# IN THE UNITED STATES DISTRICT COURT

## FOR THE DISTRICT OF HAWAII

| person,   | ) CIVIL NO. 13-00635 LEK-KSC<br>) |
|---|-----------------------------------|
| Plaintiff,  | )                                 |
| vs.   | )                                 |
| USPlabs, LLC, a Texas corporation and GNC Holdings, Inc., a Pennsylvania corporation, | )<br>)<br>)<br>)                  |
| Defendants.   | )<br>)                            |

# ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S COMPLAINT

Before the Court is USPlabs, LLC ("USPlabs") and GNC Holdings, Inc.'s ("GNC," collectively "Defendants") Motion to Dismiss Plaintiff's Complaint ("Motion"), filed on May 21. 2014. [Dkt. no. 36.] Plaintiff Everine Van Houten ("Plaintiff") filed her memorandum in opposition on July 30, 2014, and Defendants filed their reply on August 25, 2014. [Dkt. nos. 40, 41.] This matter came on for hearing on September 8, 2014. After careful consideration of the Motion, supporting and opposing memoranda, and the arguments of counsel, Defendants' Motion is HEREBY GRANTED IN PART AND DENIED IN PART for the reasons set forth below.

# **BACKGROUND**

Plaintiff filed her Complaint on November 19, 2013, asserting diversity jurisdiction pursuant to 28 U.S.C. § 1332.

## [Complaint at $\P$ 2.2.]

Plaintiff is a Hawai`i resident who purchased two containers of OxyElite Pro ("the Product"), in tablet form, on or about February 5, 2013 at a GNC store in Hilo, Hawai`i. With her purchase, she received two sample-size containers of another formulation of the Product. She consumed both during the months that followed. In March 2013, she began to experience abdominal pains, nausea, fatigue, and muscle aches. Her symptoms recurred throughout the summer, and she was hospitalized in August. [Id. at ¶¶ 1.1, 5.6-5.7.] Plaintiff was eventually "diagnosed with acute hepatitis due to an unknown cause." [Id. at ¶ 5.7.]

The Complaint alleges that Plaintiff "suffered injuries, including acute non-viral hepatitis as a result of consumption of" the Product, which "was manufactured, distributed, and sold by Defendant [USPlabs], through Defendant GNC stores in Hawai`i." [Id. at ¶ 3.1.] In addition, "[a]s a result of her consumption of the Product, Plaintiff experienced hepatic injury and associated symptoms including pain, fatigue, malaise, nausea, anorexia which required multiple medical treatments [and] hospitalization, and possible long-term liver damage." [Id. at ¶ 3.2.]

Plaintiff alleges that USPlabs

is a Texas based manufacturer of a wide variety of dietary supplements, including specifically OxyElite Pro . . . , a protein supplement marketed and sold as beneficial for muscle increase and

weight loss. OxyElite Pro was manufactured by Defendant [USPlabs] in several formulations, and sold in both power [sic] and tablet form. As stated by Defendant [USPlabs], several formulations of the Product has [sic] now been recalled by it after epidemiological and traceback investigation by the U.S. Food and Drug Administration ("FDA") and the Centers for Disease Control ("CDC") showed that use of the Product has been associated with serious adverse health consequences, namely serious liver damage and/or acute liver failure.

[Id. at ¶ 1.2 (citation omitted).] Plaintiff alleges that GNC "knowingly distributed and sold the Product in GNC retail stores locations in the State of Hawaii." [Id. at ¶ 1.3.]

Plaintiff states that, on September 9, 2013, the State of Hawai'i Department of Health ("DOH") learned about seven cases of previously healthy patients who developed "severe acute hepatitis and sudden liver failure of unknown cause." [Id. at ¶ 5.1.] All seven patients consumed the Product before the onset of their illnesses. According to Plaintiff, DOH issued a public health alert and, as of the filing of the Complaint, forty-five patients responded. Of the forty-five, twenty-four (including the original seven) have acute hepatitis and used the Product within sixty days prior to onset. [Id. at ¶¶ 5.1-5.2.] Plaintiff states that she saw the public health advisory and has been interviewed by DOH about her use of the Product and her liver injuries. [Id. at ¶ 5.8.]

On or about October 11, 2013, the FDA notified USPlabs that it may deem the versions of the Product that contain

aegeline<sup>1</sup> to be "adulterated because they contain a new dietary ingredient for which there was inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury." [Id. at ¶ 5.3.]

On November 9, 2013, USPlabs voluntarily recalled all versions of the Product. According to the Complaint, in conjunction with the recall, "[t]he FDA indicated that epidemiological evidence showed that use of these products has been associated with serious adverse health consequences, namely serious liver damage or acute liver failure, concentrated in Hawaii." [Id. at ¶ 5.4.] According to the Complaint, USPlabs stated that the recalled products contained aegeline, which "is not approved by the FDA as a dietary supplement." [Id. at ¶ 5.5.] Plaintiff alleges that USPlabs initiated the recall "after it was notified by the FDA that its OxyElite products had been linked to cases of liver injury in Hawai`i and that there was a reasonable probability that the products were adulterated."

Plaintiff alleges the following claims against

Defendants: strict liability ("Count I"); negligence

("Count II"); and breach of warranties ("Count III").

 $<sup>^{1}</sup>$  According to the Complaint, aegeline is "a synthesized version of a natural extract from the Bael tree." [Complaint at ¶ 5.5.]

Count I alleges, inter alia, that the Product "was unsafe for human consumption and caused hepatic injury." [Id. at ¶ 6.3.] Further, "the Product that the Defendants manufactured and sold to Plaintiff was in a condition that Plaintiff had not contemplated, and was in a condition that rendered the Product unreasonably dangerous for its reasonably foreseeable use."

[Id.] Count I also alleges that the Product was expected to reach Plaintiff and be consumed by her, and that she "used the Product in the manner expected and intended." [Id. at ¶ 6.4.]

Count II alleges, inter alia, that:

Defendants were negligent in manufacturing, distributing, and selling a food Product that was adulterated, not fit for human consumption, and not reasonably safe because it contained an ingredient injurious to human health and because adequate warnings or instructions were not provided, including but not limited to the warning that the Product may contain ingredients not approved by FDS [sic] for dietary supplements and thus should not be given to, or eaten by humans.[2]

<sup>&</sup>lt;sup>2</sup> The Product is subject to classification and regulation by the FDA.

The Food and Drug Administration ("FDA") has regulatory authority over whether a product is a drug, food, dietary supplement, old dietary ingredient ("ODI") or a new dietary ingredient ("NDI") under the FDA's jurisdiction. 21 U.S.C. § 351 et seq. The Food, Drug, and Cosmetic Act ("FDCA") subjects the drug, dietary supplement, and food industries to a comprehensive regulatory authority. 21 U.S.C. § 301 et seq. . . .

[<u>Id.</u> at ¶ 7.3.] Count II alleges that Defendants breached the following duties:

- "a duty to properly supervise, train, and monitor their employees, or the employees of their agents or subcontractors, engaged in the preparation of the Product, to ensure compliance with Defendants' operating standards and to ensure compliance with all applicable health regulations[;]" [id. at ¶ 7.4;]
- "a duty . . . to comply with all statutory and regulatory provisions that pertained or applied to the manufacture, distribution, storage, labeling, and sale of the Product[;]" [id. at ¶ 7.5;]
- "the duty to exercise reasonable care in the sale of the Product, to ensure that the Product it sold to Plaintiff was not adulterated, and was not potentially injurious to human health[;]" [id. at ¶ 7.6;] and
- "the duty to provide adequate warnings and instructions for the use of the Product" [id.].

Count III alleges that Defendants both gave the following warranties: an implied warranty that the Product "was fit for the ordinary purpose for which the food Product is used[;]" [id. at ¶ 8.3;] an implied warranty that the Product "was of merchantable quality, and was safe and fit for human consumption[;]" [id. at ¶ 8.4;] and an express warranty that the Product "was safe to eat" and was "safely manufactured" [id. at ¶ 8.5]. Plaintiff alleges that Defendants breached these warranties because the Product "contained an ingredient injurious to human health, and because adequate warnings or instructions

<sup>&</sup>lt;sup>2</sup>(...continued) 2014 WL 6419674, at \*4 (S.D. Cal. Dec. 9, 2013).

were not provided, including but not limited to the warning that the Product may contain ingredients not approved by FDS [sic] for dietary supplements and thus should not be given to, or eaten by humans." [Id. at ¶ 8.6.]

Plaintiff prays for the following relief: general, special, incidental, and consequential damages - including lost wages, medical and medical-related expenses, travel and travel-related expenses, emotional distress, physical pain, and physical injury; reasonable attorneys' fees and costs; and any other appropriate relief. She also requests leave to amend her Complaint, as necessary, including leave to amend after service of all parties and completion of discovery.

#### DISCUSSION

## I. Scope of the Motion

At the outset, this Court notes that Defendants' Motion seeks dismissal based on both Fed. R. Civ. P. 12(b)(2) ("lack of personal jurisdiction") and Rule 12(b)(6) ("failure to state a claim upon which relief can be granted"). The Motion asserts, inter alia, that Defendants "lack the requisite contacts for this Court to exercise personal jurisdiction over them." [Motion at 2.] The memorandum in support, however, does not contain any discussion of this argument.

USPlabs and GNC are also named as defendants in five other cases with similar factual allegations: Waikiki v. USPlabs,

LLC, et al., CV 13-00639 LEK-KSC; Akau v. USPlabs, LLC, et al., CV 14-00029 LEK-KSC; Igafo v. USPlabs, LLC, et al., CV 14-00030 LEK-KSC; Ishihara v. USPlabs, LLC, et al., CV 14-00031 LEK-KSC; and Mattson v. USPlabs, LLC, et al., CV 14-00032 LEK-KSC. The defendants in those cases also include entities and individuals who are not named in the in the instant case. USPlabs and GNC are represented by the same counsel in those cases, and they also filed motions to dismiss in those cases. See, e.g., Akau, CV 14-00029, Motion to Dismiss, filed 4/28/14 (dkt. no. 10). Although the five motions to dismiss raised a personal jurisdiction argument as to the other entities and the individual defendants, the defendants did not challenge personal jurisdiction over USPlabs and GNC. See, e.g., Akau, CV 14-00029, Mem. in Supp. of Motion to Dismiss at 6-20.

For these reasons, this Court does not construe the Motion in the instant case as challenging personal jurisdiction over USPlabs and GNC.

## II. Forum Non Conveniens/Transfer of Venue

Defendants first argue that this Court should dismiss the action based on forum non conveniens "because the United States District Court for the Western District of Texas [("Western District of Texas")] is a more appropriate forum in which to litigate this matter." [Mem. in Supp. of Motion at 5 (citations omitted).] Plaintiff responds that the doctrine of

forum non conveniens only applies to cases where the alternative forum is outside of the United States. At the hearing on the Motion, Defendants' counsel conceded that the doctrine does not apply and asked this Court to construe the Motion as requesting transfer of venue to the Western District of Texas.

This Court agrees and construes Defendants' request to dismiss the case based on forum non conveniens as a request to transfer venue pursuant to 28 U.S.C. § 1404(a). This Court adopts the venue analysis in this Court's Order Granting in Part and Denying in Part Defendants' Motion to Dismiss, filed in Akau ("Akau Order"). [CV 14-00029, Akau Order, filed 9/9/14 (dkt. no. 44), at 12-16.] Based upon the analysis in the Akau Order, this Court DENIES Defendants' request to transfer venue pursuant to § 1404(a).

# III. Failure to State a Claim

Defendants next ask this Court to dismiss all of Plaintiff's claims pursuant to Rule 12(b)(6). Defendants argue that this Court must dismiss Plaintiff's claim for attorneys' fees. Plaintiff's Complaint, however, does not include a claim for attorneys' fees; Plaintiff merely requests attorneys' fees as part of her prayer for relief. If Plaintiff prevails on the merits of this case, she will have to file a motion for attorneys' fees, and that motion must state, inter alia, the "statutory or contractual authority entitling [Plaintiff] to the

requested award." See Local Rule LR54.3(c).

As to Plaintiff's substantive claims, this Court finds that Count I contains sufficient factual allegations (which this Court must accept as true for purposes of the instant Motion) that allow this Court to draw the reasonable inference of liability. See Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). This Court therefore DENIES the Motion as to Count I.

At the hearing on the Motion, Plaintiff's counsel stated that he did not draft the Complaint, and he expressed doubt as to whether the negligent supervision, training, and monitoring claim, [Complaint at ¶ 7.4,] was a key issue in the case. This Court also finds the Complaint does not include any factual allegations to support the portions of Count II alleging negligent supervision, training, and monitoring and negligent failure to comply with applicable statutes and regulations [id. at ¶ 7.5]. Those allegations amount to mere conclusory statements of the elements of Plaintiff's different negligence

<sup>&</sup>lt;sup>3</sup> In <u>Igbal</u>, the United States Supreme Court stated:

To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." [Bell Atl. Corp. v. Twombly, 550 U.S. 554,] 570, 127 S. Ct. 1955 [(2007)]. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. Id., at 556, 127 S. Ct. 1955.

claims, and they are not enough to survive a motion to dismiss.

See Igbal, 556 U.S. at 678 ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." (citing Twombly, 550 U.S. at 555, 127 S. Ct. 1955)).

Based on Plaintiff's memorandum in opposition and counsel's arguments at the hearing: Count II is based, at least in part, on the allegation that Defendants were negligent in failing to provide a warning that the Product contained an ingredient which had not been approved by the FDA; and Count III is based, at least in part, on the allegation that the failure to include such an express warning constitutes a warranty that the Product is safe for human consumption. The Court finds that Plaintiff's Complaint does not provide sufficient notice that these theories are the basis of Counts II and III. See Brewer Envtl. Indus., LLC v. Matson Terminals, Inc., Civil No. 10-00221 LEK-KSC, 2011 WL 1637323, at \*16 (D. Hawai`i Apr. 28, 2011).

2011 WL 1637323, at \*16 (some alterations in Brewer Envtl.).

<sup>&</sup>lt;sup>4</sup> In <u>Brewer Environmental</u>, this Court stated:

Although Federal Rule of Civil Procedure 8(a)(2) requires only that a complaint include "a short and plain statement of the claim showing that the pleader is entitled to relief[,]" such a statement must sufficiently put the defendants on fair notice of the claims asserted and the grounds on which they rest. See Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007) (citation omitted). . . .

This Court therefore concludes that Counts II and III do not contain sufficient allegations to support plausible claims for relief. See Iqbal, 556 U.S. at 678. This Court also notes that, although it appears from the context of the Complaint as a whole that the reference was an inadvertent error, the portion of Count III alleging breach of the implied warranty of merchantability states that the product at issue is lettuce. [Complaint at ¶ 8.4.]

This Court GRANTS Defendants' Motion insofar as this Court DISMISSES Counts II and III. The dismissal is WITHOUT PREJUDICE because this Court finds that it is arguably possible to cure the defects in those claims by amendment. See Harris v. Amgen, Inc., 573 F.3d 728, 737 (9th Cir. 2009) ("Dismissal without leave to amend is improper unless it is clear that the complaint could not be saved by any amendment." (citation and quotation marks omitted)).

Plaintiff shall file her amended complaint by

October 30, 2014. This Court grants Plaintiff leave to amend

Counts II and III against USPlabs and GNC. If Plaintiff wishes

to make other changes - i.e. if she wishes to add new parties,

claims, or theories of liability - Plaintiff must file a motion

for leave to amend prior to the deadline set forth in the Rule 16

Scheduling Order [filed 5/21/14 (dkt. no. 37)].

## CONCLUSION

On the basis of the foregoing, Defendants' Motion to Dismiss Plaintiff's Complaint, filed May 21 2014, is HEREBY GRANTED IN PART AND DENIED IN PART. The Motion is GRANTED insofar as this Court HEREBY DISMISSES Count II and Count III WITHOUT PREJUDICE. Plaintiff shall file her amended complaint, according to the terms of this Order, by October 30, 2014. The Motion is DENIED in all other respects.

IT IS SO ORDERED.

DATED AT HONOLULU, HAWAII, September 30, 2014.



/s/ Leslie E. Kobayashi
Leslie E. Kobayashi
United States District Judge

EVERINE VAN HOUTEN VS. USPlabs, LLC, ET AL; CIVIL 13-00635 LEK-KSC; ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S COMPLAINT