’s arguments to the contrary (*see* D.I. 441 at 30) (HyperBranch stating “Plaintiffs’ allegations that ‘hydrogel has been deposited on the **substrate**’ and that HyperBranch demonstrates products outside of a surgical environment do not establish that HyperBranch forms, or is liable for forming, a hydrogel on **the tissue** of a patient as required by claim 20”) (internal citations omitted), and HyperBranch was given an opportunity to respond during oral argument (*see* D.I. 482 at 26-28, 36-37).

visualization agent must comprise dye alone or, rather, a combination of dye and air bubbles. (See Report at 29-30) Moreover, the components of a visualization agent, for purposes of infringement, are not, as HyperBranch contends, undisputed. (Objs. at 7) During claim construction, the Court held that “the term ‘visualization agent’ should not be construed in such a way as to encompass air or air bubbles alone.” (D.I. 307 at 13; D.I. 379 at 5) While the Court found that the visualization agent as described and claimed in the ’034 patent encompassed dye alone without any presence of air bubbles (*see* D.I. 307 at 12-13), the Court did not preclude a finding that a combination of dye and air bubbles could be equivalent to a visualization agent under the doctrine of equivalents. Such a factual dispute is properly left to the jury. *See Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 509-10 (1950) (explaining that equivalence is a question of fact often requiring consideration of “credibility, persuasiveness and weight of evidence”).

7. The Court has considered each of the other arguments raised by HyperBranch in its Objections *de novo* and finds that each of them lacks merit and requires no further discussion.

April 10, 2018
Wilmington, Delaware



HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE