UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

KURIN, INC.,

Plaintiff,

v.

MAGNOLIA MEDICAL TECHNOLOGIES, INC.,

Defendant.

Case No.: 3:18-cv-1060-L-LL

ORDER:

(1) SUSTAINING PLAINTIFF'S OBJECTION TO ORDER DENYING PLAINTIFF'S MOTION TO COMPEL [ECF No. 38]; AND

(2) GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION FOR PARTIAL JUDGMENT ON THE PLEADINGS [ECF No. 28]

Pending before the Court is Defendant Magnolia Medical Technologies, Inc.'s ("Magnolia") motion for partial judgment on the pleadings [ECF No. 28] and Plaintiff Kurin Inc.'s ("Kurin") objection to an order denying Kurin's motion to compel responses to Kurin's first set of requests for production of documents ("RFP") [ECF No. 38]. The Court shall determine these motions upon the moving papers without oral argument pursuant to Civil Local Rule 7.1.d.1. For the following reasons, Kurin's objection is SUSTAINED and Magnolia's motion is GRANTED IN PART and DENIED IN PART.

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I. Background

Kurin is a medical device engineering company and developed the Kurin Lock™ - a specimen diversion device that reduces the risk of blood culture contamination and associated false positive blood culture results. Magnolia also is a medical device company that developed, manufactures, and markets another blood collection device, the Steripath.

Magnolia began distributing the Steripath device in June 2014 and started selling it commercially about a year later. Kurin received its FDA 501(k) clearance to market the Kurin Lock™ on December 23, 2016 and launched its product around January 2017.

Kurin and Magnolia are competitors as they both market their devices to healthcare providers seeking to reduce the number of false-positive blood cultures. On May 29, 2018, Kurin filed a Complaint claiming Magnolia made false and misleading representations to consumers in its marketing of Steripath. Particularly, Kurin alleges that Magnolia's representations, that Steripath is registered and listed as a Class I device and Steripath's "Rx Only" packaging, falsely imply that Steripath has been FDA reviewed and approved. Magnolia subsequently filed a motion for partial judgment on the pleadings as to Plaintiff's Lanham Act, 15 U.S.C. § 1125(a), claims and state law claims. After its motion to compel responses to Kurin's first set of RFPs was denied by the magistrate judge (the "April 11 order"), Kurin filed an objection to the order. Specifically, Kurin contends the April 11, 2019 order was contrary to law by relying on a relevance objection that Magnolia did not explicitly raise. Kurin also contends that the magistrate judge clearly erred even assuming the relevance objection was raised. Both the motion and the objection have been fully briefed by both parties.

II. Legal Standard

The Ninth Circuit reminds us that "Rule 12(c) is 'functionally identical' to Rule 12(b)(6) and that 'the same standard of review' applies to motions brought under either rule." *Cafasso v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011) (citation omitted). A Rule 12(c) motion must demonstrate that the complaint lacks a cognizable legal theory or fails to allege facts sufficient to support such a theory. *See*

Balisteri v. Pacifica Police Dep't, 901 F.2d 696, 699 (9th Cir. 1988). A complaint that sets forth a cognizable legal theory will defeat a motion for judgment on the pleadings where it contains "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is facially plausible when the plaintiff pleads sufficient facts from which the court can reasonably infer that the defendant is liable for the misconduct alleged. *Id.* (citing *Twombly*, 550 U.S. at 556).

A party may object to a federal magistrate judge's non-dispositive discovery order within fourteen days of the order's service. *See* Fed. R. Civ. P. 72(a). The district will uphold the magistrate judge's order unless it is "clearly erroneous or contrary to law." *Id.*; 28 U.S.C. § 636(b)(1)(A). The "clearly erroneous" standard applies to the magistrate judge's factual determinations and discretionary decisions. *Grimes v. City and Cty. of San Francisco*, 951 F.2d 236, 240 (9th Cir. 1991). The clearly erroneous standard is "significantly deferential, requiring a definite and firm conviction that a mistake has been committed." *Concrete Pipe & Prods. v. Constr. Laborers Pension Trust*, 508 U.S. 602, 623 (1993); *Security Farms v. Int'l Brotherhood of Teamsters*, 124 F.3d 999, 1014 (9th Cir. 1997). However, district courts apply the "contrary to law" standard after independently reviewing a magistrate judge's legal conclusions. *Medical Imaging Centers of America, Inc. v. Lichtenstein*, 917 F. Supp. 717, 719 (S.D. Cal. 1996) ("Section 636(b)(1) . . . has been interpreted to provide for de novo review by the district court on issues of law.")

III. Discussion

Magnolia contends that Kurin's Lanham Act and state law claims should be dismissed to the extent the claims are based on the Steripath device's Class I designation and "Rx only" label because the U.S. Food and Drug Administration ("FDA") has primary jurisdiction over those issues under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C.A. § 301 et seq.; 21 C.F.R. § 700.3. Accordingly, Magnolia request that Kurin's allegations and claims be narrowed to exclude these issues.

In applying the doctrine of primary jurisdiction, courts "traditionally look for four factors identified in *General Dynamics*. Under this test, the doctrine applies where there is '(1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory scheme that (4) requires expertise or uniformity in administration.'"*Davel Commc'ns Inc. v. Qwest Corp.*, 460 F.3d 1075, 10867-87 (9th Cir. 2006) (quoting *United States v. Gen Dynamics Corp.*, 828 F.2d 1356, 1362 (9th Cir. 1987)).

a. Lanham Act

A Lanham Act cause of action grounded in false advertising requires a plaintiff to plead "an injury to a commercial interest in sales or business reputation proximately caused by the defendant's misrepresentations." *Lexmark Intern., Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 140 (2014). Both parties agree that *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102 (2014) is the leading case on FDCA preclusion. *See* Docs. 28-1, 29. *POM Wonderful* instructs that the FDCA and the Lanham Act "complement each other in major respects, for each has its own scope and purpose. Although both statutes touch on [medical device] labeling , the Lanham Act protects commercial interests against unfair competition, while the FDCA protects public health and safety." *POM Wonderful*, 573 U.S. at 115 (comparing *Lexmark Intern., Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 130 (2014) and *62 Cases of Jam v. United States*, 340 U.S. 593, 596 (1951) (citing 21 U.S.C. § 341) (other citations omitted)). The United States Supreme Court makes clear the distinct aims of the statutes complement one another as follows:

> "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 implement 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. By 'serv[ing] a distinct compensatory function that may motivate injured persons to come forward,' Lanham Act suits, to the extent they touch on the same subject matter as the FDCA, 'provide incentives' for manufacturers to behave well. *See Wyeth v. Levine*, 555 U.S. 555, 579 (2009). Allowing Lanham Act suits takes advantage of synergies among multiple methods of regulation. This is quite consistent with the congressional design to enact two different states, each with its own mechanisms to enhance the protection of competitors and consumers."

POM Wonderful, 573 U.S. at 115-116. This Court recognizes that the *POM Wonderful* court noted that analysis of other types of labels, i.e. drug labeling, may be different than food and beverage labeling due to statutory requirements. *Id.* at 116. The *POM Wonderful* court reasoned, however, that "if Lanham Act claims were to be precluded then commercial interests—and indirectly the public at large—could be left with less effective protection[.]" *Ibid.* Notwithstanding, the *POM Wonderful* court reinforced that actions in direct conflict with an FDA policy choice are barred. *Id.* at 120 (citing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 875 (2000) (barring a Lanham action where "the agency enacted a regulation deliberately allowing manufacturers to choose between different options[]")).

Magnolia asserts Kurin's Lanham Act claim is precluded to the extent it relies on allegations that the Steripath device is misclassified. Specifically, Magnolia challenges paragraphs 22-23 of the Complaint claiming Kurin's false advertising allegations related to the Steripath's Class I medical device status requires the Court to improperly interpret and enforce FDA regulations. The Court agrees. Magnolia demonstrated that the Steripath's classification is an issue requiring resolution as it is at the crux of Kurin's misrepresentation allegation. *See* Doc. 1 at ¶¶ 22-23(a)-(b). Magnolia also highlighted that Congress placed classification and re-classification of medical devices within the FDA's regulatory authority under the FDCA's comprehensive regulatory scheme. *See* 21 U.S.C.A. § 360c. Upon review of the statute, the Court finds that expertise and uniformity

is furthered under the FDCA as the statute established panels of experts for the purpose of securing recommendations with respect to classification of devices. *See* 21 U.S.C.A. § 360c(b). As such, the Court finds that each element of the primary jurisdiction doctrine has been satisfied. Accordingly, Kurin's Lanham Act claim is dismissed to the extent it is based on allegations that the Steripath device is misclassified. Notwithstanding, to the extent Kurin's allegations merely infer that the market or consumers has been misled by Magnolia's representation that the Steripath device is "listed and registered" a Class I device, those allegations remain. *See Innovative Health Solutions, Inc. v.DyAnsys, Inc.*, 2015 WL 2398931, at *7 (N.D. Cal. May 19, 2015) (finding plaintiff's Lanham Act claims are not precluded where plaintiff alleges that defendants falsely represented that they obtained FDA approval). Accordingly, Magnolia's motion is GRANTED IN PART and DENIED IN PART on this ground.

Magnolia also asserts that Kurin's Lanham Act claim is precluded to the extent it relies on Kurin's "Rx Only" label allegations. Specifically, Magnolia contends that Kurin's Lanham Act claim is foreclosed because the FDCA requires Magnolia to include the "Rx Only" statement on its device labeling. In opposition, Kurin contends that the "Rx Only" allegations merely require the Court to determine (1) whether the "Rx Only" label misleads consumers to believe the Steripath device is FDA approved and (2) whether any implication that the Steripath device was FDA approved caused increased sales of the device. As an initial matter, the Court finds that Kurin, as Magnolia's competitor, is entitled to bring a Lanham Act claim based on the market or consumers possibly being misled by Magnolia's "Rx Only" label. The Court recognizes that any remedial measures involving the label is likely in the FDA's domain. *See* 21 U.S.C. § 352; *see also* 21 C.F.R. § 801.109. Notwithstanding, the issue Kurin raises to be resolved, market and/or consumer reliance, is not within the FDA's primary jurisdiction. As such, Kurin's Lanham Act claim grounded in Magnolia's "Rx Only" label is not precluded by the FDCA. The Court also finds that Kurin's "Rx Only" allegations are conclusory and will not be considered to the extent the allegations fail to provide facts. *See* Doc. 1 at ¶¶ 25-26. Accordingly,

Magnolia's motion is GRANTED IN PART and DENIED IN PART on this ground.

b. State Law Claims

Magnolia then asserts that Kurin's state law claims are preempted by the FDCA for the reasons as stated above. The Court agrees with Magnolia that the state law claims are limited to the same extent as Plaintiff's Lanham Act claims. Accordingly, Kurin's state law claims are precluded to the extent they rely on the following allegations: (1) the Steripath device is misclassified as a Class I device; (2) the "Rx Only" label suggests the Steripath device is only available by prescription, to the extent no facts are alleged; and (3) the "Rx Only" implies the Steripath device has been FDA reviewed and approved, to the extent no facts are alleged.

c. Objections to Discovery Order

On April 11, 2019, Judge Linda Lopez, United States Magistrate Judge, denied Kurin's motion to compel Magnolia to produce documents responsive to Kurin's Request For Production of Documents ("RFP") Numbers 5-10. *See* Doc. 37. Kurin made the following RFP requests:

- RFP No. 5: Documents relating to any statement by Kurin that the Steripath device is available by prescription only.
- RFP No. 6: Documents relating to any evaluation regarding the FDA classification of the Steripath device.
- RFP No. 7: Documents relating to the regulation of the Steripath device by the FDA.
- RFP No. 8: Communications between Magnolia and the FDA relating to the Steripath device.
- RFP No. 9: Documents relating to any determination that the Steripath device is a Class I device.
- RFP No. 10: Documents relating to a determination that the Steripath device is not a Class II device.

In response to Kurin's RFPs, Magnolia objected to each request on one or more of the following bases: (1) overbroad and unduly burdensome; (2) not proportional to the needs of the case with respect to time and geographic scope; (3) attorney-client privilege, attorney work product doctrine, or any other applicable privilege or immunity; (4) preemption or preclusion to the extent the information sought is subject to the FDCA. *See* Doc. 34-1. In denying Kurin's motion to compel, Judge Lopez found that Kurin did not adequately demonstrate the relevance of the evidence being sought in discovery. Doc. 37 at 5. Currently at issue is Kurin's objection to that finding.

Kurin asserts Judge Lopez's finding that relevance was not demonstrated is contrary to law because Magnolia did not raise a relevance objection. "When ruling on a motion to compel, courts in this district 'generally consider[] only those objections that have been timely asserted in the initial response to the discovery request and that are subsequently reasserted and relied upon in response to the motion to compel.'" *Andreoli v. Youngevity Int'l Inc.*, 2018 WL 6334284, at * 6 (S.D. Cal. Dec. 5, 2018) (other citations omitted). "If a party fails to continue to assert an objection in opposition to a motion compel, courts deem the objection waived." *SolarCity Corp. v. Doria*, 2018 WL 467898, at *3 (S.D. Cal. Jan. 18, 2018). While the issue of relevance was raised in Magnolia's opposition to Kurin's motion to compel, the objection was not raised in its initial response to Kurin's RFPs. As such, the Court agrees with Kurin that the magistrate judge's relevance finding was contrary to law as it considered an objection not raised in Magnolia's initial response to Kurin's RFPs. Accordingly, Kurin's objection to the magistrate judge's order is SUSTAINED.

Notwithstanding, the Court affirms Judge Lopez's decision to not order the production of responsive documents. Judge Lopez found that Kurin's RFPs Nos. 5-10 were not aimed to produce "marketing documents or other documents directed to consumers. The Requests are also not limited to internal documents relating to consumer outreach. None of the Requests even reference consumers." Doc. 37 at 5. Judge Lopez noted that, read together, Kurin's RFPs sought "every document regarding the FDA

classification and regulation of the Steripath device and any statement made by [Magnolia] that the Steripath device is available by prescription only[.]" *Id.* at 6. However, Kurin contends the universe of documents that are discoverable under Rule 26 is not limited to documents directed to consumers. Doc. 38-1 at 6. Rule 26(b)(1) defines the scope of discovery as "any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case." Fed. R. Civ. P. 26(b). Kurin has repeatedly represented that the Steripath device's classification and regulation by the FDA is not at issue in this action. As such, the remaining issues in this case concern whether (1) Magnolia's representation that the Steripath device is "registered and listed with the FDA" or (2) its "Rx Only" label misled the market or consumers to believe that the device has been approved, cleared, or reviewed by the FDA. *See* Doc. 29 at 19. Due to the Court's primary jurisdiction finding above and Kurin's concession, discovery of documents responsive to RFPs Nos. 5-10 is denied. *Oppenheimer v. Fund, Inc. v. Sanders*, 437 U.S. 340, 352 (1978) ("[I]t is proper to deny discovery of matter that is relevant only to claims or defenses that have been stricken . . . unless the information is otherwise relevant to issues in the case."). Moreover, the requests lack the proportionality of which the Federal Rules demand. Accordingly, the Court is not left with a firm conviction that a mistake was made when Judge Lopez found the documents sought to be discovered did not reasonably assist Kurin in evaluating the case given the issues left before the Court. Therefore, the Court finds that Judge Lopez's finding was not clearly erroneous. Accordingly, Kurin's request for an order compelling Magnolia to produce documents responsive to RFPs Nos. 5-10 is DENIED.

IT IS SO ORDERED.

Dated: October 23, 2019

Hon. M. James Lorenz
United States District Judge