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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

World Nutrition Incorporated, Plaintiff, v. Advanced Enzymes USA, et al., Defendants.	No. CV-19-00265-PHX-GMS **ORDER**
AST Enzymes, Counter-claimant, v. World Nutrition Incorporated, Counter-defendant.	

Pending before the Court is Defendant/Counter-claimant Advanced Supplementary Technologies Corp.'s ("AST") Motion for Leave to Amend, (Doc. 105), and Plaintiff/Counter-defendant World Nutrition Incorporated ("WNI") and Counter-defendant Ryuji Hirooka's Motion to Dismiss Counter-claimant Cal-India Foods International's ("Specialty") (collectively, "Counter-defendants") Counterclaim, (Doc. 114). For the following reasons, the Motion for Leave to Amend is granted and the Motion to Dismiss is granted in part and denied in part.

BACKGROUND

WNI is engaged in the business of selling nutraceuticals, including Vitalyzm, an enzyme product. Specialty manufactures custom formulated enzymes and sells its products to AST, a direct competitor of WNI. WNI alleges that Specialty and AST falsely state that their products contain enteric-coated Serrapeptase and enteric-coated Nattokinase.

On November 21, 2019, AST asserted a Counterclaim against WNI, alleging that WNI falsely advertised that its products have some enteric coating, misrepresented the efficacy of its liquid gelcap products, falsely advertised on a website, and that WNI engaged in unfair competition. (Doc. 49.) Later, on June 25, 2020, AST filed its First Amended Counterclaim to add Hirooka, WNI's founder, as a Counter-defendant. (Doc. 84.) On December 18, 2020, Specialty also asserted a Counterclaim against Counter-defendants, alleging that WNI falsely advertises compliance with Good Manufacturing Practice ("GMP") standards and engaged in unfair competition. (Doc. 109.) In addition, as relevant here, on January 17, 2020, the Court issued a case management order which set the deadline for amended pleadings as 60 days from the date of the order. (Doc. 62.)

AST now moves to amend its First Amended Counterclaim to include new information that provides grounds for asserting a new count of false advertising under the Lanham Act and an additional basis for its unfair competition claim. (Doc. 105.) Counter-defendants also move to dismiss Specialty's Counterclaim against them. (Doc. 114.)

DISCUSSION

I. Leave to Amend

A. Legal Standards

Requests to amend a Rule 16 Order are governed by Rule 16(b)'s "good cause" standard. *Johnson v. Mammoth Recreations Inc.*, 975 F.2d 604, 609 (9th Cir. 1992). This standard "primarily considers the diligence of the party seeking the amendment." *Id.*

Leave to amend is further governed by Federal Rule of Civil Procedure 15(a), which provides that leave to amend shall be freely given when "justice so requires." Fed. R. Civ.

P. 15(a). "But a district court need not grant leave to amend where the amendment: (1) prejudices the opposing party; (2) is sought in bad faith; (3) produces an undue delay in litigation; or (4) is futile." *AmerisourceBergen Corp. v. Dialysist W., Inc.*, 465 F.3d 946, 951 (9th Cir. 2006). Leave to amend lies within "the sound discretion of the trial court"; however, this Circuit has instructed that Rule 15's policy favoring amendment "should be applied with extreme liberality." *DCD Programs, Ltd. v. Leighton*, 833 F.2d 183, 186 (9th Cir. 1987). The party opposing amendment bears the burden of establishing futility or one of the other permissible reasons for denying a motion to amend. *Angel Jet Servs., L.L.C. v. Raytheon Health Benefits Plan*, No. 2:10-CV-01385-PHX-JAT, 2011 WL 744917, at *2 (D. Ariz. Feb. 25, 2011).

B. Analysis

First, AST has demonstrated good cause to amend the Rule 16 Order. AST's discovery of new information, which forms the basis for its proposed amendment, constitutes good cause for amendment. *See, e.g.*, *Story v. Midland Funding LLC*, No. 3:15-cv-0194-AC, 2016 WL 5868077, at *2 (D. Or. Oct. 7, 2016) ("Discovery of new information after the deadline for amended pleadings passes is a potential basis for good cause to modify [a] scheduling order."). Additionally, AST demonstrated diligence in seeking the amendment. AST asserts that, after analyzing a meet and confer letter sent by WNI's counsel on October 27, 2020, it determined that it had a sufficient basis to amend its First Amended Counterclaim and that it sent a completed draft of its proposed Second Amended Counterclaim to WNI on November 17, 2020. (Doc. 105 at 6.) AST further asserts that five days after WNI indicated it would not stipulate to its proposed Second Amended Counterclaim, AST moved for this amendment. *Id.* at 7. As a relatively short amount of time has passed since AST determined it had a sufficient basis for the amendment, and WNI does not dispute that AST meets Rule 16(b)'s good cause standard, the Court finds that Rule 16(b)'s standard is met.

Further, WNI has not met its burden of establishing futility as a basis for defeating the amendment. "[L]eave to amend may be denied . . . if amendment of the complaint

would be futile." *Dakota Territory Tours ACC v. Sedona-Oak Creek Airport Auth. Inc.*, 383 F. Supp. 3d 885, 899 (D. Ariz. 2019) (quoting *Albrecht v. Lund*, 845 F.2d 193, 195 (9th Cir. 1988)). "A proposed amendment is futile if it fails to state a cognizable claim and would be subject to dismissal under Rule 12(b)(6)." *Simms v. DNC Parks & Resorts at Tenaya, Inc.*, No. 1:13-CV-2075 SMS, 2015 WL 1956441, at *2 (E.D. Cal. Apr. 29, 2015) (citing *Cervantes v. Countrywide Home Loans, Inc.*, 656 F.3d 1034, 1041 (9th Cir. 2011)).

To survive a Rule 12(b)(6) motion to dismiss, a plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). A plaintiff must set forth "the grounds of his entitlement to relief," which "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action." *Twombly*, 550 U.S. at 555. Factual allegations are accepted as true, but legal conclusions are not. *Iqbal*, 556 U.S. at 678. In the futility context, however, all inferences should be made in favor of granting leave to amend. *Angel Jet Servs.*, 2011 WL 744917, at *2 (citing *Griggs v. Pace Am. Grp., Inc.*, 170 F.3d 877, 880 (9th Cir.1999)).

In *POM Wonderful LLC v. Coca-Cola Co.*, the Supreme Court held that neither the Food, Drug, and Cosmetic Act ("FDCA") nor the Lanham Act "forbids or limits Lanham Act claims challenging labels that are regulated by the FDCA." 573 U.S. 102, 113 (2014). "The Lanham Act and the FDCA complement each other in major respects, for each has its own scope and purpose . . . the Lanham Act protects commercial interests against unfair competition, while the FDCA protects public health and safety." *Id.* at 115. However, the Court cautioned that an action may be barred where the grounds for the action directly conflict with a Food and Drug Administration ("FDA") policy choice. *Id.* at 120.

Prior to the Supreme Court's issuance of *POM Wonderful*, the Ninth Circuit held in *PhotoMedex, Inc. v. Irwin* that "a private action brought under the Lanham Act may not be pursued when . . . 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." 601 F.3d 919, 924 (9th Cir. 2010). The Ninth Circuit also commented on when the FDCA would not bar an action:

> If, for example, it was clear that an affirmative statement of approval by the FDA was required before a given product could be marketed and that no such FDA approval had been granted, a Lanham Act claim could be pursued for injuries suffered by a competitor as a result of a false assertion that approval had been granted.

Id. at 924–25.

The precedential value of *PhotoMedex* after *POM Wonderful* is not entirely clear. *See ThermoLife Intern., LLC v. Gaspari Nutrition Inc.*, 648 Fed. Appx. 609, 612 (9th Cir. 2016) (declining to rule on the precedential value of *PhotoMedex* after *Pom Wonderful*). However, in reconciling the two, courts have found that actions may go forward where the FDA's expertise is not required. *See, e.g., JHP Pharms., LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992, 1000 n.5, 1004 (C.D. Cal. 2014) (finding that claims were likely precluded by the FDCA where they "directly implicate the FDA's rulemaking authority," are not "binary factual determinations," or involve an issue where the FDA has taken "positive regulatory action"); *Genus Lifesciences Inc. v. Lannett Co.*, No. 18-cv-07603-WHO, 2019 WL 4168958, at *3 (N.D. Cal. Sept. 3, 2019) ("Courts can evaluate Lanham Act claims that do not require specialized knowledge or interpretation of the FDCA's requirements") (quoting *Belcher Pharm., LLC v. Hospira, Inc.*, No. 17-cv2353, 2018 WL 4643292, at *4 (M.D. Fla. Apr. 9, 2018)); *Allergan USA Inc. v. Imprimis Pharms., Inc.*, No. SA CV 17-1551-DOC (JDEx), 2017 WL 10526121, at *7 (C.D. Cal. Nov. 14, 2017) ("[T]he preclusion question turns on the specific nature of the claim in question—only claims where the law is unclear and the FDA's particular expertise or rulemaking authority is required as precluded by the FDCA.").

Here, AST's proposed Second Amended Counterclaim alleges that Counter-defendants falsely advertise, in violation of the Lanham Act, that their products are compliant with GMP standards. (Doc. 105–3). GMP standards, which receive their

authority from the FDCA, govern food and dietary supplement safety. *See, e.g.*, 21 C.F.R §§ 110, 111, 117. The proposed Second Amended Counterclaim alleges the following specific violations: (1) GMP standards require quality control operation but WNI "has openly admitted that 'WNI does not currently have its own quality control process;'" (2) WNI maintains "almost no documentation" despite GMP's documentation requirements; (3) GMP standards require specifications but "WNI denies the existence of any specifications altogether;" (4) in violation of GMP's requirement to retain labels under appropriate conditions "WNI did not have labels for WNI products as recent as December 2019 and [WNI] stated 'WNI does not have any other historical labels,' besides those *currently* in use;" and (5) GMP requires participants to ensure the quality control operations of the participants before it in the supply chain but WNI has not provided any supporting documentation for its representation that its vendors, Sunsho Pharmaceuticals and Enzymology Research Center, follow GMP standards. (Doc. 105–3 ¶¶ 63–64, 69, 71, 73, 75.)

As AST alleges basic, fundamental failure to follow GMP standards, it is plausible that the determination of whether Counter-defendants violated the GMP does not require the FDA's expertise. Other than arguing that there is no private right of action to enforce the FDA or its regulations, WNI does not explain why resolution of AST's proposed Second Amended Counterclaim would improperly intrude on the FDA's expertise. (Doc. 108.) Accordingly, WNI has not met its burden of showing futility. *See, e.g.*, *Allergan USA Inc.*, 2017 WL 10526121, at *8 ("Because Imprimis's alleged conduct clearly violates the plain text of the statute, the question of legality in this case does not implicate the FDA's rulemaking authority.").

II. Motion to Dismiss

A. Legal Standard

To survive dismissal for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), a complaint must contain more than a "formulaic recitation of the elements of a cause of action"; it must contain factual allegations sufficient to "raise the

right of relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). When analyzing a complaint for failure to state a claim, "allegations of material fact are taken as true and construed in the light most favorable to the non-moving party." *Smith v. Jackson*, 84 F.3d 1213, 1217 (9th Cir. 1996). However, legal conclusions couched as factual allegations are not given a presumption of truthfulness, and "conclusory allegations of law and unwarranted inferences are not sufficient to defeat a motion to dismiss." *Pareto v. F.D.I.C.*, 139 F.3d 696, 699 (9th Cir. 1998).

B. Analysis

1. Standing

In its response to the Motion to Dismiss, Specialty does not address Counter-defendants' argument that Specialty lacks standing to maintain its Lanham Act and unfair competition claims. Failure to respond to a motion "may be deemed a consent to the denial or granting of the motion and the Court may dispose of the motion summarily." LRCiv. 7.2(i); *see also Papasan v. Dometic Corp.*, No. 16-cv-02117-HSG, 2017 WL 4865602, at *18 (N.D. Cal. Oct. 27, 2017) (listing cases construing silence as a concession). Accordingly, Specialty's Lanham Act claim is dismissed.

The Court does not dismiss Specialty's unfair competition claim, however, because Counter-defendants' analysis appears to only address whether standing is appropriate for the Lanham Act claim and focuses solely on the zone of interest test articulated in *Lexmark International, Inc. v. Static Control Components, Inc.*, 572 U.S. 118 (2014). (Doc. 114 at 4–9.) The Ninth Circuit has held that the zone of interest test only applies to statutory causes of action, which Specialty's unfair competition claim is not. *See Sierra Club v. Trump*, 963 F.3d 874, 893 (9th Cir. 2020). Therefore, Specialty's failure to respond to the standing argument does not result in dismissal of the unfair competition claim.

2. Preclusion

The same rules outlined in Section I(b) apply in determining whether Specialty is precluded from basing its unfair competition claim on violations of GMP standards. The

GMP violations that Specialty alleges are also the same as AST's. (Doc. 109 ¶¶ 10–38.)

The Court finds that Counter-defendants have failed to show that Specialty's unfair competition claim is precluded. As discussed above, it is plausible that Specialty's allegations of basic, fundamental failure to follow GMP standards do not require the FDA's expertise. Counter-defendants list several sections of the GMP and argue that the "federal regulations governing good manufacturing practices for dietary supplements are detailed and extensive" but do not address why the specific violations Specialty complains of would require expertise or inappropriate interpretation. (Doc. 128 at 5–7.) Accordingly, Counter-defendants' motion to dismiss Specialty's unfair competition claim is denied.[1]

CONCLUSION

For the following reasons, AST's request for leave to amend is granted. Additionally, Specialty's Lanham Act claim is dismissed but its unfair competition claim remains. Accordingly,

IT IS THEREFORE ORDERED that Defendant/Counter-claimant AST's Motion for Leave to Amend First Amended Counterclaim (Doc. 105) is **GRANTED.** AST shall file and serve the Second Amended Counterclaim on all parties pursuant to Rule 15 of the Federal Rules of Civil Procedure within fourteen (14) days of the filing of this Order.

IT IS FURTHER ORDERED that Plaintiff/Counter-defendant WNI and Counter-Defendant Hirooka's Motion to Dismiss Counterclaimant Cal-India Food International's Counterclaim (Doc. 114) is **GRANTED** in part and **DENIED** in part as follows:

1. The Lanham Act claim is dismissed against both Counter-defendants without prejudice.

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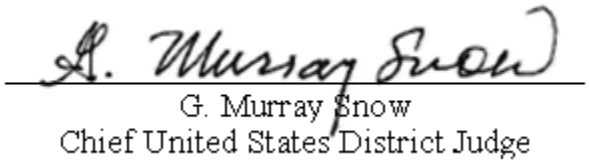
[1] Counter-defendants note that the FDA is still investigating WNI. (Doc. 114 at 11.) The warning letter indicates that the FDA's investigation relates to WNI representing certain products as drugs, not whether WNI is properly following GMP guidelines. (Doc. 110, Ex. 3.) Accordingly, based on the information contained in Specialty's Counterclaim, litigating Specialty's claim does not appear to intrude on an FDA investigation.

2. Counter-defendants' Motion is denied with respect to the unfair competition claim.

Dated this 18th day of February, 2021.



G. Murray Snow
Chief United States District Judge