UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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In re Elysium Health-Chromadex Litigation

17 Civ. 7394 (CM)

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DECISION AND ORDER DENYING IN PART DEFENDANT'S MOTION TO DISMISS THE COMPLAINT, CONVERTING THE NOERR-PENNINGTON MOTION TO A MOTION FOR SUMMARY JUDGMENT AND SETTING A SCHEDULE FOR THE SUBMISSION OF ADDITIONAL EVIDENCE; AND GRANTING IN PART AND DENYING IN PART PLAINTIFF'S MOTION TO DISMISS THE COUNTERCLAIMS

McMahon, C.J.:

On September 27, 2017, Plaintiff Elysium Health, Inc. ("Elysium") filed a complaint ("Complaint") against Defendant Chromadex, Inc. ("CMDX"), alleging violations of 43(a) of the Lanham Act, as well as state law claims of trade libel, deceptive business practices under New York General Business Law § 349, and tortious interference with prospective economic relations.

On October 26, 2017, Defendant moved to dismiss the Complaint on the ground that it failed to state a claim, principally because entertaining Elysium's lawsuit would violate the *Noerr-Pennington* doctrine, which protects a party's right to petition the Government for redress. On the same day, Defendant filed a mirror image complaint ("Counterclaim") styled *Chromadex, Inc. v. Elusium Health, Inc.*, 17 Civ. 8239.

On November 3, 2017, District Court Judge Valerie E. Caproni consolidated two cases under the caption and docket number listed above. Plaintiff moved to dismiss Defendant's Counterclaim[1] on November 16, 2017.

[1] Had these cases been before me at the time they were consolidated, I would have denominated Chromadex's complaint as an answer and its claims as counterclaims. Judge Caproni, before whom the matter was pending at the time, ordered otherwise, and I am following her order of consolidation.

For the reasons set forth below, CDMX's Motion to Dismiss Elysium's Complaint is DENIED; Elysium's Motion to Dismiss CDMX's Counterclaim is GRANTED in part and DENIED in part; and Elysium is directed to file an answer to CDMX's Counterclaim by October 12, 2018.

BACKGROUND

The underlying facts pleaded in the two complaints are essentially the same.

Elysium sells a product called Basis, which is a dietary supplement for human consumption. Elysium sells Basis directly to consumers. (Compl. ¶¶ 2, 16, Dkt. No. 1.) The supplement, which is sold as an anti-aging product, consists of two main ingredients: nicotinamide riboside ("NR") and pterostilbene ("PT"). (Compl. ¶ 2.)

Elysium and CMDX entered into agreements for the supply of NR and PT in February 2014 and June 2014, respectively. (Compl. ¶ 23.) CMDX develops, produces, and sells these bulk ingredients, licensed as NIAGEN® (the "NR" ingredient) and pTeroPure® (the "PT" ingredient), for use in consumer products. (Mem. of Law in Supp. Def.'s Mot. Dismiss ("Def.'s MTD"), at 4, Dkt. No. 20.)

At some point in 2016, the parties' business relationship soured and CMDX discontinued supplying both ingredients to Elysium. (Compl. ¶¶ 23-25; Def.'s MTD, at 5-6.) After August 2016, Elysium obtained a new supplier of NR and PT so that it could continue producing and selling Basis. (Def.'s MTD, at 6.)

On August 18, 2017, CMDX filed a citizen petition ("Citizen Petition") with the FDA. (Kupfer Decl. Ex. A, at 1.) A citizen petition is "a means afforded by the FDA for raising concerns about products the FDA reviews; any individual may file such a petition concerning scientific or

legal issues before or while the product is on the market." *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 57 (2d Cir. 2016).

CMDX's Citizen Petition asserted that it is the *only* NR supplier in the United States. It further asserted that its NR product, NIAGEN®, is sold under a New Dietary Ingredient Notification ("NDIN") filed with the FDA and has obtained generally recognized as safe ("GRAS") status. (Kupfer Decl. Ex. A, at 1.)

The Citizen Petition further alleged that while Elysium had previously purchased NIAGEN® from CMDX for use in its dietary supplement known as Basis, it was now using a new, unknown supplier(s) to produce Basis "for which no [NDIN] has been filed with the FDA and which does not have GRAS status." (Kupfer Decl. Ex. A, at 1.)

CMDX claimed it obtained and analyzed samples of Basis produced with NIAGEN® and samples produced with the NR supplied by the new supplier ("Mystery NR"). According to its laboratory analysis, the solvent toluene was discovered in Basis samples made with the Mystery NR, but was not present in samples purportedly made with NIAGEN®. (Kupfer Decl. Ex. A, at 4.) CMDX argued that the new source of NR must have contained the solvent toluene, and, as such, was "adulterated" within the meaning of 21 U.S.C. § 342(a)(1), which provides that "[a] food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health." (Kupfer Decl. Ex. A, at 5.) Put otherwise, CMDX asserted that Basis, Elysium's product, was "adulterated" under § 342(a)(1) because it was no longer using NIAGEN®, the "only source of NR that has an NDIN filed by the FDA." (Kupfer Decl. Ex. A, at 5-6.)

The Citizen Petition noted that, "The FDA has not set any allowed level of exposure to toluene through oral ingestion of a dietary supplement," (Kupfer Decl. Ex. A, at 5), but cited a 2015 Center for Disease Control ("CDC") publication, (Kupfer Decl. Ex. E), which states, "Single exposures to toluene or repeated exposures over a few weeks can cause headaches and sleepiness, and can impair your ability to think clearly. Whether or not toluene does this to you depends on the amount you take in, how long you are exposed, and your genetic susceptibility and age." (Kupfer Decl. Ex. E, at 4.)

CMDX asked the FDA to grant its Citizen Petition and to determine that (1) "Elysium's Basis product is adulterated under 21 U.S.C. § 342(a) and (f) based on the undeclared presence of toluene in the product at the level of 96-144 mg/kg," and that (2) Basis "contains a new dietary ingredient under 21 U.S.C. § 350b" (the "Mystery NR") for which Elysium had not submitted a NDIN. (Kupfer Decl. Ex. A at 2.) CMDX further asked that the FDA "take all appropriate remedial action, including [ordering] that Elysium cease distribution of its Basis product and take other appropriate enforcement action, including seizure of violating products and an injunction against the manufacturers and distributors under 21 U.S.C. §§ 332 and 334." (Kupfer Decl. Ex. A at 2.)

Elysium filed its lawsuit within weeks after the Citizen Petition was filed. The Complaint alleged that the Citizen Petition was false and misleading and that it was filed for the sole purpose of harming Elysium, rather than bringing any genuine concerns about Basis' safety to the FDA's attention. (Compl. ¶ 44.) Elysium surmised that CMDX's real motivation for filing the Citizen Petition was to gain a competitive advantage for its own competing product by disseminating the Citizen Petition to Elysium's customers, thereby calling into question the safety and regulatory status of Basis and wresting control of the consumer NR market from Elysium. (Compl. ¶¶ 13,

44.) CMDX had no expectation that the FDA would grant its Citizen Petition, according to Elysium, because CMDX knew (or, as a regulatory consultant, should have known) that the FDA does not grant such citizen petitions seeking the commencement of enforcement actions, including actions for seizure or injunctive relief. (Compl. ¶¶ 37-44.)

Elysium also alleged that, based on Certificates of Analysis (COA's) provided by CMDX to its customers, CMDX's anti-aging product pTeroPure® contains similar levels of toluene, so CMDX could not actually have believed that Basis was unsafe. (Compl. ¶ 65.)

Elysium further claimed that CMDX misstated the applicable regulatory standards for dietary supplements in order to mislead consumers regarding Basis' regulatory status. (Compl. ¶ 54-56.) While conceding that the FDA has not set an allowed level of exposure to toluene, Elysium counters that this statement is framed in a misleading way, because the FDA does not promulgate standards for the allowable levels of solvents in dietary supplements, (Compl. ¶ 54), and the FDA regulation referenced in the Petition – 21 C.F.R. 173, Subpart C – is not applicable to dietary supplements. (Compl. ¶ 56; Kupfer Decl. Ex. A, at 5.) Rather, Elysium asserts, the FDA has "regularly accepted the application of standards established by the ICH [International Conference on Harmonisation] for pharmaceuticals to nutritional supplements," and levels of toluene allegedly found in Basis were "far below the allowable levels established by the ICH." (Compl. ¶¶ 54-55.)

Finally, Elysium alleged that CMDX coordinated an effort to distribute statements from the Citizen Petition to CMDX's shareholders via an investor alert listserv that subscribers could opt into on CMDX's website, chromadex.com. (Compl. ¶¶ 100-109.) Notably, Elysium does not allege that CMDX or its agents disseminated the *actual* Citizen Petition: the Complaint states that several trade and blog articles, which relied on information from the Citizen Petition, were forwarded to the listserv by individuals who were allegedly connected to CMDX. (Compl. ¶¶ 100-

111.) Elysium claims that the articles were forwarded to the shareholder listserv at the behest of CMDX, with the ultimate goal of "leverag[ing] the Sham [Citizen] Petition to undermine Elysium in the eyes of its current and potential customers, supply chain partners, investors, and advisors." (Compl. ¶¶ 100, 109)

DISCUSSION

I. Motion to Dismiss Elysium's Complaint

A. Standard of Review for a Motion to Dismiss

Rule 12(b)(6) of the Federal Rules of Civil Procedure provides for dismissal of a complaint that fails to state a claim upon which relief may be granted. Fed. R. Civ. P. 12(b)(6). 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." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). While all reasonable inferences should be drawn in favor of the plaintiff, courts are not required to "accept as true a legal conclusion couched as a factual allegation." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The complaint must contain sufficient factual allegations to "nudge[] their claims across the line from conceivable to plausible." *Id.* at 547. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements," are not entitled to the assumption of truth and are thus not sufficient to withstand a motion to dismiss. *Iqbal*, 556 U.S. at 679.

"In considering a motion to dismiss for failure to state a claim, a district court must limit itself to the facts stated in the complaint, documents attached to the complaint as exhibits, and documents incorporated by reference in the complaint." *Hayden v. Cty. of Nassau*, 180 F.3d 42, 54 (2d Cir. 1999). A district court may also consider a document that is not incorporated by reference, where the complaint "'relies heavily upon its terms and effect,' thereby rendering the

document 'integral' to the complaint." *Rogers v. Blacksmith Brands, Inc.*, 2011 WL 6293764, at *4 (S.D.N.Y. Dec. 13, 2011) (quoting *Mangiafico v. Blumenthal*, 471 F.3d 391, 398 (2d Cir. 2006)). "A motion to dismiss a counterclaim is evaluated under the same standard as a motion to dismiss a complaint." *Orientview Technologies LLC v. Seven For All Mankind, LLC*, No. 13 Civ. 0538, 2013 WL 4016302, at *2 (S.D.N.Y. Aug. 7, 2013) (internal quotations marks omitted).

Elysium's Complaint relies on the Citizen Petition filed with the FDA by CMDX on August 18, 2017, as well as relevant FDA regulations; those documents are incorporated into the pleading. CMDX's Counterclaim appends twenty exhibits, including various magazine articles, (Countercl. Ex. G, H, M, No. 17-cv-08239-VEC, Dkt. No.7.), relevant screenshots of Elysium's website and customer testimonials therein, (Countercl. Ex. I, K, P, Q, R, S), and a screenshot of a Yahoo! Financial user board post (Countercl. Ex. N). These documents are deemed to be part of the record on a motion to dismiss. *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 152 (2d Cir. 2002) ("the complaint is deemed to include any written instrument attached to it as an exhibit or any statements or documents incorporated in it by reference.") (quoting *Int'l Audiotext Network, Inc. v. Am. Tel. & Tel. Co.*, 62 F.3d 69, 72 (2d Cir. 1995)).

Chromadex attaches other documents to its Motion to Dismiss that are not comprehended integrally into Elysium's Complaint, including several publically-available FDA responses to citizen petitions from the past ten years. (Kupfer Dec. Ex. G.) Significantly, one of these letters is of great importance in interpreting 21 C.F.R § 10.30(k), which happens to be relevant to the decision on CMDX's Motion to Dismiss Elysium's Complaint.

B. CMDX's Motion to Dismiss Elysium's Complaint is Denied

CMDX argues that Elysium's claims, both federal and state, must be dismissed as barred by the *Noerr-Pennington* doctrine. In the alternative, CMDX argues that each of Elysium's claims fails under Rule 12(b)(6); that the filing of the Citizen Petition is protected by New York's "litigation privilege" (which, it argues, applies to administrative proceedings before the FDA); and that Elysium's suit qualifies as a "SLAPP action" under New York Civil Rights Law § 70-a ("Anti-SLAPP law"), which insulates CMDX against lawsuits brought by a public applicant or permittee based on CMDX's efforts to "report on, comment on, challenge, or oppose" such petition or application. *Silvercorp Metals Inc. v. Anthion Mgmt. LLC*, 948 N.Y.S.2d 895, 899 (N.Y. Sup. Ct., N.Y. Cty., 2012); *see also* N.Y. Civ. Rights L. § 76-a. CMDX argues that, because Elysium is required to maintain FDA approval for the production and sales of Basis, Elysium is a "public applicant or permittee" under the Anti-SLAPP law. (Def.'s MTD, at 21.)

"The *Noerr-Pennington* doctrine holds that, by virtue of the right to petition guaranteed by the First Amendment, attempts to influence legislative, executive, administrative or judicial action are immune from federal antitrust liability." *Twin City Bakery Workers & Welfare Fund v. Astra Aktiebolag*, 207 F. Supp. 2d 221, 223 (S.D.N.Y. 2002). While *Noerr-Pennington* was an antitrust case, state and federal courts routinely hold that it extends further and applies to a wide range of civil actions under both state and federal law. *See, e.g.*, *Bill Johnson's Restaurants, Inc. v. NLRB*, 461 U.S. 731 (1983) (extending *Noerr-Pennington* to labor law claims); *Suburban Restoration Co. v. ACMAT Corp.*, 700 F.2d 98, 101-102 (2d Cir. 1983) ("If indeed the *Noerr-Pennington* doctrine is mandated by the first amendment, then the doctrine must also apply to Connecticut's statute and common law."); *Friends of Rockland Shelter Animals, Inc. (FORSA) v. Mullen*, 313 F. Supp. 2d 339 (S.D.N.Y. 2004) (*Noerr-Pennington* doctrine extends to tortious interference with prospective business advantage claim); *Hamilton v. Accu-tek*, 935 F. Supp. 1307, 1317 (E.D.N.Y. 1996)

("While the doctrine originated as a limit on antitrust liability, *Noerr–Pennington* has been extended by analogy to protect petitioning activity challenged under other federal statutes."); *Alfred Weissman Real Estate, Inc. v. Big V Supermarkets, Inc.*, 707 N.Y.S.2d 647 (2d Dep't 2000) (*Noerr-Pennington* doctrine extends to claim of tortious interference with prospective economic advantage and N.Y. Gen. Bus. L. § 349).

Noerr-Pennington immunity is not, however, boundless; it does not extend to governmental action that is a "mere sham to cover an attempt to interfere directly with the business relationships of a competitor." *See E. R.R. Presidents Conference v.* 365 U.S. 127, 144 (1961). Obviously, whether an actor like CMDX resorted to sham tactics in furtherance of doing in a competitor is at least in part a subjective inquiry. However, before a court will consider the subjective motive of a defendant under the "sham exception," a plaintiff must show that a challenged action was objectively baseless:

> First, the lawsuit must be objectively baseless in the sense that *no reasonable litigant could realistically expect success on the merits.* If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under *Noerr*, and a [ ] claim premised on the sham exception must fail. Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation.

Prof'l Real Estate Inv'rs, Inc. (PRE) v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60 (1993) (emphasis added). The Supreme Court has made explicit that "evidence of anticompetitive intent or purpose alone cannot transform otherwise legitimate activity into a sham." *Id.* at 49.

Elysium argues that the Citizen Petition was a sham conceived to injure the reputation of both Elysium and its product, Basis, rather than to elicit a favorable outcome from the FDA. In support of this theory, Elysium alleges that the Citizen Petition was objectively baseless because CMDX knew, or, as an industry regulatory consultant, (*see* Compl. ¶ 43), should have known, that

the FDA would not and could not grant the specific relief requested in the Petition, because seizure and injunctive relief are judicial remedies that do not fall within the scope of relief allowed by a citizen petition and, thus, CMDX could have no reasonable expectation of a favorable outcome. (Compl. ¶ 40.) For this, Elysium cites 21 C.F.R. § 10.30(k), which provides, "This [Citizen Petition] section does not apply to the referral of a matter to a United States attorney for the initiation of court enforcement action and related correspondence."

CMDX itself provided the court with evidence that it was fully aware that the specific enforcement action it sought in the Citizen Petition – a seizure order and/or an injunction against distributors of Basis – was beyond the purview of a citizen petition. One of the exhibits attached to CMDX's Motion to Dismiss is a November 29, 2016, letter from Janet C. Woodcock. M.D., Director of the FDA's Center for Drug Evaluation and Research, denying a citizen petition that sought to have the Commissioner announce an intent to take "enforcement action (including seizures, injunctions, civil penalties and/or criminal sanctions)" against manufacturers and distributors of products containing fluoride. (Kupfer Decl. Ex. G, at 1-2.) The letter denies the petition on the ground that "requests for the agency to initiate enforcement actions are not within the scope of FDA's citizen petition procedures, and this request is not an appropriate request for a citizen petition." *Id.* As this letter has been a matter of public record for nearly two years, it thus appears that CMDX was aware, at the time it filed the Citizen Petition on August 18, 2017, that the petition would be denied – which, Elysium argues, means that it had no reasonable expectation of success on the merits. *See MCI Commc'ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1156 (7th Cir. 1983) ("There can be no genuine attempt to petition the government when the petitioners know in advance that the governmental body lacks the authority to take the action desired."); *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 316 (E.D. Pa. 2011) ("Plaintiffs' evidence is

sufficient to raise genuine issues of fact as to whether the [] Petition requested relief that was contrary to FDA practice, and thus whether the [] Petition was objectively baseless."); *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 689 (E.D. Pa. 2014), *on reconsideration in part sub nom. In re Suboxone (Buprenorphine Hydrochloride & Nalaxone) Antitrust Litig.*, No. 13-MD-2445, 2015 WL 12910728 (E.D. Pa. Apr. 14, 2015) (denying *Noerr-Pennington* immunity for a citizen petition filed against a competitor where "The FDA acknowledged in its ruling that it had no authority to grant much of [the] requested relief.").

CMDX counters that it is possible for a citizen petition to generate a "favorable outcome" even if the FDA denies it. *See* 21 C.F.R. § 10.30(e)(3) ("The Commissioner may grant or deny such a petition, in whole or in part, *and may grant such other relief or take other action as the petition warrants*.") (emphasis added). I understand CMDX to argue (though not in a very articulate way) that its petition could be granted in part. In other words, even if the portion seeking enforcement action were to be denied (and it will be), CMDX points to the fact that the Citizen Petition requests other relief, including (1) the issuance of an order from the FDA declaring that Elysium's Basis product is adulterated within the meaning of 21 U.S.C. § 342(a); (2) an order declaring that Basis "contains a new dietary ingredient under 21 U.S.C. § 350b," *i.e.*, the Mystery NR for which Elysium had not submitted a NDIN (*Id.* Ex. A at 2.); and (3) "all appropriate remedial action," including ordering Elysium to cease distributing Basis. I gather that these forms of relief are administrative in nature and do not require recourse to the United States Attorney or to the courts.

Additionally, the Commissioner is empowered to take other action if action is warranted.[2] CMDX argues that if the FDA, on the basis of the evidence in the Citizen Petition, decides to open an investigation into the allegations regarding Basis, this would constitute a "favorable outcome." It argues that the Citizen Petition contains ample evidence to support its claims regarding the possible adulteration and regulatory compliance of Basis, so that it cannot be said that "no reasonable litigant could realistically expect success on the merits." *PRE*, 508 U.S. at 60. While Elysium may regard the evidence as specious, and may vehemently disagree with the position CMDX espouses, Elysium's belief about the Petition's lack of merit does not render it a sham. *See Apotex*, 823 F. 3d at 61.

Elysium argues that if CMDX's motivation had truly been to inform the FDA of a potential health issue, CMDX would have filed a trade complaint. (Compl. ¶¶ 41-43.) This mechanism, they argue, would have empowered the FDA to grant the relief sought while keeping the Petition out of the public view, thus achieving CMDX's purported ends without the effect of damaging Elysium's reputation. (Compl. ¶¶ 41-43.)

Again, CMDX has demonstrated its awareness of this possibility; Exhibit H to its Motion to Dismiss contains two letters from the FDA to citizen petitioners, converting their petitions to trade complaints. (Kupfer Decl. Ex. H.) From Elysium's perspective, the fact that CMDX chose instead to file a citizen petition is evidence that the Citizen Petition was filed in bad faith. (Compl. ¶¶ 41-43.)

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[2] Exhibit G contains several other publicly - available FDA letters denying similar citizen petitions in which the agency references other things that it "could" do - including issue a notice to health care providers about the risks from using certain products imported from overseas – in response to the receipt of information via a citizen petition that was otherwise denied.

Even if this contention is correct, it does not mean that the Citizen Petition is a sham, bringing it outside the protection of the *Noerr-Pennington* doctrine. *See Noerr*, 365 U.S. at 144. As was the case in *Noerr*, this case appears to be a "'no-holds-barred fight' between two industries both of which are seeking control of a profitable source of income." *Id.* And "[i]nherent in such fights . . . is the possibility, and in many instances even the probability, that one group or the other will get hurt by the arguments that are made." *Id.* At this stage of the analysis, evidence that CMDX intended to injure Elysium is wholly irrelevant: unless Elysium can show that the Citizen Petition was objectively baseless, CMDX cannot be deprived of *Noerr-Pennington* immunity based on the sham exception. *PRE*, 508 U.S. at 60.

Most damning on the issue of objective baselessness is Elysium's contention that CMDX's PT product, pTeroPure®, also contains toluene in levels comparable to the toluene in Basis. (Compl. ¶ 64.) Assuming *arguendo* that CMDX does not intend to market an adulterated product, it would be objectively baseless for it to argue to the FDA that a competitor's product is adulterated because it contains an ingredient that is found in CMDX's own competing product. *See In re Suboxone*, 64 F. Supp. 3d at 690 (finding citizen petition a sham where petitioner requested the FDA investigate why a pharmaceutical had not been pulled from the market, yet continued to sell the same drug).

Elysium asserts in its Complaint that Certificates of Analysis ("COAs") sent by CMDX to its customers show the presence of toluene in its product. (Compl. ¶ 65.) One ordinarily assumes the well-pleaded factual allegations of a complaint to be true for purposes of a motion to dismiss. *Iqbal*, 556 U.S. at 679. However, no copy of such a certificate is appended to the Complaint. Also, while CMDX itself appended to its Motion to Dismiss the FDA citizen petition that were referenced above, they are not properly part of the record on a motion to dismiss.

For this reason, the court is converting CMDX's Motion to Dismiss on *Noerr-Pennington* grounds to a motion for summary judgment on that basis, pursuant to Fed. R. Civ. P. 56. "When material outside the complaint is presented to and not excluded by the court, 'the motion shall be treated as one for summary judgment and disposed of as provided in [Federal Rule of Civil Procedure] 56, and all parties shall be given reasonable opportunity to present all material made pertinent to such a motion.'" *Time Warner*, 282 F.3d at 152 (citing Fed. R. Civ. P. 12(b)). Conversion to a Rule 56 Motion is the proper procedure when the disposition of a motion to dismiss calls for consideration of evidence that has been submitted to the court but is beyond the four corners of the complaint. *See Amaker v. Weiner*, 179 F.3d 48, 50 (2d Cir. 1999) ("enforcement of the conversion requirement helps ensure that courts will refrain from engaging in fact-finding when considering a motion to dismiss, and also that plaintiffs are given a fair chance to contest defendants' evidentiary assertions where a court nonetheless does consider evidence extrinsic to the complaint in that context."). Invocation of that procedure is particularly appropriate here, where the motion for summary judgment can be limited to a single, discrete issue – in this case, objective baselessness under *Noerr-Pennington*'s sham exception.

The conversion is limited to this one issue. The motion is otherwise denied. Assuming that CMDX is not immunized under *Noerr*, the Complaint easily passes the test of whether it pleads claims on which relief could be granted, pursuant to Fed. R. Civ. P. 12(b)(6).

CMDX's Citizen Petition is not protected by New York state litigation privilege. In New York, "relevant statements made in judicial or quasi-judicial proceedings are afforded absolute protection so that those discharging a public function may speak freely to zealously represent their clients without fear of reprisal or financial hazard." *Front, Inc. v. Khalil*, 24 N.Y.3d 713, 718, (2015). This immunity does not extend to administrative matters that do not qualify as "quasi-

judicial" proceedings. *Stega v. New York Downtown Hosp.*, 31 N.Y.3d 661 (2018) ("for absolute immunity to apply in a quasi-judicial context, the process must make available a mechanism for the party alleging defamation to challenge the allegedly false and defamatory statements."); *Toker v. Pollak*, 44 N.Y.2d 211, 222 (2d Dep't 1978) (no privilege where agency did not provide a hearing at which allegations could be challenged). The FDA citizen petition process is not a quasi-judicial proceeding.

Nor is the Citizen Petition protected by New York's anti-SLAPP laws under New York Civil Rights Law §§ 70-a and 76-a(1)(a). To establish an anti-SLAPP claim under New York law, "1) there must be a public application or petition, 2) the public applicant or permittee of that application must file a lawsuit against a person [that] is materially related to any efforts of the defendant to report on, comment on, rule on, challenge or oppose such application or permission, and 3) the lawsuit must be, at a minimum, substantially without merit." *Gilman v. Spitzer*, 902 F. Supp. 2d 389, 398 (S.D.N.Y. 2012), *aff'd*, 538 F. App'x 45 (2d Cir. 2013) (citing *Chandok v Klessig*, 648 F.Supp.2d 449, 460 (N.D.N.Y. 2009), *aff'd*, 632 F.3d 803 (2d Cir. 2011)). Even if ongoing FDA regulation of dietary supplements qualifies Elysium as a "public applicant or permittee," pursuant to the C.P.L.R., the Court cannot grant a motion to dismiss a SLAPP suit if "the party responding to the motion demonstrates that the cause of action has a substantial basis in law." N.Y. C.P.L.R. 3211(g); *Related Properties, Inc. v. Town Bd. of Town/Vill. of Harrison*, 802 N.Y.S.2d 221, 224 (2d Dep't 2005). Because, as already stated in this opinion, Elysium's lawsuit passes muster under Rule12(b)(6), it is not "substantially without merit" and thus cannot be characterized as a SLAPP suit.

II. Motion to Dismiss CMDX's Counterclaim

In its Counterclaim, CMDX alleges that Elysium has made a number of false statements in its advertisements, giving rise to a cause of action for false advertising and unfair competition under § 43 of the Lanham Act, deceptive trade practices and false advertising under §§ 349 and 350 of the New York General Business Law, and tortious interference with prospective economic advantage. Elysium has moved to dismiss CMDX's Counterclaim for failure to state a claim upon which relief may be granted, pursuant to Fed. R. Civ. P. 12(b)(6).

A. False Advertising and Unfair Competition Under the Lanham Act

False advertising is one form of "unfair competition," the latter being an "over-arching" field of law that encompasses other wrongful conduct that is prescribed under 15 U.S.C. § 1125(a). J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition* §4:6 (5th ed. 2017). Since, in this context, the elements of unfair competition and false advertising are identical, *see infra*, and because the parties' respective briefs evaluate these claims together, the Court will do the same.

The Lanham Act expressly forbids false or misleading descriptions or representations of fact "in commercial advertising or promotion" concerning "the nature, characteristics, qualities, or geographic origin of . . . goods, services, or commercial activities." 15 U.S.C. § 1125(a)(1)(B). To establish a Lanham Act violation under § 43, CMDX must prove that (1) the Elysium has made a false or misleading statement; (2) the false or misleading statement has actually deceived or has the capacity to deceive a substantial portion of the intended audience; (3) the deception is material in that it is likely to influence purchasing decisions; (4) the defendant placed the false or misleading statement in interstate commerce; and (5) CMDX has been injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with

its products. *Merck Eprova AG v. Brookstone Pharm., LLC*, 920 F. Supp. 2d 404, 416 (S.D.N.Y. 2013) (citing *S.C. Johnson & Son, Inc. v. Clorox Co.*, 241 F.3d 232, 238 (2d Cir. 2001)).

The parties principally dispute the first and fifth prongs – falsity and injury.

Falsity

To establish falsity, a plaintiff must show either (1) that the "challenged advertisement is literally false, *i.e.*, false on its face," or (2) "that the advertisement, while not literally false, is nevertheless likely to mislead or confuse customers." *Tiffany (NJ) Inc. v. eBay, Inc.*, 600 F.3d 93, 112 (2d Cir. 2010). CMDX alleges that a number of statements made by Elysium relating to the scientific research, chemical composition, clinical testing, purported health benefits, and FDA approval of Basis were false – all of which allegedly were designed to overstate the safety of Basis.

To the extent CMDX's false advertisement claims regarding the safety of Basis are premised on the fact that the product contains toluene, the Court is ill-equipped to say whether Elysium's statements are false, as it is no position to gauge the precise level of toluene that is acceptable in a nutritional supplement for daily human exposure. The FDA, of course, has authority to weigh in on this matter, pursuant to the Food Drug and Cosmetic Act ("FDCA"); if it so chooses, it may do so through a response to the Citizen Petition before it. *See PDK Labs v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997). *Accord Dial A Car, Inc. v. Transp., Inc.*, 82 F.3d 484, 488-90 (D.C. Cir. 1996); *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230-31 (3d Cir. 1990).

The remaining statements challenged by CMDX as literally false or misleading can be grouped into one of four categories: (1) a statement that Basis is "pure;" (2) statements that the FDA has approved or endorsed Basis when it has not; (3) statements regarding the research of the

science behind Basis; and (4) statements regarding the testing and production of Basis. (Countercl. ¶ 74.) All but one of these statements suffice to state a plausible Lanham Act violation.

i. Statement that Basis is "Pure"

CMDX alleges that Elysium misrepresented the quality of Basis in response to a single consumer email inquiry. The email response, which was posted to a Yahoo! message board by an anonymous poster named "Jeff," states in full:

> While the specific Basis formulation and the amount of each ingredient have not changed, this new production process has allowed us to take an exceptional product and make it even purer. We also have eliminated color variations and can now provide a consistently white final product, as you may have seen with your most recent shipment. This reflects our ongoing commitment to being a trusted source for our customers by continually exceeding the highest standards in the industry.

(Countercl. Ex. N.) CMDX asserts that this statement misleadingly conflates the color white with purity. It further alleges this statement is literally false because NR in its "normal state" is brown, and "the Basis product is only white because it lacks an authentic version of [NR]." (Countercl. Ex. N.)

This statement is not actionable. Accepting as true – as the Court must at this stage – that the above anonymous post is attributable to Elysium, one email between a company representative and a single consumer does not constitute "advertising and promotion" within the meaning of the Lanham Act. To qualify as "advertising and promotion, the contested representations must be (1) commercial speech, (2) made for the purpose of influencing consumers to buy a defendant's goods or services, and (3) disseminated sufficiently to the relevant purchasing public. *Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.*, 314 F.3d 48, 58 (2d Cir. 2002) (internal quotation marks, citations, and alterations omitted). The Lanham Act does not stretch to cover stray remarks. *See, e.g.*, *Chamilia, LLC v. Pandora Jewelry, LLC*, No. 04-CV-6017 (KMK), 2007 WL 2781246, at *9 (S.D.N.Y. Sept. 24, 2007) (six statements to individuals in a seemingly large market are not

actionable advertising). Because CMDX has not alleged that this purported statement by Elysium was directed at anyone other than "Jeff," the Court cannot plausibly infer on the basis of CMDX's complaint that Elysium's representations were "part of an organized campaign to penetrate the relevant market," as needed to sustain a Lanham Act claim. *Fendi*, 314 F.3d at 57.

ii. Statements that the FDA Has Approved or Endorsed Basis

Next, CMDX alleges that Elysium deceptively describes applicable FDA regulations to mislead consumers into believing that the FDA has blessed Basis as safe. Specifically, on the "Our Mission" page of Elysium's website, the following copy appears:

> Our process for all products begins with a comprehensive evaluation of all available scientific literature and culminates in a product becoming available for purchase. In between, there are many important steps. The steps below help us discover and commercialize new products. They don't all necessarily happen in this order.

(Countercl. Ex. K., at 2.) Under this module, the website explains the "FDA NDI Submission" stage:

> We conduct rigorous safety studies for new dietary ingredient (NDI) submissions to the FDA. The Federal Food, Drug, and Cosmetic Act (FD&C) requires that we submit studies to demonstrate the safety of "new dietary ingredients.

(Countercl. Ex. K., at 3.) It then goes on to describe the "Safety Testing" stage ("Typically characterized as a 'Phase 1' clinical trial, this stage determines the safety and pharmacokinetics of the compound in healthy individuals,") and the "Efficacy Testing" phase ("Typically characterized as a 'Phase 2' clinical trial, this human study looks at the safety and efficacy of a given molecule."). (Countercl. Ex. K., at 3.)

CMDX also cites a blog article published by Elysium, titled "The Real Definition of a Dietary Supplement," which describes the evolution in FDA regulation of dietary supplements and NDIN procedures:

> If a supplement maker introduced a new ingredient to the market it's supposed to notify the FDA. The FDA has had some trouble with compliance. . . . When DSHEA ("[w]hen DSHEA (Dietary Supplement Health and Education Act of 1994) was passed . . . there were roughly 4,000 products on the market; today there are more than 77,000, so needless to say there have also been many new ingredients introduced as well. Part of the reason the FDA issued its latest guidance in 2016, by its own admission, is that compliance with the NDI notification process has been inconsistent. The FDA hopes to get more notifications of NDIs submitted, thereby avoiding companies simply introducing new and potentially unsafe ingredients into the consumer market."

(Countercl. Ex. J, at 2, 9.)

At bottom, CMDX alleges that the above statements are misleading because they give consumers the impression that Basis – Elysium's only consumer product – has received FDA approval, when it purportedly has not. (Mem. of Law in Opp. Elysium's Mot. to Dismiss ("Opp. Elysium's MTD"), at 9, Dkt. No. 34.)

Drawing all inferences in favor of the non-movant, CMDX has sufficiently pleaded a Lanham Act violation. Statements relating to the government approval process of nutritional supplements, coupled with the fact that Elysium only sells one consumer product, gives rise to the plausible conclusion that Elysium's sole consumer product has undergone that process. Critically, the majority of the above statements are located under a banner on Elysium's website entitled "*How We Work*: *Our* R&D Process." (Countercl. Ex. K., at 2) (emphases added.) While certain statements, viewed in isolation, may not be actionable, courts should "not . . . engage in disputatious dissection" of speech; instead, statements must be considered "in [their] entirety" and as part of a broader advertising campaign. *Avis Rent A Car Sys., Inc. v. Hertz Corp.*, 782 F.2d 381, 385 (2d Cir. 1986) (Friendly, *J.*); *see also Reed Const. Data Inc. v. McGraw-Hill Companies, Inc.*, 49 F. Supp. 3d 385, 411 (S.D.N.Y. 2014), *aff'd*, 638 F. App'x 43 (2d Cir. 2016). The thrust of Elysium's advertising, as pleaded by CMDX, was to create an impression of FDA approval where

none existed. Accordingly, CMDX's Lanham Act claim may proceed on the basis of the above statements.

iii. Statements Regarding the Research of the Science Behind Basis

Next, CMDX alleges that Elysium misrepresents the safety of Basis by making a series of false statements about the body of anti-aging science and Elysium's role in its developments.

CMDX points to two sets of statements touting the scientific support for Basis, which purportedly were part of a "smoke and mirror marketing" campaign that was intended "to create the wholly inaccurate impression that Elysium itself played a significant role in the scientific research concerning NR, and that its current Basis product is both novel and well-researched, when in fact it is not." Countercl. ¶ 44.)

The first is an article published in *New York* Magazine on August 22, 2016, in which the author reports seeing an Elysium-sponsored banner ad on Facebook celebrating Basis as "the world's first cellular health product informed by genomics." (Countercl. Ex. G., at 3.) The second is an interview with one of Elysium's founders, Dr. Leonard Guarente, published by *Allure* magazine on October 18, 2017. Dr. Guarente is quoted as saying, "With regard to Basis, the pill seems simple, but the amount of science behind it is quite extensive." (Countercl. Ex. H, at 3.) He goes on to state, "[the science behind Basis] began almost 30 years ago. The research progressed from studying aging in yeast to the discovery of a family of proteins called sirtuins that control aging. That led to the identification of two compounds, [PT] and [NR], that activate sirtuins. . . . [Those sirtuin-stimulating compounds are the main ingredients in Basis]." (Countercl. Ex. H, at 3.)

Elysium asserts that these statements are not actionable, because "statements featured in news articles . . . do not constitute commercial speech." (Opp. Elysium's MTD at 20-21) (citing

Gmurzynska v. Hutton, 355 F.3d 206, 210-11 (2d Cir. 2004).) *Gmurzynska* does not stand for such a sweeping proposition. In *Gmurzynska*, an art gallery sued a competing gallery, its owner, and three art experts on the basis that the defendants allegedly conspired to cause a third party journalist to write an article documenting the feud between the two galleries, which centered on the authenticity of certain pieces of artwork purchased by the plaintiff-gallery. The Second Circuit affirmed the lower court's dismissal of the complaint, reasoning that the art experts' statements questioning the authenticity of the artwork were expressions of opinion that were protected under the First Amendment. *Id.* at 210-211. The court did not indicate, as Elysium contends, that otherwise false statements are immunized from Lanham Act liability by virtue of being featured in a news article. On the contrary, *Gmurzynska* specifically noted that the plaintiff failed to plead that the offending news article contained any factual assertions. *Id.* at 211.

At bottom, *Gmurzynska* stands for the proposition that a Lanham Act claim premised on the public expression of opinion is subject to special scrutiny. *Id.*at 211. That proposition is not implicated here. Rather, the above statements, when viewed in the aggregate, *see Avis Rent A Car Sys.*, 782 F.2d at 385, give rise to a plausible inference that they were part of a broader advertising campaign intended to mislead consumers into believing that Elysium developed the science behind a one-of-a-kind product. This is especially so when taking into account Elysium's statements on its website celebrating the work of its Scientific Advisory Board ("SAB") and its "Research Partnerships." (Countercl. Ex. P.) While CMDX does not allege that any one of the statements about the SAB or Elysium's research partnerships are literally false, it alleges that they create "an implied endorsement" about the research undergirding Basis, adding to the misleading nature of Elysium's alleged advertising campaign. (*Id.* ¶ 68.) As pleaded, all of these statements regarding

the research behind Basis and its role in its development are sufficient to support a Lanham Act claim.

iv. Statements Regarding the Testing and Production of Basis

Finally, CMDX alleges that statements on Elysium's website regarding clinical trials conducted on Basis were misleading because, on information and belief, Basis's only clinical trials were conducted while Basis was being produced with CMDX's NR and PT products, NIAGEN® and pTeroPure®. (Countercl. ¶ 54.)

CMDX points to the following copy on Elysium's web page titled "Our Mission," which appears under the heading "How We Work: Our R&D Process":

> **Results From Our First Clinical Trial**
> In our first clinical trial participants who took the recommended dose of Basis saw their NAD+ levels increase 40% and remain at that level for the duration of the trial.

(Countercl. Ex. K, at 2.) According to the Counterclaim, "the only clinical trials conducted with Basis were conducted with authentic ingredients previously supplied by ChromaDex, which are no longer available to Elysium." (Countercl. ¶ 3.)

On December 6, 2016, Elysium issued a public press release "announc[ing] Topline Clinical Trial Results for its First Product Basis." Id. Ex. L, at 1. This press release stated that the clinical trial, which "evaluated the safety and efficacy of Basis," "met its primary and secondary endpoints." (Countercl. Ex. L.) "The trial results, which are the first of their kind, indicate that Basis increased NAD+ levels in a sustained way." (Countercl. Ex. L, at 2.) CMDX alleges that the press release is impliedly false, because "to the extent any such study was completed, Elysium was at that time purchasing and using its supply of NR from CMDX." (Countercl. ¶ 55.)

Accepting, as the court must at this stage, that both of these representations were made to the public after Elysium severed its relationship with CMDX, such statements support a reasonable inference that Elysium misrepresented the clinical testing of the actual product being sold by Elysium at that time. Nevertheless, Elysium avers that the above statements cannot form the basis of a Lanham Act violation, because CMDX makes those assertions "on information and belief" and without affirmative evidence establishing that the sourcing, manufacturing, and third-party auditing of the current Basis product do not comport with those statements. (Mem. of Law in Supp. Elysium's Mot. to Dismiss, at 7, 9-10, Dkt. No. 32.) Where, as here, information is "particularly within [a party's] knowledge and control" – such as is the identity, qualifications, and dealings of Elysium's "mystery supplier," as well as the specific date they ceased using CMDX's ingredients in Basis – it is appropriate to plead on the basis of information and belief. *Boykin v. KeyCorp*, 521 F.3d 202, 215 (2d Cir. 2008).

In light of these factual allegations, the Court draws the reasonable inference that the website copy and press release statements regarding clinical trials are impliedly false. Accordingly, CMDX has stated a claim under the Lanham Act on the basis of these statements.

Injury

CMDX's Counterclaim gives rise to a plausible inference that CMDX has suffered a competitive injury. A competitive injury is "an injury to a commercial interest in sales or business reputation." *Lexmark Int'l, Inc. v. Statis Control Components, Inc.*, 572 U.S. 118, 139 (2014). A claim by a direct competitor, as CMDX is to Elysium, (Countercl. ¶ 19.), constitutes "the paradigmatic direct injury from false advertising." *Lexmark*, 572 U.S. at 138. CMDX alleges, at numerous places in its Counterclaim, that it suffered direct competitive injury. (*See* Countercl. ¶¶

64-66, 71, 74, 78.) As thoroughly described, these allegations are supported by sufficient factual matter, giving rise to a plausible inference of injury.

In sum, with the exception of statements whose falsity depends upon the appropriate level of toluene in nutritional supplements as well as those touting the purity of Basis, *see supra* II.A.i., CMDX has plausibly pleaded a Lanham Act violation.

B. New York's General Business Law §§ 349-50

CMDX also asserts counterclaims for deceptive trade practices and false advertising, pursuant to New York General Business Law §§ 349 and 350, respectively. (Countercl. ¶¶ 80-87.)

Section 349 prohibits "Deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state," N.Y. Gen. Bus. Law § 349(a), while § 350 prohibits "False advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state," *id.* § 350. Both claims require a showing that (1) Elyisum's act, practice, or advertisement was consumer-oriented, (2) that it was materially deceptive and misleading, and (3) that CMDX was injured as a result. *Mimedx Grp., Inc. v. Osiris Therapeutics, Inc.*, No. 16 CIV. 3645 (KPF), 2017 WL 3129799, at *14 (S.D.N.Y. July 21, 2017) (internal citations omitted). As an additional element unique to § 350, CMDX must also establish that it actually relied on Elysium's deceptive conduct. *Rodriguez v. It's Just Lunch, Int'l,* No. 07 Civ. 9227(SHS)(KNF), 2010 WL 685009, at *10 (S.D.N.Y. Feb. 23, 2010) (citing *Pelman v. McDonald's Corp.*, 396 F.3d 508, 511 (2d Cir. 2005)).

The standards for bringing a claim under §§ 349 and 350 are substantially the same as those applied to claims brought under § 43 of the Lanham Act. *Id.* (collecting cases). For this reason, the analysis is the same as well: CMDX can proceed on its claim under § 349 on the basis of the

statements above that the Court deemed sufficiently pleaded to sustain a Lanham Act claim. CMDX's claim under § 350, however, is dismissed, because CMDX has failed to plead facts tending to show that it actually relied on Elysium's allegedly false statements. *See Pelman*, 396 F.3d at 511. On the contrary, CMDX, as a sophisticated party well-versed in the science behind Basis, impliedly pleads that it did *not* rely on Elysium's advertising.

C. Tortious Interference with Prospective Economic Advantage

Finally, CMDX alleges that Elysium tortuously interfered with CMDX's prospective economic relationships by negotiating and enforcing an exclusivity provision in the parties' supply agreement, only to then "sabotage" CMDX by "refusing to pay for extraordinarily large orders of NR and conspiring with CMDX's employees against CMDX." (Opp. Elysium's MTD, at 24.) (*See also* Countercl. ¶¶ 31-38, 89-90.)

"To state a claim for this tort under New York law, four conditions must be met: (1) the plaintiff had business relations with a third party; (2) the defendant interfered with those business relations; (3) the defendant acted for a wrongful purpose or used dishonest, unfair, or improper means; and (4) the defendant's acts injured the relationship." *Catskill Dev., L.L.C. v. Park Place Entm't Corp.*, 547 F.3d 115, 132 (2d Cir. 2008) (internal citation omitted).

CMDX's counterclaim is deficient. Most fundamentally, CMDX has not pleaded that Elysium "direct[ed] some activities toward[] [a] third party and convince[d] the third party not to enter into a business relationship" with CMDX. *Black Radio Network, Inc. v. NYNEX Corp.*, No. 96 CIV. 4138 (DC), 2000 WL 64874, at *4 (S.D.N.Y. Jan. 25, 2000) (internal citations omitted). The exclusivity provision in the parties' supply contract was negotiated by and among the two sophisticated entities that were parties to that agreement – CMDX and Elysium – and was not

directed at a specific CMDX customer. Additionally, any alleged "conspiring" with CMDX's employees is, by definition, conduct directed at CMDX. CMDX's failure to plead interference with a third-party business relationship demands dismissal of its tort claim.

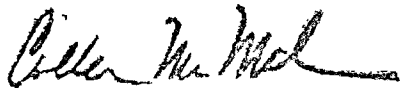
CONCLUSION

For the foregoing reasons, CMDX's Motion to Dismiss is DENIED in part. The Court is converting CMDX's Motion to Dismiss on *Noerr-Pennington* grounds to a motion for summary judgment. The parties have thirty days to submit any and all evidence that may bear on the objective baselessness of CMDX's Citizen Petition – which would include, but is not limited to the evidence referred to in Paragraph 65 of Elysium's Complaint – at which time the court will take up the *Noerr-Pennington* challenge again.

Elysium's Motion to Dismiss CMDX's Counterclaim's is GRANTED in part and DENIED in part.

The Clerk of Court is directed to remove the motions at ECF numbers 19 and 31 from the Court's list of open motions

Dated: September 27, 2018



Chief Judge

BY ECF TO ALL COUNSEL