UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

VMAS Solutions, LLC, **Plaintiff,** **v.** **MMJ Labs, LLC,** **Defendant.**	**2:17-cv-00534 JWS** **ORDER AND OPINION** **[Re: Motion at Docket 8]**

I. MOTION PRESENTED

At docket 8 plaintiff VMAS Solutions, LLC ("VMAS") moves for a preliminary injunction pursuant to Federal Rule of Civil Procedure 65(a). Defendant MMJ Labs, LLC ("MMJ") opposes the motion at docket 12. VMAS replies at docket 14. At docket 27 the court struck paragraphs four through seven of the declaration of Jeffrey P. Thennisch attached to VMAS' reply.

Oral argument was heard on April 20, 2017.

II. BACKGROUND

MMJ sells a motorized vibrating medical device called "Buzzy" that reduces the pain of hypodermic needle injections. MMJ filed a trademark application for the Buzzy mark with the United States Patent and Trademark Office ("PTO") in 2006. According to the Statement of Use that MMJ filed with the PTO in 2008, the Buzzy mark was first

used in interstate commerce on October 14, 2008.[1] The PTO issued a registration (No. 3,559,172 ("the '172 Registration")) to MMJ for the Buzzy mark in 2009.[2]

VMAS is an Arizona company doing business under the name "The TouchPoint Solution"; it was founded to sell "a wearable Bluetooth connected device, with an associated smartphone application, intended to relieve stress for the wearer" (the "VMAS Device").[3] VMAS launched the VMAS Device under the name "Buzzies" in October 2016 and one month later launched a crowdsourced funding campaign on Kickstarter.com ("Kickstarter").[4]

Conflict between MMJ and VMAS ensued. MMJ states that it discovered VMAS was using the Buzzies mark in late 2016.[5] MMJ informed VMAS in a January 2017 cease and desist letter that Buzzies infringes on the Buzzy mark.[6] VMAS responded by petitioning the PTO's Trademark Trial and Appeal Board to cancel MMJ's '172 Registration.[7] MMJ then informed Kickstarter about the parties' trademark dispute[8] and, according to VMAS, Kickstarter shut down VMAS' fundraising site based on MMJ's claim of infringement.[9] Although VMAS states that Kickstarter has since restored its campaign website, VMAS is still prohibited from using the Buzzies mark.[10]

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[1]Doc. 12-1 at 41.

[2]Doc. 8-1 at 22.

[3]*Id.* at 2–3 ¶¶ 2–3.

[4]*Id.* at 3 ¶¶ 7–9.

[5]Doc. 12-1 at 6 ¶ 27.

[6]Doc. 8-1 at 17–21.

[7]Doc. 12-1 at 20–51.

[8]*Id.* at 7 ¶ 30.

[9]Doc. 8-1 at 4 ¶¶ 14–17.

[10]*Id.* at 5.

VMAS' two-count complaint seeks (1) a declaratory judgment that MMJ's '172 registration is invalid; and (2) damages and injunctive relief for MMJ's alleged tortious interference with its business expectancies with Kickstarter. VMAS' present motion seeks a preliminary injunction enjoining MMJ "from asserting the defective '172 registration against VMAS or making any other false or disparaging statements about VMAS, including claims of infringement, in any public or commercial settings or forums, and require that VMAS retract or otherwise withdraw its infringement claim with Kickstarter."[11]

III. STANDARD OF REVIEW

Although the decision to grant or deny a preliminary injunction is committed to the district court's discretion, a preliminary injunction is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief."[12] A plaintiff seeking a preliminary injunction must satisfy the following four factors: "(1) she is likely to succeed on the merits, (2) she is likely to suffer irreparable harm in the absence of preliminary relief, (3) the balance of equities tips in her favor, and (4) an injunction is in the public interest."[13] "[I]f a plaintiff can only show that there are 'serious questions going to the merits'—a lesser showing than likelihood of success on the merits—then a preliminary injunction may still issue if the 'balance of hardships tips sharply in the plaintiff's favor,' and the other two *Winter* factors are satisfied."[14]

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[11]Doc. 8 at 15.

[12]*Winter v. Nat. Res. Def. Council*, 555 U.S. 7, 22 (2008).

[13]*Farris v. Seabrook*, 677 F.3d 858, 864 (9th Cir. 2012) (citing *Winter*, 555 U.S. at 20).

[14]*Shell Offshore, Inc. v. Greenpeace, Inc.*, 709 F.3d 1281, 1291 (9th Cir. 2013) (quoting *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1135 (9th Cir. 2011)).

IV. DISCUSSION

"To acquire ownership of a trademark it is not enough to have invented the mark first or even to have registered it first; the party claiming ownership must have been the first to actually use the mark in the sale of goods or services."[15] The Ninth Circuit in *CreAgri* held that "only *lawful* use in commerce can give rise to trademark priority."[16] The plaintiff, CreAgri, sold a dietary supplement called Olivenol "in violation of 21 U.S.C. §§ 331(a), 343(a) (prohibiting sale of misbranded food as determined by reference to the relevant regulations)."[17] The defendant, USANA Health Services ("USANA"), sold "a series of vitamins, minerals, and nutritional supplements containing an ingredient called Olivol,"[18] which CreAgri alleged was confusingly similar to its Olivenol mark. Although Olivenol was used in commerce before Olivol, the Ninth Circuit held that the Olivol mark had priority because Olivenol's use was unlawful.[19] The court provided two rationales for this result. First, "as a logical matter, to hold otherwise would be to put the government in the 'anomalous position' of extending the benefits of trademark protection to a seller based upon actions the seller took in violation of that government's own laws."[20] And second, "as a policy matter, to give trademark priority to a seller who rushes to market without taking care to carefully comply with the relevant regulations would be to reward the hasty at the expense of the diligent."[21]

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[15] *Sengoku Works Ltd. v. RMC Int'l, Ltd.*, 96 F.3d 1217, 1219 (9th Cir. 1996).

[16] *CreAgri, Inc. v. USANA Health Scis., Inc.*, 474 F.3d 626, 630 (9th Cir. 2007) (emphasis in original).

[17] *Id.* at 630–31.

[18] *Id.* at 629.

[19] *Id.* at 630.

[20] *Id.* (quoting *In re Stellar Int'l, Inc.*, 159 U.S.P.Q. 48, 51 (T.T.A.B. 1968)).

[21] *Id.*

A. VMAS' Claim that MMJ's Use of the Buzzy Mark Was Unlawful

Relying on *CreAgri*, VMAS argues that MMJ's mark is invalid because MMJ was selling Buzzy unlawfully from 2008 to 2014. The parties agree that, as a medical device, Buzzy is subject to regulation by the Food and Drug Administration ("FDA"). Under the Medical Devices Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"), "medical device manufacturers must register each device with the FDA prior to manufacture of that device so that the FDA can classify each device according to the 'level of regulatory control necessary to provide for the device's safety and effectiveness.'"[22] Devices are classified into one of three levels of oversight based on the risk they pose to the public. "Class I, which includes such devices as elastic bandages and examination gloves, is subject to the lowest level of oversight: 'general controls,' such as labeling requirements."[23] "Class II, which includes such devices as powered wheelchairs and surgical drapes, is subject in addition to 'special controls' such as performance standards and postmarket surveillance measures."[24] Class III devices receive the most federal oversight; they include "replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators."[25] "Manufacturers of such devices must obtain premarket approval from [the] FDA to market the devices pursuant to the requirements and procedures set forth in [21 U.S.C.] § 360e ('PMA')."[26]

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[22] *Seedman v. Cochlear Americas*, No. SACV 15-00366 JVS (JCGx), 2015 WL 4768239, at *6 (C.D. Cal. Aug. 10, 2015) (quoting *Tansey v. Cochlear Ltd.*, No. 13-CV-4628 SJF, 2014 WL 4829453, at *6 (E.D.N.Y. Sept. 26, 2014)). *See also* 2 JAMES T. O'REILLY & KATHARINE VAN TASSEL, FOOD AND DRUG ADMINISTRATION § 18:7 (4th ed. 2016) ("Medical device manufacturers must register each device with the FDA prior to manufacture of that device so that the FDA can classify each device according to the level of regulatory risks.").

[23] *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008) (citing 21 U.S.C. § 360c(a)(1)(A)).

[24] *Id.* at 316–17 (citing 21 U.S.C. § 360c(a)(1)(B)).

[25] *Id.* at 317 (citing 21 U.S.C. § 360c(a)(1)(C)(ii)).

[26] *Ethicon, Inc. v. Food & Drug Admin.*, 762 F.Supp. 382, 384 (D.D.C. 1991).

"Unlike a manufacturer of a Class III device, which must go through the 'rigorous'" PMA process, manufacturers of Class II devices "need only submit a 'premarket notification' to the FDA, in accordance with the less burdensome '[§] 510(k) process.'"[27] "If the FDA concludes on the basis of the § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis . . . ."[28]

Class I devices receive the least amount of regulatory scrutiny. "Most Class I devices and a few Class II devices are exempt" from the § 510(k) process altogether.[29] 21 C.F.R. Parts 862–92 contains § 510(k) exemptions for "over 800 generic types of Class I devices and 60 class II devices."[30] According to the FDA's regulatory guidance, "[i]f a manufacturer's device falls into a generic category of exempted Class I devices as defined in 21 CFR Parts 862–892, a premarket notification application and FDA clearance is not required before marketing the device in the U.S."[31]

It is undisputed that MMJ did not obtain § 510(k) clearance before it began selling Buzzy in 2008.[32] VMAS contends that such clearance was required for two reasons. First, VMAS asserts that Buzzy is a Class II device.[33] But, because this assertion is unsupported by any authority or evidence in the record, the court cannot accept it. Second, VMAS points to an August 13, 2014 decision from the FDA. In 2013

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[27] *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 925 (9th Cir. 2010) (citing 21 U.S.C. § 360(k); 21 C.F.R. § 807.100).

[28] *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996).

[29] *See* U.S. FOOD & DRUG ADMIN., *Class I / II Exemptions* (updated June 26, 2014), https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051549.htm.

[30] *Id.*

[31] *Id.*

[32] Doc. 12-1 at 13–14.

[33] Doc. 8 at 9.

MMJ submitted to the FDA a § 510(k) premarket notification application for Buzzy.[34] The FDA's August 13, 2014 decision on the application declares that the Buzzy device is substantially equivalent to devices that do not require a PMA application and clears MMJ to market the device.[35] The FDA classified Buzzy as a "therapeutic vibrator," which according to 21 C.F.R. § 890.5975 is a Class I device that is generally exempt from the § 510(k) process.[36] This exemption is subject to the limitations set out at 21 C.F.R. § 890.9.[37] With regard to non in vitro devices like Buzzy, 21 C.F.R. § 890.9 provides that a device manufacturer "must still submit a premarket notification to FDA" where the device (1) is for a use different than the intended use of a generic type of the device or (2) uses a different fundamental scientific technology than a generic type of the device. The FDA's order concludes that MMJ was required to submit a premarket notification for Buzzy because Buzzy "exceeded the [l]imitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 CFR Part 890.9)."[38] The order does not explain how Buzzy exceeded these limitations, nor does it specify which limitation or limitations were exceeded.

VMAS argues that the FDA's ruling definitively establishes that MMJ was selling Buzzy unlawfully before the date of this decision. Thus, VMAS argues, Buzzy's registration is void *ab initio*.

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[34]Doc. 12-1 at 5 ¶ 22; U.S. FOOD AND DRUG ADMIN., *510(k) Premarket Notification Database* (updated April 10, 2017), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K130631.

[35]Doc. 8-1 at 24–26.

[36]21 C.F.R. § 890.5975(b).

[37]*Id.*

[38]Doc. 8-1 at 24.

B. VMAS Has Not Shown That MMJ's Allegedly Unlawful Conduct Was Material

If unlawful use were the only requirement for extinguishing a party's trademark protection, then VMAS' motion might have merit. But the inquiry does not stop with unlawfulness. It must also be established that the unlawful conduct was "material."[39] The Ninth Circuit adopted this requirement from *General Mills*, a 1992 decision from the Trademark Trial and Appeal Board. In that case General Mills opposed Health Valley Foods' application to register the mark "Fiber 7 Flakes," arguing that it resembled its "Fiber One" mark. In turn, Health Valley Foods argued that General Mills' use of the Fiber One mark was unlawful because the product was mislabeled under the FDCA when General Mills applied for trademark registration. Although General Mills conceded that its product was mislabeled initially, it argued that this "failure to fully comply with FDA labeling requirements pertained to only eighteen packages of cereal and . . . the mistake was rectified a mere four months later when [it] commenced national distribution of FIBER ONE brand cereal."[40] Under the circumstances, the Trademark Trial and Appeal Board held that Health Valley Foods did not meet its burden of establishing materiality.[41]

In *CreAgri*, CreAgri cited *General Mills* in support of its argument that its unlawful use of the Olivenol mark was immaterial.[42] The Ninth Circuit rejected this argument, finding that the facts of the two cases were "categorically different."[43] "Whereas General Mills corrected its labeling error before its competitor's priority date—thus eventually establishing the 'lawful use in commerce' necessary for trademark protection

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[39] *S. California Darts Ass'n v. Zaffina*, 762 F.3d 921, 931 (9th Cir. 2014) (quoting *CreAgri*, 474 F.3d at 633).

[40] *Gen. Mills Inc. V. Health Valley Foods*, 24 U.S.P.Q.2d 1270, 1273 (T.T.A.B. 1992).

[41] *Id.* at 1274.

[42] *CreAgri*, 474 F.3d at 633.

[43] *Id.*

—CreAgri did not correct its labeling error before USANA's priority date, and thus, there is not a single instance of 'lawful use in commerce' prior to June 18, 2002, upon which CreAgri can base its claim of priority."[44]

The *CreAgri* court held that it was unnecessary to decide whether to adopt the test for materiality articulated in *General Mills* because CreAgri's unlawful use was material under any definition of "materiality."[45] The Ninth Circuit later clarified in *Southern California Darts* that unlawful use does not preclude trademark protection if the unlawful conduct was either "immaterial" (meaning that it was not "'of such gravity and significance that the usage [of the mark] . . . as a matter of law, [can] create no trademark rights'")[46] or "collateral" (meaning that "there is an insufficient nexus between the unlawful behavior and the use of the mark in commerce.").[47]

Neither party addresses materiality in its briefing on this motion. The court, however, cannot overlook the similarity between the facts of this case and the facts of *General Mills*. Assuming, for the sake of argument that MMJ's original usage was unlawful, MMJ corrected any labeling problems in 2014 when it received the FDA's approval to market the Buzzy device. Thus, MMJ established the lawful use in commerce necessary for trademark protection of the Buzzy mark more than two years before VMAS began using the Buzzies mark. Because MMJ, like General Mills, corrected its alleged labeling error before the opposing party's priority date, VMAS cannot establish materiality.

VMAS has not shown serious questions going to the merits of its claim for declaratory relief. Further, the success of VMAS' tortious interference claim rises or

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[44] *Id.*

[45] *Id.*

[46] *S. California Darts*, 762 F.3d at 931 (quoting *CreAgri*, 474 F.3d at 633).

[47] *Id. See also* 3 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 19:124 (4th ed. 2017).

falls with the merits of the declaratory judgment claim. In light of these rulings, it is unnecessary to address the remaining *Winter* factors.

V. CONCLUSION

Based on the preceding discussion, the motion at docket 8 is DENIED.

DATED this 20th day of April 2017.

/s/ JOHN W. SEDWICK
SENIOR JUDGE, UNITED STATES DISTRICT COURT