UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 14-cv-80930-BLOOM/Valle

INTRA-LOCK INTERNATIONAL, INC.,
a Florida corporation,

Plaintiff,

v.

JOSEPH CHOUKROUN, an individual, PROCESS FOR PRF, SARL, a French Société à responsabilité limitée, BOCA DENTAL SUPPLY, LLC, a Florida limited liability company, and JOHN DOES 1-20,

Defendants.
_____/

ORDER

This matter is before the Court upon Defendants, Joseph Choukroun, Process for PRF, SARL, and Boca Dental Supply, LLC's Motion to Strike, or in the Alternative, for Leave to File Sur-Reply ("Motion"), ECF No. [95], filed on February 13, 2015. The Court has reviewed the Motion, all supporting and opposing filings, and the record in this case, and is otherwise fully advised in the premises.

I. INTRODUCTION AND BACKGROUND

Plaintiff Intra-Lock International, Inc. ("Plaintiff") commenced this action on July 14, 2014, bringing claims for statutory and common law unfair competition (Counts I and III), false and misleading statements cognizable under 15 U.S.C. § 1125 (Count II), violations of the Florida Deceptive and Unfair Trade Practices Act (Count IV), and seeking preliminary and permanent injunctions (Count V). *See* Complaint, ECF No. [1] at ¶¶ 40-64. Plaintiff seeks entry

of a preliminary injunction against Defendants, Joseph Choukroun, Process for PRF, SARL, and Boca Dental Supply, LLC (collectively, "Defendants"), intending to enjoin Defendants' importation, marketing, promoting, offering, and selling of their non-Food and Drug Administration ("FDA") approved device (the "Competing Device"). *See* Motion for Preliminary Injunction, ECF No. [25]. On January 9, 2015, Defendants filed their Response in Opposition ("Response"), ECF No. [74], and on February 6, 2015, Plaintiff filed its Reply in Support ("Reply"), ECF No. [93].

Accompanying Plaintiff's Reply is an "OsseoNews" blog post ("Blog Post"), ECF No. [93-1], and the declaration of Karen M. Becker, Ph.D. ("Becker Declaration"), ECF No. [93-2]. Defendants object to the inclusion of the Blog Post and the Becker Declaration, professing its impropriety as newly submitted evidence which does not rebut assertions presented in Defendants' Response. *See* Mot., ECF No. [95]. Accordingly, Defendants seek to strike the Blog Post and Becker Declaration from Plaintiff's Reply, or, alternatively, implore this Court to allow Defendants to conduct additional discovery and file a Sur-Reply in response to this evidence. *See id.*

II. DISCUSSION

Rule 7.1(c) of the Local Rules of the Southern District of Florida provides that a reply memorandum "shall be strictly limited to rebuttal of matters raised in the memorandum in opposition without reargument of matters covered in the movant's initial memorandum of law." S.D. Fla. L.R. 7.1(c). Thus, "[a] reply memorandum may not raise new arguments or evidence, particularly where the evidence was available when the underlying motion was filed and the movant was aware (or should have been aware) of the necessity of the evidence." *Baltzer v. Midland Credit Mgmt., Inc.*, No. 14-20140-CIV, 2014 WL 3845449, at *1 (S.D. Fla. Aug. 5,

2014) (citing *Foley v. Wells Fargo Bank, N.A.*, 849 F. Supp. 2d 1345 (S.D. Fla. 2012); *TCC Air Servs., Inc. v. Schlesinger*, No. 05–80543–CIV, 2009 WL 565516, at *7 (S.D. Fla. Mar. 5, 2009)). However, there is a subtle yet noteworthy distinction that exists between "new arguments and evidence, on the one hand, and rebuttal arguments and evidence, on the other." *Giglio Sub s.n.c. v. Carnival Corp.*, No. 12-21680-CIV, 2012 WL 4477504, at *2 (S.D. Fla. Sept. 26, 2012) *aff'd*, 523 F. App'x 651 (11th Cir. 2013). Local Rule 7.1(c) does not prohibit the addition of affidavits and declarations accompanying a reply memorandum. *See* S.D. Fla. L.R. 7.1(c) (noting that "[a]ll materials in support of any motion, response, or reply, including affidavits and declarations, shall be served with the filing"). Thus, while raising new arguments on reply is generally inappropriate, reply evidence "may contain facts not previously mentioned in the opening brief, as long as the facts rebut elements of the opposition memorandum and do not raise wholly new factual issues." *Giglio*, 2012 WL 4477504, at *2 (citing *Burger King Corp. v. Ashland Equities, Inc.*, 217 F. Supp. 2d 1266, 1280-81 (S.D. Fla. 2002)); *see also ABCO Premium Fin. LLC v. Am. Int'l Grp., Inc.*, No. 11-23020-CIV, 2012 WL 3278628, at *4 (S.D. Fla. Aug. 9, 2012) *aff'd*, 518 F. App'x 601 (11th Cir. 2013) ("While the raising of new issues and submission of new facts in reply brief is improper, a court has the discretion to consider the additional exhibits despite this procedural shortcoming." (internal quotation and citation omitted)). With this in mind, the Court examines the Blog Post and Becker Declaration.

A. Defendant Choukroun's Blog Post

The Blog Post in question is utilized by Plaintiff for one purpose alone: to demonstrate Defendants' public representations that FDA clearance for the marketing and sale of the Competing Device was not required. *See* Reply, ECF No. [93] at 5, 10 n.13, 12. A review of the assertions contained within Defendants' Response reveals that this evidence was clearly intended

to rebut contentions contained therein, and is not newly submitted and otherwise improper evidence.

At several points in Defendants' Response, Defendants assert that Plaintiff fails to direct the Court to a single instance where Defendants have made a false statement. *See* Response, ECF No. [74] at 6-7. For example, in noting that Plaintiff must show that Defendants made false or misleading statements of fact regarding the Competing Device in order to prevail on its claim of unfair competition, Defendants state that Plaintiff "points to no instance where any of the Defendants made a false statement." *Id.* at 6 ¶ 16. On the following page, Defendants again assert that "the only evidence submitted consists entirely of anecdotal evidence and conclusory generalities advanced by [Plaintiff's] own Director of Operations, Jeffrey Sakoff, and one of its lecturers, Robert Miller." *Id.* at 7 ¶ 17. Thus, Plaintiff's reference to the Blog Post and statements made by Defendant Choukroun regarding the necessity of FDA clearance were clearly submitted in order to negate Defendants' assertion that no false statements were made. As such, the Court will not strike it.

B. The Becker Declaration

The Becker Declaration is relied on more heavily throughout Plaintiff's Reply. *See* Reply, ECF No. [93] at 4-5, 7, 10, 13, 20. In short, Becker, a purported expert on FDA registration requirements and healthcare product marketing, attests to the conclusion that Defendants' Competing Device is properly categorized as a Class II medical device[1] subject to 510(k) Premarket Notification (21 C.F.R. § 807.81) (hereinafter, "preclearance"). *See* Becker Declaration, ECF No. [93-2] at ¶ 21. After review of the Competing Device's components, technological characteristics, and intended use, Becker concludes that Defendants' categorization

[1] *See generally* 21 C.F.R. § 864.9245 (specifying that an automated blood cell separator is a Class II (special controls) device).

of the Competing Device as a Class I medical device is disingenuous. *See id.* at ¶¶ 21-22. Becker also testifies to general FDA registration requirements and her opinion of the FDA's likely assessment of the Competing Device. *Id.* at ¶¶ 24-26. Defendants contend that this testimony is improper as they have not argued the regulatory efficacy of their product. *See* Mot., ECF No. [95] at 5. Alternatively, Defendants assert that Becker's testimony is cumulative evidence, excludable under Fed. R. Evid. 403, because Plaintiff has already identified an expert witness on FDA regulatory compliance, Dr. Robert Miller. *See id.* at 6. Akin to the Blog Post, the Becker Declaration also is presented in order to refute assertions contained in Defendants' Response, and, further, is employed to support Plaintiff's position with respect to the allegedly mandatory FDA registration and 510(k) preclearance.

First, the Becker Declaration is intended to rebut Defendants' continued insistence that the Competing Device is a Class I medical device which does not require 510(k) preclearance. In their Response, Defendants point to the fact that the FDA's letter to Plaintiff does not indicate that either Plaintiff's device or Defendants' device *requires* 510(k) preclearance prior to marketing or sale. *See* Response, ECF No. [74] at 5 ¶ 10. Thus, the Becker Declaration, stating that 510(k) preclearance is required of both Plaintiff's and Defendants' device is related to this argument. Second, the registration requirements and regulatory structure on which the Becker Declaration sheds light is related to Plaintiff's initial position contained in its Motion for Preliminary Injunction. Plaintiff argues in its Motion for Preliminary Injunction that Defendants' false suggestion of not requiring FDA clearance is material to a consumer's purchasing decision and, as a consequence of this purported misrepresentation and Defendants' actual lack of 510(k) preclearance, Defendants' device is, in reality, hazardous to consumers. *See* Motion for Prelim. Inj., ECF No. [25] at 3, 12-13. The fact that the Becker Declaration seeks

to illuminate facts regarding FDA registration and preclearance requirements promotes this claim.

Defendants' remaining arguments do not support the striking of the Becker Declaration. Defendants' allegation that the Becker Declaration is improper for timeliness reasons is without merit. Discovery in this matter is ongoing and the deadline to exchange expert reports does not occur until June 2015. *See* Scheduling Order, ECF No. [37]. Additionally, striking this evidence as needlessly cumulative under Fed. R. Evid. 403 is premature at this juncture.[2] *See Avramides v. Liberty Mut. Fire Ins. Co.*, No. 8:12-CV-2104-T-27TGW, 2014 WL 202662, at *5 (M.D. Fla. Jan. 17, 2014) (finding cumulative evidence objection to be premature prior to when defendant was required to disclose which experts will be called at trial); *see also Gandhi v. Carnival Corp.*, No. 13-24509-CIV, 2014 WL 7642540, at *5 (S.D. Fla. Oct. 14, 2014). Accordingly, the Court declines to strike the Becker Declaration.

C. Allegedly Inconsistent Legal Positions

Lastly, Defendants assert that Plaintiff's allegations with respect to the 510(k) preclearance and the importance of the FDA's January 28, 2013 letter granting Plaintiff the same (the "FDA Letter") is in contradiction to prior positions taken by Plaintiff. According to Defendants, Plaintiff previously maintained that the FDA Letter was unrelated to its claim for unfair competition and that Plaintiff's current reliance on the FDA Letter is contrary to that position. The Court disagrees. Plaintiff appears to introduce the FDA Letter and its significance

[2] The Court is cognizant of the fact that the Becker Declaration contains many statements and opinions that mimic the conclusions made by Dr. Robert Miller, specifically, those conclusions with respect to Defendants' device classification as a Class II medical device and lack of necessary preclearance. *Compare* Becker Declaration, ECF No. [93-2] *with* Miller Declaration, ECF No. [25-8]. Nonetheless, it is far too early to deem this evidence cumulative and remove it from the record; Becker's qualifications and background are markedly different than Miller's and may help resolve elucidate the issue of FDA certification.

in order to demonstrate that its device has obtained 510(k) preclearance and Defendants' substantially similar device has not. This contention is not incompatible with any prior allegations and will not be enjoined.

III. CONCLUSION

Based on the foregoing, it is hereby **ORDERED AND ADJUDGED** that Defendants' Motion to Strike, or in the Alternative, for Leave to File Sur-Reply, **ECF No. [95]**, is **DENIED**

DONE AND ORDERED in Fort Lauderdale, Florida, this 18th day of March, 2015.

BETH BLOOM
UNITED STATES DISTRICT JUDGE

Copies to:
Counsel of Record