UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re Elysium Health—ChromaDex Litigation	Civil Action No. 1:17-cv-07394 (CM)

MEMORANDUM OF LAW OF CHROMADEX, INC.
IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

TABLE OF AUTHORITIES

PAGE

TABLE OF AUTHORITIES

PAGE

Cases

TABLE OF AUTHORITIES

PAGE

Statutes and Other Authorities

I. INTRODUCTION

On September 27, 2017, Elysium Health, Inc. ("Elysium") filed a complaint (Dkt. No. 1) ("Complaint") against ChromaDex, Inc. ("ChromaDex") alleging, *inter alia*, violations of § 43(a) of the Lanham Act, trade libel, deceptive business practices, and tortious interference related to allegations in a citizen petition ChromaDex filed with the Food & Drug Administration ("FDA") on August 18, 2017 ("Citizen Petition" or "Petition"). *See* Ex.[1] K (Citizen Petition).

On October 26, 2017, ChromaDex moved to dismiss the Complaint. With regard to the allegations pertaining to the Citizen Petition, ChromaDex argued Elysium's claims are barred under the *Noerr-Pennington* doctrine, which holds that by virtue of the right to petition guaranteed in the First Amendment, attempts to influence legislative, executive, administrative, or judicial action are immune from liability. In opposition to the motion, Elysium argued that the Citizen Petition falls under the "sham exception" to *Noerr-Pennington* immunity.

The Supreme Court has articulated a two-part test for whether a request for government action falls under the "sham exception":

> 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. Real Estate Investors ("PRE") v. Columbia Pictures Indus., 508 U.S. 49, 60 (1993).

On September 27, 2018, the Court issued a Decision and Order granting in part and denying in part ChromaDex's pending motion to dismiss. *In re Elysium Health—ChromaDex Litig.*, 2018 WL 4907590 (S.D.N.Y. Sept. 27, 2018). With respect to the Citizen Petition allegations, the Court converted the motion to one for summary judgment solely as it related to the "objectively baseless"

[1] "Ex." refers to exhibits to the Declaration of Troy Rhonemus, dated Oct. 29, 2018, filed together with this brief. "Decl. ¶" refers to specific paragraphs in the Rhonemus Declaration.

prong of the "sham exception" under *Noerr-Pennington*. The Court permitted the parties to submit evidence bearing on that issue. *In re Elysium*, 2018 WL 4907590 at *7, 14.

The undisputed facts establish that ChromaDex's Citizen Petition was not objectively baseless because the Citizen Petition (i) asserted legally viable arguments in favor of determinations from the FDA, (ii) sought determinations which are within the scope of the citizen petition process, and (iii) has already achieved a favorable result. Elysium's arguments are red herrings that do not cast doubt on the validity of the Petition.

II. LEGAL STANDARD

The plaintiff has the burden to establish that a request for government action was a "sham." *PRE*, 508 U.S. at 62. Where "there is no dispute over the predicate facts underlying the legal proceeding" a court may decide whether a request for government action is objectively baseless as a matter of law, without the need for discovery. *PRE*, 508 U.S. at 63 (citations omitted); *Bath Petroleum Storage, Inc. v. Market Hub Partners, L.P.*, 129 F. Supp. 2d 578, 594 (W.D.N.Y. 2000) (rejecting notion that *Noerr-Pennington* cannot be decided until completion of discovery and explaining that "such discovery would . . . effectively chill First Amendment rights which *Noerr* immunity was intended to protect"); *see also Apotex, Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 61-62 (2d Cir. 2017) (deciding objective baselessness at the pleading stage).

III. THE CITIZEN PETITION WAS REASONABLY CALCULATED TO ELICIT A FAVORABLE OUTCOME

A. The Citizen Petition Asserted Legally Viable Arguments in Favor of Determinations from the FDA

The objectively baseless inquiry examines the "legal viability" of the request for government action. *PRE*, 508 U.S. at 62. "The existence of probable cause to institute legal proceedings precludes a finding that [a] defendant has engaged in sham litigation." *Id*. *See also In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1357-59 (S.D. Fla. 2004)

(objectively baseless is similar to frivolous standard in litigation); *see, e.g., Mover's & Warehouseman Assoc. v. Long Island Moving*, 1999 WL 1243054, at *6 (E.D.N.Y. Dec. 16, 1999) (dismissed lawsuit was "'insufficient,' not groundless or objectively baseless")

The Petition requested that the FDA make two determinations. (Decl. ¶¶ 65-67; Ex. K at 2.) Each of these requests were legally viable.

First, the Citizen Petition sought a determination that Basis was adulterated because it was "injurious to health" or "presents a significant or reasonable risk of injury," under 21 U.S.C. § 342(a) and (f). (Decl. ¶ 66; Ex. K at 2.) It is undisputed that (a) at the time of the filing of the Petition, Basis contained toluene (Decl. ¶ 63; Ex. K at 22-23); (b) the Center for Disease Control ("CDC") issued a Public Health Statement warning of a "serious health concern" toluene may cause on the central nervous system and, depending on dose, duration, and how it is ingested, that toluene can cause serious temporary and permanent health effects, including death (Decl. ¶ 48; Ex. I at 3-5); (c) guidelines published by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("ICH Guidelines"), which sets safe limits for toluene in pharmaceuticals, do not apply to dietary supplements like Basis (Decl. ¶ 43; Ex. H at 1-2); and (d) there are no specifications for toluene in dietary supplements and there are no studies on the health effects of prolonged toluene consumption (Decl. ¶ 49). On these undisputed facts, ChromaDex's request for a determination that Basis was adulterated was legally viable and thus, not objectively baseless.

Elysium alleges that the toluene in Basis was safe because the "small amounts of toluene [ChromaDex] alleged to have found in Basis were well below the acceptable levels." (Complaint ¶ 9.) Elysium is asking this Court to determine the safe level of toluene in dietary supplements, and based on that assessment, to find the Petition baseless. But as the Court has already

recognized, the safety determination is for the FDA, and it may choose to act through a response to the Citizen Petition. *In re Elysium*, 2018 WL 4907590 at *8.

Elysium further alleges that by stating that FDA has "not set any allowed level of exposure to toluene in a dietary supplement," and by omitting mention of the ICH Guidelines from the Petition, ChromaDex "created the false impression that the small amounts of toluene it claimed to have found in Basis did not conform to any safety standard accepted by FDA." (Complaint ¶¶ 9, 67, 73.) These allegations are merely conjecture as to ChromaDex's subjective intent and have no bearing on the objectively baseless inquiry.

Even if the Court credited Elysium's allegations, *Noerr-Pennington* immunity still applies. In *City of Columbia v. Omni Outdoor Advertising, Inc*., 499 U.S. 365, 383-84 (1991), the Supreme Court noted that, in "*Noerr* itself, where the private party 'deliberately deceived the public and public officials' in its successful lobbying campaign, we said that 'deception, reprehensible as it is, can be of no consequence so far as the Sherman Act is concerned.'" For wrongful conduct to bring a petition with the "sham exception" it must affect the "decision making process." *Armstrong Surgical Ctr. v. Armstrong Cnty. Mem'l Hosp.*, 185 F.3d 154, 162 (3d Cir. 1999); *Interstate Props. v. Pyramid Co. of Utica*, 586 F. Supp. 1160, 1162 (S.D.N.Y. 1984). Here, there is no chance that the FDA's decision making process will be impacted by the absence of a reference to the ICH Guidelines in the Petition. Elysium filed a comment to the Citizen Petition regarding the ICH Guidelines. (Decl. ¶ 70; Ex. N at 1-3.) Likewise, ChromaDex's supplemental citizen petition, filed January 16, 2018 ("Supplemental Petition"), discussed the ICH Guidelines, and asked the FDA to issue public guidance specifying their non-applicability to dietary supplements.

(Decl. ¶ 74; Ex. P at 3.)[2] Thus, any misimpression left by the Citizen Petition was rectified, and did not render the Petition a "sham." *See Armstrong*, 185 F.3d at 168 (where the "decision makers [are] disinterested, conduct[] their own investigation, and afford[] all interested parties an opportunity to set the record straight," any misrepresentations will not render a petition "sham").

Separately, the Citizen Petition sought a determination that Basis was adulterated because it contained a new dietary ingredient for which Elysium had not submitted a new dietary ingredient notification ("NDIN"), as required by 21 U.S.C. § 342(f)(1)(B). (*See* Decl. ¶ 67; Ex. K at 2.) A new dietary ingredient requires pre-market approval through the NDIN process, or must be Generally Recognized As Safe ("GRAS"), before it can be produced or sold to the market. (Decl. ¶ 25.) Dietary supplements containing new dietary ingredients that do not have an NDIN or GRAS status are deemed adulterated by law. (Decl. ¶ 26.) ChromaDex's Niagen product both has an NDIN and also has achieved GRAS status; pTeroPure has GRAS status. (Decl. ¶¶ 28-38.) When Basis still incorporated ChromaDex's ingredients, Elysium could rely on ChromaDex's certifications and approvals. However, when testing in August 2017 revealed that Basis contained NR that was chemically different than Niagen, Elysium was required to submit a new NDIN to the FDA. (Decl. ¶¶ 67, 75.) The FDA's most recent draft guidance regarding the NDIN process provides that a new NDIN is required after a dietary ingredient is chemically altered or if a change in the way the ingredient is manufactured results in an alteration to the ingredient's chemical or

[2] Supplemental petitions are considered together with original citizen petitions, for purposes of "sham exception." *See In re Flonase Antitrust Litig*., 795 F. Supp. 2d 300, 312 n.14 (E.D. Pa. 2011) ("The May Petition and the June Supplement must be considered together because GSK intended that the FDA consider the two documents jointly, thus the two documents together comprise a single instance of petitioning the FDA." (citing *PRE*, 508 U.S. at 60 (considering a lawsuit as one collective act of petitioning, as opposed to considering each filing independently))).

molecular composition. (Decl. ¶ 75.) Thus, the undisputed facts establish that the Petition's second request presented legally viable (and compelling) arguments in favor of a determination that Basis was legally adulterated.[3]

Tellingly, Elysium's comment was silent regarding the Citizen Petition's second request. Nor has Elysium identified any basis for finding the Petition's second request objectively baseless. Standing alone, this is dispositive as to objective baselessness. *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."); s*ee also In re Flonase Antitrust Litig*., 795 F. Supp. 2d at 312 ("[C]onduct is not a sham if 'at least one claim in the [petition] has objective merit'"); *Meridian Project Sys. v. Hardin Const., Co.*, 404 F. Supp. 2d 1214, 1222 (E.D. Cal. 2005) (same); *Dentsply Int'l v. New Tech. Co*., 1996 WL 756766, at *2 (D. Del. Dec. 19, 1996) (same).

B. ChromaDex Sought Determinations That Are Within the Scope of the Citizen Petition Process

"An interested person may petition the Commissioner [of the FDA] 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 scope of "administrative action" is extremely broad:

> The citizen petition is intended to cover every form of agency administrative activity, including a refusal to act. It may relate to factual, policy, or legal issues. The regulation does not set out all of the possible activities involved because it is intended to be all-inclusive and any such list would necessarily be incomplete.

40 Fed. Reg. 22954 (1975); *see, e.g., Tummino v. Hamburg*, 936 F. Supp. 2d 162, at 186-87 (E.D.N.Y. 2013) (citizen petition properly sought to reclassify drug as over-the-counter).

[3] Elysium argues that TruNiagen, ChromaDex's consumer product which contained Niagen, also required a new NDIN under the draft guidance because it suggested a higher dose than what was presented to the FDA in the NDIN for Niagen. (Complaint ¶¶ 93-98.) However, ChromaDex sought and obtained a new NDIN for Niagen at a higher dose and, in any event, Niagen was also GRAS (a safe food additive), and did not require a new NDIN before it could be sold to consumers. (Decl. ¶¶ 31, 32, 35.)

The Citizen Petition sought two determinations that Basis was legally adulterated. (Decl. ¶¶ 65-67.) It is undisputed that these determinations fall within the scope of the FDA's authority and the citizen petition process. (Declaration of Robert A. Dormer ("Dormer Decl.") ¶ 16.)

Elysium alleges that "no reasonable petitioner would expect to obtain the relief that ChromaDex sought" because ChromaDex asked for enforcement action and the regulations provide that enforcement actions do not fall within the scope of the citizen petition process. (Complaint ¶¶ 7, 38-42 (citing 21 C.F.R. § 10.30(k)).) Not so. As the Court recognized, the real ask in the Petition was for the FDA to make two determinations; enforcement was merely a requested remedy, within the FDA's jurisdiction, that would flow from those determinations. *See In re Elysium*, 2018 WL 4907590 at *2 (noting that CMDX asked the FDA for two determinations, and further asked that the FDA take appropriate remedial action). (Dormer Decl. ¶¶ 14-18.)

The Supplemental Petition exposes the hollowness of Elysium's claim. (*See supra* at 5 n.2 (supplemental petition is considered together with the original)). In that submission, ChromaDex clarified the nature of the relief it sought, including that the FDA issue (1) public guidance regarding the use of the ICH Guidelines for dietary supplements; (2) an order under the Federal Food, Drug, and Cosmetic Act regarding the safety of nicotinamide riboside chloride containing new impurities not reviewed under the NDIN process; and (3) final guidance regarding compliance with NDIN requirements. (Decl. ¶ 74.) It is undisputed that each of these requests are within the scope of the Citizen Petition process. (Dormer Decl. ¶ 18.)

Moreover, even to the extent that ChromaDex also requested enforcement actions, its request was not objectively baseless. The regulatory scheme provides that FDA enforcement action is discretionary and excluded from the scope of the citizen petition process, so that the Agency's enforcement decisions are not subject to judicial review. *See Heckler v. Chaney*, 470

U.S. 821, 837-38 (1985) (FDA's decision not to take requested enforcement action is not subject to judicial review under general exception to reviewability for action "committed to agency discretion"). Of course, after considering a citizen petition, the FDA is free to determine in its discretion that enforcement activities are appropriate and to act accordingly. Including requests that FDA take enforcement action, along with requests for administrative actions, does not invalidate a Citizen Petition.[4] (Dormer Decl. ¶ 18.)

IV. THE CITIZEN PETITION HAS ACHIEVED A FAVORABLE RESULT

When a lawsuit or request for government action is successful, it is "by definition a reasonable effort at petition for redress and therefore not a sham." *PRE*, 508 U.S. at 61. Far from being "sham," the Citizen Petition has already achieved a favorable result. On January 25, 2018, Elysium submitted a second comment to the FDA that stated that it has now removed toluene from the Basis product. (Decl. ¶ 77; Ex. Q.) The fact that Elysium removed the toluene from Basis—***and informed the FDA that it has done so, in a comment to the Citizen Petition***—is strong evidence that the Petition was reasonably calculated to elicit a favorable result. *In re Terazosin*, 335 F. Supp. 2d at 1357-58 (lawsuit which caused defendant to modify its manufacturing process was a "reasonable effort at petitioning for redress"); *Mover's*, 1999 WL 1243054, at *7 (lawsuit

[4] The authority cited by Elysium in its opposition to the motion to dismiss is easily distinguishable. In *In re Suboxone Antitrust Litig*., 64 F. Supp. 3d 665, 690-91 (E.D. Pa. 2014) and *MCI Commc'ns Corp. v. Am. Tel. & Tel. Co*., 708 F.2d 1081, 1156 (7th Cir. 1983), the petitioner sought action which the government entity had no jurisdiction to take. Here, the FDA has the jurisdiction to take enforcement action if it chooses, so ChromaDex's request was reasonably calculated to have a favorable outcome. In *In re Flonase Antitrust Litig*., 795 F. Supp. 2d 300, 316 (E.D. Pa. 2011), there was a dispute of fact as to whether, given available information, a reasonable petitioner would have expected the FDA to grant the requested relief. Here, there is no dispute that the FDA could take enforcement action if it determined Basis was adulterated.

which settles "does not lend itself well to the label 'objectively baseless'").[5]

V. ELYSIUM'S REMAINING ARGUMENTS ARE MERITLESS

Elysium alleges three additional reasons why it believes the Citizen Petition was a "sham": (1) ChromaDex's own product contained toluene; (2) ChromaDex knew the toluene in Basis was safe because it cited the ICH Guidelines on its certificates of analysis ("COAs") and internal documents; and (3) ChromaDex could have submitted a trade complaint. Each of these arguments fail.

A. Elysium Compares Apples to Oranges

Elysium alleges that "[t]he pTeroPure that ChromaDex sold to Elysium contained levels of toluene similar to that purportedly found in the August Samples" of Basis. (Complaint ¶ 64.) This allegation is highly misleading and compares apples to oranges. Elysium sold Basis—which contained levels of toluene ranging from 96 to 144 parts per million—to retail consumers. (Decl. ¶¶ 62-63.) In contrast, ChromaDex sold nine lots of pTeroPure to Elysium, to be used as an ingredient in a manufactured product; four lots showed detectible amounts of toluene in the following amounts: 74, 7, 93, and 8 ppm. (Decl. ¶ 52.) As explained in the annexed Declaration, "[w]hen [pTeroPure] was combined with other ingredients during the manufacturing process, any toluene present in the consumer product fell to negligible levels, below detection." (Decl. ¶ 53.) ChromaDex's sale of an ingredient in bulk to a manufacturer is not comparable to Elysium's sale of a consumer product, which resulted in consumers ingesting 96 to 144 ppm of toluene.

[5] It is irrelevant that the favorable result came from Elysium, rather than the FDA. *See In re Terazosin*, 335 F. Supp. 2d at 1357 ("[T]he Court cannot agree with Plaintiffs that a plaintiff who has filed suit and receives the relief sought (e.g., monetary compensation, a change in conduct, etc.) could only have been deemed to have 'won' under *PRE* if it continued to litigate the case and received a favorable judgment from the court."); *accord P.R. Tele. Co. v. Jan Juan Cable Co.*, 196 F. Supp. 3d 248, 326 (D.P.R. 2016).

B. Elysium Mischaracterizes the Use of ICH Guidelines on ChromaDex COAs

Elysium alleges that ChromaDex knew the toluene in Basis was safe because COAs and other documents cited the ICH Guidelines as the specifications for residual solvents. (Complaint ¶¶ 68-73.) First, ChromaDex included the ICH Guidelines on COAs because it markets ingredients to pharmaceutical companies, which utilize ICH Guidelines. (Decl. ¶¶ 41-45.) Also, in some cases, ChromaDex cited the ICH Guidelines as a benchmark because there were no applicable food or dietary supplement guidelines. (Decl. ¶ 43.) ChromaDex never intended to convey to any customer that the ICH Guidelines had any applicability to dietary supplement ingredients or food, and its customers were manufacturers. (Decl. ¶ 45.) Indeed, it is common knowledge for companies operating in the industry, like Elysium, that ICH guidelines do not apply to dietary supplements. (Decl. ¶ 45.) In any event, Elysium's argument goes to ChromaDex's subjective understanding and intent, and does not bear on the objectively baseless analysis.

C. ChromaDex's Use of the Citizen Petition Rather Than Trade Complaint Process Does Not Establish Objective Baselessness

In its opposition to the motion to dismiss, Elysium argued that ChromaDex's use of a public Citizen Petition, rather than a private trade complaint, suggests bad faith. As the Court recognized, Elysium's argument is "wholly irrelevant" to the objectively baseless inquiry. *In re Elysium*, 2018 WL 4907590 at *6. In any event, there is no requirement that a petitioner elect the trade complaint option rather than the citizen petition process. Indeed, citizen petitions offer several benefits compared to trade complaints.[6] Among other benefits, a citizen petition allows for public comment; here, the public process caused Elysium to remove the toluene from Basis. (Decl. ¶ 77; Dormer Decl. ¶ 21.)

[6]For example: (1) the FDA must respond within 180 days (21 C.F.R. § 10.30(e)(2), versus no deadline for trade complaints; and (2) judicial review is available (21 C.F.R. § 10.45), whereas a trade complaint cannot be appealed, 21 C.F.R. § 10.30(k).

VI. CONCLUSION

For all of the above reasons, summary judgment should be entered in favor of ChromaDex.

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