

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF RHODE ISLAND

ALIFAX HOLDING SPA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 14-440 WES
	)	
ALCOR SCIENTIFIC INC.; and	)	
FRANCESCO A. FRAPPA,	)	
	)	
Defendants.	)	

**MEMORANDUM AND ORDER**

WILLIAM E. SMITH, Chief Judge.

Before the Court is Defendants' Motion to Strike the Declaration of Robert H. Stier, Jr. (Dkt. No. 302-2) and Exhibit Thereto (Dkt. No. 302-3), ECF No. 310. The Defendants argue that the Stier Declaration is improper and ask the Court to reject (1) counsel's Excel spreadsheet calculations and a related graph based on trial exhibit 484; (2) counsel's screen capture of information contained in what he represents is a searchable online database maintained by the U.S. Food and Drug Administration; (3) unauthenticated copies of purported "Administrative Procedures for CLIA Categorization," ECF No. 302-3, and "Guidance for Industry and Food and Drug Administrative Staff," ECF No. 321-1; and (4) an unauthenticated copy of an iSED operator's manual, ECF No. 321-2. The Court agrees. There is no basis to accept this eleventh-hour evidence. The Defendants' motion to strike is therefore GRANTED.

## I. Discussion

The First Circuit's ruling in Lussier v. Runyon, 50 F.3d 1103 (1st Cir. 1995), provides more than adequate guidance here. In that action, plaintiff tried his claims of disability discrimination to a district judge. Id. at 1106. The court heard damages-related evidence at trial concerning the plaintiff's eligibility for a disability retirement annuity but was "[d]issatisfied with the trial evidence on this subject." Id. at 1113. The court therefore ordered the parties to make post-trial submissions concerning these benefits. Id. The court ultimately relied on this new information to reduce plaintiff's damages. Id.

The First Circuit vacated the district court's judgment. Id. "It is a fundamental principle of our jurisprudence," wrote Judge Selya for the Court, "that a factfinder may not consider extra-record evidence concerning disputed adjudicative facts." Id. Certain circumstances permit a district court to exercise his or her discretion to re-open the evidentiary record. But the record in Lussier was not re-opened, thus the district court improperly weighed additional evidence without providing the parties "the standard prophylax[es]" of trial: the opportunity to object, cross-examine, impeach, and contradict. Id. at 1113, n.13. The principle of judicial notice provided no safe harbor because the relevant facts were neither generally known nor undisputed. Id.

at 1114. As the court in the Eastern District of Virginia summed it up: "Lussier espouses the proposition that a court, no matter what its motivations, may not undertake the unilateral pursuit of extra-record evidence nor under any circumstances consider evidence advanced by one party concerning disputed material facts that the opposing party is not presented an opportunity to challenge." Merccexchange, L.L.C. v. eBay, Inc., 467 F. Supp. 2d 608, 617 (E.D. Va. 2006).

Extra-record evidence of disputed material facts is precisely what Alifax has offered in the contested submissions. Regarding the Stier Declaration, counsel's use of the Microsoft Excel goes beyond creating an alternative depiction of trial exhibit 484: it creates new evidence by purporting to calculate a trendline and to report an  $R^2$  value reflecting the data's "fit." The results of specific mathematical computations are not facts that "exist in the unaided memory of the populace." United States v. Bello, 194 F.3d 18, 23 (1st Cir. 1999). Alifax notes that the members of the jury had access to a laptop running Excel, but that fact does not demonstrate that a trendline and  $R^2$  value were or are capable of being "accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2). Moreover, the trial evidence about Alcor's correlation test data (including when it was developed, what the data shows, and what -

if anything - the FDA may have used it for) are at the heart of this dispute. See Mot. by Pl. for Permanent Inj. and Mem. of Law In Supp. 1 ("Mot. for Perm. Inj."), ECF No. 302 ("[Alcor] submitted comparative test data obtained as a direct consequence of its trade secret theft to the FDA as the only test data supporting its application for a CLIA designation of iSED [sic] as 'moderately complex.'"). Consequently, the Court will not "defenestrate established evidentiary processes" to consider this additional information. Lussier, 50 F.3d at 1114.

The Court reaches the same conclusion concerning Alifax's screen captures from an FDA website, the CLIA categorization procedures, and the iSED operator's manual. See Stier Decl. ¶ 6; Mot. for Perm. Inj. Ex. C; Pl.'s Reply Mem. in Supp. of Mot. for Permanent Inj. Ex. B, ECF No. 321-2. The Court does not perceive evidence that the FDA in fact designated the iSED as "moderately complex" in mid-2014 as "hardly controversial." Pl.'s Opp'n to Defs.' Mot. to Strike 2, ECF No. 322. Again, what information Alcor submitted to the FDA and what - if anything - the FDA did with that data are disputed material facts. Alifax did not move to have this website or the information contained therein admitted at trial where the Defendants could have meaningfully assayed it. Lussier, 50 F.3d at 1114 ("[A]ccepting disputed evidence not tested in the crucible of trial is a sharp departure from standard

practice.”). Alifax has not even offered official FDA records showing the iSED’s CLIA categorization or a copy of an archived website; it has proposed a screenshot from counsel’s computer. See Stier Decl. ¶ 6. The Court is unpersuaded that, under these circumstances, taking judicial notice of the information reflected in paragraph 6 of the Stier Declaration would be proper.

As for the “Administrative Procedures for CLIA Categorization,” this document is dated October 2, 2017. Mot. for Perm. Inj. Ex. C, at 1. The FDA submissions at issue here occurred in the winter and spring of 2014. See Tr. Ex. 114, 116. The proffered document thus has no probative value and is irrelevant. See Fed. R. Evid. 401.

In reply, Alifax attempts to remedy this defect by submitting yet another new document - “Guidance for Industry and Food and Drug Administrative Staff” - dated March 12, 2014.<sup>1</sup> But this evidence is also faulty. As Alcor argues, no witness has authenticated this document<sup>2</sup> and no foundation has been laid to show that it qualifies for an exception to the hearsay bar under Fed. R. Evid. 803. These deficiencies also scuttle Alifax’s attempt to

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<sup>1</sup> The document itself appears to have been printed from a website on June 5, 2019. See ECF No. 321-1.

<sup>2</sup> On its face, the document appears to be from the website of a regulatory consultant and is therefore not self-authenticating as an “official publication” under Fed. R. Evid. 902.

introduce another iSED operator's manual, ECF No. 321-2, as does Fed. R. Evid. 201. On its face, such a document does not qualify as information "generally known." Fed. R. Evid. 201(b)(1). And as the manual does not appear to identify its effective date range, it is "subject to reasonable dispute" and inadmissible under Fed. R. Evid. 201(b)(2). See also Reply in Supp. of Defs.' Mot. to Strike the Decl. of Robert H. Stier, Jr. (Dkt. No. 302-2) and Exhibit Thereto (Dkt. No. 302-3) at 7-8, ECF No. 326.

### III. Conclusion

The Court presided over a three-week trial of this dispute that followed years of discovery. Alifax had every opportunity to produce and present the information that is the subject of the Defendant's motion long before the evidentiary record closed. Alifax offers no excuses for its failure to do so and no basis whatsoever to justify re-opening the record.

For the foregoing reasons, Defendants' Motion to Strike the Declaration of Robert H. Stier, Jr. (Dkt. No. 302-2) and Exhibit Thereto (Dkt. No. 302-3) (ECF No. 310) is GRANTED. The Declaration of Robert H. Stier, Jr. (ECF No. 302-2) is hereby deemed struck and will not be relied upon for any purpose by the Court in its post-trial rulings. The supplemental attachments to Alifax's opposition memorandum are similarly deemed struck.

IT IS SO ORDERED.



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William E. Smith  
Chief Judge  
Date: June 18, 2019