UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

REPRO-MED SYSTEMS, INC. dba RMS MEDICAL PRODUCTS,

Plaintiff and Counterclaim-Defendant,

v.

EMED TECHNOLOGIES CORPORATIONS,

Defendant and Counterclaim-Plaintiff.

No. 2:13-cv-01957-TLN-CKD

ORDER DENYING EMED'S MOTION FOR A PRELIMINARY INJUNCTION

This matter is before the Court on Defendant and Counterclaim-Plaintiff EMED Technologies Corporation's ("EMED") Motion for Preliminary Injunction. (ECF No. 83.) Plaintiff and Counterclaim-Defendant Repro-Med Systems, Inc. ("RMS"), opposes the motion. (ECF No. 95.) EMED filed a reply. (ECF No. 96.) Having reviewed the arguments raised by both parties and for the reasons set forth below, the Court hereby DENIES EMED's motion for preliminary injunction.

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I. FACTUAL BACKGROUND[1]

This lawsuit concerns medical devices used to administer immunoglobulin (human plasma and antibodies) to patients suffering from a particular immunodeficiency disorder. According to EMED, this immunoglobulin therapy — known as Subcutaneous Immunoglobulin ("SCIg") therapy — is increasingly administered at home, instead of in medical offices and hospitals. EMED further states that the SCIg market serves roughly 13,000 patients in the United States and a smaller number in Europe. Ten major customers in the U.S. purchase the majority of SCIg therapy devices, and EMED and RMS are the two primary manufacturers of these devices in the United States.

The primary SCIg devices referenced in this lawsuit are: (1) mechanical infusion pumps, (2) rate sets, and (3) subcutaneous needle sets. RMS manufactures a Freedom 60 infusion pump (the "Freedom 60"), which obtained Food and Drug Administration ("FDA") market clearance in May, 1994. The Freedom 60 has become the dominant pump in the SCIg therapy market. An infusion pump can last ten to fifteen years, but rate sets and needle sets are single-use accessories, resulting in recurring sales in the market. This motion seeks an injunction on the sale of the Freedom 60 pump, the Freedom Edge Infusion Pump and the HigH-Flo Subcutaneous Safety Needle Set in California.

A. RMS's allegedly false and misleading statements

According to EMED, the FDA issued RMS a warning letter on February 26, 2016. The warning letter discussed inspections of RMS's facilities in Chester, New York, between June 3, 2015 and June 23, 2015. The warning letter documented various violations by RMS with regards to the Freedom 60 pump, the Freedom Edge Infusion Pump and the HigH-Flo Subcutaneous Safety Needle Set and their uses. EMED focuses on specific comments and violations stated in the letter, including but not limited to the "Freedom 60 Syringe and Freedom Edge Infusion Pumps are adulterated under section 501(f)(1)(B) of the [Food, Drug, and Cosmetic] Act, 21 U.S.C. § 351 (f)(1)(B)," and "the HigH-Flo Subcutaneous Safety Needle Set is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351 (f)(1)(B)." (ECF No. 83 at 7.) EMED states the

[1] The factual background is taken from this Court's previous order (ECF No. 68), unless otherwise stated.

FDA asked RMS to cease all activities resulting in the misbranding and adulteration of the products, including commercial distribution for uses not within the products' respective FDA clearances. (ECF No. 83 at 7.) Based on the FDA warning letter, EMED argues RMS is making statements that mislead the public into believing the products are "FDA cleared," that the FDA has imposed no restrictions on the distribution of the products and that there are no safety concerns. (ECF No. 83 at 8–10.)

EMED alleges the FDA warning letter demonstrates RMS's products are not FDA cleared and its statements to the contrary are false and misleading. (ECF No. 83 at 8.) RMS's HigH-Flo needle set brochure and Freedom 60 infusion set brochure make the statements that HigH-Flo needle sets are FDA cleared for all subcutaneous medications. Yet, the warning letter states the products were not cleared for subcutaneous medications because RMS did not supply the FDA with the necessary performance data. (ECF No. 83 at 8.) Furthermore, the FDA stated in the letter "promoting subcutaneous Safety Needle Sets for this indication falls outside the cleared intended use." (ECF No. 83 at 9.) EMED argues RMS's statements therefore are misleading and constitute unlawful business practices.

As to RMS's statements that the FDA has not imposed restrictions on its products, EMED directs the Court to a letter posted to RMS's website on March 11, 2016. (ECF No. 83 at 9.) In the letter, RMS tells its customers that there is no reason to discontinue use of its products and no restrictions on manufacturing or distribution of the products. (ECF No. 83-4 at 49, Ex. H.) EMED asserts that the first statement is obviously false and the second misleading. (ECF No. 83 at 9.) To support its conclusion, EMED reminds the Court of an excerpt from the FDA warning letter in which the FDA requests that RMS immediately cease all activities resulting in the misbranding of the products, such as "commercial distribution of the devices" for uses outside of their FDA clearance. (ECF No. 83 at 9 (quoting ECF No. 83-4 at 3, Ex. A).)

Finally as to RMS's statements that there are no safety concerns about the products, EMED points to the letter RMS sent to its customers and RMS's SEC filing to demonstrate the falsity of these statements. EMED quotes multiple lines from the FDA warning letter that discuss the effects of misbranding on the safety and effectiveness of RMS's products, including "changes

in the intended use may affect the performance of the device and could significantly affect the safety and effectiveness of this device." (ECF No. 83 at 9 (quoting ECF No. 83-4 at 3, Ex. A).)

B. Other Safety Concerns Regarding RMS Products

According to EMED, RMS's products pose safety hazards and concerns because of a separate issue regarding products with faulty seals. (ECF No. 83 at 10.) EMED identifies one of the safety concerns from the FDA letter as pertaining to corrective and preventive action. (ECF No. 83 at 10.) A supplier of polyethylene bags supplied packaging with wrinkled seals to RMS. (ECF No. 83-4, Ex. M.) The FDA letter explained that RMS did not adequately verify that the supplier took corrective action to prevent defective seals from continuing to affect RMS devices. (ECF No. 83-4 at 6, Ex. A.) The FDA warning letter explained that RMS had closed its original investigation without ensuring that the cause of the seal wrinkles were corrected and would not affect the safety of RMS devices. (ECF No. 83-4 at 6, Ex. A.) RMS initiated a correction and removal of some HigH-Flo Subcutaneous Safety Needle Sets because of the seal wrinkles in March 2016. (ECF No. 83 at 10.) RMS explained that the sterility of certain needles was jeopardized by the wrinkle in the seal. (ECF No. 83 at 11.)

II. STANDARD OF LAW

Injunctive relief is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008) (citing *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (per curiam)). "The purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held." *University of Texas v. Camenisch*, 451 U.S. 390, 395 (1981) (emphasis added); *see also Costa Mesa City Employee's Assn. v. City of Costa Mesa*, 209 Cal. App. 4th 298, 305 (2012) ("The purpose of such an order is to preserve the status quo until a final determination following a trial.") (internal quotation marks omitted); *GoTo.com, Inc. v. Walt Disney, Co.*, 202 F.3d 1199, 1210 (9th Cir. 2000) ("The status quo ante litem refers not simply to any situation before the filing of a lawsuit, but instead to the last uncontested status which preceded the pending controversy.") (internal quotation marks omitted). In cases where the movant seeks to alter the status quo, preliminary injunction is disfavored and a higher level of

scrutiny must apply. *Schrier v. University of Co.*, 427 F.3d 1253, 1259 (10th Cir. 2005). Preliminary injunction is not automatically denied simply because the movant seeks to alter the status quo, but instead the movant must meet heightened scrutiny. *Tom Doherty Associates, Inc. v. Saban Entertainment, Inc.*, 60 F.3d 27, 33–34 (2d Cir. 1995).

"A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Winter*, 555 U.S. at 20. A plaintiff must "make a showing on all four prongs" of the *Winter* test to obtain a preliminary injunction. *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1135 (9th Cir. 2011). In evaluating a plaintiff's motion for preliminary injunction, a district court may weigh the plaintiff's showings on the *Winter* elements using a sliding-scale approach. *Id.* A stronger showing on the balance of the hardships may support issuing a preliminary injunction even where the plaintiff shows that there are "serious questions on the merits . . . so long as the plaintiff also shows that there is a likelihood of irreparable injury and that the injunction is in the public interest." *Id.* Simply put, Plaintiff must demonstrate, "that [if] serious questions going to the merits were raised [then] the balance of hardships [must] tip[ ] sharply in the plaintiff's favor," in order to succeed in a request for preliminary injunction. *Id.* at 1134–35 (emphasis added).

III. ANALYSIS

EMED seeks to enjoin RMS from selling the Freedom 60 pump, the Freedom Edge Infusion Pump and the HigH-Flo Subcutaneous Safety Needle Set in California. EMED argues an injunction is appropriate because RMS committed unlawful or unfair business acts in violation of California's Unfair Competition Law ("UCL"). (ECF No. 83 at 11–15.) EMED argues RMS made unlawful and unfair statements about its products which resulted in harm to EMED. (ECF No. 83 at 15.) RMS asserts EMED raises new claims of misconduct that were not part of EMED's original counter-claim and therefore EMED cannot seek an injunction based on that conduct. (ECF No. 95 at12–13.) RMS argues that EMED cannot demonstrate a likelihood of success on the merits because (1) the Food, Drug and Cosmetic Act ("FDCA") preempts EMED's claims, (2) EMED's claims fall within the jurisdiction of the FDA, (3) The FDA warning letter is

not evidence that the FDA made a determination about RMS's products, (4) RMS's statements are not false or misleading, and (5) there is no basis for the injunctive relief EMED seeks. (ECF No. 95 at 14–21.) The Court need not address RMS's arguments because it finds EMED has failed to demonstrate it will be irreparably harmed if an injunction does not issue or that the balance of hardships tips in its favor.

A. Irreparable Harm

EMED argues that it is suffering the kind of cognizable harm the UCL is intended to protect against. (ECF No. 83 at 15.) EMED asserts that if an injunction does not issue it will lose sales, revenue and market shares. (ECF No. 83 at 16.) EMED further contends there is no opportunity for EMED to recuperate its losses because the UCL traditionally offers only injunctive relief. (ECF No. 83 at 16.) RMS counters that EMED has not offered any evidence of lost market shares or any injury from RMS's sales of its products. (ECF No. 95 at 21.) RMS asserts EMED offers nothing more than an assumption that any sale to RMS necessarily comes at EMED's expense. (ECF No. 95 at 21–22.) EMED responds that EMED has spent years observing the negative correlation between EMED's sales and RMS's sales in the market. (ECF No. 96 at 13.)

Here, EMED seeks to alter the status quo by enjoining sales of RMS products in California, products RMS sold prior to and throughout this controversy. Accordingly, EMED must meet a heightened level of scrutiny. *Schrier*, 427 F.3d at 1259. Generally, evidence in the record establishing the moving party has lost market share as a result of competition is sufficient to demonstrate irreparable harm. *See Funai Elec. Co., Ltd. v. Daewoo Electronics Corp.*, 593 F. Supp. 2d 1088, 1111 (N.D. Cal. 2009) (finding lost market share as a result of patent infringement sufficient to demonstrate irreparable harm); *Smith & Nephew, Inc. v. Synthes (USA)*, 466 F. Supp. 2d 978, 982 (W.D.Tenn.2006) (holding that plaintiff in patent infringement action had established irreparable harm based on evidence that infringement by direct competitor resulted in loss of market share).

EMED cites the declaration of Joseph Barbrie in support of its argument that it will lose market share if an injunction is not granted. (ECF No. 83 at 16.) Barbrie states he has "observed

that the pumps and needle sets manufactured by EMED and RMS are essentially economic substitutes for one another. That fact, coupled with the fact that EMED and RMS basically share this market between themselves, means that the sales and market share of one company are negatively correlated with the sales and market share of the other company." (*See* Decl. of Joseph Barbrie, ECF No. 83-2 ¶ 6.) However, Barbrie's statement is not sufficient to demonstrate that EMED has actually lost market shares as a result of RMS's allegedly false and misleading statements. *See Zeltiq Aesthetics, Inc. v. BTL Industries, Inc.*, 32 F. Supp. 3d 1088, 1104 (N.D. Cal. 2014) (finding no likelihood of irreparable injury where movant did not present evidence of actual market share loss). Accordingly, the week evidence offered by EMED fails to meet the heightened level of scrutiny necessary to alter the status quo.

Barbrie's statements demonstrate a possibility that EMED may experience a loss in market shares with RMS's continued sales in the market. However, a mere possibility of harm is insufficient to demonstrate a likelihood of irreparable harm. *Zeltiq Aesthetics, Inc.*, 32 F. Supp. 3d at 1104–05. Accordingly, EMED has failed to establish that denial of an injunction would result in irreparable harm.

B. Balance of Hardships

"The purpose of preliminary injunctive relief is to preserve the status quo if the balance of equities so heavily favors the moving party that justice requires the court to intervene to secure the positions until the merits of the action are ultimately determined." *Heflebower v. U.S. Bank Nat. Ass'n*, No. CV F 13–1121 LJO MJS, 2013 WL 3864214, at *18 (E.D. Cal. July 23, 2013) (citing *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981)). EMED argues it would suffer "precisely the kind of harm against which the UCL is intended to protect, namely, anti-competitive business practices." (ECF No. 83 at 17.) EMED asserts that if an injunction does not issue it will lose sales, revenue and market shares. (ECF No. 83 at 16.) On the contrary, RMS asserts granting the injunction would (1) eliminate sales of its products in one of the largest markets in the United States; (2) have a likely spillover effect to other states because most consumers hold national accounts and would likely not want a different brand for different states; and (3) inflict substantial damage to RMS's relationships with its customers and patients. (ECF

No. 95 at 22–23.) The Court, however, must look to the possible harm that could befall both parties. *See CytoSport, Inc. v. Vital Pharm., Inc.*, 617 F. Supp. 2d 1051, 1081 (E.D. Cal. 2009) *aff'd*, 348 Fed. App'x. 288 (9th Cir. 2009). EMED would be harmed by RMS's continued statements and product sales as EMED's products may also be associated with any safety concerns arising from RMS's products. EMED may also lose market shares if RMS's are not banned. However, RMS will also suffer significant harm if the injunction is granted. Even assuming the FDA warning letter demonstrates illegal activity, EMED's proposed injunction would prohibit both unlawful sales and sales legally within RMS's FDA clearances. EMED does not seek to differentiate between the conforming and nonconforming uses that the FDA outlined in its warning letter. As RMS indicates, some customers are nationwide and may pull sales altogether. Weighing the equities against each other, the Court cannot find that the balance of hardships tips in EMED's favor.

Because EMED fails to demonstrate irreparable harm or that the balance of hardships tips in its favor, the Court need not address the other *Winter* factors. *See Winter*, 555 U.S. at 20; *Alliance for the Wild Rockies*, 632 F.3d at 1135 (*Winter* requires a plaintiff to make a showing on all of the *Winter* factors); *see also Lopez v. Brewer*, 680 F.3d 1068, 1072 (9th Cir. 2012) (sliding scale approach requires a likelihood of irreparable injury to the plaintiff).

IV. CONCLUSION

For the foregoing reasons, EMED's Motion for Preliminary Injunction (ECF No. 83) is hereby DENIED.

IT IS SO ORDERED.

Dated: June 5, 2017

Troy L. Nunley
United States District Judge