

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.
HYPERBRANCH MEDICAL
TECHNOLOGY, INC.,
Defendant.
C.A. No. 15-819-LPS-CJB

MEMORANDUM ORDER

WHEREAS, Magistrate Judge Burke issued a 27-page Report and Recommendation ("Report") (D.I. 704), dated April 20, 2018, recommending that the Court: (1) grant in part and deny in part 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 claim 10 of the '034 patent (D.I. 399); (2) deny Defendant HyperBranch Medical Technology, Inc.'s ("Defendant" or "HyperBranch") motion for summary judgment of invalidity of claim 10 of the '034 patent for obviousness (D.I. 393); and (3) deny as moot Defendant's motion for summary judgment of non-infringement of the "mixing" limitation of certain claims of the '5705 patent (id.);<sup>1</sup>

WHEREAS, on April 30, 2018, HyperBranch objected to the Report (D.I. 709)

<sup>1</sup>The underlying Report, and therefore this Order, solely addresses these three portions of the parties' motions. (D.I. 393, 399)

(“Objections” or “Objs.”), asserting it incorrectly construed the term “the hydrogel forms within 5 seconds” and incorrectly recommended summary judgment of indirect infringement;

WHEREAS, on May 10, 2018, Plaintiffs responded to HyperBranch’s Objections (D.I. 717) (“Response” or “Resp.”);

WHEREAS, on May 15, 2018, during the pretrial conference in this matter, the Court heard extensive argument from the parties relating to the Objections (*see* Tr. at 115-30);

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. 709) are SUSTAINED, Judge Burke’s Report (D.I. 704) is REJECTED to the extent described herein, and Plaintiffs’ motion (D.I. 399) is DENIED.<sup>2</sup>

2. HyperBranch contends the Report is “flawed in two key respects:” (1) its construction of the term “the hydrogel forms within 5 seconds” and (2) its reliance on evidence that is not dispositive of infringement when that claim term is properly construed. (Objs. at 4-5)

3. The parties are unable even to agree on how the Report construed the term “the hydrogel forms within 5 seconds.” In Defendant’s view, “the Report purports to construe ‘the

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<sup>2</sup>Neither party objected to the portions of the Report related to Defendant’s motion for summary judgment of (1) invalidity of claim 10 of the ’034 patent for obviousness and (2) non-infringement of the “mixing” limitation of claims 1, 6, 12, and 17 of the ’5705 patent. (D.I. 704 at 1 n.2, 19-26) Those recommendations are, therefore, ADOPTED and Defendant’s motion (D.I. 393) is DENIED as related to invalidity of claim 10 and DENIED AS MOOT as related to non-infringement of the asserted claims of the ’5705 patent.

hydrogel forms within 5 seconds’ as a ‘fully cured’ hydrogel forms in 5 seconds – not initial gel formation occurs in 5 seconds.” (*Id.* at 4) Plaintiffs, however, read the Report as “properly conclud[ing] that the claim limitation ‘the hydrogel forms’ is ‘met at the point when the material has cured and “a visible solid aggregate has been formed”” and this point can be determined ‘by way of a visual inspection.”” (Resp. at 1) In the Court’s understanding, the Report found 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,’” and that this point can be determined “by way of a visual inspection.” (Report at 10)

4. Considering this claim construction dispute *de novo*, the Court concludes that “the hydrogel forms within 5 seconds” is properly construed as “a visual solid aggregate forms within 5 seconds.”<sup>3</sup> This construction is supported by intrinsic evidence. *See, e.g.*, ’034 pat. at 8:31-37 (“[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.”); *id.* at 35:32-34 (“When the solution solidifies sufficiently so that the stir bar stops spinning, the stop watch was stopped.”). It is also supported by extrinsic evidence. (*See, e.g.*, D.I. 466 Ex. 5 at 354-57 (Plaintiffs’ expert, Dr. Mays, opining that at gel time “you start to form a three-dimensional network . . . , but there’s still reactive groups in there and they’re still mixing with one another. So you can have additional crosslinking taking place beyond the gel point”); *id.* at 357-58 (Dr. Mays explaining that the solid “starts to occur [at gel time], but there can still be liquid material in there that’s still reacting” and that POSA knows

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<sup>3</sup>Relatedly, the Court construes the term “form a hydrogel within about 60 seconds,” appearing in claim 20 of the ’034 patent, as “form a visual solid aggregate in about 60 seconds.”

solid aggregate has been formed when she can “pick it up . . . and it retains its shape”<sup>4</sup>

Satisfying this claim limitation requires that material be sufficiently cured that the crosslinking process has proceeded to a point at which a three-dimensional barrier has been formed, which may be determined by visual inspection. This limitation may be satisfied during the “gel time” phase, prior to the achievement of the “fully cured” point.

5. To the extent Defendant suggests the term must be construed such that it is only satisfied if the hydrogel is fully formed (or fully cured) within 5 seconds, so that no additional crosslinking may occur after the point at which “the hydrogel forms,” the Court is not persuaded. (*See* Objs. at 2 (“Either ‘the hydrogel forms’ is related to gel formation at the ‘gel time’ and the claim is indefinite, or the claim requires a ‘fully cured’ hydrogel and Plaintiffs[] have *no* evidence that complete crosslinking occurs within 5 seconds.”)) Defendant points to no persuasive intrinsic or extrinsic evidence to support such a narrow construction. Defendant’s best argument is that the Court’s construction renders the claim indefinite, as a person of ordinary skill in the art would not know with reasonable certainty whether a hydrogel has formed within 5 seconds, for reasons including the existence of multiple methods of assessing whether a hydrogel has formed. (*See* Objs. at 8 n.2) But just because whether a hydrogel has been “fully cured” may be measured by the sole objective standard of completion of cross-linking does not mean that a construction allowing that a hydrogel may be formed prior to that point is improperly subjective or indefinite. Instead, Defendant’s indefiniteness contention presents a genuine dispute of material fact. (*See, e.g.*, D.I. 403 Ex. 146 ¶ 252 (Defendant’s expert, Dr. Lowman

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<sup>4</sup>While Dr. Mays was referring to the ’5705 patent in this context, he clarified that the term “the hydrogel forms” would be similarly construed in the ’034 patent. (*See* D.I. 466 Ex. 5 at 362-63)

opining that use of gel time to measure when “the hydrogel forms” is “highly subjective and there are various different measures for making a determination of gel time”)) Defendant will have the opportunity to persuade a jury of this view by clear and convincing evidence.

6. The evidence on which the Report relied in recommending that summary judgment of infringement be granted may relate to gel formation, and not to a hydrogel being fully cured. Reviewing the record *de novo*, the Court determines that genuine disputes of material fact exist regarding whether the “hydrogel forms within 5 seconds” in the accused products. Therefore, summary judgment of infringement is not warranted.

May 24, 2018  
Wilmington, Delaware

  
HONORABLE LEONARD P. STARK  
UNITED STATES DISTRICT JUDGE