UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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

CHROMADEX, INC.'S REPLY IN FURTHER SUPPORT OF ITS MOTION TO DISMISS ELYSIUM HEALTH, INC.'S COMPLAINT

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I. INTRODUCTION

CMDX has spent years of time and millions of dollars ensuring the safety of its products and it regards consumer health as a guiding principle. CMDX has filed an NDIN covering its NR with the FDA, obtained GRAS recognition for its NR, and conducted human clinical trials to ensure that its NR is actually safe. Elysium has done none of the above and now sells a product contaminated with a chemical identified by the Center for Disease Control as dangerous.

After its relationship with CMDX ended, Elysium continued to deceptively market Basis as if its ingredients were still backed by the safeguards and qualifications procured by CMDX, notwithstanding that Elysium's NR ingredient was coming from a new (and unknown) source. CMDX tested the "new" Basis and found that it contains toluene, which was never in Basis when Elysium obtained its NR from CMDX. CMDX petitioned the FDA to alert the federal agency charged with regulating supplements about the adulteration and safety issues associated with Basis, and requested that the FDA exercise its discretion to use its regulatory and enforcement tools to protect consumers from unknowingly ingesting a recognized toxin to the central nervous system that can cause adverse health effects. CMDX's Citizen Petition constitutes speech which is absolutely protected by the First Amendment. It does not matter whether the FDA ultimately elects to seize Elysium's product—what matters is that CMDX exercised its free speech rights believing that the facts it shared would influence the FDA to intercede and ensure the public's safety pursuant to its legislative mandate and discretion. There is simply no *plausible* inference that can be drawn from Plaintiff's Complaint that CMDX's sole purpose was to injure and defame Plaintiff—the purpose was to bring a serious public health concern to the FDA's attention. Nothing in Plaintiff's Opposition brief—Dkt. No. 26 ("Opp.")—resuscitates, or could resuscitate, the Complaint's wholly insufficient allegations.

Immunity is absolute under the *Noerr Pennington* Doctrine unless Plaintiff persuades this

Court that *both* (1) the Petition was objectively baseless, *and* (2) it concealed a subjective intent to interfere directly with Plaintiff's business relationships. Neither element is satisfied here. First, the Petition legitimately raised public health issues for the FDA's evaluation and is objectively reasonable (and was when filed) because it appropriately sought to persuade the FDA to exercise its discretionary authority. Plaintiff is obviously wrong that the FDA's hypothetical denial of a petition mechanistically means that a petition is *per se* baseless; rather, the Court must determine whether a petition was reasonably calculated to achieve a favorable outcome when it was filed.[1] As FDA regulations make clear, the agency welcomes information submitted via citizen petition for potential discretionary enforcement actions. Second, Plaintiff also fails to allege plausible facts showing that CMDX petitioned the FDA *solely* to disparage Plaintiff's product, as opposed to *also* genuinely persuading the FDA to act. The Petition was not *solely* intended to disparage Basis or Elysium because CMDX reasonably and objectively expected (and expects) a favorable outcome from petitioning the FDA. Indeed, the harm alleged by Elysium was self-inflicted resulting from its sale of an adulterated, unsafe, contaminated product. CMDX's legitimate intention was to bring these facts to the FDA's attention to encourage the FDA to investigate and act to advance and preserve consumer health.

Plaintiff's arguments that the litigation privilege and New York's anti-SLAPP law do not apply are also wrong. Clear precedent shows that information submitted to the FDA falls under the litigation privilege, and no exception to the privilege applies because the Petition was not filed *solely* to disparage Basis. Further, Plaintiff's public pronouncements that its product is certified as safe by the FDA show that it is a "public permittee" under the anti-SLAPP law. The

[1] Although the arguments at this stage focus on whether the Petition was properly filed on day one, it is important to note that the FDA has not yet ruled on this issue. CMDX expects the Petition to either be granted or otherwise investigated and evaluated by the FDA and fully expects that the FDA will find the information it contains helpful in carrying out its mandate to protect consumers.

Petition commented on those public representations and accordingly, CMDX is entitled to protection against Plaintiff's attempt to silence it with litigation asserting liability based entirely on filing the Citizen Petition. Finally, Plaintiff attempts to conjure a factual dispute to eek past the Rule 12(b)(6) dismissal stage, but its allegations are unmoored from the very documents on which they are based and fail to plead facts supporting the required elements for each claim.

II. THE NOERR PENNINGTON DOCTRINE IMMUNIZES CMDX's SPEECH

Plaintiff concedes that all of its claims are entirely predicated on the filing of CMDX's Petition and that the Petition comes under the First Amendment and the *Noerr Pennington* Doctrine. Plaintiff instead argues that the Petition falls within the very narrow confines of the "sham exception." Opp. at 7–13. Plaintiff fails to show either of the required elements of the exception because (1) a reasonable litigant could have expected the Petition to influence FDA action, and (2) the Complaint, together with properly-considered underlying documents, fail to plausibly show that the Petition was submitted *solely* to disparage Basis. It is only "[t]he rare plaintiff who successful proves a sham," *Prof'l Real Estate v. Inv'rs, Inc. v. Colum. Pictures Indus., Inc.*, 508 U.S. 49, 75 (1993) ("*PREI*") (Stevens, J., concurring).

A. The Petition Was Reasonably Calculated To Influence FDA Action

Plaintiff argues that the Petition was baseless because the FDA allegedly does not "grant" citizen petitions requesting that it take enforcement action. Opp. at 8–10. But Plaintiff entirely ignores FDA regulations and practices which *permit* and *welcome* petitions providing information about potentially unsafe and adulterated product sold to consumers *and* the FDA considers that information in determining whether to enforce the laws, even if the specific action requested in the petition is not taken. *See* Dkt. No. 20 ("Br.") at 9–10, 14.[2] Plaintiff's

[2] Plaintiff does not dispute that FDA tells petitioners who request enforcement action that the agency "appreciate[s]

Opposition utterly ignores the rule that the FDA may not only grant or deny a petition, but also "grant such other relief or take other action as [a] petition warrants." 21 C.F.R. § 10.30(e)(3). Those facts alone lead to the conclusion that there was probable cause to file the Petition, because it was plainly not "so baseless that no reasonable litigant could realistically expect to secure favorable relief." *PREI*, 508 U.S. at 62.[3]

Plaintiff incorrectly attempts to reduce CMDX's First Amendment right to petition to whether the requested relief is "*procedurally* []available," Opp. at 9 (emphasis added), regardless of whether the relief is *substantively* available. The First Amendment is not so limited. In *Apotex, Inc. v. Acorda Therapeutics, Inc.*, the Second Circuit rejected the concept that immunity afforded a citizen petition turns on whether it is granted or denied. 823 F.3d 51, 61 (2d Cir. 2016) (there is a "distinction between arguments that fail to move the FDA and arguments that are false and objectively baseless"). The same reasoning necessarily applies here: where a petition may persuade the FDA to act, the agency's grant or denial (especially for reasons unrelated to the petition's merits) does not bear on whether the petition's arguments are objectively baseless. As in *Apotex*, the only thing that Plaintiff avers here is that the Petition may "ultimately [be] fruitless," 823 F.3d at 61, but that is not sufficient. *See also La. Wholesale Drug Co. v. Sanofi-Aventis*, 2009 WL 2708110, at *2, 4 (S.D.N.Y. Aug. 28, 2009) (petition not baseless because petitioner could have "perceive[d] some likelihood" of success although it was

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the information that you provided," such "information is often helpful for [the FDA] to identify problems with marketed products and possible violations of the laws and regulations that we enforce," and the FDA "take[s] complaints seriously" and "will evaluate th[ese] matter[s] to determine what follow-up action is appropriate." Dkt. No. 21–7 (Ex. G) at 1, 3, 5; *see also id.* at 7.

[3] A petition may ask the FDA to "take or refrain from taking any other form of administrative action," 21 C.F.R. § 10.25, which includes "every act . . . involved in the administration of any law by the Commissioner . . . ." *Id.* 10.3(a). CMDX's Petition properly requested that the FDA take remedial action to administer the Federal Food, Drug and Cosmetic Act. Although the commencement of an enforcement action is always discretionary, nothing in law precludes the filing of a petition that seeks enforcement or remedial action based on information in a petition, if the FDA chooses to pursue it. There is no law or regulation that renders the Petition procedurally improper.

denied as "based on a false premise").

PREI recognized that petitioning is broadly protected when it validly seeks to "influence governmental action." 508 U.S. at 58. For example, in *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*—the foundational case of the *Noerr Pennington* Doctrine—the Supreme Court ruled that defendants' publicity campaign was immune because it sought to "influence the passage or enforcement of laws." 365 U.S. 127, 135 (1960). Under *Noerr*, the objective reasonableness of a petition has nothing to do with its form and everything to do with whether it can convince the government to act. *See also PREI*, 508 U.S. at 56 (Doctrine immunizes activity that "freely inform[s] the government of [people's] wishes (internal quotation marks omitted)); *Friends of Rockland Shelter Animals, Inc. (FORSA) v. Mullen*, 313 F. Supp. 2d 339, 341–42 (S.D.N.Y. 2004) (immunizing defendant's advocacy letter against plaintiff because "this lawsuit is not the proper vehicle for [plaintiff] to air its grievance or achieve its goals").

Nor does Plaintiff's argument that CMDX ought to have used the trade complaint process withstand scrutiny. Opp. at 10 & n.5. Plaintiff does not provide any support for its argument that a trade complaint can force the FDA to act; the Complaint only alleges that it "accepts" them "in connection with enforcement action." Compl. ¶ 41. But the FDA also "accepts" citizen petitions "in connection with enforcement action." *See* Br. Ex. G. Further, the FDA must act on a citizen petition within 180 days, 21 C.F.R. § 10.30(e)(2) and there is no deadline for action on a trade complaint. Moreover, the citizen petition process allows the public to submit comments to FDA, 21 C.F.R. § 10.30(c), (d), which does not happen with a trade complaint. A trade complaint is no more "correct" than a citizen petition and, in any case, the distinction provides no basis for finding the Petition baseless because it was a valid attempt to influence the FDA. *See La. Wholesale*, 2009 WL 2708110, at *5 (finding denied petition not baseless in part because

"the FDA had not previously addressed the issue"); Br. at 13–15.[4]

B. The Petition Was Not Solely Aimed At Causing Plaintiff Harm

Under the second element in *PREI*, Plaintiff must show that CMDX filed the Petition "solely to damage" it. *FORSA*, 313 F. Supp. 2d at 343–44. Plaintiff's Complaint failed to allege plausible facts that would support such an extreme finding and Plaintiff's contrary arguments miss the mark.[5] First, Plaintiff now furiously backpedals from its plain allegations that CMDX's Petition "request[ed] that the FDA" act and sought to "incite an [FDA] enforcement action." Opp. at 11; Br. at 15–16. Although Plaintiff asserts in its Response to the FDA that it believes the Petition is improper and *should* not result in an enforcement action that does not mean the FDA *will* not be influenced to act. Plaintiff cannot escape its prior statements, which show that CMDX genuinely seeks FDA action to seize and enjoin the sale of Plaintiff's product. *FORSA*, 313 F. Supp. 2d at 343–44 ("Even lobbying activities that are unethical or result in deception are not actionable under the *Noerr-Pennington* doctrine.").

Second, Plaintiff incorrectly contends that CMDX had "no reasonable expectation" of the FDA taking enforcement action based on information in the Petition because it argues that a petition cannot be used to submit information on public safety to the FDA. Opp. at 11. As discussed in the opening brief, at 15–18, and in Section II.A, *supra*, that is manifestly not true.

Third, Plaintiff argues that its allegations disagreeing with the merits of the Petition mean that CMDX filed the Petition in bad faith. Opp. at 12–13. Only the FDA can decide the merits of the Petition, 21 U.S.C. § 337(a), and Plaintiff's allegations do not establish that CMDX acted

[4] The cases cited by Plaintiff are not controlling and, in any event, are inapposite. *MCI Communications Corp. v. AT&T Co.*, 708 F.2d 1081 (7th Cir. 1983), and *In re Suboxone Antitrust Litig.*, 64 F. Supp. 3d 665, 690–91 (E.D. Pa. 2014), analyzed whether the agency had the legal *authority*; here, Plaintiff expressly alleges that the FDA has the authority to seize and enjoin its product, Compl. ¶ 40. *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 316 (E.D. Pa. 2011), involved a petition that had "no public safety implications" and the requested relief was "contrary to FDA practice," which (as revealed by the Complaint and underlying documents) is plainly not true with the Petition.

[5] Plaintiff is wrong in claiming that CMDX "excises the second part of the [*PREI*] standard." *See* Br. at 15, 16.

with the sole intent to harm Basis. Br. at 15–18. As a matter of law without such a showing, the sham exception simply and clearly does not apply.

III. CMDX'S PETITION IS PROTECTED UNDER THE LITIGATION PRIVILEGE

Plaintiff incorrectly argues that the litigation privilege does not apply to the Petition for two reasons: an FDA investigation is not "quasi-judicial" and the *Williams* exception permits the claims here. Opp. at 13–15. The first argument is easily rejected. Speech preliminary to an FDA action, like CMDX's Petition, is absolutely privileged. *Stega v. N.Y. Downtown Hosp.*, 148 A.D.3d 21, 28 (1st Dep't 2017). Plaintiff's attempt to distinguish *Stega* fails: if the FDA acted in its discretion to seize and enjoin Plaintiff's product that would by definition occur before a court and thus have all of the requisite procedural safeguards. *See* 21 U.S.C. §§ 332 (providing jurisdiction to "district courts of the United States"), 334 (same). Plaintiff's *Williams* argument is also incorrect. The *Williams* exception is "a narrow one" and only applies when the allegations demonstrate that the "action was brought maliciously and solely for the purpose of later defaming the plaintiff." *Frydman v. Verschleiser*, 172 F. Supp. 3d 653, 672-73 (S.D.N.Y. 2016); *see also D'Annunzio v. Ayken, Inc.*, 876 F. Supp. 2d 211, 221 (E.D.N.Y. 2012). For the reasons in Section II.B, *supra*, Plaintiff completely fails to show that the Petition was filed *only* to harm Elysium; thus, the *Williams* exception does not apply.[6]

IV. NEW YORK'S ANTI-SLAPP LAW APPLIES TO PLAINTIFF'S ACTION

Plaintiff incorrectly argues that it is not a "public . . . permittee" under the anti-SLAPP law. Opp. at 15–17. Plaintiff does not dispute that it publicly claims that the safety of its product Basis is approved by the FDA and that its facilities are "compliant" with "regulations as stipulated by the FDA." Dkt. No. 21-1 (Ex. A) at 3–4. Nor does Plaintiff argue that it has *no*

[6] Contrary to Plaintiff's argument, Opp. at 15, CMDX cited authority to show the privilege applies to Lanham Act claims. *See, e.g.*, *Pactiv Corp. v. Perk-Up, Inc.*, 2009 WL 2568105, at *7 (D.N.J. Aug. 18, 2009).

permission from the FDA to sell Basis. Those affirmative representations, plus the legal requirement that Plaintiff file an NDIN with the FDA and continue to operate under its regulations, are sufficient to conclude that it is a "permittee." *Silvercorp Metals Inc. v. Anthion Mgmt. LLC*, 948 N.Y.S.2d 895, 900-01 (2012) (finding company a permittee because it "must obtain permission from the [federal agency]" in order to operate and "continues to be subject to [the agency's] rules and regulations"); Br. at 20–22.

V. EACH OF PLAINTIFF'S CLAIMS FAIL UNDER RULE 12(b)(6)

1. *Falsity*: Plaintiff's claims do not allege falsity. Plaintiff does not deny that Basis lacks a filed NDIN, and contains toluene, which is toxic to humans.[7] And Plaintiff concedes that the FDA has "set no independent standards for solvent levels in nutritional supplements." Compl. ¶ 8; Opp. at 4. Plaintiff thus agrees that its only contention is whether the *amount* of toluene in Basis, when taken twice daily as Plaintiff instructs, will cause harm to a human being.

Plaintiff turns to the ICH Guidelines to save its claims, noting that it alleged that the FDA "regularly accepts submissions from dietary supplement manufacturers relying on the ICH Guidelines." Opp. at 18–19. But even if that is true (and Plaintiff offers nothing but a conclusory allegation), Plaintiff does not allege how these supplement-specific approvals render the Petition's claims with respect to the toluene in Basis false. Tellingly, nowhere does Plaintiff allege that the FDA has approved the new ingredients in Basis under the ICH Guidelines. Furthermore, Plaintiff fails to allege a single specific FDA pronouncement actually "adopting" the ICH Guidelines for supplements. Plaintiff offers instead a document titled "Tables and List

[7] Plaintiff attacks the CDC Report, insinuating that the toluene in Basis is somehow different from the toluene in the CDC Report. Opp. at 19–20. But the CDC Report specifically discusses toluene ingested from "food or drink," Dkt. No. 21-5 (Ex. E) at 3, 8, which shows that it applies to Plaintiff's product. And Plaintiff does not dispute the accuracy of the CDC Report. It is thus properly considered by the Court on this motion. *Apotex*, 823 F.3d at 60 (relying on federal guidance when "publicly available and its accuracy cannot reasonably be questioned").

Guidance for Industry," Opp. at 19 n.12, that merely confirms that the ICH Guidelines are (a) not binding on the FDA or the public and (b) apply only to pharmaceuticals.

Next, Plaintiff argues that its allegations that CMDX omitted information from the Petition regarding its GRAS status are sufficient, Opp. at 20, but "the Lanham Act does not impose an affirmative duty of disclosure," and omissions are only actionable "if they render affirmative statements false or misleading." *Casper Sleep, Inc. v. Mitcham*, 204 F. Supp. 3d 632, 638 (S.D.N.Y. 2016).[8] Further, Plaintiff has alleged nothing more than a bald assertion that CMDX's ingredients are not GRAS. This incomprehensible and new assertion of a problem with CMDX's GRAS cannot render its Petition false or misleading.

Plaintiff's allegations of CMDX's alleged omission regarding its pterostilbene ingredient is similarly an inactionable omission and without merit. CMDX pointed out in its opening brief that there is a clear difference between a wholesaler selling an ingredient with full transparent disclosure of its contents, and a manufacturing retailer selling a consumer facing, ready-to-ingest, supplement with no disclosure as to its harmful contents. Plaintiff's argument that CMDX's Petition is infirm because it allegedly omits information regarding a wholesale *ingredient* conflates the stark difference between an ingredient and a retail consumer product. Br. at 23.[9]

2. *Other Failures:* Plaintiff fails to revive its Lanham Act and § 349 claims because

[8] Additionally, "the Lanham Act does not prevent commercial actors from putting a positive spin on the nature of their goods or services," *Casper*, 204 F. Supp. 3d at 639; consequently, the mere fact that the Petition contained positive statements about CMDX's ingredients do not show that it was misleading.

[9] Plaintiff's final attempt to avoid dismissal on falsity grounds is to contend that this case will not intrude on the FDA's authority to determine whether the toluene in Basis is unsafe. Opp. at 21. But Plaintiff has it backward: its disagreement with the merits of the Petition *cannot be alleged by a private party*. 21 U.S.C. § 337(a). Plaintiff alleges that the Petition is false and misleading, Compl. ¶¶ 136–57, which by definition would require a finding that the toluene in Basis is not a threat to human safety. Such a judgment would directly intrude on the FDA's ability to regulate Plaintiff's product. Given that this issue is before the FDA, and Plaintiff has advanced the same arguments there as here, the Court should decline the invitation to intervene. Br. at 24.

it does not allege sufficient dissemination of the Petition. Opp. at 22. A few emails, some of which were forwarded to a "blinded" email list by unaffiliated parties, "is insufficient to satisfy the requirement that representations be disseminated widely." *Fashion Boutique v. Fendi*, 314 F.3d 48, 58 (2d Cir. 2002). Further, Plaintiff cannot avoid the Lanham Act's "commercial speech" element, requiring the alleged false advertising emanate from speech that proposes a commercial transaction. *Bilinski v. Keith Haring Found.,* 96 F. Supp. 3d 35, 47 (S.D.N.Y. 2015). As Plaintiff concedes, the statement must be in an "advertisement." Opp. at 22 n.13.

Plaintiff's argument that CMDX's Petition was an injury to the public under § 349 also fails. Opp. at 22-23. Plaintiff fails to plead how the public was injured by CMDX reporting adulteration and safety issues to the FDA.[10] Further, Plaintiff's conclusory allegation of § 349's territoriality requirement, Compl. ¶ 150, fails to allege "at the very least, that the deceptive transaction occurred in New York." *4 K & D Corp. v. Concierge Auctions, LLC*, 2 F. Supp. 3d 525, 548 (S.D.N.Y. 2014). Plaintiff's remaining arguments, regarding its trade libel and tortious interference claims, are also without merit. Plaintiff's allegations of malice are grounded in subjective views as opposed to objective facts, and are thus insufficient. *Chamilia, LLC v. Pandora Jewelry*, 2007 WL 2781246, at *12 (S.D.N.Y. Sept. 24, 2007); and Paragraphs 35, 59, 90, and 100-118 of the Complaint only underscore its failure to plead that CMDX knew of its business relationships.

VI. CONCLUSION

For the reasons articulated above, the Court should grant CMDX's Motion to Dismiss.

[10] *Securitron Magnalock Corp. v. Schnabolk*, 65 F.3d 256, 264 (2d Cir. 1995), cited by Plaintiff, Opp. at 23, is inapposite. In *Securitron*, the defendant lied about its competitor's product—a security lock used in hospitals and schools—in writing to authorities that the lock failed to operate under certain circumstances. Such blatant lies written for the purpose of causing a competitor to lose its public contracts constitutes an injury to the public welfare; filing a petition with the FDA regarding an undisclosed toxin does not. *UPS Store v. Hagan*, 99 F. Supp. 3d 426, 441-42 (S.D.N.Y. 2015) is also inapposite because it was alleged that customers paid inflated prices for services.

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