UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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

MEMORANDUM OF LAW IN OPPOSITION TO
DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

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In accordance with this Court's Decision and Order (the "Order") (ECF No. 44), converting Defendant ChromaDex, Inc.'s ("ChromaDex") Motion to Dismiss (ECF No. 19) to a motion for summary judgment on the "single, discrete issue" of "objective baselessness under *Noerr-Pennington's* sham exception" (Order at 14), Plaintiff Elysium Health, Inc. ("Elysium") submits this Memorandum of Law and accompanying Declaration of Joseph N. Sacca ("Sacca Decl."), and incorporates by reference all of its arguments that bear on this issue from its Memorandum of Law in Opposition to ChromaDex's Motion to Dismiss (ECF No. 26) and its letter to the Hon. Valerie Caproni, dated January 24, 2018 (ECF No. 39).

PRELIMINARY STATEMENT

ChromaDex cannot meet its burden of demonstrating the absence of issues of material fact concerning the objective baselessness of its citizen petition submitted to the United States Food and Drug Administration ("FDA") in August 2017 ("Sham Petition") because the evidence demonstrates no reasonable petitioner could have realistically expected success on the merits.

In the Sham Petition, ChromaDex asserted Elysium's product Basis was purportedly "adulterated" within the meaning of the Food, Drug, & Cosmetic Act, 21 U.S.C. §301 *et seq.* ("FDCA"), because miniscule amounts of toluene it allegedly contained supposedly rendered it "injurious to health." In its Order, the Court stated that "[m]ost damning on the issue of objective baselessness is Elysium's contention that [ChromaDex's pterostilbene] product, pTeroPure®, also contains toluene in levels comparable to the toluene in Basis," and observed that, "[a]ssuming *arguendo* that [ChromaDex] 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 [ChromaDex's] own competing product." (Order at 13.) The evidence submitted with this filing – including the Certificates of Analysis ("COAs") described in paragraph 65 of Elysium's Complaint (ECF No. 1) – shows just what Elysium alleged,

that ChromaDex sold pTeroPure containing toluene at levels similar to what it claimed to find in Elysium's Basis. For this reason, and those discussed below, the Sham Petition was objectively baseless.

The same logic holds with ChromaDex's assertion in the Sham Petition that Elysium's product was "adulterated" because it was sold without a New Dietary Ingredient Notification ("NDIN"). Evidence demonstrates that ChromaDex's competing product was sold without an NDIN at the time ChromaDex submitted the Sham Petition. Just as this Court observed that it would be objectively baseless for ChromaDex to assert that Elysium had sold a product rendered unsafe by the same substance found in ChromaDex's own product (Order at 13), so too was it objectively baseless for ChromaDex to complain that Elysium's product was adulterated and merited enforcement action by virtue of purported noncompliance with a regulatory requirement with which ChromaDex did not comply.

Moreover, evidence – including evidence submitted by ChromaDex in support of its motion to dismiss – demonstrates that the relief ChromaDex sought in its Sham Petition was not available through the citizen petition process, further underscoring that no reasonable petitioner could realistically have expected success on the merits.

Finally, ChromaDex's motion for summary judgment should also be denied on procedural grounds. Elysium has not had the opportunity to take discovery in this action as discovery was stayed, over Elysium's objections, just five weeks after Elysium filed its Complaint. ChromaDex has yet to respond to the discovery requests Elysium served prior to the stay, nor has it produced a single document in this action. The evidence Elysium submits here it obtained through its now-terminated commercial relationship with ChromaDex and from publicly available sources. If this Court deems this evidence insufficient, it should permit Elysium the opportunity to take discovery.

PROCEDURAL HISTORY AND STATEMENT OF FACTS

The relevant procedural history and facts are set forth in the accompanying Sacca Declaration and in Elysium's memorandum of law in opposition to ChromaDex's motion to dismiss. (ECF No. 26.)

ARGUMENT

I. CHROMADEX'S SHAM PETITION IS OBJECTIVELY BASELESS BECAUSE NO REASONABLE PETITIONER COULD REALISTICALLY EXPECT SUCCESS ON ITS MERITS

ChromaDex cannot meet its burden of demonstrating the absence of material issues of fact as to whether its Sham Petition was "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993). A court can rule on the objective baselessness prong as a matter of law only "[w]here there is no dispute over the predicate facts of the underlying [petitions]." *Id.* at 63. "The question whether a petition is a sham is generally a question of fact for the jury[.]" *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 310 (E.D. Pa. 2011) (citations omitted). "Objective baselessness is assessed at the time of filing." *In re Restatsis Antitrust Litig.*, 2018 WL 4473632, at *13 (E.D.N.Y. Sept. 18, 2018). If the parties contest the basis of a citizen petition, such as the "credibility and scientific merit of supporting materials," summary judgment is inappropriate. *See, e.g.*, *In re Prograf Antitrust Litig.*, 2014 WL 4745954, at *11 (D. Mass. June 10, 2014).

A. No Reasonable Petitioner Would Expect FDA to Conclude that Toluene Rendered Basis "Injurious to Health" and "Adulterated"

ChromaDex asserted in its Sham Petition that, because Elysium's product Basis allegedly contained minute amounts of toluene, which ChromaDex claimed to be injurious to health, it purportedly was "adulterated" within the meaning of the FDCA. ChromaDex, however, has sold

a pterostilbene product, which it branded as pTeroPure, containing toluene at levels comparable to those it claimed to have found in Basis. Notably, ChromaDex has admitted that pTeroPure contained toluene. (ECF No. 20 at 5.)

In its Order, this Court noted Elysium's allegation that COAs ChromaDex sent to its customers showed the presence of toluene in pTeroPure at levels similar to those it claimed it found in Basis, but observed that no examples of those COAs were appended to Elysium's Complaint. (Order at 13.) We submit those now. Two COAs that accompanied ChromaDex's shipments of pTeroPure, which described pTeroPure as "Food Grade Bulk Material," revealed the presence of toluene at levels of 93 and 74 parts per million ("ppm"), respectively. (Sacca Decl. ¶¶ 6-8; Exs. 2, 3.) These levels were comparable to the toluene level of 96-144 ppm that ChromaDex alleged was in Basis. (Sacca Decl. ¶ 4; Ex. 1 at 5.) As this Court noted, "[a]ssuming *arguendo* that [ChromaDex] does not intend to market an adulterated product, it would be objectively baseless for it to argue to the FDA that [Elysium's] product is adulterated because it contains an ingredient that is found in [ChromaDex's] own competing product." (Order at 13.)

Further evidence that the presence of toluene in the small amounts present in pTeroPure and alleged to be in Basis was not injurious to health and did not render Basis "adulterated" is found in the agreement under which ChromaDex supplied pTeroPure to Elysium. In that agreement, ChromaDex "represents and warrants that to the best of its knowledge [pTeroPure] may be lawfully sold under the [FDCA]." (Sacca Decl. Ex. 4 at 7.2.) By warranting that its pTeroPure product, which ChromaDex knew contained toluene, could be "lawfully sold" under the FDCA, ChromaDex evidenced that the presence of toluene at the levels reflected in the COAs – levels similar to the level of toluene it claimed to have found in Basis – does not render a product "adulterated" under the FDCA.

Moreover, the level of toluene ChromaDex alleged to be present in Basis was far below the level routinely accepted by FDA, which relies on standards established by the International Conference on Harmonisation ("ICH") for acceptable levels of residual solvents. ChromaDex cited those very guidelines as the specification for the allowable levels of toluene in pTeroPure in its COAs, and they set the limit at 890 ppm, more than six times the highest level of toluene ChromaDex claimed to have found in Basis. (Sacca Decl. Ex. 2 at 1.) Notwithstanding its own reliance on the ICH guidelines, ChromaDex asserted in the Sham Petition that "FDA has not set any allowed level of exposure to toluene through oral ingestion in a dietary supplement" (Sacca Decl. Ex. 1 at 5), in an effort to create the false impression that no amount of toluene is permitted, and thereby call into question the safety of Basis.

ChromaDex then compounded this misstatement by arguing to this Court in its motion to dismiss that "the ICH Guidelines apply only to pharmaceuticals." (ECF No. 20 at 5.) But ChromaDex is well aware that FDA has accepted submissions asserting the safety of dietary supplements that expressly rely on the ICH guidelines establishing acceptable amounts of toluene and other residual solvents in pharmaceuticals. ChromaDex has cited those very same guidelines in submissions it has made to FDA in which it has claimed to have established the safety of its dietary ingredient Niagen. (*See* Sacca Decl. ¶¶ 16-17 & Exs. 9, 10.) ChromaDex prominently advertises that FDA has accepted these submissions. (Sacca Decl. Ex. 11.)

In addition, ChromaDex sold products containing pTeroPure directly to consumers under the brand name BluScience (Sacca Decl. ¶ 13, Exs. 7, 8), and claimed that the pTeroPure, which ChromaDex has knowingly sold with toluene present, was "self-affirmed Generally Recognized As Safe (GRAS), demonstrating the safety of the ingredient." (Sacca Decl. Ex. 8 at 2.)

B. No Reasonable Petitioner Would Expect FDA to Sanction a Competitor for Conduct in Which It Also Engaged

ChromaDex's Sham Petition also baselessly asserted that Basis was purportedly "adulterated" because it was sold without an NDIN covering the nicotinamide riboside ("NR") it contained. (Sacca Decl. Ex. 1 at 2.) ChromaDex sells NR branded as "Niagen," and markets and sells its own direct-to-customer NR product called "Tru Niagen." (*See* Sacca Decl. Exs. 12, 14.) At the time ChromaDex filed its Sham Petition, the Niagen in Tru Niagen was not covered by any NDIN.

ChromaDex began selling Niagen in June 2013. (Sacca Decl. Ex. 12.) In its February 3, 2014 agreement to sell Niagen to Elysium, ChromaDex represented that "Niagen may be lawfully sold under the" FDCA. (Sacca Decl. Ex. 13 at § 3.8.) ChromaDex did not submit an NDIN relating to Niagen to FDA until August of 2015. (Sacca Decl. Ex. 10.)

That NDIN submission stated, in pertinent part:

> ChromaDex, Inc. proposes to use Niagen as a sole active ingredient in a dietary supplement capsule formulation. Each capsule (one serving) contains Niagen at a level of no more than 180 mg . . . . Consumers are recommended to take no more than one capsule or one serving a day. This provides a daily intake of Niagen of no more than 180 mg.

(Sacca Decl. Ex. 10 at 2.) The NDIN purported to establish the safety of Niagen only "at the intended level of use." (*Id.*) At the time it filed the Sham Petition, ChromaDex sold Tru Niagen at a recommended intake level of 250 mg per day. (Sacca Decl. Ex. 14.) Thus, the NDIN in effect at the time ChromaDex filed its Sham Petition did not cover the product it sold, because Tru Niagen exceeded the 180 mg daily intake covered by the NDIN by 70 mg, or about 40 percent. It was objectively baseless for ChromaDex, the seller of its own NR-containing product not covered by an NDIN, to argue that Elysium's NR product, which ChromaDex contended was not covered by an NDIN, was therefore adulterated and merited enforcement action.

C. No Reasonable Petitioner Could Expect FDA to Grant Relief Unavailable Through the Citizen Petition Process

In the Sham Petition, ChromaDex requested that FDA take enforcement action against Elysium. (Sacca Decl. Ex. 1 at 2 (twice requesting FDA "take all appropriate remedial action, including that Elysium cease distribution of its Basis product and take other appropriate enforcement action"), and at 6-7 (twice requesting that "FDA should immediately require 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").)

In its Order, this Court recognized that ChromaDex "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." (Order at 10.) Attached to the Sacca Declaration are the four letters ChromaDex provided the Court that were issued by FDA where FDA denied a citizen petition on the grounds that "requests for the agency to initiate enforcement actions are not within the scope of FDA's citizen petition procedures." (Sacca Decl. Exs. 15-18.)

The Court also understood ChromaDex to argue that some of the relief it sought was administrative in nature. (Order at 11.) ChromaDex was disingenuous in suggesting that. The regulation governing citizen petitions requires those seeking administrative relief by way of "request[ing] the Commissioner to issue . . . an order" to include in the "Actions Requested" section of their petitions "the exact wording requested for the proposed order." 21 C.F.R. § 10.30 (a)(3). The Sham Petition's "Action Requested" section made no attempt to meet this requirement, (*see* Sacca Decl. Ex. 1 at 2), thus evidencing that ChromaDex did not seek administrative relief. Moreover, after asking FDA to determine that Basis was adulterated (but, notably, not asking FDA

to issue any order to that effect), the Sham Petition purported to ask that FDA "immediately require 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." (Sacca Decl. Ex. 1 at 2, 6-7) (emphasis added). ChromaDex's use of the phrase "other appropriate enforcement action" demonstrates that all of the requested relief it requested was of the same type, *i.e.*, enforcement action. *In re Enron Creditors Recovery Corp.*, 380 B.R. 307, 322 (S.D.N.Y. 2008) (McMahon, C.J.) ("[U]nder *ejusdem generis*, where several specific terms are followed by a more general term, the general term is deemed to share the characteristics of the specific terms that precede it.").

Indeed, the example citizen petitions cited by ChromaDex in support of its argument that an improper request for enforcement action may nonetheless result in FDA offering some undefined "favorable outcome" instead further evidence the objective baselessness of the Sham Petition. In one example, the petitioner requested both a declaration that the products at issue were misbranded and enforcement action (Sacca Decl. Ex. 19 at 1-2), thus arguably requesting administrative relief alongside enforcement action just as this Court observed ChromaDex's petition could be interpreted. Yet, FDA nonetheless declined to bifurcate the request and rejected the petition in its entirety on the grounds that it improperly requested enforcement action. (Sacca Decl. Ex. 15.) This powerfully undermines any suggestion that ChromaDex's cursory inclusion of the request that FDA take the intermediate step of finding Basis to be adulterated as part of taking enforcement action renders the Sham Petition anything other than objectively baseless.

II. ELYSIUM SHOULD HAVE THE OPPORTUNITY TO CONDUCT DISCOVERY, WHICH HAS BEEN STAYED OVER ELYSIUM'S OBJECTION

As discussed above, the existing evidence of the objective baselessness of the Sham Petition requires denial of ChromaDex's motion for summary judgment. Should the Court

disagree, however, Elysium should be permitted discovery in this case. Although Elysium served document requests and interrogatories on ChromaDex promptly after commencing this action (Sacca Decl. ¶¶ 32-36; Exs. 20, 21), Judge Caproni stayed discovery until disposition of the motions to dismiss, over the objections of Elysium, just five weeks after the case was filed. To date, ChromaDex has not responded to the discovery requests or produced any documents.

When faced with a motion for summary judgment, the "nonmoving party must have had the opportunity to discover information that is essential to his opposition to the motion for summary judgment." *Hellstrom v. U.S. Dep't of Veterans Affairs*, 201 F.3d 94, 97 (2d. Cir. 2000) (quotation and citation omitted) (overturning grant of summary judgment because plaintiff "was denied the opportunity to conduct discovery of any sort, and was even precluded from taking depositions"). Indeed, "summary judgment should only be granted if *after discovery*, the nonmoving party has failed to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof." *Id*. (emphasis in original). "Only in the rarest of cases may summary judgment be granted against a plaintiff who has not been afforded the opportunity to conduct discovery." *Id.*; *see also Miller v. Wolpoff & Abramson LLP*, 321 F.3d 292, 303-04 (2d. Cir. 2003) (Sotomayor, J.) (same).

The "rare cases" in which "summary judgment is appropriate even though no discovery has occurred" are when "it is evident from the face of the complaint that discovery would be futile," such as when facts in documents appended to a plaintiff's own complaint contradict his claim, or because facts regarding a plaintiff's failure to exhaust administrative remedies are not disputed. *Irving v. Philips*, 2017 WL 85427, at *1 (W.D.N.Y. Jan. 10, 2017). This litigation is not one of those "rarest of cases" in which discovery would be futile. Indeed, we respectfully submit that the Court's conversion of ChromaDex's motion to dismiss to one for summary

judgment on the issue of objective baselessness and its direction to the parties to submit evidence on that issue (Order at 27) demonstrates that it is manifestly *not* evident from Elysium's Complaint that discovery would be futile.

"[A] party resisting summary judgment on the ground that it needs discovery in order to defeat the motion must submit an affidavit showing (1) what facts are sought to resist the motion and how they are to be obtained, (2) how those facts are reasonably expected to create a genuine issue of material fact, (3) what effort affiant has made to obtain them, and (4) why the affiant was unsuccessful in those efforts." *Miller*, 321 F.3d at 303. (quotations omitted). As detailed in the Sacca Declaration, Elysium has served document requests that target material issues of fact that relate to, among other issues, the issue of objective baselessness of the Sham Petition. (Sacca Decl. ¶ 32; Ex. 20 at 5-10.) Elysium also served interrogatories to identify potential deponents. (Sacca Decl. ¶ 33; Ex. 21 at 2.) Because of the discovery stay, ChromaDex has not responded, or produced any documents in response, to Elysium's document requests, nor has it responded to the interrogatories. Accordingly, a grant of summary judgment against Elysium would be inappropriate at this stage. *Hellstrom*, 201 F.3d at 97.

CONCLUSION

For the foregoing reasons, ChromaDex's motion for summary judgment should be denied.

Dated: New York, New York
October 29, 2018

Respectfully submitted,

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