UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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

MEMORANDUM OF LAW IN SUPPORT OF
MOTION FOR LEAVE TO FILE FIRST AMENDED COMPLAINT

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes and Other Authorities

I. INTRODUCTION

Pursuant to Federal Rule of Civil Procedure 15(a)(2), Plaintiff ChromaDex, Inc. ("Plaintiff" or "ChromaDex") requests leave to file a proposed First Amended Complaint ("FAC"), attached as Exhibit 1 to the Declaration of David Kupfer.

This action seeks redress for several false and misleading statements made by Elysium in its advertisements and marketing materials, giving rise to causes of action for false advertising and unfair competition under § 43 of the Lanham Act and deceptive trade practices under § 349 of the New York General Business Law ("GBL").

ChromaDex seeks leave to file the proposed FAC. The FAC adds three new categories of false and misleading statements, each of which adequately pleads the elements of claims under the Lanham Act and GBL § 349 as articulated by the Court in the motion to dismiss order, provides additional information regarding several of the false and misleading statements at issue in the original complaint, deletes facts which are no longer relevant to ChromaDex's claims based on the Court's motion to dismiss order, and streamlines the presentation of relevant background information and the allegations supporting its claims.

Further, as Rule 26(a) disclosures and initial discovery requests have not yet been served by the parties, there can be no prejudice to Defendant by amending the complaint at this time. In fact, this is the most auspicious time to file an amended pleading.

II. FACTUAL BACKGROUND AND PROCEDURAL HISTORY[1]

ChromaDex, a publically traded nutraceutical company founded in 1999, is at the forefront of the development of dietary supplements that improve cellular function and vitality as

[1] ChromaDex and Elysium are also engaged in concurrent litigation in the Central District of California (Civil Action no. 8:16-cv-02277-CJC-DFM). That action concerns ChromaDex's claims for breach of contract and fraudulent deceit, as well as Elysium's counterclaims.

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 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 under § 43 of the Lanham Act, and deceptive trade practices under GBL § 349. 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*., 2019 WL 275115 (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.

The Court dismissed ChromaDex's claims regarding toluene in Basis and Elysium's statements that Basis is "pure" because the statement was not contained in an advertisement. *Id*. at *9. The Court also dismissed ChromaDex's claims for tortious interference and under GBL § 350. *Id*. at *13.

The parties have not yet served Rule 26(a) disclosures or initial discovery requests in this action. Discovery was stayed during the pendency of the dispositive motions. (Dkt. No. 27.) On February 29, 2019, counsel for ChromaDex sought consent from Elysium to file a proposed case management plan. The parties are currently negotiating the terms of that plan.

III. THE PROPOSED FIRST AMENDED COMPLAINT

The proposed FAC accomplishes four things. *First*, the FAC adds 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.

Second, it deletes facts which are no longer applicable to this action following the Court's motion to dismiss order. *Third*, the FAC streamlines the presentation of relevant background information and the allegations supporting its claims, including facts relating to the historical relationship of the parties. *Fourth*, the FAC provides additional information regarding Elysium's misrepresentations as to statements regarding the testing and production of Basis and the research of the science behind Basis—both categories of false and misleading statements which were asserted in the original complaint.[2]

[2] While the majority of the claims and information in the FAC was alleged in the original complaint, the structure, organization, and verbiage of ChromaDex's allegations have been substantially modified in the FAC. Accordingly, a "redline" comparison between the original and new pleading would not be helpful to the Court and has not been attached. ChromaDex would be happy to generate and provide a comparison upon request.

IV. LEGAL STANDARD

Under Federal Rule of Civil Procedure 15, a party may amend its pleading either with the opposing party's written consent or with the Court's leave. Fed. R. Civ. P. 15(a)(2). Such "leave to amend a pleading should be freely granted when justice so requires." *Agerbrink v. Model Serv. LLC*, 155 F. Supp. 3d 448, 452 (S.D.N.Y. 2016) (internal quotations omitted). Specifically, the court should grant leave "absent undue delay, bad faith, undue prejudice, or futility[.]" *In re Facebook, Inc., IPO Secs. & Derivative Litig.*, 43 F. Supp. 3d 369 (S.D.N.Y 2014) (citing *Forman v. Davis*, 371 U.S. 178, 172 (1962). None of the above apply in this case.

V. LEAVE TO AMEND SHOULD BE GRANTED

A. ChromaDex's Amendments Are Not Futile

Futility hinges on a finding that the proposed amended complaint would not survive 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"); *see also Summit Health, Inc. v. APS Healthcare Bethesda, Inc.*, 993 F. Supp. 2d 379, 403 (S.D.N.Y. 2014), *aff'd sub nom. APEX Emp. Wellness Servs., Inc. v. APS Healthcare Bethesda, Inc.*, 725 F. App'x 4 (2d Cir. 2018) ("leave to amend may be denied on the basis of futility if the proposed claim would not withstand a Rule 12(b)(6) motion to dismiss").

The Amended Complaint adds three new categories of false and misleading statements by Elysium, each of which meets the elements of a Lanham Act claim (as described by the Court in the motion to dismiss order):

> that (1) the Elysium has made a false or misleading statement; (2) the false or misleading statement has actually deceived or has the capacity to deceive a substantial portion of the intended audience; (3) the deception is material in that it is likely to influence purchasing decisions; (4) the defendant placed the false or

> misleading statement in interstate commerce; and (5) CMDX has been injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its products."

2018 WL 4907590, at *8. The new categories of statements are discussed, *ad seriatim*.

i. *Basis does not contain the amount of advertised NR*

First, the FAC alleges that while Elysium advertises that each Basis dose contains at least 250 mg of NR, many doses actually contain less than the advertised amount:

> 94. Elysium advertises that a dose of Basis contains 250 mg of NR. However, testing of commercially available Basis revealed that as many as a third of Basis doses sold to consumers contain materially less NR.
>
> 95. On information and belief, the amount of NR in Basis is highly material to Elysium's customers. Elysium advertises that daily intake of a standard dose of 50 mg of PT and 250 mg of NR (the contents of Basis), may increase NAD+ levels by 40%. Consumers are led to believe that they will achieve certain results with a recommended dose of Basis, when they may need far more Basis to receive the recommended amount of NR.
>
> 96. On information and belief, Elysium fails to conduct adequate testing to ensure that its new ingredients contain consistent amounts of NR, were as potent as advertised, and were stable after production.

(FAC, ¶¶ 94-96) (internal citations omitted).

ChromaDex's allegations adequately plead the first three elements of a claim under § 43 of the Lanham Act; that Elysium made false statements, which are likely to deceive, and are material to consumers. In addition, ChromaDex alleges injury and a nexus to interstate commerce. (FAC ¶¶ 106, 107.)

ii. *Elysium fails to warn consumers that Basis may raise levels of "Bad Cholesterol" and claims Basis is "safe" and "pure"*

Second, the FAC alleges that Elysium's claims that Basis is safe and pure are false and misleading and belied by its failure to warn consumers that, according to its own research, the PT in Basis causes significantly increased risk of higher Bad Cholesterol:

> 97. Elysium fails to warn consumers that the active ingredient PT in Basis has now been shown to increase low density lipoprotein cholesterol (LDL-C), often referred to as "Bad Cholesterol."

> 98. Elysium's own research, shows that daily administration of NR plus PT produced a clinically statistically significant increase in total cholesterol driven entirely by increased LDL-C.
>
> 99. LDL-C leads to a buildup of cholesterol in arteries and high levels of LDL-C raise the risk of coronary artery disease and may lead to heart attacks. Increased levels of LDL-C, therefore, present serious health risks for consumers.
>
> 100. Despite the fact that Elysium's own clinical study established this risk, the Basis product labels and Elysium's marketing materials are devoid of any warning of the increased levels of LDL-C and the associated health risks. These health risks would be highly material to the purchasing decisions of consumers.
>
> 101. Elysium's advertisements are not only deceptive by omission, but also contain affirmative misrepresentations. Elysium's claims that Basis is "safe" and "pure" and that it prioritizes "quality, safety, and efficacy," are false and misleading and are plainly belied by its failure to warn consumers about the substantial risks posed by Basis.

(FAC ¶¶ 97-101) (internal citations omitted.)

Again, ChromaDex's allegations adequately plead the first three elements of a claim under § 43 of the Lanham Act. ChromaDex also alleges injury and a nexus to interstate commerce. (FAC ¶¶ 106, 107.)

iii. ***Elysium falsely represents to consumers that it is the exclusive licensee of a patent for the use of NR***

Finally, the FAC alleges that Elysium's advertisements claiming to be the exclusive licensee to a Harvard and Mayo Clinic patent on the use of NR in supplements to treat age-related diseases are false and misleading:

> 63(e)(i). ChromaDex is the exclusive licensee of numerous patents related to NR, including patents covering the composition-of-matter and "crystal morphology," or atomic structure, of isolated NR (Nos. 8,197,807 and 8,383,086)—the most important patents one can hold for a compound.
>
> 63(e)(ii). On August 16, 2018, Elysium announced that it had entered into an exclusive license agreement with the Mayo Clinic and Harvard University related to the uses of NR . . . .
>
> 63(e)(iii). Elysium's announcement is intended to make consumers believe that Elysium is the exclusive licensee of a patent obtained by Harvard and the Mayo Clinic and is now the only party that can sell NR supplements for use in connection

> with ageing or age-related diseases. Exclusive access to such a patent, and from such preeminent institutions, would be highly material to consumers.
>
> 63(e)(iv). In reality, Elysium has licensed a patent application—not an issued patent. Moreover, by the time of Elysium's announcement, all of the claims in this patent application had either been abandoned by the inventor or rejected by the U.S. Patent and Trademark Office as obvious or anticipated by prior art.

(FAC ¶¶ 63(e)(i)-(iv).)

Again, these allegations adequately plead the first three elements of a claim under § 43 of the Lanham Act. ChromaDex also alleges injury and a nexus to interstate commerce. (FAC ¶¶ 106, 107.)

Accordingly, ChromaDex's newly-added categories of false and misleading statements sufficiently plead claims under § 43 of the Lanham Act and GBL § 349.

iv. ***No other changes to the FAC render ChromaDex's initially upheld claims futile***

The majority of the claims in the FAC have not changed. Elysium has already challenged—and this Court already upheld—claims related to Elysium's 1) "Statements that the FDA has approved or endorsed Basis," 2018 WL 4907590, at *9, 2) "Statements Regarding the Research of the Science behind Basis," *id*. at *10-11,and 3) "Statements Regarding the Testing and Production of Basis," *id*. at * 12. As to each of these categories of false and misleading statements, the Court found that ChromaDex had stated Lanham Act claims under the 12(b)(6) pleading standard. *Id*. at *9-13. The additional allegations regarding these categories of false and misleading statements bolster ChromaDex's claims, and do not render them futile. *See e.g*., FAC ¶ 63(b)(iv)(Elysium's misrepresentations in a recent social media post); ¶ 63(d)(ii) (Elysium's misrepresentations regarding a clinical trial); ¶ 80 (Elysium misrepresents that Basis is "the culmination of more than 25 years of aging research"); ¶¶ 81-84 (Elysium's

misrepresentations regarding Dr. Guarente's qualifications); ¶ 86 (Elysium's misrepresentations in a magazine profile).

B. Elysium Will Suffer No Prejudice from the Filing of the Amended Pleading

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 plaintiff from bringing a timely action in another jurisdiction." *Monahan v. N.Y.C. Dept. of Correction*, 214 F.3d 275 (2d Cir. 2000).

Considering the current posture of the action, the filing of the FAC will not cause any prejudice to Elysium. The Court only recently decided the remainder of the parties' dispositive motions and discovery in the action is just getting under way. The parties are negotiating a case management plan and have not yet served Rule 26(a) disclosures or initial discovery requests. *See A.V. by Versace, Inc. v. Gianni Versace S.p.A.*, 87 F. Supp. 2d 281 (S.D.N.Y. 2000) (holding that there is no prejudice where "discovery has not yet been completed"); *see also A.V.E.L.A., Inc. v. Estate of Monroe*, 34 F. Supp. 3d 311, 316-17 (S.D.N.Y. 2014) (collecting cases and finding that delay periods of roughly four to five months are "not significant enough" to cause prejudice).

Far from being an inappropriate or prejudicial time to amend, this is the most auspicious time for ChromaDex to file an amended complaint, as it would allow *both* parties to calibrate their Rule 26(a) disclosures and discovery requests to the new and revised allegations.

VI. CONCLUSION

For the above-stated reasons, ChromaDex respectfully requests that the Court grant ChromaDex leave to amend its Complaint.

Dated: March 8, 2019
New York, New York

COOLEY LLP

S/ Alan Levine

Alan Levine
David H. Kupfer
1114 Avenue of the Americas
New York, NY 10036
Tel: 212-479-6000
Fax: 212-479-6275
alevine@cooley.com
dkupfer@cooley.com

Michael Attanasio
Barrett J. Anderson
4401 Eastgate Mall
San Diego, CA 92121-1909

Peter J. Willsey
1299 Pennsylvania Ave., NW Suite 700
Washington, D.C. 20004-2446

Attorneys for Plaintiff ChromaDex, Inc.