JS-6

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

NUTRITION DISTRIBUTION LLC, an Arizona Limited Liability Company, Plaintiff, v. IRONMAG LABS, LLC, a Nevada Limited Liability Company, ROBERT DIMAGGIO, an individual, and DOES 1 through 10, inclusive, Defendants.	CASE NO. CV 15-8233-R ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

Before the Court is Defendants' Motion to Dismiss Plaintiff's First Amended Complaint (Dkt. No. 14), which was filed on February 26, 2016. Although this Court previously denied the parties' stipulation for Plaintiff to file a First Amended Complaint (Dkt. No. 12), Plaintiff's fourth cause of action will still be addressed since its outcome has no effect on the Court's ruling. This matter was taken under submission on March 30, 2016.

Plaintiff's complaint, in short, alleges that Defendants made statements about its products that are false or misleading based on provisions of the Federal Food, Drug, and Cosmetic Act

("FDCA"), and that are contrary to and violate provisions of the FDCA concerning "dietary supplements," and that those statements violate the Lanham Act and California's Business and Professions Code. While Plaintiff argues that Defendants are attempting to couch Plaintiff's false advertising and unfair competition claims "as a private enforcement action of the FDCA," there are times in which some Lanham Act suits might be precluded by the FDCA. *JHP Pharm., LLC v. Hospira,* Inc., 52 F. Supp. 3d 992, 998 (C.D. Cal. 2014). For example, the Ninth Circuit held, in *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010), that "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." In such circumstances, those claims would require the expertise of the FDA to resolve.

Plaintiff's complaint alleges that Defendants' products, OSTA RX and Super DMZ 4.0 are falsely advertised as safe dietary supplements because they instead contain a "new drug" or "prescription drug" as defined by the FDCA and are thus unsafe unless taken under the direction of a medical professional. The alleged "new drug" or "prescription drug" ingredient identified by Plaintiff is Ostarine; however, Defendants rightfully assert that the FDA has yet to make a final determination under the FDCA about whether Ostarine is in fact a "new drug." As the Ninth Circuit has previously held, in cases requiring determinations of technical and scientific questions, a "district court should decline to review anything less than a final administrative determination on the classification of the product." *Dietary Supplemental Coal., Inc. v. Sullivan*, 978 F.2d 560, 563 (9th Cir. 1992).

Defendants' correctly argue that in the absence of a final determination by the FDA, Plaintiff's claims necessarily fall under the primary jurisdiction of the FDA. Under the primary jurisdiction doctrine, a court, though having jurisdiction to hear the complaint, may in some situations "refer" the matter to an administrative agency for resolution of a particular technical issue. *See Reiter v. Cooper*, 507 U.S. 258, 268 (1993). 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." *United States v. Gen. Dynamics Corp*., 828 F.2d 1356, 1362 (9th Cir. 1987).

Without a final determination or any clear statement by the FDA on this issue, the Court or a jury, would have to apply the FDCA definitions to the substances at issue to determine whether OSTA RX and Super DMZ 4.0 are or contain a new or prescription drug that may not be sold or included in a dietary supplement. Such an expedition requires expertise and uniformity in administration, not practicable through the courts. *See Astiana v. Hain Celestial Grp., Inc*., 783 F.3d 753, 760 (9th Cir. 2015). "The determination of whether a drug is "new," and whether it can be lawfully marketed under the FDCA, involves complex issues of history, public safety, and administrative priorities that Congress has delegated exclusively to the FDA. *JHP Pharm*., 52 F. Supp. 3d at 1004. Additionally, whether Defendants' products are "misbranded" as dietary supplements requires the same type of technical determination as whether an ingredient constitutes a new or prescription drug. The same is true of Plaintiff's allegations that Defendants engaged in false advertising because of their statements and omissions about the health effects of Defendants' products.

Plaintiff's next allegation that Defendants acted "illegally" in advertising and selling its products because they contain an ingredient "not legal' in dietary supplements under the FDCA likewise requires a final determination by the FDA. "[U]nlike a mere determination that a drug is or is not FDA-approved, the allegation that the drugs are being sold *unlawfully* is an issue that would require a more complex finding from the agency." *JHP Pharm*., 52 F. Supp. 3d at 1003 (emphasis in original). If the Plaintiff were to pursue the matter with the FDA through its administrative procedures and obtain a clear statement from the agency that the Defendants are selling their products illegally, and if the Defendants continued to falsely advertise that their products complied with the law, then a federal court could hear a Lanham Act claim for false advertising. *See id*. at 1004.

Plaintiff's second and third claims for relief for unfair competition and false advertising under California Business and Professions Code sections 17200 et sq. and 17500 et seq. are based on the same violations of the FDCA supporting Plaintiff's Lanham Act claim. Accordingly,

because Plaintiff's state law claims are indistinguishable from the Lanham Act claim, they are also precluded by the primary jurisdiction doctrine.

Plaintiff's final claim in its First Amended Complaint is a claim for violation of the Civil Racketeer Influenced and Corrupt Organizations Act ("RICO"). While the Court denied the parties' stipulation for Plaintiff to file a First Amended Complaint, the Court will nevertheless discuss this final claim as it does not affect the outcome of this Court's ruling. In 18 U.S.C. § 1964(c), RICO provides a private right of action for damages to "[a]ny person injured in his business or property by reason of a violation," as pertinent here, of § 1962(c), which makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate … in the conduct of such enterprise's affairs through a pattern of racketeering activity." Although RICO is to be liberally construed, not all injuries are compensable thereunder; RICO standing requires compensable injury and proximate cause. *Newcal Indus., Inc. v. Ikon Office Sol*., 513 F.3d 1038, 1055 (9th Cir. 2008). RICO does not provide a cause of action for all types of injury to property interests, but only for injuries resulting in concrete financial loss. *Mattel, Inc. v. MGA Entm't, Inc.*, 782 F. Supp. 2d 911, 1019 (C.D. Cal. 2011). It is the plaintiff's burden to substantiate "some tangible financial loss" that corresponds with the loss of that business or property interest. *Id*. Here, Plaintiffs have failed to sufficiently allege any concrete loss and instead simply assert that Defendants' business has diverted customers from Plaintiff. With a complete lack of any stated tangible financial loss, Plaintiff has failed to meet its burden in establishing that Defendants' conduct was the proximate cause of its alleged injury.

IT IS HEREBY ORDERED that Defendants' Motion to Dismiss is GRANTED. (Dkt. No. 14).

Dated: April 6, 2016.

MANUEL L. REAL
UNITED STATES DISTRICT JUDGE