IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

MIMEDX GROUP, INC., **Plaintiff,** **v.** **LIVENTA BIOSCIENCE, INC., MEDLINE INDUSTRIES, INC., and MUSCULOSKELETAL TRANSPLANT FOUNDATION,** **Defendants.**	**CIVIL ACTION FILE** **NO. 1:14-CV-1178-MHC**

ORDER

This case comes before the Court on the Special Master's Report and Recommendations ("R&Rs") on the parties' summary judgment motions and motions to exclude. In this action, Plaintiff MiMedx Group, Inc. ("Plaintiff" or "MiMedx") asserts that Defendants Liventa Bioscience, Inc., Medline Industries, Inc. and Musculoskeletal Transplant Foundation (collectively, "Defendants") have infringed United States Patent No. 8,709,494, attached as Ex. F to Am. Compl.

[Doc. 6-6] ("the '494 Patent").[1] The Special Master has provided six R&Rs, recommending that the Court:

1. Grant Defendants' Motion to Exclude the Trial Testimony of Dr. Andrew Hopkinson [Doc. 206] with respect to the use of forceps testing regarding the absence of the spongy tissue and about the presence of the epithelial cellular layer, but otherwise deny the motion [Doc. 293] ("Hopkinson R&R");
2. Grant Defendants' Motion to Exclude the Trial Testimony of Dr. Rosemary Hoffman Tambouret [Doc. 204] with respect to her testimony about Hemotoxylin and Eosin ("H&E") staining tests regarding the absence of the spongy layer, but otherwise deny the motion [Doc. 294] ("Tambouret R&R");
3. Grant Plaintiff's Motion to Exclude the Opinions and Testimony of Helen N. Jones, Ph.D. [Doc. 200] with respect to any testimony regarding the FDA letter beyond its four corners, and otherwise deny the motion [Doc. 295] ("Jones R&R");

[1] Initially, MiMedx asserted that Defendants had infringed several other patents; however, the parties jointly stipulated to dismissal of the claims for these additional patents. Joint Stipulation [Doc. 198].

4. Deny Defendants' Motion to Exclude the Trial Testimony of Ivan T. Hofmann [Doc. 202] in full [Doc. 296] ("Hofmann R&R");
5. Deny Defendants' Motion for Summary Judgment that the '494 Patent's Asserted Claims Are Not Patent Eligible Under 35 U.S.C. § 101 [Doc. 212] and grant Plaintiff's Motion for Summary Judgment that Claims 1, 2, 4, 5, 9, and 10 of U.S. Patent No. 8,709,494B2 Are Patent Eligible Under 35 U.S.C. § 101 [Doc. 210] in full [Doc. 297] ("§ 101 R&R"); and
6. Deny Defendants' Motion for Summary Judgment of Non-Infringement of the '494 Patent [Doc. 216] in full [Doc. 298] ("Non-Infringement R&R").

I. BACKGROUND

The Court appointed Sumner Rosenberg on January 5, 2017, as Special Master (the "Special Master") to preside over the relevant motions and submit R&Rs to the Court. See Order [Doc. 265]. The Special Master reviewed the briefs of the parties and held a hearing on March 30, 2017. On May 31, 2017, the Special Master submitted the R&Rs. On June 16, 2017, both sides filed objections to the

R&Rs.[2] See Defs.' Objs. to R&R Concerning Defendants' Motion to Exclude Hoffman Testimony [Doc. 303] ("Defs.' Hoffman Objs."); Defs.' Objs. to R&R Concerning Defendants' Motion to Exclude Hopkinson Testimony [Doc. 304] ("Defs.' Hopkinson Objs."); Defs.' Objs. to R&R Concerning Defs.' Mot. for Summ. J. on Non-Infringement [Doc. 305] ("Defs.' Non-Infringement Objs."); Defs.' Objs. to R&R on Cross-Mots. for Summ. J. on Patent Eligibility/Ineligibility [Doc. 306] ("Defs.' § 101 Objs.");[3] Pl.'s Objs. to R&Rs [Doc. 300] ("Pl.'s Objs."). On June 30, 2017, each side responded to the opposing side's objections to the R&R. See Defs.' Resp. to Pl.'s Objs. on Hoffman [Doc. 312] ("Defs.' Hoffman Resp."); Defs.' Resp. to Pl.'s Objs. on Cross-Mots. for Summ. J. [Doc. 314] (Defs.' § 101 Resp."); Defs.' Resp. to Pl.'s Objs. on Hopkinson [Doc. 315] ("Defs.' Hopkinson Resp."); Defs.' Resp. to Pl.'s Objs. on Def.'s Mot. for Summ.

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[2] Because the parties have fully briefed their objections to the R&Rs, and the Court has sufficient information to determine the merits of the parties' objections, Defendants' Motion for Oral Argument [Doc. 308] is **DENIED**.

[3] Defendants filed a Motion for Leave to File Separate Objections to Distinct Reports and Recommendations [Doc. 302]. Plaintiff does not oppose [Doc. 319]. Defendants' Motion is **GRANTED**.

J. [Doc. 316] ("Defs.' Non-Infringement Resp."); Pl.'s Resp. to Defs.' Objs. [Doc. 309] ("Pl.'s Resp.").[4]

The '494 Patent relates to the preparation of tissue grafts from placental membranes. The use of human placental membranes for grafts is well-known, but the '494 Patent addresses improved methods for producing such grafts, as well as products produced from the processes. The '494 Patent deals primarily with separating the amniotic membrane (amnion) and chorion, which compose the placental membrane, processing the amnion and chorion, and recombining them into a graft.

II. LEGAL STANDARD

A. Standard of Review for Special Master's R&Rs

All parties have filed objections to the R&Rs. Accordingly, the Court must decide *de novo* all objections to findings of fact or conclusions of law made or recommended by a master. FED. R. CIV. P. 53(f)(3)-(4). "Unless the appointing order establishes a different standard of review, the court may set aside a master's ruling on a procedural matter only for an abuse of discretion." FED. R. CIV. P. 53(f)(5).

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[4] The parties seek leave to file various documents under seal [Docs. 301, 307, 311, 317]. For good cause shown, these motions are hereby **GRANTED**.

B. Standard of Review for Motions to Exclude

Federal law applies to the admissibility of expert testimony in this case. Flury v. Daimler Chrysler Corp., 427 F.3d 939, 944 (11th Cir. 2005) (in diversity cases, the Federal Rules of Evidence govern the admissibility of evidence in federal court); see also Hendrix ex rel. G. P. v. Evenflo Co., 609 F.3d 1183, 1193 (11th Cir. 2010) ("Although the standards for finding causation are governed by [state] law, we apply federal law to determine whether the expert testimony proffered to prove causation is sufficiently reliable to submit it to the jury."). Federal Rule of Evidence 702 governs the admissibility of expert testimony and provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> > (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> > (b) the testimony is based on sufficient facts or data;
> > (c) the testimony is the product of reliable principles and methods; and
> > (d) the expert has reliably applied the principles and methods to the facts of the case.

FED. R. EVID. 702. The Supreme Court has directed that

> [u]nlike an ordinary witness, see Rule 701, an expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation. See Rules 702 and 703.

> Presumably, this relaxation of the usual requirement of firsthand knowledge . . . is premised on an assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline.

Daubert v. Merrell Dow Pharms., 509 U.S. 579, 592 (1993). Because of the broader range of testimony permitted under Rule 702, the Supreme Court has indicated that district courts are to perform a critical "gatekeeping" function concerning the admissibility of all expert testimony to ensure that an expert witness's testimony is not only relevant, but reliable. United States v. Frazier, 387 F.3d 1244, 1260 (11th Cir. 2004) (citing Kumho Tire Co. v. Carmichael, 526 U.S. 137, 147 (1999); Daubert, 509 U.S. at 589 n.7, 597). In particular, district courts are "charged with screening out experts whose methods are untrustworthy or whose expertise is irrelevant to the issue at hand." Corwin v. Walt Disney Co., 475 F.3d 1239, 1250 (11th Cir. 2007).

In performing this gatekeeping function, the Eleventh Circuit has developed "a rigorous three-part inquiry" to determine the admissibility of expert testimony under Rule 702, that considers whether:

> (1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in Daubert; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue.

Frazier, 387 F.3d at 1260 (quoting City of Tuscaloosa v. Harcros Chems., Inc., 158 F.3d 548, 562 (11th Cir. 1998)). "While there is inevitably some overlap among the basic requirements—qualification, reliability, and helpfulness—they remain distinct concepts and the courts must take care not to conflate them." Id.

"A district court's gatekeeper role under Daubert 'is not intended to supplant the adversary system or the role of the jury.'" Maiz v. Virani, 253 F.3d 641, 666 (11th Cir. 2001) (quoting Allison v. McGhan Med. Corp., 184 F.3d 1300, 1311 (11th Cir. 1999)); accord Daubert, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."); Adams v. Lab. Corp. of Am., 760 F.3d 1322, 1332, 1334 (11th Cir. 2014) ("Bias in an expert witness's testimony is usually a credibility issue for the jury. . . . The risk of bias would mean, at most, that [the expert's] testimony is to some extent 'shaky,' and shakiness goes to the weight of her testimony, not its admissibility.") (citations omitted). Rather, the Court's role as a gatekeeper under Daubert "is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire Co., 526 U.S. at 152 (1999).

The proponent of expert testimony "always bears the burden to show that his expert is qualified to testify competently regarding the matters he intended to address; the methodology by which the expert reached his conclusions is sufficiently reliable, and the testimony assists the trier of fact." Frazier, 387 F.3d at 1260 (quoting McCorvey v. Baxter Healthcare Corp., 298 F.3d 1253, 1257 (11th Cir. 2002) (internal punctuation omitted)); see also Cook ex rel. Estate of Tessier v. Sheriff of Monroe Cty., Fla., 402 F.3d 1092, 1107 (11th Cir. 2005) (explaining that it is the proponent's burden to lay the foundation for admission of expert testimony).

1. Qualification of the Expert

There are various ways for determining whether an expert is qualified. "While scientific training or education may provide possible means to qualify, experience in a field may offer another path to expert status." Frazier, 387 F.3d at 1260-61. Federal Rule of Evidence 702 provides that an expert's qualification may be based on "knowledge, skill, experience, training, or education." FED. R. EVID. 702 advisory committee's note (2000 amends.) ("Nothing in this amendment is intended to suggest that experience alone . . . may not provide a sufficient foundation for expert testimony."). Thus, "there is no mechanical checklist for measuring whether an expert is qualified to offer opinion evidence in a particular

field." Santos v. Posadas de Puerto Rico Assocs. Inc., 452 F.3d 59, 63 (1st Cir. 2006).

2. Reliability of the Principles and Methodology

Rule 702, in conjunction with Rules 403 and 703, imposes a standard of evidentiary reliability that contrasts with the generous approach to admissibility reflected in Rules 401 and 402. Allison, 184 F. 3d at 1310; see also Kumho Tire Co., 526 U.S. at 149; Daubert, 509 U.S. at 589-91. The district court has "substantial discretion in deciding how to test an expert's reliability and whether the expert's relevant testimony is reliable." United States v. Majors, 196 F.3d 1206, 1215 (11th Cir. 1999) (citation and quotation omitted). Specifically, when expert "testimony's factual basis, data, principles, methods, or their application are called sufficiently into question, . . . the trial judge must determine whether the testimony has 'a reliable basis in the knowledge and experience of [the relevant] discipline.'" Kumho Tire Co., 526 U.S. at 149 (quoting Daubert 509 U.S. at 592).

"[T]he proponent of the testimony does not have the burden of proving that it is scientifically correct, but that by a preponderance of the evidence, it is reliable." Allison, 184 F.3d at 1312 (citation omitted). Thus, the inquiry into reliability must focus on "principles and methodology" and not the expert witness's conclusions. Daubert, 509 U.S. at 595. While an expert's qualifications

may bear on the reliability of his proffered testimony, qualifications alone do not guarantee reliability. Frazier, 387 F.3d at 1261 (citing Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd., 326 F.3d 1333, 1341-42 (11th Cir. 2003)). Because "one may be considered an expert but still offer unreliable testimony," it remains a basic foundation for admissibility under Rule 702 and Daubert that proposed expert testimony must be based on "good grounds." Id.

Daubert delineates a list of "general observations" for determining whether expert testimony is sufficiently reliable to be admitted under Rule 702, including: (1) whether the theory in question can be and has been empirically tested, that is, whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability; (2) whether the theory in question has been subjected to peer review and publication; (3) the theory's known or potential error rate and whether that rate is acceptable; and (4) whether the theory is generally accepted in the scientific community. Daubert, 509 U.S. at 593-94; see also City of Tuscaloosa, 158 F.3d at 566 n. 25. The advisory committee notes for Rule 702 have collected additional factors that courts consider in assessing the reliability of expert testimony:

> (1) Whether experts are proposing to testify about matters growing naturally and directly out of research they have conducted

> independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying.
> (2) Whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion.
> (3) Whether the expert has adequately accounted for obvious alternative explanations.
> (4) Whether the expert is being as careful as he would be in his regular professional work outside his paid litigation consulting.
> (5) Whether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert would give.

FED. R. EVID. 702 advisory committee's note (2000 amends.) (internal quotation marks and citations omitted).

3. Assistance to the Trier of Fact

Finally, the Court must assess whether the expert testimony is helpful to the trier of fact. This factor turns on whether the expert testimony "concerns matters that are beyond the understanding of the average lay person." Frazier, 387 F.3d at 1262. "Proffered expert testimony generally will not help the trier of fact when it offers nothing more than what lawyers for the parties can argue in closing arguments." Id. at 1262-63.

C. Standard of Review for Summary Judgment Motions

Summary judgment is appropriate when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). A party seeking summary judgment has the burden of informing the district court of the basis for its motion, and identifying those portions of the

record which it believes demonstrate the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions," and cannot be made by the district court in considering whether to grant summary judgment. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986); see also Graham v. State Farm Mut. Ins. Co., 193 F.3d 1274, 1282 (11th Cir. 1999).

If a movant meets its burden, the party opposing summary judgment must present evidence that shows there is a genuine issue of material fact or that the movant is not entitled to judgment as a matter of law. Celotex, 477 U.S. at 324. In determining whether a genuine issue of material fact exists to defeat a motion for summary judgment, the evidence is viewed in the light most favorable to the party opposing summary judgment, "and all justifiable inferences are to be drawn" in favor of that opposing party. Anderson, 477 U.S. at 255; see also Herzog v. Castle Rock Entm't, 193 F.3d 1241, 1246 (11th Cir. 1999). A fact is "material" only if it can affect the outcome of the lawsuit under the governing legal principles. Anderson, 477 U.S. at 248. A factual dispute is "genuine" if the evidence would permit a reasonable jury to return a verdict for the nonmoving party. Id.

"If the record presents factual issues, the court must not decide them; it must deny the motion and proceed to trial." Herzog, 193 F.3d at 1246. But, "[w]here the record taken as a whole could not lead a rational trier of fact to find for the non-moving party," summary judgment for the moving party is proper. Matsushita, 475 U.S. at 587.

III. ANALYSIS

A. Hopkinson R&R

The Special Master recommends that the Court grant Defendants' Motion to Exclude the Trial Testimony of MiMedx's expert Dr. Andrew Hopkinson only with respect to: (1) the use of forceps testing regarding the absence of the spongy tissue, (2) the presence of the epithelial cellular layer, and (3) any documentation on or validation of the spear test (i.e., the specific work done by or for Dr. Hopkinson at the University of Nottingham or NuVision). Each side objects to portions of this R&R.

1. Spear Test

Defendants object to the Special Master's recommendation that Dr. Hopkinson be allowed to testify regarding spear testing, arguing that: (1) Dr. Hopkinson "failed to test complete samples of the Accused Products" and "does not know what sample size portions he tested;" (2) his "assertions of

confidentiality over critical documents" related to these opinions have deprived Defendants of their right to cross-examine him on the test method's reliability; and (3) the spear test is not reliable under Daubert. Defs.' Hopkinson Objs. at 1.

a. Sample Size

Defendants' arguments that Dr. Hopkinson (1) did not follow the plain language of the '494 Patent claims and the Court's construction of the "washing/cleaning" terms, and (2) did not test a sufficient sample size (see Defs.' Hopkinson Objs. at 4-14) go to the weight, not admissibility, of Dr. Hopkinson's testimony. See Rosenfeld v. Oceania Cruises, Inc., 654 F.3d 1190, 1193 (11th Cir. 2011). The Court agrees with the Special Master that the question of the substantial absence of the spongy tissue "is most appropriate for determination by the jury, and on this subject Dr. Hopkinson's testimony would 'assist the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue.'" Hopkinson R&R at 11. (quoting Allison, 184 F.3d at 1309).

b. Confidentiality

The Court agrees with the Special Master that "the documents [over which Dr. Hopkinson asserted confidentiality] are not material to the testimony to be given by Dr. Hopkinson such that his testimony should be excluded on that basis."

Hopkinson R&R at 9. The Special Master did not give any weight to any validation of the reliability of the spear test from the confidential documents. Hopkinson R&R at 9.[5]

c. Reliability

Defendants object that spear testing is not reliable under Daubert. However, there is no definitive test for reliability under Daubert; rather, the inquiry is "a flexible one." Daubert, 509 U.S. at 593-94. MiMedx need not prove that Dr. Hopkinson's results are scientifically correct, but only that his methodology is reliable (by a preponderance of the evidence). Allison, 184 F.3d at 1312 (citation omitted).

Defendants rely on their expert, Dr. Aplin, who opined that the spear test is unreliable. See Defs.' Hopkinson Objs. at 19-20. The Special Master correctly concluded that Dr. Aplin's opinions regarding the thickness or thinness of the spongy layer and the wetness or dryness of and type of spear used "go more towards the weight of Dr. Hopkinson's particular test results than the reliability of

[5] Further, information on how to use the spear test is not included in the only relevant document Defendants requested. See Hopkinson Dep. at 54. The Special Master correctly concluded that Defendants "did not make a formal request for" the documents of NuVision Biotherapies Ltd., the ophthalmic biotechnology company of which Dr. Hopkinson is founder and CEO, that were related to the spear test. Hopkinson R&R at 10.

the test." Hopkinson R&R at 8-9. See Rosenfeld, 654 F.3d at 1193 ("[I]n most cases, objections to the inadequacies of a study are more appropriately considered an objection going to the weight of the evidence, rather than its admissibility.").

Defendants also object that spear testing is not "simple to understand and appreciate" because Dr. Hopkinson testified that extensive training is required to properly perform such testing. See Defs.' Hopkinson Objs. at 23. However, as the Special Master correctly found, Dr. Hopkinson's testimony was referring to the manufacturing process as a whole, not merely the spear testing. Hopkinson R&R at 10. Videos showing the simplicity were provided along with Dr. Hopkinson's expert report, and were shown to the Special Master during oral argument. Tr. at 176-78. The Special Master correctly concluded that the spear test "is simple to understand and appreciate, even by a lay jury, and there is sufficient evidence to show that it can be used to identify spongy material in the context of placental grafts." Hopkinson R&R at 10.

The Court agrees with the Special Master that "the ultimate question of the substantial absence of the spongy tissue is most appropriate for determination by the jury, and on this subject Dr. Hopkinson's testimony would assist the trier of fact, through the application of scientific, technical, or specialized expertise, to

understand the evidence or to determine a fact in issue." Hopkinson R&R at 11 (internal quotations omitted).

Defendants' objections to the Hopkinson R&R are **OVERRULED**.

2. Forceps Testing

MiMedx objects to the Special Master's recommendation that Dr. Hopkinson's use of the forceps test be excluded. Pl.'s Objs. at 2. It contends that Defendants acknowledge the test's reliability, and that the Special Master admits the test is an accepted method of removing spongy material from tissues. Id.

First, the Court notes that the Special Master in no way endorsed the use of forceps testing for these purposes. Rather, he simply stated, "the use of plastic forceps is an accepted practice for removing spongy material *from tissues*." Hopkinson R&R at 12 (emphasis added). The parties do not dispute that forceps testing is appropriate in many situations (such as removing spongy layer from fresh placenta). Rather, the dispute is over whether forceps testing is appropriate for a *dehydrated tissue graft*. On this, the Special Master makes no statement that forceps testing is appropriate.

The Court is not persuaded that Defendants or their experts endorsed the use of forceps testing for this purpose. Although MiMedx attempts to rely on Defendants' expert Dr. John Aplin's use of the forceps method, Pl.'s Objs. at 20-

21, Dr. Aplin only referred to using the forceps method for fresh placenta, not a dehydrated tissue graft. See Dep. of Dr. John Aplin, taken Sept. 9, 2016 [Doc. 256] ("Aplin Dep.") at 86-87, 170; Expert Rpt. of Dr. John Aplin, attached as Ex. 4 to Defs.' Mot. to Exclude Trial Test. of Dr. Rosemary Hoffman Tambouret [Doc. 205-3] ("Aplin Rpt.") ¶¶ 95-96, 103-06, 127, 136, 139, 141. Similarly, the article cited by MiMedx, Pl.'s Objs. at 21, does not discuss the use of forceps testing to determine whether substantially all the spongy layer was removed from a dehydrated placental tissue graft. See generally Harminder S. Dua, Jose A.P. Gomes, Anthony J. King, and V. Senthil Majarajan, The Amniotic Membrane in Ophthalmology, DIAGNOSTIC AND SURGICAL TECHNIQUE [Doc. 231-14].

Dr. Hopkinson's opinion contains only one reference to forceps testing. Hopkinson Rpt. ¶ 118. This supports the Special Master's conclusion that "the reliability of forceps testing has not been sufficiently established." Hopkinson R&R at 12. The Special Master correctly found that MiMedx "provide[d] no substantial evidence of the reliability of the forceps test" and that Dr. Hopkinson "presents no evidence in support of the validity of forceps testing as a means to

show that the spongy layer has been substantially removed from a placental tissue graft."[6] Id.

3. "Retains an Epithelial Layer" Limitation

MiMedx also objects to the Special Master's recommendation that Dr. Hopkinson's opinions regarding the "retains an epithelial layer" limitation be excluded. Pl.'s Objs. at 2. It contends that Dr. Hopkinson conducted independent testing to support his opinions through emulating Defendants' manufacturing process, and properly relied on his interpretation of factual evidence to confirm his conclusions. Id. However, Dr. Hopkinson stated in his report that his process emulations are irrelevant to infringement, and only his testing of the actual accused products matters. Hopkinson Rpt. ¶ 32.

His reports do not demonstrate that his "cellular debris" observations made during the emulations are reliable under Daubert. Dr. Hopkinson's expert reports provide no analysis of the stains prepared by MiMedx's expert Dr. Rosemary Hoffman Tambouret. See Hopkinson Rpt. ¶ 161 (stating simply that "I have also observed hematoxylin and eosin stains of the Accused Products, and believe that those stains depict an epithelial layer on the Accused Products. I also understand

[6] There is no evidence that the Special Master required "scientific certainty." See Pl.'s Objs. at 21.

that another of MiMedx's experts, Dr. Tambouret, has opined similarly."). His reports fail to provide any opinion on how the "retains an epithelial cellular layer" limitation would be construed by a person of skill in the art. As the Special Master noted, "none of Dr. Hopkinson's testimony sets forth what would constitute the retention of the epithelial cellular layer to one of ordinary skill in the art in the context of the accused products. Therefore, Dr. Hopkinson's testimony regarding this issue should be excluded." Hopkinson R&R at 13. The Court agrees with the Special Master that Dr. Hopkinson's opinions based on Defendants' deposition testimony are "basically conclusions and arguments that can be brought out at trial by cross-examination of the witnesses and arguments by trial counsel." Id.

Therefore, MiMedx's objections to the Hopkinson R&R are **OVERRULED**.

4. Remaining Recommendations Regarding Dr. Hopkinson

Finally, the Special Master states:

> Liventa seeks, more generally, to preclude testimony by Dr. Hopkinson about deposition testimony of others. MiMedx responds that the cited instances relate to scientific issue about which Dr. Hopkinson's testimony will be helpful to the jury.
>
> It is premature and inappropriate to address such specific potential trial testimony at this stage of the proceedings. Certainly, the Court can rule at trial on any objections to testimony that may constitute improper advocacy.

Hopkinson R&R at 14. Neither side has objected to this recommendation, and the Court finds no clear error in it.

B. Tambouret R&R

The Special Master recommends that MiMedx's expert Dr. Rosemary Hoffman Tambouret's testimony on H&E testing be excluded because such testing is not reliable in determining whether the spongy layer is substantially removed from a dehydrated placental tissue graft. Tambouret R&R at 8. In support of his recommendation, the Special Master relied on: (1) the fact that there is "no evidence of testing H&E staining for dehydrated placental grafts, nor any peer review of this application of the procedure;" and (2) the evidence that it is difficult or impossible "to use H&E staining to identify the spongy layer in a tissue graft produced by separating the amnion and chorion of a placenta and subsequently combining the layers and dehydrating them." Id. at 7-8. Regarding the latter, the Special Master states that Dr. Tambouret "is trying to prove a negative—that is that the spongy layer is substantially removed in the grafts at issue," rendering it "difficult to understand how the test can be used to prove the absence of something that just may be unseeable." See id.

MiMedx objects, arguing that Defendants and their attorneys "did the same test . . . to assess whether the spongy layer purportedly remained in their accused

graft." Pl.'s Objs. at 1-2. Specifically, MiMedx relies on: (1) Defendants' expert Dr. John Alpin; (2) statements by Defendants' counsel; (3) statements made by Defendants' scientist Stephanie Sun; (4) Defendants' witnesses Semler and Dasgupta; (5) Defendants' expert Dr. Helen Jones; and (6) Defendants' interrogatory responses. MiMedx also contends that the Daubert factors support permitting Dr. Tambouret's testimony. The Court will examine MiMedx's objections *seriatim*.

1. Dr. Aplin's Testimony

Although MiMedx argues that Defendants' expert John Aplin, Ph.D., provided testimony that supports its argument that H&E testing is reliable for the relevant purposes, Dr. Aplin actually stated that H&E is *not* an accepted methodology "for attempting to quantify the amount of spongy tissue remaining in multi-layered, dehydrated tissue grafts." Alpin Rpt. ¶ 166 ("Dr. Tambouret states that H&E is a 'well-established histology stain' that is 'widely used in pathology.' Tambouret Rpt. at ¶ 44. I agree. Dr. Tambouret does not state, however, that H&E is an accepted methodology for attempting to quantify the amount of spongy tissue remaining in multi-layered, dehydrated tissue grafts. In my opinion it is not."). The other paragraphs of Dr. Alpin's report cited by MiMedx concern the use of H&E in other contexts (which, as the Special Master states, have established

use and validity). See id. ¶¶ 210-43. Paragraph 175 of Dr. Aplin's report supports Defendants' position. Id. ¶ 175 ("Dr. Tambouret's use of her H&E images to determine the presence of spongy tissue was not a reliable technique, and her inability to distinguish spongy tissue from other connective tissue in the H&E images does not support a conclusion that no spongy tissue is present."). Dr. Aplin opines that a person of skill cannot reliably determine the presence of spongy tissue using H&E staining due to tissue compression. Id. ¶¶ 180-81, 192.[7] The Court finds that, far from supporting MiMedx's argument, Dr. Aplin's report supports Defendants' position.

2. Opinion of Defendants' Counsel

Similarly, MiMedx's argument that Defendants' counsel opined that H&E is reliable for determining the presence of spongy layer in a dehydrated graft, see Pl.'s Objs. at 8-12, is not supported by the evidence. MiMedx relies on a letter provided to Defendants by Defendants' counsel Sandra Kuzmich, Ph.D. See April 6, 2012, Letter, attached as Ex. 27 to Pl.'s Opp'n to Defs.' Mot. to Exclude Trial Testimony of Dr. Rosemary Hoffman Tambouret [Doc. 234-21]. However, the letter states that "the spongy layer is not removed during the drying process.

[7] The Court is not persuaded that it should deny the Daubert motion as based on Dr. Alpin's "fabricate[d]" standard for reliability, see Pl.'s Objs. at 16-17. The R&R considered a variety of factors, not solely Dr. Alpin's report.

Instead, the spongy layer shrinks due to dehydration." Id. at MTF0099516 n.140. This does not support MiMedx's objection.

3. Stephanie Sun's Comments

MiMedx further argues that a histology image purporting to depict the presence of the spongy layer via H&E in a dehydrated graft on which Defendants' scientist Stephanie Sun comments supports its argument that H&E testing is reliable for such a purpose. Pl.'s Objs. at 9-12. However, Sun's belief that the spongy layer was present in this image appears to be based on her knowledge that "neither the chorion nor amnion was scraped" in the manufacturing process. Image, attached as Ex. 14 to Pl.'s Opp'n to Defs.' Mot. to Exclude the Trial Testimony of Dr. Rosemary Hoffman Tambouret [Doc. 234-13]. Similarly, Sun's phrase "band of color difference from amnion to chorion" does not imply the identification of spongy layer; she does not refer to spongy tissue in that phrase.[8] Id. The Court finds nothing in Sun's comments to demonstrate that she believed H&E testing to be reliable for this purpose.

MiMedx also contends that "Sun testified that she understood the spongy layer existed in MTF's dehydrated grafts because, according to her, H&E showed

[8] The Court similarly is not persuaded by MiMedx's assertion that Defendants "sought to hide" the full image. See Pl.'s Objs. at 11. Defendants submitted the full image to the Court as an exhibit [Doc. 234-13].

the presence of the spongy layer." Pl.'s Objs. at 12. This is the same testimony relied on by Tambouret in opining that Sun had difficulty assessing the presence of the spongy layer due to tissue compression. Tambouret Rpt. [Doc. 205-2] ¶ 75 ("Like Drs. [sic] Semler and Dr. Dasgupta, Dr. Sun, testified that it was more difficult to see the spongy layer via H&E staining because the tissue 'is compressed.' Sun Tr. at 365:16-367:20. Though Dr. Sun testified that she believed the H&E stains to show the spongy layer because it is 'a light pink band,' Dr. Sun also testified that 'it's also the same color with the rest of the amnion so it's harder to tell.' Sun Tr. at 367:10-20."). The remainder of Sun's testimony cited by MiMedx (see Sun Dep. at 175-79, 207-12, 229, 292, 297-98, 373) fares no better. Her statement that the tissue is compressed supports Dr. Alpin's opinion that compression during dehydration makes H&E an unreliable method for assessing the presence of spongy layer in a dehydrated placental tissue graft. Alpin Rpt. ¶ 169. Thus, Sun's testimony does not support MiMedx's objections.

4. Other Deposition Testimony

MiMedx also relies on deposition testimony of Defendants' witnesses Dr. Eric Semler and Dr. Anouska Dasgupta. See Pl.'s Objs. at 12 ("MTF's corporate designee [Semler] testified that MTF identified the spongy layer using H&E, including on dehydrated tissue. And a third MTF scientist [Dasgupta] agreed.")

(citations omitted)). In fact, Tambouret considered this testimony. She indicated that Semler believed "the spongy layer is 'difficult to see' and becomes 'hard to see' in the Accused Products since they are dehydrated." Tambouret Rpt. ¶ 73. Tambouret considered Dasgupta's testimony, but concluded that the testimony merely expressed Dasgupta's belief that "the spongy layer was 'very difficult' to distinguish from the surrounding layers via histology." Id. ¶ 74. Therefore, these witnesses also fail to support MiMedx's objections.

5. Purported Reliance by Dr. Jones

MiMedx's contends that Defendants' expert Dr. Helen Jones endorsed H&E testing for these purposes by relying on a MiMedx e-mail in which Dr. Thomas Koob, MiMedx's Chief Scientific Officer, approved the accuracy of a histology image labeling MiMedx's EpiFix product as having a spongy layer. See Pl.'s Objs. at 12-13. However, Dr. Jones relied on the e-mail as an admission by MiMedx concerning its product, EpiFix, to support her opinion that EpiFix does not embody any of the asserted claims of the '494 Patent. See Expert Rpt. of Dr. Helen Jones [Doc. 234-16] ¶¶ 317-18; Dep. of Helen N. Jones, Ph.D., taken Sept. 29, 2016 [Doc. 256] ("Jones Dep.") at 259-60.

In addition, the Court is not persuaded by MiMedx's objection that Jones used H&E staining to identify the spongy layer in dehydrated tissue. See Pl.'s

Objs. at 13. The tissue Dr. Jones examined was a natural placenta, rather than a dehydrated tissue graft; Dr. Jones has never used H&E on commercially-processed and dehydrated placental tissue grafts. Jones Dep. at 363-64. Therefore, Dr. Jones fails to support MiMedx's objections.

6. Documents

The documents cited by MiMedx from Defendants' interrogatory responses similarly are unpersuasive. See Pl.'s Objs. at 14. MiMedx cites to a 2013 internal MiMedx e-mail an admission by MiMedx that the accused products retain spongy tissue. That e-mail includes an H&E image of an accused product labeled as having an "intermediate layer" (a spongy layer) present. Defs.' Suppl. Interrogatory Resps., attached as Ex. 9 to Defs.' Mot. to Exclude Tambouret Test. [Doc. 234-8] at 17-18. The interrogatory response does not constitute an endorsement by Defendants of H&E testing for this purpose. MiMedx also relies on a presentation containing H&E images of dehydrated and non-dehydrated tissue, which includes an image of a graft made by MiMedx, not Defendants; further, Defendants' interrogatory response states that they are relying on images "at various stages of the process" rather than the final product. Id. at 16.

Finally, MiMedx relies on a document depicting staining of dehydrated tissue, purportedly to demonstrate spongy layer in a dehydrated H&E graft. Image,

attached as Ex. 13 to Defs.' Mot. to Exclude Tambouret Test. [Doc. 234-12]. However, this document illustrates, as MiMedx admits, "a stain other than H&E." Pl.'s Objs. at 14. This cannot, therefore, be used to support MiMedx's arguments about H&E.[9]

The documents cited thus fail to support MiMedx's objections.

7. Daubert Factors

Although MiMedx correctly states that the Daubert factors are flexible and non-exhaustive, MiMedx fails to demonstrate that the Special Master misapplied any of the factors. Because Dr. Tambouret failed to demonstrate that H&E is reliable with respect to the requirements of the '494 Patent claims, the Court agrees with the Special Master that "H&E testing is not reliable when applied to determining whether the spongy layer is substantially removed from a dehydrated placental tissue graft, and that Dr. Tambouret's testimony on this subject should be excluded." Tambouret R&R at 8. The Court finds that the Special Master properly applied the Daubert factors with respect to Dr. Tambouret's opinion.

8. Remaining Recommendations Regarding Dr. Tambouret

[9] The Court is not persuaded by MiMedx's argument that the compression problem that is associated with H&E also applies to other staining techniques. See Pl.'s Objs. at 14. The paragraph of Dr. Aplin's report relied upon by MiMedx refers only to H&E testing. Aplin Report ¶ 175.

The Special Master also recommends that Dr. Tambouret's opinion based on samplings of accused products be included because it would assist the trier of fact. Tambouret R&R at 9-11. Finally, the Special Master recommends that Dr. Tambouret's opinions that attempt to synthesize or interpret fact witness deposition testimony be ruled on at trial. Tambouret R&R at 11. Neither side has raised any objection to these conclusions, and the Court finds no clear error in them.

Therefore, MiMedx's objections to the Tambouret R&R are **OVERRULED**.

C. Jones R&R

The parties have not objected to, and the Court finds no clear error in, the Special Master's recommendation regarding Defendants' expert Dr. Helen Jones.

D. Hofmann R&R

The Special Master recommends that the Court deny Defendants' motion to exclude MiMedx's expert Ivan T. Hofmann's testimony regarding what constitutes a reasonable royalty fee. Defendants object to the R&R, contending that Hofmann's report relied on "an improper 'totality of the evidence' approach" and that Hofmann should be precluded from testifying about "agreements MiMedx concedes (i) are not comparable to the patent license at issue in the 'hypothetical

negotiation,' and (ii) Mr. Hofmann did not rely upon in calculating a reasonable royalty." Defs.' Hofmann Objs. at 1.

1. Totality of the Evidence

Defendants object to the Special Master's recommendation to allow Hofmann's testimony that the reasonable royalty should include a $1,000,000 up-front payment. Defendants' objection to the $1,000,000 royalty is to the conclusion rather than the methodology (as Defendants do not object to the 10% running royalty). This is appropriate for the jury to weigh. See, e.g., i4i Ltd. P'ship v. Microsoft Corp., 598 F.3d 831, 854 (Fed. Cir. 2010).

Here, Hofmann quoted the Snoasis agreement's royalty rate paragraph in his report. The Special Master found as follows:

> Mr. Hofmann also generally considers such factors as the market for the patented products (Hofmann report [Doc. 203-2], ¶¶ 96-98), the growth of the market (id., ¶¶ 100-106), MiMedx' general unwillingness to grant bare licenses and desire to supply product at a transfer price (id., ¶¶145, 155-157); that Defendants are direct competitors (id., ¶¶ 158-162), and the profitability and commercial success of the patented product (id., ¶¶ 166-170). This analysis is based on asserted facts outside of the two agreements MiMedx asserts as comparable, and leads to conclusions about the various [Georgia-Pacific Corp. v. United States Plywood Corp., 318 F. Supp. 1116 (S.D.N.Y. 1970)] factors that are more than merely "superficial recitation of the Georgia-Pacific factors, followed by conclusory remarks." See Whitserve, 694 F.3d at 31.

Hofmann R&R at 10. He continued:

> While it is true that Mr. Hofmann does not call out a specific royalty rate as a starting point, the royalty rate paragraph from Snoasis is quoted in his report, and that is the only comparable royalty rate presented. All the other factors discussed by Mr. Hofmann (as mentioned above) are necessarily subjective, and whether Mr. Hofmann "started" with a royalty rate to which he applied the other factors one-by-one, or if he just considered them all together, it will be useful to a jury to consider his opinion . . . subject to cross-examination by the other party.

Id. at 11-12. The Court agrees. See Ericsson, Inc. v. D-Link Sys., Inc., 773 F.3d 1201, 1232 (Fed. Cir. 2014) ("Although we recognize the desire for bright line rules and the need for district courts to start somewhere, courts must consider the facts of record when instructing the jury and should avoid rote reference to any particular damages formula.").

2. Consideration of Other Agreements

Defendants object also to Hofmann's consideration of agreements other than those with Snoasis and Nutech, the two agreements on which Hofmann relied in his report. Defs.' Hofmann Objs. at 5-7. Specifically, these agreements include: (1) various MiMedx "reseller" agreements, (2) three defendant agreements, and (3) summary licensing information obtained from Royalty Source. See Hofmann R&R at 8. Defendants do not dispute that Hofmann considered these other agreements; they simply note that the agreements did not form the basis for Hofmann's calculation. See id. Hofmann did not state that these other agreements

were directly comparable and did not rely on the materials from the "Royalty Source" database in arriving at his reasonable royalty amount; he simply used them as informative to the reasonableness of his conclusion. Hofmann Rpt. ¶¶ 189, 195-98. There is nothing in the R&R to recommend excluding the portion of Hofmann's report considering these agreements and, upon reviewing the record, the Court agrees that this type of consideration is appropriate.

Therefore, Defendants' objections to the Hofmann R&R are **OVERRULED**.

E. § 101 R&R

The Special Master recommends that MiMedx's motion for summary judgment regarding patent eligibility be granted and Defendants' motion for summary judgment regarding patent eligibility be denied. See generally § 101 R&R. Specifically, the Special Master concluded as follows:

> In the present case, merely separating the amnion from the chorion and using the amnion layer as a graft is analogous to the DNA gene [which the Court held was not patentable] in [Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2117 (2013)] being separated from its surrounding genetic material. On the other hand, the claimed tissue graft where the amnion and chorion layers are cleaned (i.e. having substantially all of the blood clots and the spongy/connective tissue removed) and laminated together absent such spongy/connective tissue [is] analogous to the cDNA [which the Court held was patentable] in Myriad. The tissue grafts as claimed are indeed "something new" and that is sufficient to find they are not products of nature.

Id. at 9.

1. "Something New" Standard

Defendants object to the Special Master's recommendation, contending that the R&R incorrectly uses a "something new" rather than a "markedly different" standard to analyze patent eligibility. See generally Defs.' § 101 Objs. They argue that the claimed grafts do not have characteristics that are "markedly different" from naturally-occurring placental tissue. Id. at 12. They contend that, as in Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948), "the amnion/chorion membranes of the asserted '494 patent claims are 'minimally manipulated' so they perform no new or improved function or utility; they have the same effect as they always had, they perform in their natural way, and they serve the ends nature originally provided." Id. at 15.

In fact, the Special Master followed the Supreme Court's recent decisions in Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347, 2354 (2014), and Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012). The Federal Circuit recently summarized the two-part test articulated in these cases as follows:

> Step one asks whether the claim is directed to one of the patent-ineligible concepts. If the answer is no, the inquiry is over: the claim falls within the ambit of § 101. If the answer is yes, the inquiry

> moves to step two, which asks whether, considered both individually and as an ordered combination, the additional elements transform the nature of the claim into a patent-eligible application. Step two is described as a search for an inventive concept.

Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1047 (Fed. Cir. 2016) (internal citations and punctuation omitted).

"Markedly different" is far from a mandated standard of analysis under § 101; rather, as MiMedx points out, the Supreme Court first used the phrase "markedly different" in this context in Diamond v. Chakabarty, 447 U.S. 303, 310 (1980), as a *sufficient*, not a *necessary*, demonstration of patentability, not to establish a new standard, and never used the phrase again in this context in a majority or plurality opinion until Myriad, 133 S. Ct. at 2117 (distinguishing Chakabarty). Pl.'s § 101 Resp. at 5-6. Further, the Special Master noted the relevant portions of both Chakabarty and Myriad in its analysis. § 101 R&R at 6-7. The Federal Circuit never has used the "markedly different" test as necessary for patent eligibility; other than mere quotations, it only has used the phrase once in this context, see In re Roslin Institute (Edinburgh), 750 F.3d 1333, 1337 (Fed. Cir. 2014), and did so to describe a sufficient (not a necessary) characteristic of patent-eligible subject matter.

As the Special Master pointed out, Myriad used the "markedly different" language in finding a gene was not patentable, but used "something new language"

in determining that another gene *was* patentable. See § 101 R&R at 9 (quoting Myriad, 133 S. Ct. at 2019). Despite Defendants' protests to the contrary, the Special Master uses the term "something new" as it is used in Myriad (*i.e.*, not found in nature and not patent ineligible natural phenomena), rather than to mean "novel." See § 101 R&R at 9.[10]

2. Other Objections

Defendants further argue that the fact that the '494 Patent does not explicitly mention the spongy layer precludes patentability. Defs.' § 101 Objs. at 13-14. However, the record treats the spongy layer as extraneous tissue to be removed. See '494 Patent at 1, 3, 6. Similarly, Defendants argue that their § 101 motion should be granted because MiMedx did not identify any benefit of removing the spongy layer during prosecution. See Pl.'s § 101 Objs. at 14. However, there is no requirement that every benefit be identified during prosecution. See, e.g., Knoll

[10] Even if the Court were to agree with Defendants' argument regarding the standard and particular language used, to succeed in its argument that the '494 Patent does not present patentable subject matter, Defendants would have to demonstrate that: (1) the '494 Patent is directed to a natural phenomenon; and (2) the '494 Patent does not transform such naturally-occurring subject matter into patent-eligible subject matter. See Rapid, 827 F.3d at 1047. Defendants have failed to do so. Here, removing the spongy tissue distinguishes the claimed tissue grafts from any natural phenomenon: amnion and chorion layers with their intermediate spongy layers removed do not exist in nature. See File History, attached as Ex. 4 to Pl.'s Mot. for Summ. J. [Doc. 210-7] at 5 (noting that "the product lacks the natural intermediate layer").

Pharm. Co. v. Teva Pharm. USA, Inc., 367 F.3d 1381, 1385 (Fed. Cir. 2004) ("Evidence developed after the patent grant is not excluded from consideration, for understanding of the full range of an invention is not always achieved at the time of filing the patent application. It is not improper to obtain additional support consistent with the patented invention, to respond to litigation attacks on validity. There is no requirement that an invention's properties and advantages were fully known before the patent application was filed, or that the patent application contains all of the work done in studying the invention, in order for that work to be introduced into evidence in response to litigation attack. Nor is it improper to conduct additional experiments and provide later-obtained data in support of patent validity.").

Next, Defendants argue that MiMedx's products do not comport with FDA regulatory requirements that commercial embodiments be "minimally manipulated." See Defs.' § 101 Objs. at 12, 15. However, FDA Guidance demonstrates that a product can be altered and remain patent-eligible as long as it does not change the tissue's utility for reconstruction, repair, or replacement. U.S. Dep't of Health and Human Servs., Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products, Draft Guidance for Industry and

Food and Drug Administration Staff, attached as Ex. 4 to Decl. of Leah W. Feinman in Supp. of Pl.'s Reply in Supp. of Mot. for Summ. J. [Doc. 271-5] at 6.

Finally, MiMedx's reliance on marketing, investor materials, and other non-technical documents fails. "The § 101 inquiry must focus on the language of the Asserted Claims themselves." Synopsys, Inc. v. Mentor Graphics Corp., 839 F.3d 1138, 1149 (Fed. Cir. 2016) (citation omitted).

The Court agrees with the Special Master that "[t]he tissue grafts as claimed are indeed 'something new' and that is sufficient to find they are not products of nature." See § 101 R&R at 9. Therefore, Defendants' objections to the § 101 R&R are **OVERRULED**.

F. Non-Infringement R&R

Defendants' Motion for Summary Judgment on Non-Infringement rests largely on its argument that the Court should exclude Dr. Hopkinson's testimony regarding spear testing. The Special Master recommends denying Defendants' motion for summary judgment because he has recommended admitting Dr. Hopkinson's testimony regarding spear testing. Non-Infringement R&R at 3.

Defendants object, arguing that: (1) Dr. Hopkinson's "no dabbing" process emulation demonstrates non-infringement; and (2) his emulation testing discarded

the chorion layer and never tested it for presence of spongy layer, rendering the process unreliable. See generally Defs.' Non-Infringement Objs.[11]

1. "No Dab" Control Group

Although Defendants argue that any graft made consistent with the "no dab" control group could retain spongy layer, see Defs.' Non-Infringement Objs. at 13-16, the Court is not persuaded. Dr. Hopkinson testified that the spongy layer was "noticeably reduced" and "the entire spongy materials had gone." Hopkinson Dep. at 214-15. Dr. Hopkinson referred to this as a "control group" and not indicative of how amniotic tissue would be processed. June 24, 2016, Rpt. [Doc. 216-7] ("June 24 Rpt.") ¶ 129. Further, as the Special Master states, even if, in the "no dabbing" sample, the spongy layer technically remains intact, there are factual issues regarding the extent to which accused products were made with the "no dabbing" procedure. Non-Infringement R&R at 4.

2. Emulation Testing

Defendants argue for the first time that the emulation testing should be considered unreliable due to Dr. Hopkinson's failure to test the chorion for the presence of spongy layer. Defs.' Non-Infringement Objs. at 11-13. The Court

[11] Defendants also object to the sample size tested in spear testing; however, the Court has addressed these objections in the context of the Hopkinson R&R.

could decline to entertain this objection because Defendants did not raise the argument before the Special Master. See Williams v. McNeil, 557 F.3d 1287, 1292 (11th Cir. 2009). However, Defendants' objection also fails on the merits. Dr. Hopkinson tested the amnion for presence of spongy layer, and concluded that none existed. June 24 Rpt. ¶¶ 121-36. As MiMedx points out, Dr. Hopkinson's decision is sensible because research shows that more of the spongy layer sticks to the amnion than to the chorion after separation. See Mahmood Farazdaghi, Jiri Adler, and Sameera M. Farazdaghi, Electron Microscopy of Human Amniotic Membrance [sic], ADVANCES IN TISSUE BANKING VOL. 5, attached as Ex. 1 to Pl.'s Non-Infringement Resp. [Doc. 316-1] at 164 ("Although [spongy layer] adheres to both membranes, its adhesion to amnion is stronger[.]").

Defendants' objections regarding the Non-Infringement R&R are **OVERRULED**.

IV. CONCLUSION

For the foregoing reasons, it is hereby **ORDERED** that Defendants' objections [Docs. 303, 304, 305, 306] are **OVERRULED**, Plaintiff's objections [Doc. 300] are **OVERRULED**, and the Special Master's Report and Recommendations [Docs. 293, 294, 295, 296, 297, 298] are **ADOPTED** as the Opinion and Order of this Court.

It is further **ORDERED** that Defendants' Motion to Exclude the Trial Testimony of Dr. Andrew Hopkinson [Doc. 206] is **GRANTED** as to his testimony about the use of forceps testing regarding the absence of the spongy tissue and about the presence of the epithelial cellular layer, but otherwise **DENIED**.

It is further **ORDERED** that Defendants' Motion to Exclude the Trial Testimony of Dr. Rosemary Hoffman Tambouret [Doc. 294] is **GRANTED** as to Dr. Tambouret's testimony about H&E testing regarding the absence of the spongy layer, but otherwise **DENIED**.

It is further **ORDERED** that Plaintiff's Motion to Exclude the Opinions and Testimony of Helen N. Jones, Ph.D. [Doc. 200] is **GRANTED** as to any testimony regarding the FDA letter beyond its four corners, and otherwise **DENIED**.

It is further **ORDERED** that Defendants' Motion to Exclude the Trial Testimony of Ivan T. Hofmann [Doc. 202] is **DENIED**.

It is further **ORDERED** that Defendants' Motion for Summary Judgment that the '494 Patent's Asserted Claims Are Not Patent Eligible Under 35 U.S.C. § 101 [Doc. 212] is **DENIED**.

It is further **ORDERED** that Plaintiff's Motion for Summary Judgment that Claims 1, 2, 4, 5, 9, and 10 of U.S. Patent No. 8,709,494B2 Are Patent Eligible Under 35 U.S.C. § 101 [Doc. 210] is **GRANTED**.

It is further **ORDERED** that Defendants' Motion for Summary Judgment of Non-Infringement of the '494 Patent [Doc. 216] is **DENIED**.

It is further **ORDERED** that Defendants' Motions for Leave to File Matters Under Seal [Docs. 307, 311] are **GRANTED** and Plaintiff's Motions for Leave to File Matters Under Seal [Docs. 301, 317] are **GRANTED**. The Clerk is **DIRECTED** to seal the un-redacted copies of the documents contained in the following docket entries: Docs. 300, 303, 304, 305, 306, 309, 312, 314, 315, and 316.

It is further **ORDERED** that Defendants' Motion for Leave to File Separate Objections [Doc. 302] is **GRANTED**, and Defendants' Motion for Oral Argument [Doc. 308] is **DENIED**.

It is further **ORDERED** that the parties file their consolidated proposed pre-trial order within thirty (30) days of the date of this Order.

IT IS SO ORDERED this 11th day of August, 2017.

MARK H. COHEN
United States District Judge