UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re Elysium Health-ChromaDex Litigation	:	Civ. No. 17-cv-07394 (VEC)
	:	ECF Case
	:	Electronically Filed
	:	**Oral Argument Requested**

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

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PRELIMINARY STATEMENT

Underlying ChromaDex's claims for false advertising and unfair competition and brief in opposition to Elysium's motion to dismiss ("Opp.") is a premise that ChromaDex fails to adequately plead: that upon switching suppliers of the two ingredients of its nutritional supplement, Elysium essentially created a new product containing ingredients whose source is "unknown" (Compl. ¶ 39)[1] and therefore unsafe. ChromaDex's own curiosity about who replaced it as Elysium's supplier, however, does not require Elysium to disclose that information, and Chromadex certainly cites no FDA regulation or caselaw holding otherwise. In attempting to paint Elysium's newly-sourced product as a danger to consumers, Chromadex focuses on certain characteristics of Elysium's newly-sourced Basis—its trace amounts of a solvent and that it purportedly meets the legal definition for "adulteration"—and argues these render Basis unsafe and Elysium's statements to consumers misleading. Faced with its own admissions that the same characteristics apply to its "safe" products, however, ChromaDex now attempts to rewrite its complaint. But Chromadex's baseless information and belief pleading, twisted interpretations of Elysium's statements, and contradictory allegations still fail to state plausible claims of false advertising and unfair competition. ChromaDex's claim for tortious interference, which lacks allegations of tortious conduct, interference, or injury, also fails.

I. CHROMADEX'S STATUTORY CLAIMS FAIL AS A MATTER OF LAW

A. ChromaDex Admits Many of the Challenged Statements Are Not Advertising

ChromaDex's contention that numerous of the statements it challenges—appearing in magazine articles, Elysium's informational blog, and a one-off private reply to a customer query (Br. at 20-21)—are subject to the Lanham Act misreads its own authority establishing that the

[1] Capitalized terms have the same definitions as in Elysium's brief in support of its motion to dismiss ("Br.").

Lanham Act's prohibition on false advertising applies only to commercial speech, sufficiently disseminated. ChromaDex essentially admits that the statements identified by Elysium are not themselves "commercial speech" or widely disseminated but nonetheless asserts that they qualify as "advertising or promotion" because they are "properly alleged as part of Elysium's organized campaign to advertise and promote" Basis. (Opp. at 8.) This is not the law. "Commercial advertising or promotion" under the Lanham Act comprises "commercial speech" "made for the purpose of influencing the purchasing decisions of the consuming public" and "disseminated sufficiently." *Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.*, 314 F.3d 48, 56-57 (2d Cir. 2002). Whether speech is part of an "organized campaign" is relevant to whether commercial speech is sufficiently disseminated, *see id.* at 57; the Second Circuit has never suggested, as ChromaDex urges, that noncommercial speech might nonetheless constitute advertising because a plaintiff pleads association with an "organized campaign."

Numerous of the statements ChromaDex relies upon are not "commercial speech," which "does no more than propose a commercial transaction," or else are insufficiently disseminated. *Gmurzynska v. Hutton*, 355 F.3d 206, 210 (2d Cir. 2004). ChromaDex curiously attempts to distinguish *Gmurzynska*'s holding that statements featured in news articles on general topics of interest are not commercial speech by contending that case involved an allegation that a defendant "caused" media outlets to publish certain articles. (Opp. at 8 n.4.) The absence of an allegation that Elysium was behind the articles at issue here only emphasizes, however, that those articles were on "a matter of public concern"—developments in anti-aging research (*see* Compl. Exs. G, H, M)—with which Dr. Guarante's statements were "inexplicably intertwined," and thus not commercial speech. *Boule v. Hutton*, 328 F.3d 84, 91 (2d Cir. 2003). Further, in contending that these statements and Elysium's blog post were made "for the sole purpose" of

promoting Basis (Opp. at 8 n.4), ChromaDex ignores that existence of intent to promote a product is a separate question from whether statements constitute "commercial speech." *See Fendi*, 314 F.3d at 57. Unlike the publications in ChromaDex's cases, Elysium's challenged blog article does not even mention Basis or Elysium's operations. Finally, in its reliance on Elysium's private response to a customer query, ChromaDex overlooks the requirement that commercial speech be "sufficiently disseminated" to constitute advertising; whether it can be "easily inferred" (Opp. at 10) that Elysium delivers that response to all such customer inquiries sheds no light on whether those inquiries are propounded by enough customers so that this response would be widely (or at all) disseminated. *See Fendi*, 314 F.3d at 58.

B. ChromaDex Does Not Adequately Plead Falsity of Any Statement

ChromaDex's statement that this Court may not determine on a Rule 12(b)(6) motion that it has inadequately pled the existence of false and misleading statements is flatly contrary to binding authority. *See Fink v. Time Warner Cable*, 714 F.3d 739 (2d Cir. 2013). ChromaDex's allegations, either entirely conclusory or in conflict with other allegations, do not meet its obligation to plead sufficient "factual matter" to render its claims "plausible on [their] face," which is fatal to its complaint here. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

1. ChromaDex Fails to Allege the Existence of Literally False Statements

ChromaDex's assertions that Elysium has made literally false statements are entirely unsupported and thus implausible. ChromaDex first contends that Elysium falsely represents to consumers that "its current Basis product is made with ingredients approved by the FDA" and "Elysium submitted Basis to the FDA for approval," and claims as factual support that "Elysium no longer uses the CMDX ingredients to which those FDA-approvals appertain." (Opp. at 12.) ChromaDex tellingly does not actually quote or cite to any such statement by Elysium, because none exists. Rather, ChromaDex challenges "on information and belief" the statements that

Elysium "conduct[s] rigorous safety studies for new dietary ingredient (NDI) submissions to the FDA" and that Basis is manufactured in cGMP-compliant facilities and undergoes quality audits. (Compl. ¶ 40, 51, 53.)[2] As such, its unrelated "factual support" is no support at all, and its "information and belief" allegations are entirely without the good faith basis such allegations require. (*See* Br. at 9-10.)[3] ChromaDex next contradicts its own argument regarding Elysium's description of Basis as the "only supplement clinically proven to raise NAD+ levels" and the "first cellular health product informed by genomics." (Br. at 8). ChromaDex contends that the existence of Niagen, which preceded Basis and underwent clinical testing, establishes falsity, yet admits that Niagen is an "ingredient" and not a "supplement" product (Compl. ¶ 18-19), as Elysium's challenged statements reference. Next, ChromaDex unsuccessfully attempts to abandon the position taken its complaint that "Basis cannot be considered 'pure.' In its normal state, NR is brown." (Compl. ¶ 58.) ChromaDex now claims that it is Elysium that attempts to falsely conflate color and purity, and refers to its Niagen GRAS supplement to argue that purity in reality is measured by the percentage of NR in a product. (Opp. at 13 (citing Ex. B at 6, 9). Yet, its own Sham Petition establishes that Basis made with ChromaDex-sourced ingredients has a lower percentage of NR and is thus less "pure" than Basis as currently sourced. (Br. at 10-11.)

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[2] ChromaDex inexplicably repeats this argument in a footnote, claiming in circular fashion that it pleads a good faith basis for its allegation that Basis lacks FDA approvals because it pleads "CMDX is the only manufacturer with an NDIN and GRAS status to produce NR, which leads to the natural inference that the mystery source of Elysium's NR must not have the same FDA approvals." (Opp. at 12 n.7.) In addition to being unconnected to the actual representations ChromaDex challenges, the claim that ChromaDex is the only manufacturer with an NDIN and GRAS status is contradicted by the immediately preceding assertion that "Elysium controls the facts of whether its new ingredients have FDA approval." (*Id.*) In other words, ChromaDex admits it has no knowledge of whether it is the only manufacturer with the requisite FDA approvals.

[3] ChromaDex also claims that its allegation that Basis "contain[s] a toxic industrial solvent" (Compl. ¶ 69) supports its information and belief allegations regarding cGMP compliance, the audits performed on Basis, and Elysium's conduct of safety studies in connection with FDA submission, but does not actually link the allegations by alleging, *e.g.*, that solvent residue is incompatible with production in cGMP-compliant facilities or the performance of quality audits or studies. *See Navarra v. Marlborough Gallery, Inc.*, 820 F. Supp. 2d 477, 487 (S.D.N.Y. 2011) (rejecting information and belief allegations where "abject speculation" of wrongdoing involved conduct "just as consistent with an alternative, lawful explanation of events").

Finally, confronted with its own touting of Elysium's studies, ChromaDex has abandoned its allegations that Elysium misrepresents that it has conducted clinical testing on Basis, but now newly contends Elysium has made literally false statements by "saying that the Basis it is selling [] is the same as the Basis tested in the recent clinical trial it published." (Opp. at 13.) Elysium's actual language (*see* Compl. ¶ 54-55), which describes clinical testing on "[Elysium's] first product, Basis," does not contain the "unambiguous" message ChromaDex claims, and it thus fails to establish literal falsity. *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 63 (2d Cir. 2016). Indeed, the primary statement underlying this claim is a press release from December 2016—a period when, ChromaDex claims, Elysium was using ingredients sourced from ChromaDex. *See, e.g.*, *Reed Constr. Data Inc. v. McGraw-Hill Cos.*, 49 F. Supp. 3d 385, 415 (S.D.N.Y. 2014), *aff'd*, 638 F. App'x 43 (2d Cir. 2016) (evaluating whether plaintiff offered evidence that statement was "literally false when made"). ChromaDex's implicit contention that by sourcing the same ingredients from different suppliers, Elysium essentially began marketing a new product and was therefore no longer entitled to rely on its previous study (and was indeed obligated to rescind its previous statements about its product) has no support in FDA regulations or the law, as is obvious from ChromaDex's failure to cite any authority for its assertion.

2. <u>The Complaint Pleads No Impliedly False Statements</u>

ChromaDex's attempts to show that Elysium's advertisements it does not allege to be literally false nonetheless misled consumers are no more successful. ChromaDex's allegations here rely on premises that it fails to adequately plead—that Basis is unsafe and lacking requisite regulatory approvals—and implausible misreadings of Elysium's advertisements where "nothing in the [challenged] statements themselves suggests [the] meaning" ChromaDex claims consumers infer. *XYZ Two Way Radio Serv. Inc. v. Uber Techs., Inc.*, 214 F. Supp. 3d 179, 183-85 (E.D.N.Y. 2016). ChromaDex's response to Elysium's authority showing that implicit

representations about FDA approval are insufficient to state a claim for false advertising (*see* Br. at 16-17) is to pivot, and now claim that it alleges Elysium expressly represents Basis to be FDA-approved. (*See* Opp. at 15 n.10.) It cannot, however, escape its own complaint, which alleges that Elysium's purported deception of consumers is based on "weaving references to the FDA" in its advertising, to "foster[] the incorrect notion" Basis has been "somehow approved or endorsed" by FDA. (Compl. ¶ 48-53.) These allegations plead no "express statement" of FDA approval.[4]

ChromaDex next attempts to avoid the holding of *Rexall Sundown, Inc. v. Perrigo Co.*, 657 F. Supp. 2d 9 (E.D.N.Y. 2009) by claiming Elysium "attribute[d] a specific test performed on certain active ingredients to a product containing different and untested ingredients." (Opp. at 15.) This assertion misses the point: As *Rexall* makes clear, a party must show that a "clinically tested" label is "unambiguous[ly]" false by, *e.g.*, referring specifically to a product's current formulation when that formulation had not in fact undergone clinical testing. 651 F. Supp. 2d 9, 35 (E.D.N.Y. 2009). "Attributing" a clinical test to a product containing the same active ingredients, simply sourced from a new supplier (*see* Compl. ¶ 39), where that "attribution" does not specifically refer to the source of the ingredients, does not "unambiguously" convey a false message.[5] And contrary to its assertion (Opp. at 15 n.11), ChromaDex nowhere pleads that "the tests relied upon do not prove the proposition for which they are cited," as it does not plead Basis

[4] ChromaDex's efforts to manufacture an express statement through misleading excision of Elysium's actual language cannot survive an actual review of the statement it purports to cite. *Compare* Opp. at 14-15 (claiming that Elysium's advertising represents "that 'all products' are submitted to the FDA for an NDIN before 'becoming available for purchase'") *to* Compl. Ex. K ("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 [which include 'we conduct rigorous safety studies for new dietary ingredient (NDI) submission to the FDA'] help us discover and commercialize new products" (emphasis added).)

[5] The statements ChromaDex challenges describe the clinically-tested Basis as containing NR and pterostilbene (*see id.* Ex. L), as it undisputedly still does (*id.* ¶ 39), and make no reference to ChromaDex or Niagen.

containing newly-sourced NR and pterostilbene would not raise NAD+ levels as Basis containing the same ingredients as sourced from ChromaDex did.

Next, ChromaDex attempts to escape its pleading burden by arguing that Elysium raises a "factual dispute" regarding the plausibility of ChromaDex's claims that Elysium's customers have been left with highly-specific false impressions from Elysium's general statements regarding the history of NR research and Elysium's advisors and partnerships. (Opp. at 15-16.) Elysium raises no factual dispute but has instead highlighted that "nothing in the [challenged] statements themselves suggests th[e] meaning" ChromaDex imputes to consumers, and ChromaDex offers no factual assertions to support its conclusory allegations of deception. (*See* Br. at 17 n.10.)[6] The identification of contradictions between ChromaDex's allegations themselves and material of which this Court is entitled to take judicial notice likewise raises no factual dispute but instead justifies disregarding those allegations as implausible, leaving ChromaDex's claims of falsity totally without support. (*See* Br. at 18 n.11.) Finally, ChromaDex's suggestion this Court may not as a matter of law find that the context of Elysium's alleged misstatements, which include statements directly contradicting the alleged endorsement of Basis by Elysium's SAB and that militate against the impression that Elysium submitted an NDIN for Basis and that FDA has "blessed" its sale, renders its statements not misleading (Opp. at 16-17), is entirely incorrect. *See Kommer v. Bayer Consumer Health*, 252 F. Supp. 3d 304, 312 (S.D.N.Y. 2017).

3. <u>ChromaDex Fails to Plead Basis Is Unsafe and Consumers Are Misled</u>

The heart of ChromaDex's claims is that Elysium has misrepresented the safety of its product, which relies on a premise—that Basis is unsafe—that ChromaDex has failed to

[6] ChromaDex's conclusory argument that it is "certainly plausible" consumers receive the impression Basis is "endorsed by all-star scientists and well-known research universities" (Opp. at 16) is supported by no facts and at odds with well-developed authority in the Second Circuit regarding whether and to what extent an implied endorsement in an advertisement exists. *See, e.g.*, *Oliveira v. Frito-Lay, Inc.*, 251 F.3d 56, 61 (2d Cir. 2001).

adequately plead. Confronted with its own admissions that the factors that it alleges render Basis unsafe—that it purportedly contains trace amounts of a substance that may be hazardous in sufficiently high quantities and that it purportedly meets the legal standard for "adulteration"—apply with equal strength to its own products, which ChromaDex repeatedly proclaims to be safe, ChromaDex now attempts to disclaim its reliance on these factors. (Opp. at 17-18.) ChromaDex cannot so easily disavow its own pleading, however, which makes clear that ChromaDex's claim that Basis is unsafe rest on its allegations of adulteration (*see* Compl. ¶ 41 ("[B]ecause Elysium has failed to submit a [*sic*] NDI notification for the new ingredient, the current Basis product is considered by the FDA to be 'adulterated' . . . despite Elysium's claims of safety and purity")) and the inclusion of toluene. (*See id.* ¶ 42 ("In fact, Basis is far from 'safe.' Since switching from the use of ChromaDex ingredients to a wholly unregulated version of the ingredients, Elysium's Basis product is now contaminated with the toxin Toluene. . . . As such, Elysium's Basis product is unsafe for human consumption.").) ChromaDex alleges that Elysium "cannot simply state that consumption is safe and at the same time entirely withhold from those same customers the presence of toluene and its attendant dangers." (Opp. at 19.) Omissions are only actionable under the Lanham Act where they render affirmative statements misleading, however; ChromaDex's contention that Elysium has lied by its "failure to reveal to consumers that they are ingesting [toluene] amidst Elysium's effort to persuade them that Basis is safe" (*id.* at 18) thus requires plausibly pleading that the omitted information is inconsistent with an impression of safety so that its absence is misleading. (Br. at 11.) ChromaDex has not done so. Although it argues Elysium "casts stones" (Opp. at 20) in highlighting ChromaDex's admissions on its own products, ChromaDex ignores its burden to plead facts that make plausible its claim Basis is unsafe and Elysium misrepresented that safety by omission; by highlighting

that ChromaDex admits the facts it pled to establish that Basis is unsafe apply to ChromaDex's own "safe" products, Elysium shows that ChromaDex's allegations contradict each other and are thus implausible, rendering its conclusion that Basis is unsafe unsupported. (*See* Br. at 12-16.)[7]

ChromaDex's astounding contention that it does not allege that the toluene levels in Basis are unsafe (Opp. at 20) is flatly contradicted by the complaint. (*See* Compl. ¶ 42 ("In fact, Basis is far from 'safe.' . . . Elysium's Basis product is now contaminated with the toxin Toluene.") In order for this Court to determine that Elysium has misled consumers by purportedly billing Basis as safe without disclosing the presence of toluene, it must determine that omission rendered its statements of safety misleading, which necessarily requires an independent analysis of the safety of the toluene levels. ChromaDex's caselaw is not to the contrary: *Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH*, 843 F.3d 48 (2d Cir. 2016), involved the doctrine of preclusion, where FDA had previously provided guidance. Here, whether the toluene levels in Basis are unsafe is (ChromaDex argues) an open question requiring FDA's technical expertise and thus appropriate for the doctrine of primary jurisdiction. (*See* Br. at 13-14.) ChromaDex's disclaimer of its attempt to enforce the FDCA by "private right of action" (Opp. at 21) is further belied by its demand this Court enjoin Basis sales until compliant with applicable regulations.

C. ChromaDex's Claims Suffer Numerous Additional Deficiencies

ChromaDex has also failed to plead numerous additional elements of its claims. (Br. at 21-22.) Most significantly, its contention the "very logical inference" from its allegation that

[7] ChromaDex's contention that it is "untrue" that TruNiagen is adulterated because "NDIN dosage restrictions apply only to ingredients, not to supplements like TruNiagen" (Opp. at 19) tellingly cites to no FDA regulation. The FDA dosage guidance cited by Elysium by its terms applies to "supplements" (*see* Br. Ex. F at 29-30), not ingredients, and ChromaDex's unsupported legal conclusion may thus be disregarded here. *See Apotex*, 823 F.3d at 61 n.5. Too, its attempt to minimize the extent to which the adulteration of TruNiagen contradicts its claims about the adulteration of Basis rendering it unsafe by newly "represent[ing] [to the Court] that it has the necessary support [to sell TruNiagen] based on extensive clinical trials" (Opp. at 20 n.15) similarly cites no FDA regulation and represents a classic, impermissible attempt to modify a pleading by statements in opposition to a motion to dismiss. *See Wright v. Ernst & Young LLP*, 152 F.3d 169, 178 (2d Cir. 1998).

TruNiagen competes with Basis is that consumers "would be more likely to choose Basis" (Opp. at 21 (emphasis added)) overlooks the requirement that it actually plead an injury. *See Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1395 (2014).

II. CHROMADEX'S TORTIOUS INTERFERENCE CLAIM IS INADEQUATE

Finally, ChromaDex's claim for tortious interference with prospective economic advantage fails to plead nearly every element necessary to state such a claim. ChromaDex's argument its claim is not precluded (*see* Br. at 24-25) because the California action involved "false representations in placing large orders of NR" in 2016 instead of Elysium's purported "interference with CMDX's business relationships before the supply agreement was executed" (Opp. at 24) is expressly contradicted by the preceding paragraph, describing ChromaDex's claim as based on the "one-two punch" including "refusing to pay for extraordinarily large orders of NR [in 2016]." (*Id.*) Even if not precluded, ChromaDex has no response to the authority making clear that allegations that a party had fraudulent intent in participating in negotiations do not meet the high bar for "criminal or tortious" conduct. *See Valley Lane Indus. Co. v. Victoria's Secret Direct Brand Mgmt., L.L.C.*, 455 F. App'x 102, 106 (2d Cir. 2012). ChromaDex's contention Elysium "elevates form over substance" (Opp. at 25) in highlighting that the conduct alleged was directed at ChromaDex similarly ignores that the claim involves "by definition, conduct directed not at the plaintiff itself, but at the party with which the plaintiff has or seeks to have a relationship." *Carvel Corp. v. Noonan*, 3 N.Y.3d 182, 192 (2004). Finally, ChromaDex misstates its final pleading defect: Elysium does not argue it does not plead "causation" (Opp. at 25) but instead points out that ChromaDex, in neglecting to allege any third parties were induced to terminate any relationship, has failed to plead injury altogether. (Br. at 25.)

CONCLUSION

Accordingly, Elysium respectfully requests dismissal of the complaint with prejudice.

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Respectfully submitted,

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