UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CA13-cv-1957LIFORNIA

EMED TECHNOLOGIES CORPORATION,
Counterclaim-Plaintiff and Defendant.

v.

REPRO-MED SYSTEMS, INC. (d/b/a RMS MEDICAL PRODUCTS),

Counterclaim-Defendant and Plaintiff,

No. 2:13-cv-1957-TLN-CKD

ORDER

This matter is before the Court on Counterclaim-Plaintiff EMED Technologies Corporation's ("EMED") motion for a preliminary injunction. (ECF No. 41.) Counterclaim-Defendant Repro-Med-Systems, Inc. ("RMS") has opposed the motion. (ECF No. 66.) For the reasons set forth below, EMED's motion for a preliminary injunction (ECF No. 41) is GRANTED.

FACTUAL ALLEGATIONS

A. Relevant Market

This lawsuit concerns medical devices used to administer immunoglobulin (human plasma and antibodies) to patients suffering from a particular immunodeficiency disorder. According to

EMED, therapy for this disorder – known as Subcutaneous Immunoglobulin ("SCIg") therapy – is increasingly administered at home, instead of in medical offices and hospitals. The SCIg market serves roughly 13,000 patients in the U.S. 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. (ECF No. 41-1 at 3.)

The primary SCIg devices referenced in this lawsuit are: (1) mechanical infusion pumps; (2) rate sets; and (3) subcutaneous needle sets. RMS develops and 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. (ECF No. 41-1 at 3–4.)

Rate sets are the sole focus of the instant motion. Rate sets are a type of tubing that regulate the flow of infusion between the pump and the needle sets.[1] RMS and EMED are the only two suppliers of rate sets for use with the Freedom 60. (ECF No. 41-1 at 4.) In January, 2013, EMED completed development of two different rate sets: (1) "Infusets", which were intended to compete directly with RMS on design and price with equivalent performance; and (2) patent-pending rate sets called "VersaRate," which allow the user to adjust the flow rate when using a mechanical pump to compensate for changing environmental factors, such as changes in temperature. EMED claims its Infusets are FDA cleared through 510(k)s issued in January, 1994 and May, 2014, and its VersaRate sets are FDA cleared through a 510(k) issued in 2012.[2] (ECF No. 41-1 at 4–6.)

B. <u>False and Misleading Statements</u>

According to EMED, until the late 2000s, RMS and EMED coexisted harmoniously in the marketplace but beginning in 2011, RMS undertook to push EMED out of business. (ECF No. 41-1 at 4.) Specifically, EMED alleges that RMS has made and continues to make false and

[1] RMS would refer to these as "flow rate control tubing sets".

[2] The significance of an FDA 510(k) is stated more fully below.

misleading statements to consumers about EMED products. These statements include:[3]

1) In or about December, 2012, RMS sent a "Safety Bulletin" to its customers, stating:

> We recently learned that attempts have been made to encourage users of the FREEDOM60[] to use non-RMS flow rate tubing with the FREEDOM60 pump. This information causes us to be concerned because, to the best of our knowledge, such knock-off tubing has not been cleared by the FDA for use with the FREEDOM60[] pump, nor tested in accordance with our stringent release criteria to confirm that it can be safely and effectively used in the RMS FREEDOM60[] Syringe Infusion System. RMS believes this knock-off tubing, marketed as the same product, fails to meet RMS specifications. Furthermore, we believe that using such non-RMS tubing with the FREEDOM60[] Syringe Infusion System could potentially result in **uncontrolled flows that could lead to patient injury or death.**
>
> While RMS investigates whether legal action against unauthorized sets is necessary to protect customers and patients, we urge you to use caution and refer to the product labeling including the FREEDOM60[] *Instructions for Use* which includes the following precaution:
>
> Caution: Use only FREEDOM60 tubing sets manufactured by RMS Medical Products. Use of any other tubing may cause the syringe to eject from the pump and eventually cause internal damage to the pump. Use of any other flow rate control tubing set may cause over or under delivery or medication to the patient, which could result in injury or death.
>
> Please keep in mind that patient safety may be compromised by the use of unapproved and incompatible flow control tubing sets to deliver drugs. In addition, regulatory, patent infringement, reimbursement, and other issues may also arise. Moreover, use of non-RMS flow rate tubing voids the warranty for the FREEDOM60[] Syringe Infusion Pump.
>
> Please note that the FREEDOM60[] Calculator is designed and tested for use only with FREEDOM60[] Syringe Infusion Pump connected to RMS FREEDOM60[] Flow Rate Tubing. Using the calculator with non-RMS tubing may result in inaccurate flow rates.

(Decl. of Paul Lambert, ECF No. 42, Ex. O, bold and underline in original.) EMED alleges that as of September 11, 2014, which is also the date of filing for the instant injunction, the Safety Bulletin was available on RMS' website, and it showed up as the top Google search entry when typing in "Freedom60 customers". (EMED's Reply, ECF No. 67-1 at 6.) EMED also asserts that

[3] EMED has attached numerous exhibits in support of the instant motion, some of which contain the statements alleged to be false and misleading. (*See* ECF Nos. 42 & 67.) The Court has attempted to include herein such statements referenced by EMED in its motion and reply. (*See* ECF Nos. 41-1 & 67-1.)

statements to the effect that use of non-RMS rate sets voids the warranty for the Freedom 60 appears in RMS' four most recent SEC Form 10-Q's. (ECF No. 41-1 at 13; ECF No. 42, Ex.'s J, K, L, Y.)

2) RMS' Freedom 60 User's Manual[4] contains a warranty provision that states in relevant part:

> **Conditions of Warranty:** This warranty does not apply to any product, or part thereof, which has been repaired or altered outside of the Manufacturer's facility in a way so as, in Manufacturer's judgment, to affect its ability or reliability, or which has been subjected to misuse, negligence or accident. Misuse includes, but is not limited to, use without compliance with the device operating instructions or use with non-approved accessories or disposable items.

(ECF No. 42, Ex.'s R & S, bold in original.)

3) RMS stated in its July 15, 2013 SEC Form 10-Q:

> We have become aware of a new mechanical pump entry on the market which we do not believe to have FDA approval. … The company offering this product is also representing that it is capable of manufacturing lower cost accessories which can be used with the FREEDOM60[]. We have issued Safety Bulletins to all customers advising them that any non-RMS product used on our FREEDOM60[] Systems may be unsafe, can create a health risk to the patient, including death, and would void the warranty of the pump.

(ECF No. 42, Ex. K.)

4) RMS stated in its July 15, 2014 SEC form 10-Q:

> There is a mechanical pump, manufactured by a competitor, which we do not believe to have FDA clearance. The new pump uses a prior design of a simple coil spring which does not create a constant pressure and which had been removed from the market several years ago. The competitor offering this product is also representing that it is capable of manufacturing lower cost accessories which can be used with the FREEDOM60. We have recommended that our customers use RMS tubing and needle sets exclusively for the best performance, accuracy, and safety. We are currently involved in legal proceedings with such competitor involving various claims and counter-claims.

(ECF No. 42, Ex. Y.)[5]

[4] EMED alleges the User Manual is published on RMS' website. (ECF No. 41-1 at 9; ECF No. 42, Ex. S.)

[5] Related statements to those made in the July, 2013 and July, 2014 10-Q's are also contained in RMS' January, 2014 10-Q. (*See* ECF No. 42, Ex. L.)

5) As of September 11, 2014, RMS' website contained the following statement regarding its "Precision" rate sets which are designed for use with the Freedom 60:

> That's why it has to be Precision – it's the only tubing specifically designed and FDA-cleared to have the accuracy necessary for the safe, controlled, dynamically-responsive infusions of the FREEDOM 60.

(ECF No. 42, Ex. Z.)

6) An article appeared on NASDAQ.com, dated October 7, 2014, quoting from a prior RMS "public filing"[6] which included statements that "any non-RMS product" used with the Freedom 60 might be unsafe. (Decl. of Josiah Prendergast, ECF No. 67-5, Ex. 5.) The article also states: "We discussed this issue [i.e. competitors selling "knock-off" products] with REPR [i.e. RMS] management, who told us that they believe that the prevalence of "copycats" is not an isolated event. Investors who are concerned about knock-off products stealing significant market share should note that patients that use needle sets other than REPR's will void the warranty of the FREEDOM60 pump." (ECF No. 67-5, Ex. 5) (emphasis omitted).

C. Customer Response

EMED alleges RMS' false statements have negatively affected customers' purchasing decisions. For example:

1) In December, 2012 a customer wrote to EMED stating: "The Freedom 60 warranty is voided if we use sets other than the RMS products. This is documented in the user manual. Accordingly, the EMED sets have not been proven to be accurate with the use of the Freedom 60 pump. Taking these things into consideration, I have asked our locations to discontinue use of the EMED sets." (Decl. of Joseph Barbrie, ECF No. 41-3, Ex. A.)

2) Another customer wrote to EMED in December, 2012: "What is the answer to the current 'argument' floating around out there with regard to specific device usage with regard to FDA product licensing approval?" (ECF No. 41-3, Ex. B.)

3) Another customer wrote to EMED in December, 2012: "We are trying to figure out if

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[6] The Court is unable to locate the specific excerpt from the NASDAQ article in one of the SEC form 10-Q's noted, *supra*.

there is a safety issue as RMS claims with your rate controllers in Freedom pumps." (ECF No. 41-3, Ex. C.)

4) In November, 2013, A UK distributor wrote to EMED, stating: "The question of compatibility concern is with all your sets, not just the Infuset extension sets. Companies in the UK are stating that any sets that are designed to be used with their [RMS] pumps, voids the warranty and any insurance claims if something goes wrong." (Decl. of Peter Kollings, ECF No. 41-2, Ex. F.)

5) On or about May 6, 2013, Coram, a major health care provider, declined to purchase EMED rate sets. (ECF No. 41-3 ¶ 9.)

6) Several customers have required EMED to provide an indemnity agreement before agreeing to purchase EMED rate sets, including Vital Care, Acreedo, Biofusion, MSD, BioRx, and Innomar Strategies Inc.[7] (ECF No. 41-3 ¶ 10.)

7) EMED alleges: "As of result of RMS' false and misleading statements, EMED has lost and continued to lose rate set sales, which in turn caused EMED's SCIg revenue to fall roughly 33 percent since January, 2014, creating irreparable injury."[8] (ECF No. 42 ¶ 21.)

PROCEDURAL HISTORY

On September 20, 2013, RMS filed a complaint against EMED based on allegations of patent infringement. (ECF No. 2.) On October 11, 2013, EMED filed an answer and counterclaims against RMS. (ECF No. 7.) On December 2, 2013, RMS filed an answer to EMED's counterclaims. (ECF No. 12.) On December 6, 2013, RMS filed an amended complaint. (ECF No. 14.) On January 7, 2014, EMED filed an answer to the amended complaint and again asserted counterclaims. (ECF No. 21.) On January 28, 2014, RMS filed an answer to EMED's January 7, 2014, counterclaims. (ECF No. 26.)

On September 11, 2014, EMED filed the instant motion for preliminary injunction and a

[7] RMS responds that when asked to produce these agreements, EMED could only produce one hold- harmless agreement with a Canadian company from June, 2013, and two open-ended emails with potential customers without final agreements. (ECF No. 66-1 at 17.)

[8] It appears EMED attributes this drop in revenue not just to RMS' statements regarding EMED's rate sets, but more generally to RMS' statements about EMED products, and to alleged patent infringement of EMED's needle sets, which are not the subject of this motion. (*See* ECF No. 42 ¶ 21.)

memorandum in support. (ECF Nos. 41 & 41-1.) On the same date, EMED also filed declarations from Peter Kollings, Director of Regulatory Affairs and Quality Assurance for EMED, and Joseph Barbie, Vice President of Sales and Marketing for EMED, and accompanying exhibits. (ECF Nos. 41-2 & 41-3.) On the same date, EMED also filed a declaration from EMED CEO Paul Lambert, and accompanying exhibits. (ECF No. 42.)

On November 19, 2014, RMS filed an opposition to the motion for preliminary injunction, a memorandum in support, accompanying exhibits, and a declaration from RMS CEO Andrew Sealfon with accompanying exhibits. (ECF Nos. 66 & 66-1 – 66-3.)

Also on November 19, 2014, EMED filed a reply to the opposition. (ECF No. 67-1.) On the same date, EMED also filed supplemental declarations from Joseph Barbrie, Peter Kollings, Paul Lambert, and Josiah Prendergast, with accompanying exhibits. (ECF Nos. 67-2 – 67-5.)

LEGAL STANDARD

The Ninth Circuit has set forth the standard for evaluating a motion for a preliminary injunction:

> A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest. We evaluate these factors via a sliding scale approach, such that serious questions going to the merits and a balance of hardships that tips sharply towards the plaintiff can support issuance of a preliminary injunction, so long as the plaintiff also shows that there is a likelihood of irreparable injury and that the injunction is in the public interest.

Arc of California v. Douglas, 757 F.3d 975, 983 (9th Cir. 2014) (internal citations and quotation marks omitted).

EMED's counterclaims are as follows: 1) false advertising under the federal Lanham Act, 15 U.S.C. § 1125(a); 2) false advertising under California state law, Cal. Bus. & Prof. Code § 17500; and 3) violations of California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200. For the purposes of this motion, the Court considers the California false advertising claim and the UCL claim.[9]

[9] Because the Court finds EMED has raised serious questions going to the merits of the state law claims, it does not

False advertising under Cal. Bus. and Prof. Code § 17500 "makes it unlawful for a business to disseminate any statement 'which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading....'" *Arizona Cartridge Remanufacturers Ass'n, Inc. v. Lexmark Int'l, Inc.*, 421 F.3d 981, 985 (9th Cir. 2005) (citing Cal. Bus. & Prof. Code § 17500).

A claim under California's UCL prevails if RMS has engaged in "any unlawful, unfair or fraudulent business act or practice [or] unfair, deceptive, untrue or misleading advertising…." Cal. Bus & Prof. Code § 17200. In order to prevail on said claim, EMED must "(1) establish a loss or deprivation of money or property sufficient to qualify as injury in fact, i.e., *economic injury,* and (2) show that the economic injury was the result of, i.e., *caused by,* the unfair business practice or false advertising that is the gravamen of the claim." *Bower v. AT & T Mobility, LLC*, 196 Cal. App. 4th 1545, 1554 (2011) (citing *Kwikset Corp. v. Superior Court*, 51 Cal. 4th 310, 322 (2011)).

The Court notes that for claims under Cal. Bus. & Prof. Code §§ 17500 and 17200, California courts have:

> recognized that any violation of the false advertising law ... necessarily violates the UCL. We have also recognized that these laws prohibit not only advertising which is false, but also advertising which although true, is either actually misleading or which has a capacity, likelihood or tendency to deceive or confuse the public. Thus, to state a claim under either the UCL or the false advertising law, based on false advertising or promotional practices, it is necessary only to show that members of the public are likely to be deceived.

Kasky v. Nike, Inc. 27 Cal. 4th 939, 951 (2002) (internal quotations marks, alterations, and citations omitted).

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address the Lanham Act claim, although there is substantial similarity between a Lanham act claim and a California false advertising claim. The elements of a Lanham Act Claim, 15 U.S.C. § 1125(a), are: "(1) a false statement of fact by the defendant in a commercial advertisement about its own or another's product; (2) the statement actually deceived or has the tendency to deceive a substantial segment of its audience; (3) the deception is material, in that it is likely to influence the purchasing decision; (4) the defendant caused its false statement to enter interstate commerce;[] and (5) the plaintiff has been or is likely to be injured as a result of the false statement, either by direct diversion of sales from itself to defendant or by a lessening of the goodwill associated with its products." *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997).

ANALYSIS

A. Serious Questions Going to the Merits

i. Compatibility of EMED and RMS products

EMED and RMS dispute the extent to which EMED rate sets can be used with the Freedom 60. According to EMED, from 2002 to 2005, RMS contracted with EMED for the "manufacture of microbore tubing for RMS' branded rate sets," and during this time EMED sold at least 155,000 units of microbore tubing to RMS. (ECF No. 67-4 ¶ 5.) As part of this business relationship, RMS provided EMED with specifications necessary to manufacture the tubing, including tubing length, inner diameter, outer diameter, and the required flow rate to be achieved. Accordingly, even though RMS no longer provides tubing specifications to EMED, EMED is able to, and does specifically design its rate sets for the Freedom 60 pump. EMED also specifically designs its "female luer lock", used with rate sets and the infusion pump, with a "disc geometry to meet the specific geometry of the Freedom 60 pump." (ECF No. 67-4 ¶¶ 6–11.) EMED further states that the Freedom 60 is used in combination with a flow rate calculator, to determine things such as the time of delivery and total flow rate, and that "[f]or years the [Freedom 60] Calculator provided clinicians with instructions for using not only RMS needle sets but EMED's needle sets as well." (ECF No. 67-4 ¶ 12.) Thus, EMED argues, it is wrong to assert that EMED accessories cannot be used with RMS products, including the Freedom 60.

RMS alleges that before issuing the December, 2012 Safety Bulletin, RMS tested EMED's products and found that EMED's Infuset products did not provide flow rates that are compatible with the advertised RMS equivalent. For example, according to RMS, the maximum flow position on the VersaRate, if used with the Freedom 60, could allow for uncontrolled flow. (ECF No. 66-3 ¶ 4.) RMS states that EMED's "testing protocols showed that EMED does not test their products properly. For example, EMED tested its products using a low viscosity fluid (0.9% saline solution), even though their products are meant to be used with much higher viscosity fluid." (ECF No. 66-3 ¶ 4.) RMS also alleges that "because RMS closely guards the [Freedom 60] pump's specifications and release criteria as trade secret, RMS believed that non-

RMS products could not possibly have been tested in accordance with RMS' stringent release criteria." (ECF No. 66-1 at 4) (internal alterations omitted). Regarding EMED's prior contracting to provide tubing to RMS from 2002 to 2005, RMS states that this tubing was combined with other components at RMS facilities, and "at no time did EMED manufacture complete tubing sets for RMS, and RMS never provided EMED with any of its flow rate or other specifications beyond telling EMED what diameters of tubing it wishes to acquire." (ECF No. 66-3 ¶ 11.)

Further, RMS attributes EMED's alleged decline in revenue to the fact that unlike RMS, EMED "cannot sell a total system for treating patients; EMED has been seeking FDA clearance for a complete system of an infusion pump, flow rate control sets, and needle sets for years to no avail." (ECF No. 66-1 at 3.) RMS states that its Freedom 60, rate sets, and needle sets were cleared for use together by the FDA in a 1994 510(k). (ECF No. 66-1 at 3.) In response, EMED alleges: "This is untrue because RMS' 1994 510(k) summary makes no mention of needle sets and RMS did not have branded needle sets until 2011, when they were separately cleared. [] In fact, RMS used to provide a calculator for clinicians to use EMED's needle sets with the Freedom 60 pump." (*See* ECF No. 67-1 at 2.)

At this time there are not enough undisputed facts for the Court to make findings regarding the extent to which EMED's testing procedures were equivalent to RMS', or whether the alleged superiority of RMS' "total system" is the reason for EMED's decline in revenue. These findings likely would require a more formal presentation of the evidence. The Court notes this as context for the analysis below.

ii. FDA 510(k)

The FDA explains that:

> A 510(k) requires demonstration of substantial equivalence to another legally U.S. marketed device. Substantial equivalence means that the new device is at least as safe and effective as the predicate. A device is substantially equivalent if, in comparison to a predicate it: [1] has the same intended use as the predicate; and has the same technological characteristics as the predicate; [or 2] has the same intended use as the predicate; and has different technological characteristics and the information submitted to FDA [] does not raise new questions of safety and effectiveness [] and

> demonstrates that the device is at least as safe and effective as the legally marketed device.[10]

(ECF No. 42, Exhibit A, excerpting a description of the 510(k) process from the FDA's website; bullet points and emphases from original omitted.)

See also 21 C.F.R. § 807.92(a):

> A 510(k) summary shall be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence. FDA will accept summaries as well as amendments thereto until such time as FDA issues a determination of substantial equivalence. All 510(k) summaries shall contain the following information: […] (3) An identification of the legally marketed device to which the submitter claims equivalence. A legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I (the predicate), or a device which has been found to be substantially equivalent through the 510(k) premarket notification process.

iii. 510(k) clearance for VersaRate sets

The majority of the parties' briefing concerns EMED's Infusets, discussed *supra*. It is disputed that EMED's VersaRate sets have received FDA clearance for use with the Freedom 60. (ECF No. 66-1 at 12–13; ECF No. 41-2 ¶ 7; ECF No. 42 ¶ 10.) The 510(k) documents submitted by EMED state that VersaRate sets received FDA clearance in December, 2012, "for use in the intravascular infusion of fluids to be delivered to the patient in a precise manner for no more than 72 hours." (ECF No. 42, Ex. E) These documents do not mention VersaRate's specific use with the Freedom 60. In contrast, the May, 15, 2014, 510(k) cleared Infusets for use specifically with the Freedom 60. RMS directs the Court's attention to internal emails between EMED officers which, construed in a light favorable to RMS, show doubt on the part of EMED regarding its FDA clearance. *See e.g.* ECF No. 66-2, Ex. 14, email from Joseph Barbrie to Carlos Gutierrez, dated January 24, 2014 ("You has [sic] very good comments regarding how we can provide this information even though we do not have FDA clearance for VersaRate use with F60 pump.")

EMED's position regarding VersaRate sets and Infusets appears to be that they can be used with a variety of SCIg pumps, including the Freedom 60. (*See* ECF No. 41-2 ¶¶ 7-9.)

[10] The Court takes judicial notice of the FDA's description of a 510(k), contained in ECF No. 42, Ex. A. RMS offers no opposition.

However at this time, the Court cannot find that VersaRate sets were 510(k)-cleared for use specifically with the Freedom 60.

iv. 1994 510(k)

EMED states that its Infusets are FDA cleared for use with the Freedom 60 through 510(k)s issued in January, 1994 and May 15, 2014. EMED also maintains that the May, 2014 510(k) was unnecessary because the 1994 510(k) was sufficient to provide clearance for use with the Freedom 60. (ECF No. 42 ¶ 9.)

Regarding the 1994 510(k), the attached 510(k) documents do not mention "Infusets". They refer to a "Churchill-H Extension Tube" and other component parts. (ECF No. 42, Ex.'s B & C.) Simply put, the Court cannot conclude from these documents that in 1994 the FDA provided 510(k) clearance for the Infusets currently being sold by EMED for use specifically with the Freedom 60.

EMED asserts that from 2002 to 2005, it "supplied RMS with microbore tubing – the key component of RMS rate control sets – to be sold under the RMS brand." (ECF No. 41-1 at 11; *see* Supp. Decl. of Paul Lambert, ECF No. 67.) Emails from EMED to its customers also state this position. For example, the December 17, 2012, email from Joe Barbrie to a customer inquiry, states:

> I assure you, EMED's [Infuset] sets and the resulting validation to cross-reference RMS rate control sets were performed under stringent engineering/laboratory controls and documented per our ISO-13485-2003. In addition, EMED actually contract manufactured these same sets for RMS when the pump was first introduced. Therefore, we fully understand the engineering requirements to manufacture a high-quality comparable device. Our advantage, just as with Soft-Glide™ SCIg Infusion Tubing Sets is a great track record for high quality, delivery performance, manufacturing cost efficiency and an ideology to provide a fair price to our customers.
>
> We actually used the Freedom60 as the predicate device when submitting (and testing) our FDA 510(k) for our own pump. The slides show the near-exact comparison of EMED's extension sets as compared to RMS rate control sets. There is considerable engineering documentation to support these slides.

(ECF No. 41-3, Ex. B.)

In response, RMS alleges that, "the FDA in April 2013 recognized that EMED was

operating without appropriate clearance, expressed its concerns to EMED, and recommended that EMED file a new 510(k) to gain approval for use of the Infuset with the F60 pump." (ECF No. 66-1 at 10.) For example, in April, 2013, the FDA wrote to Paul Lambert, stating; "[W]e have been unable to identify a clearance number for the Infuset tubing sets, the Infuset sets with indications for use with the Freedom60 … We request that you provide us with the FDA clearance number for [this and other products]." (ECF No. 66-2, Ex. 5.) At one point during his deposition Peter Kolling stated, and internal emails between EMED officers show, some concession that the FDA had "recommended" that EMED file a 510(k) specific to use of the Infusets with the Freedom 60. (ECF No. 66-2, Ex. 7 at 8:6–20; Ex. 12.) Despite EMED's position that the 1994 510(k) was sufficient, EMED did in fact file for the pump-specific 510(k) clearance it ultimately obtained in May, 2014.

EMED counters that the FDA never threatened enforcement action regarding EMED's marketing of Infusets for use with the Freedom 60, and that due to delay on the FDA's part, EMED felt compelled to simply file for a new, Freedom 60-specific 510(k), which it received in May, 2014. (ECF No. 67-1 at 3.)

At this juncture it is unclear whether Infusets had FDA 510(k) clearance pursuant to the 1994 510(k). Given the history between the companies, RMS' vague statements as to why EMED's testing was inadequate or why its flow rate was incompatible with RMS equivalents (Sealfon Decl., ECF No. 66-3 ¶ 4), and EMED's assertions that it did, in fact, design its rate sets based off the Freedom 60 model, RMS' argument that rate sets produced by EMED (currently called Infusets) lacked such clearance is not convincing. However given the lack of clarity on this issue, the Court cannot find that Infusets had Freedom 60-specific FDA clearance pursuant to the 1994 510(k).

v. May, 2014 510(k) for Infusets

It is undisputed that the May, 2014 510(k) provided clearance for Infusets to be used with the Freedom 60. The May 15, 2014 FDA 510(k) letter states: "We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above [Infuset Flow Control Extension Set] and have determined the device is substantially equivalent (for the

indications for use stated in the enclosure) to legally marketed predicate devices [and others] ….”). (ECF No. 42, Ex. D.) The “Indications for Use” form further states: “[t]he Infuset[] Flow Control Extension Set is intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a contained [sic] to a patient’s vascular system.” (ECF No. 42, Ex. D.)

Because Infusets received Freedom 60-specific clearance via the May 15, 2014, 510(k), the Court looks next to allegedly false or misleading statements made by RMS after May 15, 2014.

vi. RMS’ statements regarding Infusets after May, 15, 2014

As discussed herein, the alleged injurious statements made by RMS do not mention EMED by name. However, EMED argues it was apparent to customers that when RMS referenced “non-RMS” products in the context of the Freedom 60, it was referring to EMED products. EMED bases its arguments on the small size of the market, the small number of customers, and the fact that only RMS and EMED produce rate sets for use with the Freedom 60. (*See* ECF No. 41-1 at 6.)

The critical statements as highlighted by EMED are contained in the Safety Bulletin RMS sent to customers in December, 2012. At the time EMED filed for a preliminary injunction in September, 2014 –after it received May, 15, 2014 510(k) clearance for its Infusets – the Safety Bulletin was available on RMS’ website, and it showed up as the top Google search entry when typing in “Freedom60 customers”. (ECF No. 67-1 at 6.) That bulletin contained statements that “knock-off tubing” was not FDA cleared for use with the Freedom 60; that using these rate sets “could lead to patient injury or death”; that Freedom 60 customers were cautioned to only use RMS products; and that using the “Freedom 60 Calculator” with non-RMS tubing could result in “inaccurate flow rates.” (ECF No. 42, Ex. O.) Although it is unclear whether or to what extent RMS management offered commentary that was included in the October 7, 2014, article appearing on NASDAQ.com, statements similar to those contained in the Safety Bulletin were included in that article. These statements are false or misleading, because they contradict the fact that Infusets were FDA cleared to be used safely with the Freedom 60. (ECF No. 67-5, Ex. 5.)

As of September, 2014, in its description of RMS' "Precision" rate set, RMS' website also contained the statement: "That's why it has to be Precision – it's the only tubing specifically designed and FDA-cleared to have the accuracy necessary for the safe, controlled, dynamically-responsive infusions of the FREEDOM 60." (ECF No. 42, Ex. Z.) RMS makes much of the fact that this sentence describes rate sets "designed *and* FDA-cleared to have the accuracy necessary…" (emphasis added). That is, RMS argues that even if Infusets received FDA clearance they still were not FDA cleared *and* designed to have the accuracy necessary for use with the Freedom 60. However, the Court views this statement to be misleading in light of the May, 2014 510(k), which cleared Infusets to be used safely with the Freedom 60.

EMED has raised serious questions going to the merits of whether the aforementioned statements are untrue or misleading, which should have been known to RMS at the time the instant motion was filed in September, 2014. *See* Cal. Bus. & Prof. Code § 17500.

vii. The Freedom 60 warranty

EMED argues that RMS has made and continues to make statements regarding the warranty on the Freedom 60, which would violate the Magnuson-Moss Act, 15 U.S.C. § 2302(c). Section 2302(c) states:

> No warrantor of a consumer product may condition his written or implied warranty of such product on the consumer's using, in connection with such product, any article or service (other than article or service provided without charge under the terms of the warranty) which is identified by brand, trade, or corporate name…[11]

For example, the Safety Bulletin states that "use of non-RMS flow rate tubing voids the warranty for the FREEDOM60 Syringe Infusion Pump." (ECF No. 42, Ex. O.) The User Manual for the Freedom 60 also states: "Conditions of Warranty: This warranty does not apply to any product, or part thereof, which has been repaired or altered outside of the Manufacturer's facility, in a way so as, in Manufacturer's judgment, to affect its stability or reliability, or which has been subjected to misuse, negligence or accident. Misuse includes, but is not limited to, use without compliance with the device operating instructions or use with non-approved accessories or

[11] This condition may be waived by the Federal Trade Commission. 15 U.S.C. § 2302(c).

disposable items." (ECF No. 42, Ex. R.) Some of the SEC filings that were previously noted herein (*e.g.* the filing from the July 15, 2013 SEC Form 10-Q) also contained the statement that use of non-RMS rate sets with the Freedom 60 voided the warranty on the Freedom 60. (ECF No. 42, Ex. K.)

In contrast, EMED points out that RMS' 1994 510(k) application for the Freedom 60 indicated that use of RMS-branded rate sets was not necessary for safe infusion. That application stated: "microbore tubing with Luer lock fittings [i.e. rate sets] is commercially available from various vendors []. All materials in the fluid path of the Freedom 60 Syringe Infusion Pumps are commercially available and are used in other legally marketed devices under the same conditions." (ECF No. 42, Ex. G.)

RMS responds that EMED has no standing to bring Magnuson-Moss Act claims, because the Act permits suits by either 1) the Attorney General or Federal Trade Commission or 2) consumers. *See* 15 U.S.C. § 2310(c) and (d). However, "Section 17200 [i.e. the UCL] does not require that a plaintiff prove that he or she was directly injured by the unfair practice or that the predicate law provides for a private right of action." *Gregory v. Albertson's Inc.,* 104 Cal. App. 4th 845, 851 (2002) (citing *Saunders v. Superior Court* 27 Cal. App. 4th 832, 839 (1994). *See also Samura v. Kaiser Foundation Health Plan, Inc.* 17 Cal. Ap. 4th 1284, 1299 (1993) (Cal. Health and Safety Code violations, for which enforcement was delegated exclusively to the Department of Corporations, nonetheless could form a UCL claim); *People v. McKale* 25 Cal. 3d 626, 632–33 (1979) (agreeing that "even though a specific statutory enforcement scheme exists, a parallel action for unfair competition is proper pursuant to applicable provisions of the Business and Professions Code," and also interpreting *People v. Hill* 66 Cal. App. 3d 320 (1977) to mean that "a concerned district attorney may prosecute an action for unfair competition predicated on violations of the Accountancy Act notwithstanding provisions for a special enforcement agency").

RMS directs the Court to *Sybersound* 517 F.3d 1137, 1151–52 (9th Cir. 2008), which upheld the dismissal of a UCL claim based on, among other things, the fact that underlying violations of a state law copyright infringement claim were federally preempted, and thus the

plaintiff had no standing to sue. However *Sybersound* cited approvingly to the California appellate court's holding in *Gregory,* 104 Cal. App. 4th at 851 ("Section 17200 does not require that a plaintiff prove that he or she was directly injured by the unfair practice or that the predicate law provides for a private right of action"). The specific issue here is not preemption, but whether a statute's enforcement scheme, precluding enforcement by EMED of that statute, nonetheless permits EMED to state a UCL claim. The California case law, cited *supra,* supports the position that EMED can bring such claim.

RMS argues that it acted in good faith and had no reason to believe its warranty statements were improper. (ECF No. 66-1 at 14.) However, RMS does not appear to contest that voiding the Freedom 60's warranty based on use of non-RMS products would in fact violate the Magnuson-Moss Act. Section 2302(c) of the Act states: no warrantor may condition a product's warranty "on the consumer's using, in connection with such product, any article or service … which is identified by brand, trade, or corporate name," and RMS' Safety Bulletin states "use of non-RMS flow rate tubing voids the warranty for the FREEDOM60[]."

Ultimately, EMED does not bring a counterclaim for a violation of the Magnuson-Moss Act. However, the fact that the Safety Bulletin, which was sent to customers in 2012, describes a type of warranty that is unlawful and which appears to be directed specifically at EMED products, leads the Court to find EMED has raised serious questions going to the merits of a claim for "unfair or fraudulent" practices or "unfair, deceptive, untrue, or misleading advertising." Cal. Bus. & Prof. Code § 17200.

B. Balance of Hardships

At the outset, RMS argues that EMED cannot seek equitable relief if it has unclean hands. *See Adler v. Fed. Republic of Nigeria,* 219 F.3d 869, 877 (9th Cir. 2000) (citing *Precision Instr. Mfg. Co. v. Automative Maintenance Machinery Co.,* 324 U.S. 806, 814 (1945) ("The unclean hands doctrine 'closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief, however improper may have been the behavior of the defendant'"). Specifically, this argument is made in response to EMED's arguments regarding RMS' warranty provision. RMS directs the Court to a draft version of a user

manual for EMED's "SCIg Infusion System", which describes the operating instructions and warranty for that system. (ECF No. 66-2, Ex. 18.) The operating instructions state: "Use only EMED Infusets to control the flow; using any other device/tubing to control the flow rate may result in unsafe conditions for patient." (ECF No. 66-2, Ex. 18 at EM015611.) The warranty provision further states: "EMED Technologies Corporation ("Manufacturer") warrants the SCIg60 Infuser to be free from defects in materials and workmanship under normal use, if used in accordance with device operating instructions and under the direction of authorized medical personnel. Failure to comply with these conditions will result in a void warranty." (ECF No. 66-2, Ex. 18 at EM015611.)

EMED responds, however, that as an initial matter, its pump is not yet on the market. EMED also alleges that the language quoted by RMS, *supra*, is from a draft version and is not currently in use. (ECF No. 67-1 at 5.) By contrast, the current user manual states: "Limited Warranty: EMED Technologies Corporation ("Manufacturer") warrants the SCIg60 Infuser to be free from defects in materials and workmanship under normal use." (ECF No. 67-5, Ex. 8 at EM025202.) RMS makes no specific allegations that EMED has disseminated the draft version of the manual, and does not allege any customer response to it. Thus without more, the Court declines to bar equitable relief based on the unclean hands doctrine. See *U-Haul Intern, Inc. v. Jartran, Inc.*, 522 F. Supp. 1238, 1255 (D. Ariz. 1981) (citing *Markel v. Scovil Mfg. Co.*, 471 F. Supp. 1244, 1255 (W.D.N.Y. 1979) (uncleans hands will be applied 'only where some unconscionable act of one coming for relief has immediate and necessary relation to the equity that he seeks in respect of the matter in litigation'"); *Kelley Blue Book v. Car-Smarts, Inc.*, 802 F. Supp. 278, 292 (C.D. Cal. 1992).

Ultimately, the balance of hardships tips sharply in EMED's favor. EMED has produced evidence that RMS' false or misleading statements have elicited negative customer response as evidenced by the December, 2012 customer emails. EMED also alleges that it has lost a major customer, that its revenue has declined, and that customers have requested that EMED sign indemnity agreements before completing purchases. On the other hand, RMS' enjoinment from making false or misleading statements in the future, and eliminating such statements that are

currently available on its website, should cause RMS minimal to no hardship.[12]

C. Irreparable Harm

RMS argues that undue delay in filing for the instant injunction means that EMED will not suffer irreparable harm. RMS points out the following: (1) EMED waited to file nearly two years after receiving the December, 2012 customer emails questioning whether EMED's products could be used with the Freedom 60; (2) EMED waited to file over 16 months after sending a cease-and-desist letter to RMS; (3) EMED waited to file over one year after sending a second cease-and-desist letter; and (4) EMED waited to file 11 months after asserting its counterclaims in the instant lawsuit. (ECF No. 7) *See e.g., Oakland Tribune, Inc. v. Chronicle Publ.'g Co.,* 762 F.2d 1374 (9th Cir. 1985) ("Plaintiff's long delay before seeking a preliminary injunction implies a lack of urgency and irreparable harm").

EMED responds that it filed the instant motion on September 11, 2014, after it learned that RMS continued to claim that only RMS products could safely be used with the Freedom 60 pump, even though the FDA provided 510(k) clearance in May, 2014. EMED argues that injuries to its reputation are cumulative from the period prior to the May, 2014 510(k) clearance, and that after this clearance, RMS continued to disseminate false and misleading statements. For instance, an article on NASDAQ.com, dated October 7, 2014, quoted from a prior RMS "public filing"[13] which included statements that "any non-RMS product" used with the Freedom 60 might be unsafe. (ECF No. 67-5, Ex. 5.) EMED also points to both the allegedly misleading statements on RMS' website and in the Safety Bulletin available on RMS' website which were in existence at the time of filing for this injunction.

The Court acknowledges RMS' point that EMED's time of filing for the instant injunction does not appear to demonstrate irreparable harm, given EMED's position that in December, 2012, its rate sets were FDA cleared for use with the Freedom 60, and given its knowledge at that time that RMS was making statements to customers that EMED products could not be used safely with

[12] Regarding the Safety Bulletin on its website, RMS states that due to a "technical glitch" it is unable to remove the Safety Bulletin, but provides no specific reason for why this is the case. (ECF No. 66-1 at 11.)

[13] The Court is unable to locate this specific excerpt in one of the SEC form 10-Q's noted, *supra*.

the Freedom 60. However, the Ninth Circuit has cautioned that "delay is but a single factor to consider in evaluating irreparable injury; courts are 'loath to withhold relief solely on that ground.' *Arc of Cal. v. Douglas*, 757 F.3d 975, 990 (9th Cir. 2014) (quoting *Lydo Enters., Inc. v. City of Las Vegas*, 745 F.2d 1211, 1214 (9th Cir. 1984)). EMED's motion for the injunction was filed in September, 2014, roughly 4 months after EMED received 510(k) clearance for the Infusets. However, given that some false or misleading statements were still being publicly disseminated at that time, the time frame stated by RMS is not enough to deny the motion solely based on undue delay.

RMS also points to internal EMED emails apparently showing EMED's belief that RMS' statements have had no effects on customers. (ECF No. 66-1 at 15.) Specifically, in a January 13, 2014, email from Barbrie to Lambert, Barbrie stated: "You cannot continue to blame the customer. From their perspective, they are not sensitive to anything but an FDA recall, Warning Letter, or some other valid legal judgment proving infringement." (ECF No. 66-2, Ex. 15.) In a June 19, 2014, email from Barbrie to Lambert, Barbrie stated: "RMS has done a very good job selling the "Total System" concept. I know I have told you this many times, but believe me, it is the main reason why we are in this position." (ECF No. 66-2, Ex. 4.)

However, on review of the entirety of the emails contained in these exhibits (ECF No. 66-2, Ex.'s 4 & 15), the Court notes that RMS has simply omitted certain key excerpts that show EMED's concern with the allegedly unlawful statements, discussed *supra*. For instance, a prior email from the January 13, 2014, email chain, from Barbrie to Lambert, states: "It does not matter what they [i..e our customers] think or believe. Our customers have been told the Freedom60 pump warranty will be void and that FDA has not cleared Infusets for use with F60 pump. I have provided every piece of engineering data and comparative analysis we have and still, they do not want to chance it. Obviously, they are being told all kinds of things to dissuade the use of Infusets." (ECF No. 66-2, Ex. 15.) The June, 19, 2014, email also states: "Some [customers] have told me they use the total RMS and prefer getting the full system of related products for one manufacturer and that the warranty void of the pump bothers them." (ECF No. 66-2, Ex. 4.) RMS' reference to these emails actually supports EMED's position that EMED was concerned

about RMS disseminating false or misleading statements to EMED customers.

RMS also argues that EMED fails to identify any specific threat of future irreparable harm. *See Winter*, 555 U.S. at 222 ("Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with [the Supreme Court's] characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief"); *Villegas v. Schulteis*, 2010 WL 3341888, at *3 (E.D. Cal. Aug. 25, 2010). RMS argues that the only harm RMS' statements could have caused are: 1) EMED's having to execute indemnity agreements with certain customers; and 2) customers in December, 2012 expressing concerns via email because of warranty and safety concerns. With respect to the indemnity agreements, RMS asserts that EMED has exaggerated the number of customers who actually requested such indemnity agreements, and when EMED was specifically asked to produce such agreements, EMED produced only one hold-harmless agreement, from June, 2013, and two other open-ended emails with potential customers but without final agreements. (*See* ECF No. 66-1 at 17.) The Court agrees with RMS' argument that the threat of irreparable harm presented in *POM Wonderful LLC v. Purely Juice, Inc.* 2008 WL 4222045 (C.D. Cal. July 17, 2008), analogized by EMED to the instant case, is not quite on point. As RMS points out, *POM Wonderful* involved a bench trial on the merits before issuance of the injunction, and involved false statements – that the juice at issue was 100 percent pomegranate juice – related to "the primary reason" that customers purchased the product. *Id.* at *12.

However, EMED has alleged sufficient facts to support the "likelihood of irreparable harm" factor. EMED has produced customer emails showing that issuance of the Safety Bulletin in December, 2012 raised concerns about the safety of EMED's rate sets and whether their use would void the warranty on the Freedom 60. At the time the motion for an injunction was filed, that Safety Bulletin was still on RMS' website and was the first entry queued by the Google search, "Freedom60 customers". Further, at the time the motion for an injunction was filed, RMS' website also contained a misleading statement regarding its rate sets being the only rate sets "specifically designed and FDA-cleared" for use with the Freedom 60. EMED also points out that an article on NASDAQ.com, from October, 2014, repeated similar statements to those

contained in the Safety Bulletin regarding possible safety issues if a person used non-RMS products with the Freedom 60. EMED has also alleged – though this claim cannot be substantiated without more formal fact finding – that it has lost significant revenue due the allegedly false and misleading statements disseminated by RMS. On balance, EMED has shown a likelihood of irreparable harm.

D. Public Interest

With due consideration to the allegations presented by both parties at this stage in the proceedings, the Court finds that a preliminary injunction serves the public interest because it bars the dissemination of untrue, misleading, or unfair statements regarding the medical devices at issue in this case.

E. Bond Requirement

Federal Rule of Civil Procedure 56(c) permits a court to grant preliminary injunctive relief "only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." However, "[d]espite the seemingly mandatory language, Rule 56(c) invests the district court with discretion as to the amount of security required, *if any.* In particular, [t]he district court may dispense with the filing of a bond when it concludes there is no realistic likelihood of harm to the defendant from enjoining his or her conduct." *Johnson v. Couturier*, 572 F.3d 1067, 1086 (9th Cir. 2009)(citing *Jorgensen v. Cassiday*, 320 F.3d 906, 919 (9th Cir. 2003); *Barahona-Gomez v. Reno*, 167 F.3d 1228, 1237 (9th Cir. 1999)) (internal quotation marks omitted).

At this time there is no realistic likelihood of harm to RMS from enjoining the communications discussed in this Order, therefore, the Court does not require a bond.[14]

ORDER

A preliminary injunction is hereby issued against RMS, its officers, employees, agents, subsidiaries, affiliates, related companies, successors, resellers, distributors, and all those in concert or participation with them who receive actual notice of this order. Such entities and

[14] RMS makes no argument for a bond to be required at this time, but requests the right to do so if EMED's motion is granted. RMS may so move upon issuance of this order, but RMS is cautioned to consider the need for a bond in light of the narrow injunction issued herein.

persons are enjoined from advertising, publicly disseminating, or for a commercial advantage making statements that:

(1) only RMS rate sets (flow rate control tubing sets) have FDA clearance for use with the Freedom 60;

(2) only RMS rate sets (flow rate control tubing sets) may be safely used with the Freedom 60;

(3) the warranty on the Freedom 60 is conditioned upon use of RMS rate sets (flow rate control tubing sets); or

(4) are otherwise inconsistent with the 510(k)s issued by the FDA for the devices at issue in this case, including: the January, 1994 510(k) (No. K935642); the December, 2012 510(k) (No. K123729) for the VersaRate; and the May, 2014 510(k) (No. K140133) for Infusets.

RMS shall make all reasonable efforts to delete from its website those statements that would violate this injunction.[15]

Dated: June 16, 2015

Troy L. Nunley
United States District Judge

[15] Such efforts shall include modifying or taking down the Safety Bulletin, available at http://www.rmsmedicalproducts.com/downloads/news/latest/FREEDOM60_CAUTION.pdf, and modifying or taking down the Freedom 60 User Manual, referenced by EMED at ECF No. 41-1 at 9.