UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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

MEMORANDUM OF LAW OF PLAINTIFF CHROMADEX, INC. IN SUPPORT OF ITS MOTION FOR LEAVE TO FILE ITS PROPOSED SECOND AMENDED COMPLAINT

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I. INTRODUCTION

Pursuant to Federal Rule of Civil Procedure 15(a)(2), Plaintiff ChromaDex, Inc. ("Plaintiff" or "ChromaDex") respectfully requests leave to file a proposed Second Amended Complaint ("SAC"). Pursuant to the current case management plan ("CMP"), the deadline for amending pleadings is February 10, 2020. (Dkt. Nos. 77 & 92.) Consistent with the CMP's language, the parties may amend pleadings by that date without leave of court. However, Plaintiff recognizes that the Civil Case Management Plan and Scheduling Order typically used by Judge Liman, to whom this case was recently reassigned, sets a corresponding deadline for *making a motion* to amend. Accordingly, Plaintiff makes this motion in an abundance of caution.

In its proposed SAC, ChromaDex does not add any causes of action. It merely identifies additional instances of false advertising by Elysium regarding the effect of its product in treating cancer, expanding lifespan, and improving cognition, as well as allegations that Elysium sold product with high levels of a known carcinogen, contradicting Elysium's advertisements regarding the safety and purity of its product and the quality of its supply chain. These new allegations are largely premised on documents and information that have come to light in the related litigation between the parties in the Central District of California (8:16-cv-02277-CJC-DFM) and Elysium's public statements. The C.D. Cal. documents and information were recently made available for use in this action through an amendment to the relevant protective order and unsealing of court records.

Elysium will suffer no prejudice. The parties have not exchanged documents or conducted depositions in this action. Further, the determination of liability for the newly identified allegations will depend in large part—if not entirely—on documents and information in Elyisum's possession. For example, if advertising regarding the ability of its products to treat cancer and cure diseases is supported by science, Elysium would be in possession of relevant data and studies. Similarly, Elysium and its supplier are in exclusive possession of documents and information related to Elysium's supply chain and quality control.

The motion for leave should be granted.

II. FACTUAL BACKGROUND AND PROCEDURAL HISTORY

ChromaDex, a publicly traded nutraceutical company founded in 1999, is at the forefront of the development of dietary supplements that improve cellular function and vitality as people age. Its primary products, an ingredient called Niagen® and a consumer product called Tru Niagen®, contain a molecule called nicotinamide riboside ("NR"), which is clinically proven to increase NAD+ levels in human cells and is believed to have important anti-aging effects. ChromaDex has been the industry leader in the science, research, and development of isolated NR as an ingredient in dietary supplements and other products.

Elysium is a dietary supplement start-up founded in 2014. Elysium's lone product, Basis, contains two active ingredients: NR and pterostilbene ("PT"). For years, ChromaDex was Elysium's sole supplier of NR. Today, Elysium and ChromaDex are competitors in the consumer market for NR supplements.

This action seeks redress for several false and misleading statements made by Elysium in its advertisements and marketing material, giving rise to causes of action for false advertising and unfair competition under section 43 of the Lanham Act and deceptive trade practices under section 349 of the New York General Business Law ("GBL"). This action describes several false and misleading statements made by Elysium in its advertisements and marketing materials, giving rise to claims for false advertising and unfair competition. Many of these statements stem from Elysium's strategic plan to emulate ChromaDex and create an unmerited veneer of scientific competence and credibility.

On September 27, 2017, Elysium commenced an action in this District and filed a complaint against ChromaDex relating to a citizen petition ChromaDex had filed with the Food and Drug Administration regarding the presence of toluene in Basis. (Dkt. No. 1.) On October 26, 2017, ChromaDex commenced an action and filed a complaint against Elysium relating to false and misleading advertising. (Dkt. No. 23.) The two actions were consolidated (Dkt. No. 27) and each side moved to dismiss. (Dkt. No. 19, 31.)

On September 27, 2018, the Court converted ChromaDex's motion to dismiss Elysium's complaint (relating to the citizen petition) to a motion for summary judgment. *In re Elysium Health-ChromaDex Litig.*, 2018 WL 4907590, at *14 (S.D.N.Y. Sept. 27, 2018). The Court later granted summary judgment in favor of ChromaDex and dismissed Elysium's complaint. *In re Elysium Health-ChromaDex Litig.*, 354 F. Supp. 3d 330 (S.D.N.Y. Jan. 3, 2019).

The Court also granted in part and denied in part Elysium's motion to dismiss ChromaDex's claims (previously denominated by the Court as counterclaims) relating to Elysium's false and misleading advertising. Specifically, the Court ruled that ChromaDex had stated Lanham Act claims regarding: 1) statements suggesting that the FDA has approved or endorsed basis; 2) statements that Elysium "played a significant role in the scientific research concerning NR, and that its current Basis product is both novel and well-researched"; and 3) statements which falsely represented that Elysium's clinical trials were conducted on ingredients used in the current iteration of Basis. *In re Elysium Health-ChromaDex Litig.*, 2018 WL 4907590, at *9-13. The Court also upheld ChromaDex's claims under GBL § 349, which relied on substantially the same allegations as the Lanham Act claims, because the elements of claims under GBL § 349 "are substantially the same as . . . claims brought under § 43 of the Lanham Act." *Id.* at *13.

ChromaDex thereafter filed an amended complaint on consent. (Dkt. No. 79.) The amended complaint added three new categories of false and misleading statements Elysium made in its advertising and marketing materials. These include: (i) false labeling and advertising that misrepresents the amount of NR in each Basis capsule, (ii) Elysium's false claim that Basis is "pure," and its concomitant failure to warn consumers that Elysium's own clinical study established a risk that the PT in Basis may significantly raise LDL-C ("Bad Cholesterol") and thus create an undisclosed health risk to anyone taking Basis, and (iii) Elysium's false and misleading statement that it is the exclusive licensee of a Harvard and Mayo Clinic patent on the use of NR for "dietary supplement applications in the slowing of aging and age-related diseases," when its license relates to a patent application for which all of the claims were either abandoned

by the inventor or rejected by the U.S. Patent and Trademark office as obvious and anticipated by prior art.

Subsequent to ChromaDex's first request to amend the complaint, the Court entered the CMP which provided that "[n]o pleading may be amended after August 9, 2019." (Dkt. No. 77.) That deadline was extended to February 10, 2020. (Dkt. 92; *see also* Fed. R. Civ. P. 6(a)(2)(C).)

III. THE PROPOSED SECOND AMENDED COMPLAINT

A copy of the proposed SAC is attached as Exhibit 2 to the Declaration of Prashanth Chennakesavan ("Chennakesavan Declaration"). Additionally, for the Court's convenience, a redline comparison of ChromaDex's proposed SAC against its first amended complaint is attached as Exhibit 1 to the Chennakesavan Declaration.

ChromaDex's proposed SAC identifies additional false and misleading claims made by Elysium. Specifically, the proposed SAC includes allegations that Elysium (1) introduced high levels of acetamide, a known carcinogen, into its Basis product despite promoting itself as setting a new standard for quality and purity for consumer products; and (2) makes unsubstantiated disease prevention, cognitive benefit, and longevity claims.

The first category of allegations expand upon false advertising statements in the FAC regarding the safety and purity of Basis. The second identifies additional Elysium advertising touting the positive benefits from the PT in Basis, an issue that is already part of this litigation. These new allegations thus fit within the claims already asserted against Elysium and provide further important support for ChromaDex's contention that Elysium's shortcuts in development and testing of Basis has serious consequences for consumers.

IV. LEGAL STANDARD

Federal Rule of Civil Procedure 15 provides that a court "should freely give leave [to amend] when justice so requires." Fed. R. Civ. P. 15(a)(2). "The policy behind this rule is that liberal amendment promotes judicial economy by making it possible to dispose of all contentions between parties in one lawsuit." *Kreisler v. P.T.Z. Realty, L.L.C.*, 318 F.R.D. 704, 706 (S.D.N.Y. 2016) (internal alteration and quotation marks omitted). Leave to amend should be

given "absent evidence of undue delay, bad faith or dilatory motive on the part of the movant, undue prejudice to the opposing party, or futility." *Monahan v. N.Y.C. Dep't of Corr.*, 214 F.3d 275, 283 (2d Cir. 2000).

Because Plaintiff's request for leave to amend is within the deadline for amendment set by the operative scheduling order, Federal Rule of Civil Procedure 16(b)'s more stringent "good cause" standard for modifying scheduling orders is not applicable here. *See* Fed. R. Civ. P. 16(b)(4).

V. LEAVE TO AMEND SHOULD BE GRANTED

A. ChromaDex's Amendments Are Not Futile

To determine whether a proposed pleading is futile, courts analyze whether it would withstand a motion to dismiss. *See AEP Energy Servs. Gas Holding Co. v. Bank of Am., N.A.*, 626 F.3d 699, 726 (2d Cir. 2010) ("Leave to amend may be denied on grounds of futility if the proposed amendment fails to state a legally cognizable claim or fails to raise triable issues of fact"). When deciding a motion for leave to amend, 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.")).

ChromaDex's claims in this action arise out of Elysium's deceptive advertising and false claims. As explained in the first amended complaint, Elysium deceptively and falsely markets its dietary supplement pills as safe, effective, and based on years of research, comprehensive FDA regulatory approvals, and clinical and quality assurance testing. The new allegations in the proposed Second Amended Complaint are further support of Elysium's conduct. Accordingly, the amendment is not futile. *See Freeman v. Timberlake*, No. 06 Civ. 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 . . . .").

B. No Undue Delay or Bad Faith Exist and Elysium Will Suffer No Prejudice from the Filing of the Second Amended Complaint

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). The Second Circuit has instructed that "[m]ere delay . . . 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. v. Fluor Corp.*, 654 F.2d 843, 856 (2d Cir. 1981).

Here, ChromaDex has acted in good faith and expeditiously to amend the complaint within the scheduling order deadline. Notably, a substantial portion of the new allegations are based on documents produced by Elysium in the Central District of California Action. ChromaDex sought to modify the protective order in that action to allow for the cross-use of discovery produced pursuant thereto. However, Elysium declined to stipulate to such a provision, the issue had to be litigated, and was only finally resolved on January 16, 2020, when the District Judge in that action issued an order denying Elysium's objection to the Magistrate Judge's modification of the protective order to add a cross-use provision. On the same day, the specific documents and information supporting many of the new allegations in the SAC were ordered unsealed and made part of the public record.

Moreover, Elysium will not suffer undue prejudice from the filing of the SAC. Undue prejudice traditionally results when granting leave to amend 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 non-movant from bringing a timely action in another jurisdiction." *Monahan*, 214 F.3d at 275. The parties are in the process of finalizing a proposed protective order and ESI stipulation, with documents responsive to pending discovery requests to be produced thereafter. Neither party has scheduled depositions or conducted any third-party discovery. Accordingly, given the stage of discovery, no prejudice will result.

VI. CONCLUSION

For the foregoing reasons, the motion for leave should be granted.

Dated: New York, New York
February 9, 2020

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