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 OF DEFENDANT AND COUNTER-CLAIMANT ELYSIUM HEALTH, INC. IN SUPPORT OF ITS MOTION FOR LEAVE TO FILE ITS PROPOSED ANSWER AND SECOND AMENDED COUNTERCLAIMS

Esterina Giuliani
Joseph N. Sacca
Benjamin D. Pergament
BAKER & HOSTETLER LLP
45 Rockefeller Plaza
New York, New York 10111
Tel.: (212) 589-4200
Fax: (212) 589-4201
egiuliani@bakerlaw.com
jsacca@bakerlaw.com
bpergament@bakerlaw.com

Attorneys for Defendant and Counter-Claimant Elysium Health, Inc.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES

Page(s)

Statutes

Rules

Other Authorities

PRELIMINARY STATEMENT

Defendant and counter-claimant Elysium Health, Inc. ("Elysium") seeks leave to amend its counterclaims against plaintiff and counter-defendant ChromaDex, Inc. ("ChromaDex"). The amended pleading includes new allegations that ChromaDex knowingly made false claims (and continues to do so) to consumers about the supposed efficacy of its products. Those misrepresentations – false claims as to clinically proven results when in fact the only published clinical data shows that ChromaDex's Tru Niagen product is *not* effective – harm consumers and competitors alike.

Granting Elysium leave to amend its counterclaims to include allegations (but no new counterclaims) about ChromaDex's false claims should be granted under the well-established principles governing leave to amend under Federal Rule of Civil Procedure 15(a)(2). Discovery has only just begun in this action and thus ChromaDex will suffer no prejudice from the amendment; Elysium has acted promptly and in good faith in seeking leave to amend; and the new allegations buttress Elysium's pending false advertising and unfair competition counterclaims against ChromaDex, and thus are not futile. Elysium therefore respectfully seeks leave to file the Proposed Answer and Second Amended Counterclaims attached as Exhibit A to the concurrently filed Declaration of Esterina Giuliani (Giuliani Decl.").[1]

BACKGROUND

I. Factual Background

Elysium sells a dietary supplement, Basis, that combines nicotinamide riboside (sometimes called "NR") and pterostilbene. Elysium purchased NR and pterostilbene from ChromaDex from

[1] For the Court's convenience, a redline comparison of Elysium's proposed amended pleading against its prior Answer and Amended Counterclaims is attached as Exhibit B to the Declaration of Esterina Giuliani.

2014 until mid-2016, when Elysium learned that ChromaDex was in breach of multiple provisions of the parties' contracts. Further investigation revealed that beyond simply breaching those contracts, ChromaDex had affirmatively attempted to deceive Elysium about those breaches by, among other things, concealing information from Elysium and making affirmative misrepresentations about its dealings with other customers.

Over time, the reason for ChromaDex's poor treatment of Elysium became apparent. ChromaDex proved interested in supplying Elysium with NR only long enough for Elysium to build a consumer base for NR. Once it had, ChromaDex sought to benefit from the consumer base Elysium built by organizing a campaign to influence consumers away from Elysium (and other competitors) and to eliminate Elysium from the market for NR-containing supplements. ChromaDex's plot to eliminate Elysium failed, and now Elysium (with its product Basis) and ChromaDex (with its product Tru Niagen) are competitors selling NR direct to consumers. ChromaDex now again seeks to eliminate Elysium, this time by attempting to burnish Tru Niagen's credentials with consumers on the strength of demonstrably false claims regarding its product, Tru Niagen.

II. Relevant Procedural History

Elysium answered ChromaDex's original complaint in this action on October 12, 2018, asserting three counterclaims, all of which arose out of ChromaDex's misleading national advertising campaign to sell its dietary supplement, Tru Niagen, the sole active ingredient in which is ChromaDex's Niagen, ChromaDex's trade name for NR. ECF No. 45.

First, Elysium counterclaimed for false advertising under the Lanham Act, 15 U.S.C. 1125(a), based on the myriad false and misleading misrepresentations of fact found throughout ChromaDex's advertising for its products Niagen and Tru Niagen. ECF No. 45 at ¶¶ 92-96. Specifically, Elysium's false advertising counterclaim was based on ChromaDex's

misrepresentations that its products: (a) contain an ingredient (NR) that was discovered by ChromaDex's lead scientist, when it was not; (b) contain NR from the "only" seller of the ingredient, which is patently false; (c) have been "rigorously tested" and "rigorously reviewed" by FDA for safety and efficacy, which they have not; (d) can raise NAD levels by 60%, without disclaiming that such an increase has only been observed in subjects taking four times the recommended amount; and (e) can treat or prevent serious and potentially life-threatening diseases, when there is no adequate basis for these claims. *Id*. at ¶ 94. In addition, Elysium alleged that ChromaDex had falsely described the NR in Elysium's Basis as "counterfeit" – another false claim warranting relief. *Id*.

Second, Elysium brought a counterclaim for unfair competition (also under the Lanham Act) based on ChromaDex's knowingly false claims that its product had been reviewed by FDA for safety and efficacy, as well as for misleading consumers by marketing its product as a treatment for myriad diseases without any legitimate basis to do so. *Id.* at ¶¶ 97-100.

Third, Elysium brought a counterclaim for deceptive business practices under New York General Business Law § 349, based on ChromaDex's false and misleading misrepresentations of fact. *Id.* at ¶¶ 101-104.

ChromaDex thereafter amended its complaint against Elysium on consent. ECF No. 79. Elysium answered ChromaDex's First Amended Complaint by filing its Answer to First Amended Complaint and Amended Counterclaims on April 10, 2019. ECF No. 82. In its Amended Counterclaims, Elysium added a fourth counterclaim, for copyright infringement under the Copyright Act, based on ChromaDex's use of Elysium's copyrighted and original works in its national advertising campaign. *Id.* ¶¶ 131-34.

III. The Proposed Answer and Second Amended Counterclaims Details ChromaDex's Demonstrably False Claims Concerning Niagen and Tru Niagen's Supposed Efficacy.

Elysium's Proposed Answer and Second Amended Counterclaims ("PSAC") amplifies the counterclaims already asserted against ChromaDex by identifying additional false and misleading claims ChromaDex has made in its campaign to compete with Elysium. Specifically, ChromaDex has attempted to trick consumers into believing that Tru Niagen is, like Basis, clinically proven to raise NAD levels when, in fact, *clinical trials prove the opposite*, that Tru Niagen has no effect on NAD levels.

Tru Niagen is ChromaDex's direct-to-consumer dietary supplement product and contains NR at 300mg per serving. The PSAC chronicles ChromaDex's campaign to affirmatively deceive its own customers by falsely advertising the efficacy of its Tru Niagen product and falsely claiming that Tru Niagen has been clinically proven to raise NAD levels. ChromaDex continually advertises Tru Niagen as being "clinically proven" to raise NAD levels, and in an October 24, 2018 press release, ChromaDex claimed that "Niagen was clinically-studied at 300mg to increase NAD in 2016, published in the journal *Nature Communications*." But ChromaDex's claims are false: the very trial ChromaDex touted in its press release, which is the *sole* published human clinical trial that has assessed the effects of Tru Niagen (*i.e.*, NR at an intake of 300mg), found that Tru Niagen had no effect on NAD levels.

The PSAC further details that ChromaDex misled consumers by claiming that Tru Niagen raises NAD levels by 60% while omitting or minimizing that this figure came from a study that did not test Tru Niagen and instead tested Niagen at a dosage of 1,000mg, *more than three times Tru Niagen's intake level*, and omitting that, of the two published clinical trials assessing the effect of 1,000mg of NR on NAD levels, one showed the 60% increase while the other showed that it had no effect at all. And because Tru Niagen does not raise NAD as ChromaDex claims, all of its

other advertising claims that are dependent on the notion that Tru Niagen actually raises NAD – such as its claims that Tru Niagen improves cellular health, improves DNA health, and boosts mitochondrial health and energy – are equally false.

The new allegations in the PSAC show that, faced with this damning clinical trial data, ChromaDex directed the authors of the only published study to test Tru Niagen to present misleadingly aggregated summaries of the data to conceal the absence of any statistically significant effect on NAD at doses of either 300mg or 1,000mg per day, in a transparent attempt to gin up statistical significance where there was none. And in yet another attempt to mislead consumers with unreliable and false data, ChromaDex took matters into its own hands to manipulate the design of a *second* clinical trial – completed two years ago but as yet unpublished – by requiring its participants to adhere to a restrictive diet that would artificially impact their NAD levels in an effort to manufacture the effects that the October 2016 trial had failed to demonstrate, rendering any resulting data irredeemably tainted and unreliable.

ChromaDex's advertisements claiming that Tru Niagen is clinically-proven to raise NAD levels, whether based on its published or unpublished clinical trials, are substantially false and misleading, and are and were intended to lure customers away from Elysium, which truthfully discloses that, at its recommended daily intake (250 mg of NR and 50 mg of pterostilbene), its product Basis has been clinically proven to increase NAD levels by 40%. If consumers knew that Tru Niagen was not in fact clinically proven to raise NAD, and if consumers knew that data from a clinical trial commissioned by ChromaDex actually demonstrated that Tru Niagen did not increase NAD, they undoubtedly would not purchase the product, and would instead likely buy Elysium's Basis, which *is* clinically proven to work to raise NAD. Elysium therefore seeks leave to amend its counterclaims to seek relief for ChromaDex's knowingly false and deceptive claims.

ARGUMENT

I. Leave to Amend Should be Freely Granted Under Rule 15 Unless ChromaDex Can Show Undue Prejudice, Undue Delay, Bad Faith, or Futility.

On a motion for leave to amend, "[t]he court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2). Accordingly, leave to amend "should not be denied unless there is evidence of undue delay, bad faith, undue prejudice to the non-movant, or futility." *Milanese v. Rust-Oleum Corp.,* 244 F.3d 104, 110 (2d Cir. 2001) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)). And while the Second Circuit notes that the trial court has broad discretion in ruling on a motion to amend, *Local 802, Associated Musicians of Greater New York v. Parker Meridien Hotel*, 145 F.3d 85, 89 (2d Cir. 1998), a motion to amend should be granted where "the plaintiff has at least colorable grounds for relief…" *Soley v. Wasserman*, No. 08 Civ. 9262 (KMW) (FM), 2013 WL 6244146, at *1 (S.D.N.Y. Dec. 3, 2013) (quoting *S.S. Silberblatt, Inc. v. E. Harlem Pilot Block–Bldg. 1 Hous. Dev. Fund Co., Inc.,* 608 F.2d 28, 42 (2d Cir. 1979)). Importantly, the party opposing leave to amend has the burden of demonstrating undue prejudice, undue delay, bad faith, or futility. *See*, *e.g.*, *Blagman v. Apple, Inc.*, No. 12 Civ. 5453 (ALC) (JCF), 2014 WL 2106489, at *3 (S.D.N.Y. May 19, 2014) (finding opposing party failed to show bad faith); *Alexander Interactive, Inc. v. Adorama, Inc.*, No. 12 Civ. 6608 (PKC) (JCF), 2014 WL 113728, at *4 (S.D.N.Y. Jan. 13, 2014) (granting motion to amend where moving party showed amendment proffered viable claims and thus was not futile); *Margel v. E.G.L. Gem Lab Ltd.*, No. 04 Civ. 1514 (PAC) (HBP), 2010 WL 445192, at *3 (S.D.N.Y. Feb. 8, 2010) (granting motion to amend where non-moving party's need to conduct additional discovery was insufficient to show undue prejudice).

II. No Undue Prejudice, Undue Delay, Bad Faith, or Futility Exists.

A. ChromaDex will not be unduly prejudiced.

ChromaDex cannot meet its burden of showing that it will be unduly prejudiced by the PSAC. While prejudice to the opposing party "has been described as the most important reason for denying a motion to amend, only *undue* prejudice warrants denial of leave to amend." *Agerbrink v. Model Serv. LLC*, 155 F. Supp. 3d 448, 454 (S.D.N.Y. 2016) (internal marks omitted) (emphasis in original). To determine whether undue prejudice exists, courts consider whether the proposed amendment would "(i) require the opponent to expend significant additional resources to conduct discovery and prepare for trial; (ii) significantly delay the resolution of the dispute; or (iii) prevent the plaintiff from bringing a timely action in another jurisdiction." *Block v. First Blood Assocs.*, 988 F.2d 344, 350 (2d Cir. 1993).

The PSAC's new allegations almost exclusively focus on ChromaDex's claims regarding Tru Niagen's efficacy—and the clinical trial data showing those claims to be false. The new allegations therefore expand upon Elysium's prior allegations that ChromaDex misleadingly touts the efficacy of its products, and thus should come as no surprise to ChromaDex. *See Camoia v. City of New York*, No. 09-cv-2545 (SLT) (LB), 2013 WL 867199, at *2 (E.D.N.Y. Mar. 7, 2013) (finding no undue prejudice where "defendants were put on notice of plaintiff's [new] claims by the original pleading, and the claims which plaintiff seeks to add arise out of the same set of facts already alleged."); *see also* Wright & Miller, 6 Fed. Prac. & Proc. Civ. § 1487 (3d ed.) (explaining courts allow amendments when "opponent could not claim surprise").

Moreover, this case is in the earliest stages of discovery. While the parties have exchanged initial disclosures, interrogatories and document requests, the parties have not begun the meet and confer process, and have not produced a single document in this action, nor have the parties noticed, scheduled, or taken any depositions. And, pursuant to the Case Management Plan (ECF

No. 77), the parties may amend their pleadings up to August 9, 2019 ("No pleadings may be amended after August 9, 2019").

Granting Elysium leave to amend the counterclaims to add allegations concerning ChromaDex's false claims to efficacy—claims that trick consumers and harm Elysium, its competitor—can easily be incorporated into the parties' discovery going forward and thus pose no threat of prejudice to ChromaDex, let alone the "substantial prejudice" that ChromaDex must show to defeat the motion. *Jose Luis Pelaez, Inc. v. McGraw-Hill Glob. Educ. Holdings LLC*, No. 16-CV-5393 (KMW), 2018 WL 1115517, at *2 (S.D.N.Y. Feb. 26, 2018) (requiring "substantial prejudice"). As a result, the new allegations will neither delay resolution of the action nor materially expand the scope of discovery. *See, e.g.*, *State Teachers Ret. Bd. v. Fluor Corp.*, 654 F.2d 843, 856 (2d. Cir. 1981) (reversing denial of leave to amend where "no trial date had been set by the court," and "the amendment will not involve a great deal of additional discovery"); *Blagman*, 2014 WL 2106489, at *4 (finding no undue prejudice where amendment would require additional discovery but neither a summary judgment briefing schedule nor trial date had been set); Wright & Miller, 6 Fed. Prac. & Proc. Civ. § 1484 (3d ed.) ("If no prejudice is found, then leave normally will be granted."). Because the PSAC neither materially expands the scope of discovery nor alters the nature of the claims or defenses at issue, ChromaDex cannot claim prejudice. *See M.E.S., Inc. v. Safeco Ins. Co. of Am.*, No. 10-CV-02798 (PKC)(VMS), 2014 WL 2931398, at *3 (E.D.N.Y. June 27, 2014) (granting leave to amend where defendant could not claim surprise because proposed amendment "mostly elaborate[d]" on earlier pleading).

B. Elysium acted expeditiously and in good faith.

While undue delay is a factor to consider on a motion for leave to amend, "[d]elay is rarely fatal to a Rule 15 motion if it can be explained." *Refco Grp. Ltd. v. Cantor Fitzgerald*, L.P., No. 13 Civ. 1654 (RA) (HBP), 2015 WL 4097927, at *7 (S.D.N.Y. July 6, 2015). Indeed, the Second

Circuit has instructed that "[m]ere delay, however, absent a showing of bad faith or undue prejudice, does not provide a basis for the district court to deny the right to amend." *State Teachers Ret. Bd.*, 654 F.2d at 856. Here, Elysium acted in good faith and moved expeditiously to amend its counterclaims based on ChromaDex's brazenly false claims to clinical efficacy. Indeed, ChromaDex persists in its false claims to this day, continuing to falsely claim as of the date of the filing of this brief that Tru Niagen raises NAD by 40-50%.

ChromaDex's deceptive and false advertising campaign is ongoing, and Elysium's motion for leave to amend its counterclaims to add allegations concerning that ongoing campaign is in good faith, is timely, and should be granted. *See Commander Oil Corp. v. Barlo Equip. Corp*., 215 F.3d 321, 333 (2d Cir. 2000) (upholding grant of leave to amend after several years of delay); *Rachman Bag Co. v. Liberty Mutual Ins. Co.*, 46 F.3d 230, 235 (2d Cir.1995) (same); *Block v. First Blood Associates*, 988 F.2d at 350–51 (same); *Margel v. E.G.L. Gem Lab Ltd.*, No. 04 Civ. 1514, 2010 WL 445192, at *10 (S.D.N.Y. Feb. 8, 2010) (collecting cases).

C. The new allegations go to the heart of Elysium's pending counterclaims and thus are not futile.

"An amendment to a pleading will be futile if a proposed claim could not withstand a motion to dismiss pursuant to Rule 12(b)(6)." *Dougherty v. Town of N. Hempstead Bd. of Zoning Appeals*, 282 F.3d 83, 88 (2d Cir. 2002). When deciding a motion for leave to amend, however, the court need not decide the merits of a proposed claim "but merely satisfy itself that it is colorable and not frivolous." *Sumitomo Elec. Research Triangle, Inc. v. Corning Glass Works*, 109 F.R.D. 627, 628 (S.D.N.Y. 1986); *see also Todd v. Exxon Corp.*, 275 F.3d 191, 198 (2d Cir. 2001) (quoting Scheuer v. Rhodes, 416 U.S. 232, 236 (1974) ("The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.")); *In re Winstar*

Commc'ns, No. 01 CV 11522 (GBD), 2006 WL 473885, at *2 (S.D.N.Y. Feb. 27, 2006) (leave to amend should be given if proposed claims "are colorable and not frivolous.").

Elysium's First, Second, and Third Counterclaims against ChromaDex are all premised on ChromaDex's deceptive advertising and false claims. The PSAC merely elaborates on the lengths to which ChromaDex has gone to deceive its own customers, to lure customers away from Elysium on the strength of false promises, and ultimately to harm its competitor, Elysium. The new allegations in the PSAC therefore buttress its existing counterclaims, all three of which depend upon allegations of false or deceptive practices toward consumers. Because the PSAC amplifies Elysium's counterclaims—counterclaims that ChromaDex has never moved to dismiss, choosing instead to answer, *see* ECF No's 56, 83—the amendment is not futile and should be allowed. *Freeman v. Timberlake*, No. 06 CV 1112 GBD, 2007 WL 184817, at *2 (S.D.N.Y. Jan. 25, 2007) ("The proposed second amended complaint neither asserts additional causes of action nor alters the theory of recovery set forth in the first amended complaint. Rather, it merely pleads the factual allegations with greater specificity. . . Accordingly, plaintiff's motion for leave to file a second amended complaint is granted."); *Aekyung Co. v. Intra & Co.*, No. 99 CIV. 11773 (LMM), 2005 WL 1845088, at *4 (S.D.N.Y. Aug. 3, 2005) ("Defendants do not, nor could they, argue that they would be prejudiced by the amended pleading, as the new facts merely amplify existing allegations …").

CONCLUSION

ChromaDex's false claims harm both consumers and ChromaDex's competitors alike. The new allegations about those misrepresentations that Elysium seeks to add in its amended pleading go to the heart of the pending counterclaims and thus should be resolved in this dispute. Discovery is only now getting underway in this action, and ChromaDex cannot show undue burden, undue delay, futility, or bad faith. Elysium therefore respectfully requests that the Court grant Elysium

leave to file the Proposed Answer and Second Amended Counterclaims annexed to the concurrently filed Declaration of Esterina Giuliani, under the well-established principles governing leave to amend under Federal Rule of Civil Procedure 15(a)(2).

Dated: New York, New York
June 10, 2019

Respectfully submitted,

BAKER & HOSTETLER LLP

By: */s/ Esterina Giuliani*

Esterina Giuliani
Joseph N. Sacca
Benjamin D. Pergament
BAKER & HOSTETLER LLP
45 Rockefeller Plaza
New York, New York 10111
Tel.: (212) 589-4200
Fax: (212) 589-4201
egiuliani@bakerlaw.com
jsacca@bakerlaw.com
bpergament@bakerlaw.com

Attorneys for Defendant and Counter-Claimant Elysium Health, Inc.