Imagenetix, Inc. v. Frutarom USA, Inc. Doc. 56

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IMAGENETIX, INC., Plaintiff, vs. FRUTAROM USA, INC., Defendant.	CASE NO. 12CV2823-GPC(WMC) **ORDER DENYING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT; GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION FOR SUMMARY JUDGMENT; AND STAYING CASE**

On July 26, 2013, Plaintiff Imagenetix, Inc. ("Plaintiff" or "Imagenetix") filed a motion for summary judgment on the "issue of Frutarom's liability for breach of express warranty."[1] (Dkt. No. 35.) On August 23, 2013, Frutarom USA, Inc. ("Defendant" or Frutarom") filed an opposition. (Dkt. No. 36.) Plaintiff filed a reply on September 6, 2013. (Dkt. No. 37.)

On October 23, 2013, Defendant Frutarom USA, Inc. filed a motion for summary judgment as to all causes of action in the complaint. (Dkt. No. 45.) Plaintiff filed an opposition on November 8, 2013. (Dkt. No. 49.) Defendant filed a reply on November 22, 2013. (Dkt. No. 51.) Based on the foregoing, the Court DENIES Plaintiff's motion for summary judgment on the breach of express warranty issue; GRANTS Defendant's motion for summary judgment on the basis of primary jurisdiction; DENIES

[1]Plaintiff seeks partial summary judgment on the issue of whether Defendant breached the express warranty in the Supply and Marketing Agreement, not whether Defendant breached the contract as alleged in the first cause of action.

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Defendant's motion for summary judgment on the issue of preemption and Plaintiff's failure to provide notice and an opportunity to cure; and STAYS the action pending a determination by the U.S. Food and Drug Administration ("FDA").

Background

Frutarom was the exclusive United States distributor of BLIS K12, a probiotic product developed and manufactured by BLIS Technologies, a New Zealand Company. (Dkt. No. 1, Compl. ¶ 7.) BLIS Technologies derived BLIS K12 from the naturally occurring bacterium *Streptococcus salivarius*. (Dkt. No. 36-2, D's Response to P's Separate Statement of Undisputed Material Fact ("SSUF"), No. 1.) Effective September 1, 2009, the parties entered into a Supply and Marketing Agreement ("Agreement"), where Frutarom would supply Imagenetix with BLIS K12. (Dkt. No. 49-1, Pl's Response to D's SSUF, No. 1.) In the Agreement, Imagenetix agreed to incorporate BLIS K12 into certain dietary supplements, named BioGuard, that Imagenetix would manufacture, market, distribute, and sell in an exclusive territory. (Id., No. 2.) Frutarom also agreed that "the Raw Material [BLIS K12] shall conform to all applicable Federal, State and local laws, regulations and rules." (Id., No. 3.)

Shortly after launching the product, a consumer complained that a tablet of BioGuard had made his wife seriously ill. (Dkt. No. 36-2, D's Response to P's SSUF, No. 28.) The consumer filed an adverse event report with the FDA and notified Plaintiff that the FDA had barred import of a BLIS K12 product in 2008. (Dkt. No. 35-3, Spencer Decl. ¶ 6.) After investigating the consumer complaint, Plaintiff learned that the FDA had not approved a New Drug Application ("NDA") for BLIS K12 and that a New Dietary Ingredient ("NDI") pre-market notification also had not been filed for BLIS K12. (Id. ¶ 8.) Plaintiff stopped selling BioGuard. (Id. ¶ 7.)

Although the Agreement extended through 2011, the parties agreed to part ways in April 2011. (Dkt. No. 49-1, P's Response to D's SSUF, No. 4.) On August 1, 2012, Imagenetix sent a letter to Frutarom claiming that BLIS K12 did not comply with the FDCA, demanding over $1,000,000 or it would seek legal action. (Dkt. No 45-4, Ohta

Decl., Ex. B.) The FDA has never found that BioGuard is an unapproved new drug or that its distribution violated the FDCA. (Dkt. No. 49-1, P's Response to D's SSUF, No. 6.) Plaintiff has never received a warning letter about BioGuard and the FDA has never seized any of the BioGuard product. (Dkt. No. 45-4, Ohta Decl., Ex. C, Spencer Depo. at 71:15-20.)

Plaintiff alleges that Defendant breached its express warranty in two way: First, BLIS K12 was a drug that required an approved new drug application, and second, even if it were not a drug, BLIS K12 was a dietary supplement, and Defendant failed to submit safety data and other information to the FDA and allow the FDA to evaluate the product's safety as the active ingredient in BLIS K12 is a unique *S. Salivarius K12* strain which didn't exist prior to October 15, 1994. (Dkt. No. 1, Compl. ¶¶ 15, 17.) Moreover, Plaintiff argues that BLIS K12 was legal to sell only if it qualified as an "old" dietary ingredient under the Dietary Supplement Health and Education Act of 1994 ("DSHEA") (i.e., if it was marketed in the United States prior to October 15, 1994) or as a dietary ingredient that has "has been present in the food supply as an article used for food in a form in which the food has not been chemically altered." (Dkt. No. 35-1 at 5.)

On November 21, 2012, Plaintiff filed a complaint against Defendant for breach of contract; intentional misrepresentation; negligent misrepresentation; fraud in the inducement; and violation of California Business & Professions Code section 17200. (Dkt. No. 1, Compl.) An answer was filed on March 8, 2013 along with a Counterclaim against Plaintiff for breach of contract. (Dkt. No. 15.) On March 20, 2013, Plaintiff filed an answer to the counterclaim. (Dkt. No. 19.)

Discussion

Plaintiff seeks partial summary judgment solely on the issue of whether Defendant breached its express warranty in the Agreement. Defendant also filed a motion for summary judgment on all causes of action.

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A. Legal Standard for Motion for Summary Judgment

Federal Rule of Civil Procedure 56 empowers the Court to enter summary judgment on factually unsupported claims or defenses, and thereby "secure the just, speedy and inexpensive determination of every action." Celotex Corp. v. Catrett, 477 U.S. 317, 325, 327 (1986). Summary judgment is appropriate if the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). A fact is material when it affects the outcome of the case. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

The moving party bears the initial burden of demonstrating the absence of any genuine issues of material fact. Celotex Corp., 477 U.S. at 323. The moving party can satisfy this burden by demonstrating that the nonmoving party failed to make a showing sufficient to establish an element of his or her claim on which that party will bear the burden of proof at trial. Id. at 322-23. If the moving party fails to bear the initial burden, summary judgment must be denied and the court need not consider the nonmoving party's evidence. Adickes v. S.H. Kress & Co., 398 U.S. 144, 159-60 (1970).

Once the moving party has satisfied this burden, the nonmoving party cannot rest on the mere allegations or denials of his pleading, but must "go beyond the pleadings and by her own affidavits, or by the 'depositions, answers to interrogatories, and admissions on file' designate 'specific facts showing that there is a genuine issue for trial.'" Celotex, 477 U.S. at 324. If the non-moving party fails to make a sufficient showing of an element of its case, the moving party is entitled to judgment as a matter of law. Id. at 325. "Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no 'genuine issue for trial.'" Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). In making this determination, the court must "view[] the evidence in the light most

favorable to the nonmoving party." Fontana v. Haskin, 262 F.3d 871, 876 (9th Cir. 2001). The Court does not engage in credibility determinations, weighing of evidence, or drawing of legitimate inferences from the facts; these functions are for the trier of fact. Anderson, 477 U.S. at 255.

B. Primary Jurisdiction of the FDA

Defendant argues that all the claims should be dismissed under the primary jurisdiction doctrine. Plaintiff disagrees.

The primary jurisdiction doctrine "allows courts to stay proceedings or to dismiss a complaint without prejudice pending the resolution of an issue within the special competence of an administrative agency." Clark v. Time Warner Cable, 523 F.3d 1110, 1114 (9th Cir. 2008). The doctrine is a "prudential" one where the court determines that a claim implicates technical and policy questions that should be first addressed in by the relevant agency with regulatory authority over the relevant industry rather than by the courts. Syntek Semiconductor Co., Ltd. v. Microchip Tech., Inc., 307 F.3d 775, 780 (9th Cir. 2002).

Primary jurisdiction does not apply every time a court is presented with an issue conceivably within the agency's expertise but only used if a claim "'requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency,' . . . and if 'protection of the integrity of a regulatory scheme dictates preliminary resort to the agency which administers the scheme.'" Clark, 523 F.3d at 1114 (citations omitted). If a district court applies the doctrine of primary jurisdiction, the issue is "referred" to the relevant agency and the court either stays the proceedings or dismisses the case without prejudice so the parties may seek an administrative ruling. Id. at 1115; see also Syntek, 307 F.3d at 782; Astiana v. Hain Celestial Grp., Inc., 905 F. Supp. 2d 1013, 1015 (N.D. Cal. 2012) (if doctrine applies, court can either stay proceedings or dismiss the case without prejudice).

Although there is no fixed formula, the Ninth Circuit has looked to four factors when applying the doctrine: "(1)[a] 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 authority that (4) requires expertise or uniformity in administration." Syntek, 307 F.3d at 781.

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*. There is no private right of action under the FDCA. Perez v. Nidek Co., Ltd., 711 F.3d 1109, 1119 (9th Cir. 2013) (citing 21 U.S.C. § 337(a) ("all such proceedings for the enforcement, or to restrain violations, of [the Act] shall be by and in the name of the United States.")).

Classification of a product such as whether the product is a drug, biological product or food involves "complex chemical and pharmacological considerations" and "determination of technical and scientific questions." Biotics Research Corp. v. Heckler, 710 F.2d 1375, 1377 (9th Cir. 1983) (citations omitted); Dietary Supplemental Coalition, Inc. v. Sullivan, 978 F.2d 560, 563 (9th Cir. 1992); see also Weinberger v. Hynson,Westcott & Dunning, Inc., 412 U.S. 609, 627 (1973) (new drug[2] decisions are best left to agency expertise). Primary jurisdiction to determine evidentiary matters concerning drugs about which it has a special expertise should be granted to the agency. See CIBA Corp. v. Weinberger, 412 U.S. 640, 643–44 (1973) (because of its expertise, the FDA should make the threshold determination of whether a drug is a "new drug").

The underlying issue on all Plaintiff's causes of action is whether BLIS K12 is a drug, dietary supplement, old dietary ingredient ("ODI") or a new dietary ingredient

[2]"New drug" is distinct from "drug" under the FDCA. See 21 U.S.C. § 321(g)(1) with § 321(p)

("NDI") which must be determined prior to adjudicating whether Defendant is liable to Plaintiff. Classification of a product is within the primary jurisdiction of the FDA. See Biotics Research Corp., 710 F.2d at 1377.

Plaintiff cites to many cases in support of its argument that primary jurisdiction does not apply; however these cases concern product labeling/misbranding and not a classification of a product. The mislabeling cases are distinguishable because the FDA had already provided guidance, informal and formal, on the issue of labeling and the court's role was to determine whether the labels were misleading to the reasonable consumer, which does not require FDA expertise. See Kosta v. Del Monte Corp., No. 12-cv-01722-YGR, 2013 WL 2147413, at *9-10 (N.D. Cal. May 15, 2013); Brazil v. Dole Food Co., Inc., 935 F. Supp. 2d 947, 959 (N.D. Cal. Mar. 25, 2013); Ivie v. Kraft Foods Global, Inc., No. C-12-02554-RMW, 2013 WL 685372, at *7 (N.D. Cal. Feb. 25, 2013); Bruton v. Gerber Products Co, No. 12-CV- 02412-LHK, 2013 WL 4833413, at *11-12 (N.D. Cal. Sept. 6, 2013); Morgan v. Wallaby Yogurt Co., Inc., 13cv296-WHO, 2013 WL 5514563, at *4 (N.D. Cal. Oct. 4, 2013) (whether a label is misleading is within the ability of the Court and frequently determined by courts). The instant case is not a food labeling/misbranding case but a case to determine whether BLIS K12 should be classified a drug, dietary supplement, ODI or NDI, an issue that should be left to the expertise of the relevant agency, the FDA.

Plaintiff also argues that the case does not present issues of first impression as the FDA has addressed the issues through industry guidance and/or warning letters. Defendant asserts that the FDA has not given a clear indication on whether BLIS K12 is a new drug, food, NDI or ODI.

While Plaintiff asserts that the FDA has issued informal "guidance on all of the relevant issues", (Dkt. No. 37, P's Reply at 11; see Dkt. No. 49, Pl's Opp. at 7), Plaintiff does not present them to the Court. The Court notes that in Plaintiff's moving papers, it discusses warning letters where the FDA has deemed purported dietary supplements, including probiotic products, drugs on the ground that the

manufacturer/distributor was making improper therapeutic claims. (Dkt. No. 35-1 at 15; Dkt. Nos. 35-8, P's NOL, Exs. 12, 13, 14, 15.) However, Plaintiff has not demonstrated that warning letters to other dietary supplement manufacturers constitute guidance on BLIS K12. See Dietary Supplemental Coalition, Inc., 978 F.2d at 563-64 (in determining "final agency action", court explained that "FDA is not bound by a previous position taken in a different case with different facts.")

In addition, an import refusal issued against another product using BLIS K12 is not evidence of a violation of the FDCA by BLIS K12 or BioGuard. See id. While Dietary Supplemental Coalition was a case about a review of a final agency action, the Court noted that while Plaintiff argued that the FDA had already made up its mind as to CoQ10 and cites to FDA seizures, the court held that seizures themselves do not amount to final agency position on all uses of CoQ10, and "the FDA is not bound by a previous position taken in a different case with different facts." Id. at 564. "The FDA has not waived its right to make that determination by taking a legal position in separate actions." Id. at 564.

On October 22, 2008, BLIS K12 Travel Guard was refused admission into the United States. (Dkt. NO. 36-2, D's Response to P's SSUF, No. 33.) On September 19, 2008, the FDA placed a shipment of BLIS K12 Travel Guard on hold pending FDA review. (Dkt. No. 35-5, P's NOL, Ex. 11.) The product was detained, then reviewed and investigated by the FDA, and then refused entry. (Id.)

The import refusal as to Travel Guard, another product incorporating BLIS K12, does not address the specific facts in this case and cannot be deemed to be clear guidance as to its position on whether BLIS K12 is a drug, or dietary supplement and does not amount to evidence that the distribution or sale of BLIS K12 or BioGuard violated the FDCA.

Plaintiff further argues that primary jurisdiction is not appropriate because it has no avenue to obtain an FDA ruling on the legality of BLIS K12 that was subject to the Agreement since the BLIS K12 at issue was delivered between 2009 and 2011 and the

legality of that product turns on how it was being marketed and promoted at the time. Defendant contends that Plaintiff could seek review through a citizen petition under 21 C.F.R. § 10.30.

In Velasco, the defendant ceased selling the product at issue as it complied with the FDA's request that defendant immediately cease distribution of the product. Velasco v. SEI Pharms., Inc., No. 12cv1060-WQH-MDD, 2013 WL 2444646, at 4 (S.D. Cal. June 5, 2013). The court declined to stay or dismiss the complaint because the defendant failed to identify an available procedure for the parties to seek an administrative ruling from the FDA if the Court were to stay or dismiss the case. Id.; see Golden Hill Paugussett Tribe of Indians v. Weicker, 39 F.3d 51, 60 (2d Cir.1994) (noting, in considering issue of primary jurisdiction, that "[t]here clearly is a public interest in reasonably prompt adjudication").

FDA regulations expressly provide that an interested person may "petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25(a). The petition may take the form of a citizen's petition under 21 C.F.R. § 10.30. The Commissioner's decision on such a petition, which must be made within 180 days, 21 C.F.R. § 10.30(e)(2), is reviewable in federal court as a final agency action, 21 C.F.R. § 10.45(d), with an appropriate administrative record having been developed, 21 C.F.R. § 10.30(i). See Biotics Research Corp., 710 F.2d at 1378; Sanofi-Aventis U.S. LLC v. FDA, 842 f. Supp. 2d 195, 198 n.5 (D.D.C. 2012).

Here, while Plaintiff has stopped selling BioGuard, it does not appear that Defendant has ceased selling BLIS K12 and the issue as stated by Plaintiff is "whether BLIS K12 was legal to sell." (Dkt. No. 37 at 12.) An available administrative procedure is available for Plaintiff to seek an administrative ruling. See 21 C.F.R. § 10.25(a).

Plaintiff lastly argues that the FDA is not able to award damages and primary jurisdiction will only hinder, not aid, efficiency as Plaintiff will have to return once the

agency makes a determination on the classification of BLIS K12. Despite the inconvenience to Plaintiff in seeking an administrative ruling before returning to this Court, the purpose of primary jurisdiction is commit to the regulatory agency issues of first impression or particularly complicated issues as mandated by Congress. See Clark, 523 F.3d at 1114. Moreover, the regulations require that the Commissioner is to make a decision within 180 days of the filing of such petition. Therefore, the time to seek an administrative ruling will not be prolonged or extended. Once the FDA makes a determination, Plaintiff may return to this Court and seek damages against Defendant.

Under the four factors announced in Syntek, the Court concludes that primary jurisdiction applies in this case.

B. Preemption

Defendant also argues that Plaintiff's state law claims are preempted by the FDCA. Plaintiff disagrees.

Under the Supremacy Clause, the laws of the United States "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2. Accordingly, "state laws that conflict with federal law are 'without effect.'" Mut. Pharm. Co., Inc. v. Bartlett, —— U.S. ——, 133 S. Ct. 2466, 2473 (2013) (citations omitted). "Federal preemption occurs when: (1) Congress enacts a statute that explicitly pre-empts state law; (2) state law actually conflicts with federal law; or (3) federal law occupies a legislative field to such an extent that it is reasonable to conclude that Congress left no room for state regulation in that field." Chae v. SLM Corp., 593 F.3d 936, 941 (9th Cir. 2010) (citations omitted). As stated, there are three categories of preemption: express, field and conflict. See id. Field and conflict preemption are subcategories of implied preemption. Stengel v. Medtronic, Inc., 714 F.3d 1224, 1230 (9th Cir. 2013). Defendant argues that implied preemption applies in this case, and it appears that it specifically relies on conflict preemption as Defendant relies on Buckman Co v.

Plaintiffs' Legal Comm., 531 U.S. 341 (2001), a conflict preemption case.

Conflict preemption occurs when it would be "impossible for a private party to comply with both state and federal requirements," English v. General Elec. Co., 496 U.S. 72, 79 (1990), or where the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

Many of the preemption cases cited by the parties concern the Medical Device Amendments ("MDA") to the FDCA. Those cases established that the MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal law duty under the MDA." Stengel v. Medtronic, Inc., 704 F.3d 1224, 1228 (9th Cir. 2013) (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 474 (1996); Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001) and Riegel v. Medtronic, Inc., 552 U.S. 312, (2008)).

Of these cases, only Buckman dealt with conflict preemption. In Buckman, the plaintiff sued the manufacturer for harm sustained resulting from an allegedly defective orthopedic bone screw under state tort law for making fraudulent representation to the FDA. Plaintiff alleged that had the defendant not misrepresented certain material facts to the FDA, it would not have approved the screws and plaintiff would not have been injured. The Supreme Court held that plaintiff's state law claim for "fraud on the FDA" was impliedly preempted by the FDA's power to punish and to deter fraud against it. Id. at 348. The Court explained that "the conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance . . . can be skewed by allowing fraud-on-the-FDA claims." Id. at 348.

In a recent Ninth Circuit case, Perez, the patient brought a putative class action against the manufacturer's use of Laser for hyperopia despite lack of premarket approval by the FDA in violation of the FDCA and state law. Perez v. Nidek Co., Ltd.,

711 F.3d 1109,1112 (9th Cir. 2013). The plaintiffs did not claim to have been injured in any manner but brought a state law claim of "fraud by omission" on the theory that the defendants had failed to disclose to them that the Laser was not FDA approved for hyperoptic surgeries. Id. at 1117. The Court held that this cause of action was not only expressly preempted under the Medical Device Amendments but also impliedly preempted based on conflict preemption. Id. at 1118-19. As to implied preemption, the court explained that the fraud by omission claim conflicts with the FDCA's enforcement scheme similar to the "fraud on the FDA" claims in Buckman. Id. at 1119. The court explained that the fraud by omission claim exists solely because of the FDCA requirement and that "[a]lthough Perez is not barred from bringing any fraud claim related to the surgeries, he cannot bring a claim that rests solely on the non-disclosure to patients of facts tied to the scope of PMS approval." Id. at 1119-20. In essence, Plaintiff was seeking to privately enforce provisions of the FDCA, which is prohibited under the FDCA.

In Kobar ex rel Kobar v. Novartis Corp., 378 F. Supp. 2d 1166, (D. Az. 2005), the court applied Buckman to a drug approval process case. Id. at 1174. The Court held that state law immunized drug manufacturers from punitive damages in products liability cases unless plaintiff could prove fraud on the FDA. The court noted that the reasoning of Buckman has been readily applied to other statutory schemes and found preemption of state law claims when an essential elements of those claims was fraud on the FDA. Id. at 1174 (citing cases). In "every case where a court has analyzed whether a federal regulatory scheme preempts state law claims that require a plaintiff to prove as an essential element fraud on the federal agency responsible for administering the federal scheme, the court has found preemption of the state law claim." Id. at 1174.

This case concerns a supply and marketing contract between two companies where Plaintiff alleges that Defendant breached its express warranty in the Agreement that BLIS K12 shall "conform to all Federal, State and local laws, regulations, and

rules" because BLIS K12 was not approved or authorized by the FDA as a drug or as a dietary supplement. Plaintiffs are not seeking to solely enforce FDA regulations or allege that Defendant failed to follow FDA regulations regarding BLIS K12, but are seeking relief based on state law claims concerning a provision in the Supply and Marketing Agreement that happen to be based on the FDCA requirements. Plaintiff is suing because Defendant's conduct breached the express warranty provision in the Agreement by failing to comply with the FDCA. Plaintiff is not suing because Defendant failed to comply with the FDCA, but rather because Defendant's failure to comply the FDCA was a violation of state contract and tort law. See Perez, 711 F.3d at 1120. Moreover, Plaintiff's causes of action do not require it to prove an essential element of fraud on the federal agency. See Kobar, 378 F. Supp. 2d at 1174. Accordingly, the Court concludes that Plaintiff's state law causes of action are not preempted by the FDCA and DENIES Defendant's motion for summary judgment.

C. Failure to Provide Defendant with Notice and an Opportunity to Cure

Defendant also moves for summary judgment arguing that Plaintiff is barred from bringing any claim regarding the Agreement because it failed to provide Defendant with notice and an opportunity to cure. Plaintiff argues that it is not barred by the notice and cure provision in the Agreement.

The Agreement states, "[n]otwithstanding the foregoing, this Agreement may be terminated upon ninety (90) days' written notice in the following events: . . . (c) Either party fails to perform any obligation under this Agreement and fails to cure said default after ninety (90) days' written notice from the other specifically identifying the defaulted performance." (Dkt. No. 45-3, Ohta Decl., Ex. A at ¶ 15.)

While Defendant argues that a party is barred from bringing a claim under a contract where the party breaches the notice and opportunity to cure provision, Plaintiff contends that it was relieved of its obligations under the contract because performance was illegal and Defendant materially breached the Agreement when it failed to comply with the FDCA. See Cal. Civ. Code §1441; Brown v. Grimes, 192 Cal. App. 4th 265,

277 (2011) ("[w]hen a party's failure to perform a contractual obligation constitutes a material breach of the contract, the other party may be discharged from its duty to perform under the contract.") This issue cannot be determined until the FDA determines whether BLIS K12 is a drug, dietary supplement, ODI or NDI.

Therefore, genuine issues of material fact exist precluding summary judgment. Accordingly, the Court DENIES Defendant's motion for summary judgment based on the notice and cure provision in the Agreement.

D. Stay or Dismissal

The Court must decide whether to dismiss the action or stay the action pending referral of the issue to the administrative agency. Typically, if courts conclude that the dispute that forms the basis of the action is within the agency's primary jurisdiction, the case should be dismissed without prejudice so the parties may pursue their administrative remedies. Syntek, 307 F.3d at 782. However, if the statute of limitation may prevent Plaintiff from refiling its claim, the court may stay the proceedings pending the outcome of the administrative process. Id.

Here, while not addressed by the parties, the statute of limitations may prevent Plaintiff from refiling its claim. Therefore, the Court STAYS the case pending resolution of the issue before the FDA.

Conclusion

Based on the above, the Court DENIES Plaintiff's motion for summary judgment on the liability for breach of warranty and GRANTS Defendant's motion for summary judgment as to the issue of primary jurisdiction but DENIES Defendant's motion for summary on the issue of preemption and Plaintiff's failure to provide notice and an opportunity to cure. The Court STAYS this action pending a determination by the FDA

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on whether BLIS K12 is a drug, dietary supplement, old dietary ingredient or new dietary ingredient. The parties shall cooperate in expediting the presentation and explanation of this question to the FDA and will notify the Court promptly of any determination by the FDA.

IT IS SO ORDERED.

DATED: December 9, 2013

HON. GONZALO P. CURIEL
United States District Judge