United States District Court Northern District of California 1

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UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA SAN JOSE DIVISION

TELEBRANDS CORP., Plaintiff, v.

VINDEX SOLUTIONS LLC, et al., Defendants. Case No. 21-cv-00898-BLF

ORDER GRANTING IN PART MOTION FOR TEMPORARY RESTRAINING ORDER

Plaintiff Telebrands Corp. ("Telebrands") filed the complaint in this action on February 4, 2021 asserting claims against Defendants VindEx Solutions LLC ("VindEx"), Cornerstone Trading, LLC ("Cornerstone"), Gloria Business, Inc. ("Gloria"), Techno Zone, LLC ("Techno Zone"), Okapi, LLC ("Okapi"), Henan Derun New Material Technology Co., Ltd. ("Henan Derun"), Shen Zhen Hei Shi Investment Ltd. ("Shen Zhen"), and XNH US ("XNH") (collectively "Defendants") for violations of state unfair competition laws. See Compl., ECF 1. Simultaneously with filing the complaint, Telebrands filed a motion seeking a temporary restraining order ("TRO") and an order to show cause why a preliminary injunction should not issue. See Mot., ECF 3. The Court ordered that notice be given by alternative means and held a hearing on the motion on February 11, 2021, at which counsel for Telebrands, VindEx, Techno Zone, Okapi, and Gloria appeared. At the hearing Plaintiff withdrew its motion as to Defendants VindEx, Techno Zone, and Okapi in order to facilitate settlement discussions. As to those Defendants the TRO is terminated without prejudice. By separate Order, the Court extended the time for Defendants to submit written responses to February 12, 2021 at noon. ECF 12. On February 12, 2021 before noon, Gloria filed a written response and declaration from its attorney Zheng Liu. ECF 24.

As set forth below, Telebrands' motion is GRANTED IN PART as to the remaining Defendants. Those Defendants are HEREBY ORDERED TO SHOW CAUSE, in writing and on or before February 25, 2021, why the preliminary injunction requested by Telebrands should not issue. Telebrands may file a reply on or before March 4, 2021 at 12:00 pm. A video hearing on Telebrands' motion for a preliminary injunction is set for March 11, 2021 at 9:00 a.m.

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BACKGROUND

The verified complaint, the declaration of Telebrands Executive Vice President and Chief Operating Officer Bala Iyer, and the declaration of Exponent, Inc. ("Exponent") Principal Engineer Jorge Ochoa establish the following facts. *See generally* Compl.; Iyer Decl., ECF 3-1; Ochoa Decl., ECF 22. Telebrands markets and sells products through retail and third-party marketplaces such as Amazon and Facebook. Iyer Decl. ¶ 2. "Among the products offered by Telebrands is the Hempvana Rocket, a handheld transcutaneous electrical nerve stimulation ("TENS") unit. The Hempvana Rocket is a pain-relieving pen that uses TENS therapy in the form of direct electrical stimulation to muscles." *Id.* ¶ 3. TENS units are classified as Class II medical devices by the United States Food and Drug Administration ("FDA"). *Id.* ¶ 4. Pursuant to 21 C.F.R. § 882.5890, manufacturers of Class II medical devices must first submit a 510(k) premarket notification to the FDA indicating that their medical device is substantially similar to predicate medical devices, and obtain clearance from the FDA before they may distribute the medical device within the United States. *See also* ¶¶ Ochoa Decl. 7-8.

Upon belief that other business entities and individuals were selling unauthorized TENS
devices similar to Hempvana, Telebrands hired Exponent to (1) evaluate competing medical
devices, (2) determine whether those devices were TENS units, and (3) determine whether the
device distributors had sought out and obtained clearance from the FDA after submitting 510(k)
premarket notifications. Iyer Decl. ¶¶ 5-6; Ochoa Decl. ¶¶ 10-14 (describing methodology).
Exponent evaluated the following devices: (1) the Zolaro Meridian Energy Acupuncture Pen

1	distributed by Techno Zone; (2) the AOBBiY Acupuncture Massager Pen distributed by Gloria;
2	(3) the BreoLife Electronic Acupuncture Pen distributed by Cornerstone ; (4) the Scree
3	SmartChoice4U Direct distributed by VindEx; (5), the FORTIVO Acupuncture Massage Pen by
4	Okapi; (6) the UniforU Massager Pen distributed by Henan Derun; (7) the Blitzby 5-in-1
5	Acupuncture Pen distributed by Shen Zhen; and (8) the FOHYLOY Meridian Energy
6	Acupuncture Pen distributed by XNH. Iyer Decl. ¶ 7; Ochoa Decl. ¶ 11; see also ECF 21, Exh. A
7	(Exponent Report). Exponent concluded that all of the devices were TENS units, but none were
8	cleared by the FDA as a Class II medical device. Iyer Decl. ¶ 8; Ochoa Decl. ¶¶ 12-14.
9	Telebrands alleges that Defendants' "unlawful business practices" post harm to Telebrands
10	because
11	by unlawfully distributing the competing TENS units without first
12	obtaining clearance through an FDA 510(k) premarket notification, Defendants received an unfair advantage. Defendants have avoided
13	the costs of seeking proper clearance from the FDA. However, not only are Defendants distributing their TENS units nationally, they have the hereofit of the Hermiteure Restories represents to be set their
14	have the benefit of the Hempvana Rocket's popularity to boost their products' visibility, which they will use unfairly and unlawfully to compete against Telebrands and dilute the market for TENS units
15	when no such competition is permitted to occur pursuant to FDA regulations.
16	Compl. ¶ 8. It also alleges that Defendants' marketing and advertising materials omit the fact that
17	Defendants have not sought and obtained $510(k)$ premarket notification clearance from the FDA.
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19	According to Telebrands, this failure to inform creates a substantial likelihood that customers "will
20	be confused or misled into purchasing Defendants' TENS units believing them to be equivalent to
21	the Hempvana Rocket." $Id. \P 9$.
22	On January 22, 2021, Telebrands served VindEx, Cornerstone, Techno Zone, Gloria, and
23	Okapi with cease and desist letters. Iyer Decl. ¶ 9. Telebrands was unable to serve Chinese-based
24	Defendants Henan Derun, Shen Zhen, and XNH by mail "as their addresses were difficult to
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ascertain as internet searches for each company's address and contact information were inconsistent and unreliable among different sources." *Id.* \P 10.

On February 4, 2021, Telebrands filed the complaint and instant motion for a temporary restraining order. On February 8, 2021, the Court issued an Order directing Defendants to respond to the motion and directing Telebrands to serve Defendants with notice of the Order via email or Amazon Seller Messaging Assistant. *See* ECF 9, 12. Plaintiff has confirmed service as authorized. ECF 11. The Defendants who appeared at the hearing also received full copies of all of Plaintiff's papers. The non-appearing Defendants, Henan Derun, Shen Zhen, XNH and Cornerstone, received notice of the TRO hearing. ECF 11. The Court finds that this is adequate notice of the TRO hearing for those non-appearing Defendants.

II. LEGAL STANDARD

12 The standard for issuing a temporary restraining order is identical to the standard for 13 issuing a preliminary injunction. Stuhlbarg Int'l Sales Co., Inc. v. John D. Brush & Co., 240 F.3d 14 832, 839 n.7 (9th Cir. 2001); Lockheed Missile & Space Co. v. Hughes Aircraft, 887 F. Supp. 1320, 1323 (N.D. Cal. 1995). An injunction is a matter of equitable discretion and is "an 15 16 extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled 17 to such relief." Winter v. Natural Resources Defense Council, Inc., 555 U.S. 7, 22 (2008). A 18 plaintiff seeking preliminary injunctive relief must establish "[1] that he is likely to succeed on the 19 merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that 20 the balance of equities tips in his favor, and [4] that an injunction is in the public interest." Id. at 20. "[I]f a plaintiff can only show that there are serious questions going to the merits – a lesser 21 22 showing than likelihood of success on the merits – then a preliminary injunction may still issue if 23 the balance of hardships tips sharply in the plaintiff's favor, and the other two Winter factors are satisfied." Friends of the Wild Swan v. Weber, 767 F.3d 936, 942 (9th Cir. 2014) (internal 24 25 quotation marks and citations omitted).

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III. DISCUSSION

Telebrands has satisfied the requirements for issuance of a TRO, that a TRO is appropriate in this case, and that no security is warranted. As discussed at the hearing, it is the Court's view that the scope of injunctive relief requested by Telebrands is too broad. Accordingly, the Court will grant Telebrands' modified request for a TRO. *See* ECF 20 (narrowed request).

A. Analysis

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1. Likelihood of Success on the Merits

The Court begins its analysis by considering Telebrands' showing on the first *Winter* factor, likelihood of success on the merits. Telebrands' motion for TRO is based primarily on the California Unfair Competition Law. Cal. Bus. & Prof. Code § 17200 *et seq*.

11 "The UCL is a broad remedial statute that permits an individual to challenge wrongful 12 business conduct 'in whatever context such activity might occur." Lozano v. AT & T Wireless 13 Servs., Inc., 504 F.3d 718, 731 (9th Cir. 2007) (quoting Cel-Tech Commc'ns, Inc. v. Los Angeles 14 Cellular Tele. Co., 20 Cal.4th 163, 83 Cal.Rptr.2d 548, 561, 973 P.2d 527 (1999) (citation omitted)). It prohibits "unfair competition," which it defined as including "any unlawful, unfair or 15 16 fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising...." Cal. 17 Bus. & Prof.Code § 17200. Because the statute is written in the disjunctive, it is violated where a 18 defendant's act or practice is (1) unlawful, (2) unfair, (3) fraudulent, or (4) in violation of section 19 17500 (false or misleading advertisements). Cel-Tech, 83 Cal.Rptr.2d at 565, 973 P.2d 527. Each 20 prong of the UCL is a separate and distinct theory of liability; thus, the "unfair" practices prong offers an independent basis for relief. South Bay Chevrolet v. Gen. Motors Acceptance Corp., 72 21 22 Cal.App.4th 861, 85 Cal.Rptr.2d 301, 316–317 (1999) (citation and quotation omitted).

In order to bring a claim under the UCL, "a plaintiff must establish: (1) 'a loss or
deprivation of money or property sufficient to qualify as injury in fact, i.e., economic injury'; and
(2) 'that that *economic injury* was the result of, i.e., *caused by*, the unfair business practice or false

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1 advertising that is the gravamen of the claim." Ivie v. Kraft Foods Glob., Inc., 961 F. Supp. 2d 2 1033, 1046 (N.D. Cal. 2013) (quoting Kwikset Corp. v. Superior Court, 51 Cal.4th 310, 322, 120 3 Cal.Rptr.3d 741, 246 P.3d 877 (2011) (emphases in original)).

As discussed above, Telebrands has presented extensive evidence, through the verified complaint, the declarations of Bala Iyer and Jorge Ochoa, and the Exponent Report, that Defendants are currently engaging in unfair business practices by distributing TENS devices without prior 510(k) premarket clearance by the FDA. Compl. ¶¶ 37-47; Iyer Decl. ¶¶ 7-8; Ochoa Decl. ¶ 13-14; ECF 21, Exh. A (Exponent Report). Telebrands has also presented evidence that 8 Defendants' unfair practices have caused them economic injury, namely the loss of Hempvana sales. This unambiguous evidence is sufficient to establish that Telebrands is likely to succeed on 10 its unfair competition claims.

12 Gloria contends that "[i]t is impermissible for Telebrands, a private party, to base its UCL 13 claims on the Food, Drug and Cosmetics Act ("FDCA"). Regulations of the FDCA cannot be 14 privately enforced, it is the government that exclusively holds this right." ECF 24 at 3-4. The Court agrees with Gloria that the FDCA does not grant a private right of action. 21 U.S.C. § 15 16 337(a) ("proceedings for the enforcement, or to restrain violations, of this Act shall be by and in 17 the name of the United States."). However, the Ninth Circuit has made clear that the FDCA does 18 not preempt all state law claims.

19 In Perez v. Nidek Co., the Ninth Circuit described the "narrow gap through which a state-20 law claim must fit to escape preemption by the FDCA: The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must 21 22 not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted 23 under Buckman [Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001)])." 711 F.3d 1109, 1120 (9th Cir. 2013) (emphasis in original, internal quotation marks and citation omitted). The plaintiff in 24 25 Perez brought a state law fraud-by-omission claim against the manufacturer of a surgical laser,

1 along with doctors who used the laser, for failing to disclose that it was not approved by the FDA. 2 Id. at 1112. The Ninth Circuit agreed with the district court's finding that plaintiff's claim was 3 predicated on "matters [] within the enforcement authority of the FDA, not this Court" an, 4 accordingly, "[did] not squeeze through this gap." Id. at 1120; see also Somers v. Beiersdorf, Inc., 5 467 F. Supp. 3d 934, 937 (S.D. Cal. 2020) (FDCA preempted plaintiff's claims that "Defendant 6 engaged in illegal conduct by unlawfully making skin firming representations about its 7 [product]"). Similarly, in Optivus Tech., Inc. v. Ion Beam Applications S.A., the Federal Circuit 8 held that a district court erred in dismissing plaintiff's UCL claim based on a failure to exhaust 9 administrative remedies. 469 F.3d 978 (Fed. Cir. 2006). The Federal Circuit revived the claim, reasoning that "[plaintiff] is not seeking to contest an agency determination; rather, it is claiming 10 11 that [defendant] engaged in unfair competition under California law by marketing a medical 12 device without FDA approval." Id. at 986. Here, Telebrands is bringing a claim against 13 Defendants for conduct that violates the FDCA, but is not suing *because* the conduct violates the 14 FDCA—it is suing because Defendants' conduct subjects Telebrands to unfair competition under California law. See generally Compl. As such, Telebrands' claim threads the narrow gap 15 articulated in Perez. 16

17 Gloria's remaining objections are either irrelevant to the UCL claim before the Court, have 18 been rectified by Telebrands' supplemental submissions, or are without factual basis. See ECF 24-19 1. For example, although Gloria contends that Telebrands' motion for a TRO is "inconsistent," it 20 does not explain what is inconsistent about it. Id. at 3-4. And while Gloria insists that Bala Iyer does not have the proper expertise to offer opinions about TENS units and FDA guidelines, this 21 22 objection ignores Telebrands' supplemental declaration from Jorge Ochoa, a biomedical engineer 23 with considerable experience in and education relevant to evaluating medical devices. Id. at 4-7; see Ochoa Decl. ¶ 2-4. Finally, although Gloria argues that Telebrands does not claim any 24

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intellectual property assets over the Hempvana, this is irrelevant to Telebrands' asserted UCL claim.

2. Irreparable Harm

Telebrands has established that it is likely to suffer irreparable harm if a TRO is not granted. The record indicates that without injunctive relief, Defendants' business practices will cause Telebrands to unfairly lose out on Hempvana sales and dilute the Hempvana brand. Compl. ¶¶ 46-49. To this end, "Defendants have already been distributing their products on third-party marketplaces without the proper clearances, and due to the enhanced search functionality of thirdparty marketplaces such as Amazon, Telebrands anticipates that the expenditures made to create a brand for the Hempvana Rocket will inadvertently inure to the great benefit of Defendants. Defendants will be able to piggyback off of the money spent on and popularity gained by the advertising for the Hempvana Rocket." *Id.* ¶ 47. The evidence also shows that without preliminary relief, Telebrands will continue to be forced to unfairly compete against Defendants, who have dodged the transactional costs of obtaining FDA clearance after making a 510(k) submission. *Id.* ¶¶ 46-49

3. Balance of Equities

The balance of equities favors Telebrands' motion for a TRO. As detailed above, Telebrands faces harm to its financial and market position based on Defendants' sales practices. Meanwhile, Telebrands' injunction requests only that Defendants comply with mandatory FDA regulations; if the Court were to grant injunctive relief, Defendants could return to distributing competing TENS units as soon as they complied with FDA regulations. And, based on the record evidence, there does not appear to be any basis for Defendants' non-compliance with FDA regulations.

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- 4. Public Interest
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1 Finally, the public interest favors issuance of a TRO. A TRO will further the public's 2 interest in ensuring fair competition among business entities. See Fresenius Med. Care Holdings, 3 Inc. v. Baxter Int'l, Inc., No. C 03-1431 SBA, 2008 WL 928496, at *5 (N.D. Cal. Mar 21, 2008) 4 ("the Federal Circuit has observed that the public interest is clearly served by healthy, fair 5 competition"). Injunctive relief also promotes the public's interest in ensuring the safety of 6 medical devices. See 21 U.S.C. § 393(b)(1) & (2); see also DISH Network L.L.C. v. Ramirez, No. 7 15-cv-04712-BLF, 2016 WL 3092184, at *19 (N.D. Cal. June 2, 2016) ("when a prospective 8 injunction would do no more than require Defendant to comply with federal and state ... laws, 9 then the public has an interest in the enforcement of the statutes.") (internal quotation marks omitted)). 10

B. Security

Federal Rule of Civil Procedure 65(c) provides that "[t]he court may issue a preliminary injunction or a temporary restraining order 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." Fed. R. Civ. P. 65(c). The Ninth Circuit has "recognized that Rule 65(c) invests the district court with discretion as to the amount of security required, if any." Jorgensen v. Cassiday, 320 F.3d 906, 919 (9th Cir. 2003) (internal quotation marks and citation 18 omitted) (italics in original). "The 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." Id.

Nothing in this record suggests that Defendants will be prejudiced by an injunction 21 22 prohibiting them from distributing uncleared TENS units within the United States. Accordingly, 23 the Court finds it appropriate to issue injunctive relief without requiring Telebrands to provide security. 24

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C. Date of Hearing on Motion for Preliminary Injunction

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The TRO issued after notice and hearing and thus the Court will set the hearing for the Preliminary Injunction on March 11, 2021 at 9:00 am. In the event that the non-appearing Defendants, Henan Derun, Shen Zhen, XNH and Cornerstone, contest that they were provided notice of the motion for TRO, they may request reconsideration of the TRO and seek an expedited hearing.

IV. ORDER

Telebrands' motion for a TRO is GRANTED as follows:

(1) Defendants, Cornerstone Trading, LLC, Henan Derun New Material Technology Co., Ltd., XNH US, Gloria Business, Inc., and Shen Zhen Hei Shi Investment Ltd. (collectively, "Defendants"), appear before this Court by Zoom video conference on March 11, 2021 at 9:00 a.m. or as soon thereafter as the matter may be heard, to show cause, if any there be, why an order for a Preliminary Injunction should not be made and entered pursuant to Federal Rule of Civil Procedure 65, restraining and enjoining Defendants, whether directly or through any other name or affiliated entity, from distributing the following uncleared TENS units within the United States:

a. Defendant Henan Derun New Material Technology Co., Ltd.'s UniforU brand Massager pen;

b. Defendant Shen Zhen Hei Shi Investment Ltd.'s Blitzby brand 5-in-1 Acupuncture Pen;

c. Defendant XNH US's FOHYLOY brand Meridian Energy Acupuncture Pen;

d. Defendant Cornerstone Trading LLC's Breolife brand Electronic Acupuncture Pen; and

e. Defendant Gloria Business, Inc.'s AOBBiY brand Acupuncture Massager Pen.(2) Defendants, and all those acting in concert or participation with Defendants, shall not

destroy, erase, or otherwise make unavailable and shall immediately cease

1	implementation of any and all company policies, procedures or practices for the
2	deletion of digital information including emails and, removal or destruction, in the
3	normal course of business, of all documents, data, tangible things, and other materials
4	relating to this case, including, emails, data, databases, cloud storage, and paper and
5	electronic data and documents, including any and all metadata.
6	(3) Pending the hearing of March 11, 2021 and ruling on Plaintiff's request for a
7	Preliminary Injunction, the Court hereby enters the following Temporary Restraining
8	Order:
9	a. restraining and enjoining Defendants, whether through any other name or entity
10	from distributing the following uncleared TENS units within the United States
11	either through third-party marketplaces including Amazon or Facebook by
12	telephone, in retail stores or through any other medium within the United
13	States:
14	i. Defendant Henan Derun New Material Technology Co., Ltd.'s UniforU
15	brand Massager pen;
16	ii. Defendant Shen Zhen Hei Shi Investment Ltd.'s Blitzby brad 5-in-1
17	Acupuncture Pen;
18	iii. Defendant XNH US's FOHYLOY brand Meridian Energy Acupuncture
19	Pen;
20	iv. Defendant Cornerstone Trading LLC's Breolife brand Electronic
21	Acupuncture Pen; and
22	v. Defendant Gloria Business, Inc.'s AOBBiY brand Acupuncture
23	Massager Pen.
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United States District Court Northern District of California

1	(4) The Temporary Restraining Order provisions set forth herein shall expire at 5:00 pm on
2	March 11, 2021 unless before then Defendants consent, or the Court, for good cause,
3	orders an extension.
4	(5) This Temporary Restraining Order, Order to Show Cause, and all papers Telebrands
5	has submitted in support of its Motion for the same, shall be served on Defendants no
6	later than February 16, 2021. Telebrands shall file proofs of service with this Court no
7	later than February 18, 2021.
8	(6) Defendants may file any papers in opposition to the issuance of a Preliminary
9	Injunction on later than February 25, 2021.
10	(7) Telebrands may file and serve any reply papers prior to the Show Cause hearing no
11	later than 12:00 pm on March 4, 2021.
12	(8) Plaintiff may serve written expedited discovery on Defendants which shall be
13	responded to within 10 days of service as authorized herein. Telebrands is granted
14	leave to propound written discovery compelling Defendants to produce a list of any
15	and all channels of commerce through which they are currently selling their
16	unauthorized TENS unit and depose any and all declarants who filed declarations in
17	connection with this Preliminary Injunction and who sign Defendants' responses to
18	Telebrands' written discovery demands.
19	(9) Plaintiff is authorized to serve the foregoing papers by the alternate means authorized
20	by the Court for service of Plaintiff's Order to Show Cause. Plaintiff is not authorized
21	to serve the summons and complaint in this matter by alternative service in the absence
22	of a separate motion setting forth Plaintiff's good faith, diligent efforts to effect service
23	under to Federal Rule of Civil Procedure 4.
24	IT IS SO ORDERED.
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United States District Court Northern District of California Dated: February 12, 2021

Ken fally heeman BETH LABSON FREEMAN United States District Judge