IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH

CENTRAL DIVISION

CATHETER CONNECTIONS, INC., Plaintiff, vs. IVERA MEDICAL CORPORATION, Defendant.	ORDER AND MEMORANDUM DECISION Case No. 2:14-CV-70-TC

On May 28, 2014, Plaintiff Catheter Connections, Inc. filed its Sealed Emergency Motion for Temporary Restraining Order and Preliminary Injunction (Doc. No. 190). Catheter Connections' motion seeks to enforce its false advertising and unfair competition claims under the federal Lanham Act as well as Utah and California statutes and common law.[1] The same day the motion was filed, the court held a status conference during which the court ordered Defendant Ivera Medical Corporation to address only the threshold issue of whether Catheter Connections' four claims are barred because they are precluded by the federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301, which is administered by the Food and Drug Administration (FDA). This order addresses only that issue. For the reasons set forth below, the court holds that Catheter Connections' first claim (concerning FDA 510(k) approval) is

[1]See Lanham Act Section 43(a), 15 U.S.C. §§ 1125(a), 1116(a); Utah Code Ann. §§ 13-11a-3(1)(d), (1)(g); Utah Code Ann. § 13-5-8; Cal. Bus. & Prof. Code § 17200.

precluded, but the remaining claims are not.

BACKGROUND

Plaintiff Catheter Connections, Inc. and Defendant Ivera Medical Corporation are competitors in the medical device market for infection-control devices. The Food and Drug Administration (FDA) regulates medical devices.

The medical devices at issue here are disinfectant caps incorporated into intravenous (IV) lines that deliver fluids and drugs to patients. The devices are designed to prevent infection and, at the same time, prevent the disinfectant (typically 70% isopropyl alcohol (IPA)) from entering the plaintiff's bloodstream. Catheter Connections markets its product as DualCap. Ivera markets its product as Curos Tips and is currently marketing and selling the Rev. G model of Curos Tips.

To understand the nature of Catheter Connections' false advertising claims, the court provides a brief history of the pertinent aspects of the Curos Tips development.

Before marketing the X13 model (the predecessor to the Rev. G model, and the sale of which has since been enjoined by the court)[2] and the Rev. G. model, Ivera submitted a prototype model of the Curos Tips device—internally called X10—to the FDA for 510(k) approval to market the medical device. On November 26, 2012, the FDA issued a 510(k) clearance letter based on information related to the X10 model. The FDA, in the 510(k) clearance letter contains an "Indications for Use Statement" that provides the following:

The Curos Tips are intended for use as a disinfecting cleaner for male luer

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[2]In this case, Catheter Connections not only alleges false advertising but also patent infringement. In a separate order, this court enjoined Ivera from selling the X13 model of its Curos Tips device. Ivera has since redesigned, and now markets, the Curos Tips product, which is internally referred to as Rev. G. That model is the focus of the motion now before the court.

> connectors. Curos Tips will disinfect the male luer (3) minutes after the application and will cover the luer until removed. The effectiveness of the Curos Tips was tested in vitro against Staphylococcus aureus, Staphylococcus epidermidis, Escherichia call, Pseudomonas aeruginosa, Candida glabrata, and Dandida albicans. The Curos Tips may be used in the home or healthcare facility.

(Pl.'s Emergency Mot. & Mem. for TRO & Prelim. Inj. (Doc. No. 190) at xx, Shapiro Sealed Decl. ¶¶ 7-8 (quoting 510(k) letter) (emphasis added).)

In December 2012, Ivera began marketing and selling Curos Tips that were based on the newly designed X13 model. Ivera used the language from the 510(k) clearance letter on its Curos Tips website and product packaging for the X13 model.

On February 2, 2014, Catheter Connection filed patent infringement and unfair competition claims against Ivera in this court. It then filed a motion seeking a preliminary injunction based on its patent infringement claims. On April 24, 2014, the court enjoined Ivera from the sale of its Curos Tips male luer disinfecting caps (Model X13). (Doc. No. 98.)

After the injunction was issued, Ivera marketed a modified X13—internally referred to as "Rev. G"—as the Curos Tips product. Ivera did not obtain a 510(k) clearance from the FDA specifically based on the Rev. G model. But it represents to its customers, or at least implies, that no additional 510(k) clearance is necessary.[3]

On May 28, 2014, Catheter Connections filed its Emergency Motion for Temporary Restraining Order and Preliminary Injunction (Doc. No. 190) [hereinafter "Emergency Motion"] alleging that Ivera's advertising and sale of the new Rev. G model of its Curos Tips disinfecting

[3]Catheter Connections asserts that "[t]here can be no argument that the target audience is assuming the X10 510(k) clearance covers the Rev. G and that this is a critical part of the purchase decision." (Pl.'s Sealed Emergency Mot. & Mem. for TRO (Doc. No. 190) at 6.)

caps violates the Lanham Act as well as state unfair competition and advertising laws. In its motion, Catheter Connections seeks to enjoin Ivera from making the following false (according to Catheter Connections) representations about Rev. G in public:

1) that Rev. G does not need FDA clearance independent of the 510(k) clearance letter the FDA issued in November 2012;

2) that Rev. G keeps the disinfectant (70% isopropyl alcohol or "IPA") from leaking into the infusion line and posing a risk to the patient. (On its website and in product literature, Ivera states that "Curos Tips are designed to keep the alcohol precisely where it is needed — on the exterior of the male luer.");

3) that Ivera tested Rev. G and found it to be effective against six specific microorganisms; and

4) that the FDA has found that Rev. G is effective against six specific microorganisms.

(See Emergency Motion at 6-11.)[4]

In response to the motion, Ivera contends that no private right of action exists to challenge the above representations. Ivera reasons that Catheter Connections' claims under the Lanham Act and similar state law claims are barred because medical device testing and regulatory approval are exclusively handled by the FDA under the FDCA (which expressly authorizes the FDA to determine whether a medical device is safe and effective and what labeling should be included on the device for sale within the market).

[4]Some of Catheter Connections' papers refer to five claims, but the court can only find four that Catheter actually discusses in any substantive way.

ANALYSIS[5]

A. The Lanham Act versus the Food, Drug & Cosmetic Act (FDCA)

Section 43(a) of the Lanham Act prohibits "false or misleading description of fact, or false or misleading representation of fact" concerning the "nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities." Lanham Act § 43(a), 15 U.S.C. § 1125(a). To prevail on its Section 43(a) claim, Catheter Connections must show "(1) that defendant made material false or misleading representations of fact in connection with the commercial advertising or promotion of its product; (2) in commerce; (3) that are likely to cause confusion or mistake as to (a) the origin, association or approval of the product with or by another, or (b) the characteristics of the goods or services; and (4) injure the plaintiff." Cottrell, Ltd. v. Biotrol Int'l, Inc., 191 F.3d 1248, 1252 (10th Cir. 1999) (internal citations omitted).

Under the FDCA, the FDA has exclusive jurisdiction over approval of medical devices and courts do not have the authority to decide issues that fall under the FDA's administrative authority. To that end, the FDCA provides that no private right of action exists to enforce provisions of the FDCA because the FDA has the exclusive power and discretion to enforce the FDCA. See 21 U.S.C. § 337(a).[6]

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[5]For clarification, the court notes that although the parties use the term "preemption" in their briefs, the proper term for determining whether claims under one federal statute are barred by another federal statute (here, whether Catheter Connections' Lanham Act claims are barred by the FDCA) is "preclusion." See Pom Wonderful LLC v. The Coca-Cola Company, 189 L. Ed. 2d 141, 150 (June 12, 2014). In contrast, when analyzing whether a state law cause of action is barred by a federal statute, the term to use is "preemption." Id.

[6]There is, however, a provision that allows a private party to file a citizen petition with the FDA requesting that the FDA determine the issue. 21 C.F.R. §§ 10.25, 10.30 (2012).

Ivera contends that the first element of a claim under Lanham Act Section 43(a) ("material false or misleading representations of fact in connection with the commercial advertising or promotion of its product") may not be adjudicated by the court in this particular instance because the court would have to interpret FDA regulations to make a determination on the claims. Specifically, Ivera states that "[a]ll of [Catheter Connections'] allegations rest on Catheter Connections' assertion that the X13 and Rev. G designs required a new 510(k) application and approval." (Def.'s Opp'n (Doc. No. 207) at 6.)

Under the FDA's pre-market approval process, which must be followed when a manufacturer wants to market an original device, the medical device must be "approved" or "cleared" by the FDA before it is introduced into the market. Medical devices may be "cleared" for marketing by the FDA if the manufacturer can show that its device is "substantially equivalent" to a lawfully-marketed "predicate device" under a premarket notification submission process, resulting in a "510(k)-cleared" device. See 21 U.S.C. §§ 360(k) & 360c(i) (FDCA §§ 510(k) & 513(i)); 21 C.F.R. Part 807, Subpart E. Ivera received 510(k) clearance for its X10 model of the Curos Tips. Catheter Connections asserts, among other things, that Ivera did not receive a 510(k) clearance letter for Rev. G, and so Ivera's statements that Rev. G is approved under the FDCA is false. Ivera points to an FDA regulation that sets forth when a premarket notification (510(k)) submission is required before a modified medical device may be introduced into interstate commerce:

> The following constitute[s] significant changes or modifications that require a premarket [i.e., 510(k)] notification:
>
> > (i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or

> modification in design, material, chemical composition, energy source, or manufacturing process.

21 C.F.R. § 807.81(a)(3). The FDA allows the manufacturer to make this decision in the first instance. See, e.g., FDA, "Deciding When to Submit a 510(k) for a Change to an Existing Device" (1997), attached as Ex. B to Canal Decl. (Doc. No. 208-3); FDA, "The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry" (Oct. 4, 2002), attached as Ex. C to Canal Decl. (Doc. No. 208-4).

Catheter Connections claims that Ivera should have concluded that the modification in Rev. G "could significantly affect the safety or effectiveness of the device" and that Ivera's contrary conclusion and subsequent release of Rev. G to the market violates the FDA's 510(k) requirement. Catheter Connections then asserts that Ivera's representation—that a new 510(k) clearance letter is not needed for the Rev. G model—falsely implies to customers that the Rev. G model is safe and effective.

Ivera responds that the court would have to interpret the regulation in order to decide whether Ivera's representation— that its 510(k) letter applies to its Rev. G model—violates the Lanham Act, and that, Ivera says, interferes with the FDA's exclusive jurisdiction. Quoting PhotoMedex, Inc. v. Irwin, 601 F.3d 919 (9th Cir. 2010), Ivera notes that the claims in that case were preempted because plaintiff alleged that the defendant misrepresented that a modified device had received FDA clearance, which was an attempt to enforce a violation of the FDCA. "Because the FDCA forbids private rights under that statute, a private action brought under the Lanham Act may not be pursued when, as here, the claim would require litigation of the alleged

underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation." Id. at 924.

The Tenth Circuit has approved a general framework for courts to follow when determining whether the FDA has exclusive jurisdiction to decide claims brought under the Lanham Act:

> "Affirmative misrepresentations . . . are generally actionable under the Lanham Act, even if the product is regulated by the FDA. Most obviously, a false statement of FDA approval is actionable. It is also clear that, because no private right of action exists under the FDCA, a plaintiff may not use the Lanham Act as an alternative vehicle by which to seek redress for an FDCA violation. Moreover, claims that require direct interpretation and application of the FDCA are not properly recognized because such matters are more appropriately addressed by the FDA[.]"

Cottrell, Ltd. v. Biotrol Int'l, Inc., 191 F.3d 1248, 1254-55 (10th Cir. 1999) (emphasis added) (quoting Braintree Labs, Inc. v. Nephro-Tech, Inc., 1997 U.S. Dist. LEXIS 2372, No. 96-459-JWL, 1997 WL 94237 (D. Kan. Feb. 26, 1997), at *2)). If the circumstances "inherently require" court interpretation of the FDCA and implementing regulations, the area of inquiry is precluded. Id. at 1256.

Catheter Connections cites to the very recent United States Supreme Court decision in Pom Wonderful LLC v. The Coca-Cola Company, 189 L. Ed. 2d 141 (June 12, 2014), for the proposition that the Lanham Act overlaps with the FDCA in the areas of marketing and advertising and that its false advertising claims related to FDA approval may go forward. Pom Wonderful leaves open the possibility that Catheter Connections' claims do not intersect with the FDA's regulatory expertise.

In Pom Wonderful, "POM alleged that the name, label, marketing, and advertising of

Coca-Cola's juice blend mislead consumers into believing the product consists predominantly of pomegranate and blueberry juice when it in fact consists predominantly of less expensive apple and grape juices. That confusion, POM complained, causes it to lose sales." 189 L. Ed. 2d at 149 (internal citations omitted). The Court ultimately held that competitors may bring Lanham Act claims such as Pom Wonderful's claims challenging food and beverage labeling under Lanham Act § 43(a).

> The two statutes complement each other with respect to remedies in a more fundamental respect. Enforcement of the FDCA and the detailed prescriptions of its implementing regulations is largely committed to the FDA. The FDA, however, does not have the same perspective or expertise in assessing market dynamics that day-to-day competitors possess. Competitors who manufacture or distribute products have detailed knowledge regarding how consumers rely upon certain sales and marketing strategies. Their awareness of unfair competition practices may be far more immediate and accurate than that of agency rulemakers and regulators. Lanham Act suits draw upon this market expertise by empowering private parties to sue competitors to protect their interests on a case-by-case basis.

Id. at 152.

Here, Catheter Connections is trying to protect its interests in the market, just as Pom Wonderful was doing in the case against The Coca-Cola Company.

1. Ivera's First Representation

Catheter Connections alleges that Ivera is engaging in false advertising when it represents (or implies) that Rev. G does not need FDA clearance independent of the 510(k) clearance letter the FDA issued in November 2012. The court finds that this claim is precluded by the FDCA.

Catheter Connections points to the following "admissions" by Ivera to support its position that the court has all the facts necessary to determine that Ivera needed a new 510(k) clearance for the Rev. G model:

- Ivera's 510(k) submission was based solely on testing performed using the X10 prototype;
- the use of a threaded insert, mating plunger, and medical grade foam to inhibit the flow of IPA was stated in the 510(k) submission to be the X10's "theory of operation," an each of these design elements has admittedly been abandoned;
- the X10 had a fundamentally different design than the final product [the X13], including removal of the foam and a significant change to the shape of the plunger where it contacts the male luer; and
- Rev. G "is fundamentally different from the old design."

(Catheter Connections' Reply (Doc. No. 216) at 8.) Catheter Connections says that here, because of those admissions, the court "does not need any special scientific expertise to make the determination that the X13 and Rev. G changes 'could' significantly affect safety and efficacy." (Id.)

But the purported admissions do not answer the question of whether the design change "could significantly affect the safety or effectiveness of the device[.]" FDCA § 510(k)(i). The statements simply acknowledge that changes to the design have been made. Ivera, by making those statements, does not in any way admit that those changes could result in a change in the performance of the device that would require a new 510(k) submission. The court would still need to determine whether Ivera made the correct choice under the FDA regulations to refrain from submitting another 510(k) notice for FDA approval. That decision is within the FDA's exclusive jurisdiction.

Catheter Connections essentially argues that Ivera has not complied with FDCA Section 510(k). But as the United States Supreme Court has noted, Section 337(a) of the FDCA "leaves no doubt that it is the [FDA] rather than private litigants who are authorized to file suit for

noncompliance with the medical device provisions." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 n.4 (2001).

In Photomedex, Inc. v. Irwin, the Ninth Circuit stated that "where the FDA permits Defendants to determine whether their laser device was covered by clearance previously given to a similar device and to market their device without an affirmative statement of approval by the FDA [under FDCA Section 510(k)], we conclude that the [Lanham Act] claim by PhotoMedex may not proceed." 601 F.3d 919, 922 (9th Cir. 2010). The same situation exists here. The initial decision lay in Ivera's hands. If that decision was wrong, the next step lies with the FDA, which may enforce the section and require a new submission by Ivera.

For the foregoing reasons, the court finds that Catheter Connections' first claim under the Lanham Act—that Ivera is falsely advertising that the current Curos Tips model has FDA approval—is precluded.

2. Ivera's Second, Third, and Fourth Representations

The court finds that the second, third, and fourth claims are not barred by the FDCA. For each of those, a determination of the issues raised by Catheter Connections would not require FDA expertise and would not require the court to interpret the FDCA or FDA regulations.

In its second representation, Ivera claims that the Rev. G model keeps the disinfectant (70% isopropyl alcohol or "IPA") from leaking into the infusion line and posing a risk to the patient. On Ivera's website and in product literature, Ivera states that "Curos Tips are designed to keep the alcohol precisely where it is needed — on the exterior of the male luer." (Ex. G to Bob Rogers Decl. (Doc. No. 142-7).) In its third representation, Ivera advertises that it has tested its Curos Tip (Model Rev. G) and found it to be effective against six specific microorganisms. And,

in its fourth representation, Ivera implies that the FDA has found Rev. G to be effective against six microorganisms.

Analogizing the situation before this court to the situation in Pom Wonderful, Catheter Connections states that "[t]he nature, functionality and features of a medical device are fundamental to the attractiveness of the device to consumers, just like the nature, amount or type of fruit in a juice beverage is fundamental to the attractiveness of the beverage. It is clear from Pom Wonderful that claims based upon false statements about the nature of a regulated product are not barred by the FDCA." (Pl.'s Reply (Doc. No. 216) at 2-3.)

In claims two, three, and four, Catheter Connections focuses on the substance of Ivera's representations in the context of the medical device market and what drives buyers' purchasing decisions. Although the claims involve a medical device regulated under the FDCA, "'the simple fact that a matter touches upon an area dealt with by the FDA is not a bar to proceedings with a claim under the Lanham Act.'" Pom Wonderful LLC v. Ocean Spray Cranberries, Inc., 642 F. Supp. 2d 1112, 1118 (C.D. Cal. 2009) (quoting Mutual Pharm. Co. v. Ivax Pharms., Inc., 459 F. Supp. 2d 925, 935 (C.D. Cal. 2006)).

For the second claim, the issue of whether the Rev. G model actually keeps the IPA "on the exterior of the male luer" is "fundamental to the attractiveness" of the device. Evaluation of this claim will require consideration of facts about the function of the device, not any interpretation or application of FDA policy or regulatory requirements.

When analyzing the third claim, the question to answer (at least for the first element of a Lanham Act Section 43(a) claim) will be (1) whether Ivera tested the Rev. G model for its effectiveness on six specific microorganisms; and, if so, (2) whether the testing shows the results

Ivera touts to its potential customers. Favorable results of testing would increase the attractiveness of the device and this affects Catheter Connections' place in the market.

The fourth claim is also factually based: Catheter Connections contends that FDA could not have determined that the Rev. G model was effective against six different microorganisms because Rev. G was not tested for those microorganisms. Certainly, affirmative FDA approval of the device's effectiveness is another characteristic of the product that would attract customers. The question is not whether the FDA should have granted approval, but whether FDA made a finding of fact about the product.

Analysis of the three claims will focus on the effect such representations have on Catheter Connections, as Ivera's competitor, in the market. Accordingly, they are not precluded by the FDCA.

B. FDCA versus Utah and California Unfair Competition and False Advertising Laws

State law claims relating to medical devices are expressly preempted by the FDCA when state law would require the manufacturer to do something different from or in addition to the requirements of the FDCA and the FDA. See Riegel v. Medtronic, Inc., 552 U.S. 312, 328-30 (2008). The FDCA contains an express preemption clause barring any state law or court decision based on state law from imposing "any requirement" related to a medical device that is "different from, or in addition to" any FDA requirement, and "which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the FDCA]." 21 U.S.C. § 360k(a) (2011). However, when the duties of a manufacturer under the FDCA are parallel to the requirements of state law, the state law claims are not preempted. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996).

Catheter Connections has filed its claims under state laws based on the very same behavior it challenges under the Lanham Act: Ivera's alleged misrepresentations to consumers about the functionality, characteristics, and approval of the Rev. G model of its Curos Tips. None of the state laws are regulating medical devices. Instead, the issues to be addressed under the state laws are the same as those brought under the Lanham Act. The court's analysis of the preclusion issue applies with equal force to the state law claims. To the extent Catheter Connections' claims are co-extensive with its Lanham Act claims, the court reaches the same result.

ORDER

For the foregoing reasons, the court holds that Catheter Connections' claim about FDA 510(k) clearance is precluded and preempted by the FDCA. The remaining claims, however, are not.

Given the court's decision, the parties must finish briefing the merits of the non-barred issues raised in the injunction motion. No later than fourteen days from the date of this order, Ivera must file an opposition to the Emergency Motion concerning Catheter Connections' request for injunctive relief on its second, third, and fourth claims. Catheter Connections may file a reply no later than fourteen days after service of the opposition.

SO ORDERED this 17th day of July, 2014.

BY THE COURT:

Tena Campbell

TENA CAMPBELL
U.S. District Court Judge