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VIA ECF

February 28, 2020

Honorable Lewis J. Liman
United States District Court
Southern District of New York
500 Pearl St.
New York, NY 10007-1312

Re: In re Elysium Health-ChromaDex Litigation, No. 17 Civ. 7394 (LJL)

Dear Judge Liman,

We represent Plaintiff ChromaDex, Inc. ("ChromaDex" or "Plaintiff") in the above-referenced matter. Pursuant to the Court's February 14, 2020 Order, ECF No. 128, we respectfully submit this joint letter with Defendant Elysium Health, Inc. ("Elysium" or "Defendant") updating the Court on the status of the case. The parties address the five topics specified in the Court's Order below.

1. A brief statement of the nature of the case and the principal defenses thereto

a. ChromaDex's Statement

i. Background and ChromaDex's Second Amended Complaint

ChromaDex, founded in 1999, is the only patent-holding supplier of an ingredient called nicotinamide riboside ("NR") in the United States. NR is clinically proven to increase NAD+ levels in human cells, which is critical for healthy cellular metabolism, mitochondria, and cellular repair. ChromaDex has invested many years and resources rigorously testing its NR for purity and safety. ChromDex's NR is sold under a New Dietary Ingredient Notification ("NDIN") on file with the U.S. Food and Drug Administration ("FDA"), and it is also Generally Recognized As Safe ("GRAS") by the FDA. ChromaDex has also received regulatory approvals for NR from the European Food Safety Authority, Health Canada, and the Therapeutic Goods Administration of Australia. ChromaDex has been the industry leader in the science, research, and development of NR as an ingredient in dietary supplements and other products, and is engaged in a global distribution effort with Nestlé in connection with functional and medical foods. ChromaDex is the exclusive licensee of patents owned by Dartmouth University related to the composition of matter of NR.

Elysium is a dietary supplement start-up founded in 2014 and had no prior experience with NR or any other supplement ingredients. Elysium's sole product, Basis, contains two active ingredients: NR and pterostilbene ("PT"). Until 2016, ChromaDex was Elysium's sole supplier of NR. In 2016, ChromaDex gave notice of non-renewal of its supply agreements with Elysium for both NR and PT after Elysium refused to pay for $3 million of product ordered and refused to constructively engage to resolve the dispute. Unbeknownst to ChromaDex, during this time, Elysium was engaged in a plot to

recruit key ChromaDex employees, who stole and transmitted to Elysium ChromaDex's trade secrets and confidential information. Breach of fiduciary duty, trade secrets, and contract claims related to that conduct are being litigated in an action in the Central District of California, which is scheduled for trial on May 12, 2020. When Elysium exhausted its legitimate supply of NR from ChromaDex, Elysium procured a new unknown source of NR for its consumer-facing product. Today, Elysium sells NR-based products to consumers by infringing on ChromaDex's intellectual property rights. A patent case related to Elysium's willful infringement is being litigated in the District of Delaware.

Elysium initiated this action in 2017 by suing ChromaDex for allegedly making a sham petition to the government after ChromaDex filed a citizen petition with the FDA. ChromaDex tested samples of Elysium's new NR formulation, which revealed that Elysium's Basis contained excessive levels of toluene, a processing solvent which is used in paint thinner and fingernail polish, and which can cause serious cognitive, nervous system, and brain damage with sustained use as recommended by Elysium. ChromaDex appropriately filed its citizen petition to bring these serious health and safety issues to the attention of the FDA, requesting an investigation and, if appropriate, an enforcement action. Chief Judge McMahon granted summary judgment as to Elysium's sham petition claims based on the *Noerr-Pennington* doctrine, finding that ChromaDex's petition "was reasonably calculated to elicit a favorable outcome, and, indeed, succeeded in doing so." ECF No. 69 at 7-8. Elysium conceded that "the presence of toluene in Basis posed potential harm to consumers" and removed the solvent. *Id.* at 8.

In October 2017, ChromaDex filed a separate action seeking redress for Elysium's false and misleading statements in advertising and marketing materials, which was consolidated with this action on November 3, 2017. In its operative Second Amended Complaint, ChromaDex asserts 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"). Specifically, Elysium falsely advertises to consumers, *inter alia*, that: (i) it was the "first" to market a supplement proven to raise NAD+ levels, implying that it (instead of ChromaDex) is the pioneer in this space; (ii) it was involved in the 25+ years of research and development surrounding NR (Elysium was not founded until 2014); (iii) FDA approves or endorses Basis (FDA does not); (iv) Basis is backed by clinical studies (even though the studies were based on ChromaDex's NR); (v) it is the exclusive licensee of a patent for the use of NR in slowing aging (ChromaDex is the licensee); (vi) Basis is safe and effective (even though Elysium's manufacturing process included high level of acetamide, a known carcinogen); and (vii) Basis can prevent or treat serious diseases (including cancer, Alzheimer's, heart disease, and diabetes), reverse cognitive decline, and increase lifespan (even though there is no study supporting such claims and some that show the *opposite*).

ii. Statement regarding Elysium's Third Amended Counterclaims

Each time ChromaDex has unearthed and asserted additional examples of Elysium's false and misleading advertising, Elysium has asserted counterclaims accusing ChromaDex of engaging in false advertising. Elysium filed the most recent iteration of if counterclaims after ChromaDex filed a motion for leave to file its Second Amended Complaint. Elysium accuses ChromaDex of engaging in false advertising for representations that are well supported, including that: (i) NR increases NAD+ levels in subjects (a claim that is supported by multiple peer-reviewed clinical studies); and (ii) ChromaDex's NR is safe (ChromaDex, unlike Elysium, has received multiple New Dietary Ingredient

Notification and Generally Recognized As Safe acknowledgements from FDA). In addition, Elysium claims ChromaDex is responsible for statements made by third parties over whom ChromaDex has no control regarding the benefits of NR even though ChromaDex (again, unlike Elysium) explicitly states in its advertising that Tru Niagen is not an FDA-approved drug and cannot be used to treat any disease. In addition, Elysium asserts a copyright infringement claim for the use of some graphics in advertising. ChromaDex denies any and all liability.

b. Elysium's Statement

Elysium has sold a dietary supplement called Basis since 2015. Basis contains two ingredients, nicotinamide riboside (NR) and pterostilbene (PT). Elysium was co-founded by Dr. Leonard Guarente, the director of the Paul F. Glenn for Biology of Aging Research at MIT. Dr. Guarente dedicated his career to studying the genetic and molecular causes of aging. In 1999, Dr. Guarente's lab found that if they activated the SIR2 gene, yeast would live longer. Soon after this discovery, they found that SIR2 required a molecule called NAD, or nicotinamide adenine dinucleotide, to function. NAD+ is a critical coenzyme found in every cell in the body, and it's involved in hundreds of metabolic processes. However, NAD+ levels decline with age. NR, which is a naturally-occurring form of vitamin B3, is a highly efficient precursor to NAD+.

ChromaDex used to supply Elysium with NR and PT from 2014 to mid-2016. ChromaDex breached the supply agreement, by, among other things, overcharging Elysium. This dispute is the subject of litigation pending before the Central District of California.

After the decline of the supplier relationship between Elysium and ChromaDex, ChromaDex entered the market with a product called Tru Niagen. Now, Elysium and ChromaDex are direct competitors. Basis and Tru Niagen both contain NR, but differ in critical ways. First, Tru Niagen does not contain any PT. A comparison of the clinical studies of the effects of NR versus the clinical studies of the effects of NR plus PT suggest that NR and PT have a synergistic effect that significantly increases NAD+ levels. Second, Elysium and ChromaDex obtain their respective NR supplies from different sources and by different methods of production. ChromaDex makes NR using solvents that leave behind contaminants, such as acetamide, a carcinogen. Elysium has invested millions of dollars in developing its own method of creating NR, which does not result in such contaminants.

When ChromaDex launched Tru Niagen, it also launched a smear campaign against Elysium to try to diminish Elysium's reputation in the market. In August 2017, ChromaDex filed a citizen petition with the FDA asserting that Basis contained the solvent toluene. Tellingly, ChromaDex's own product contained toluene and the petition sought relief that the FDA did not have the authority to grant. Furthermore, the levels of toluene in Basis were far below the allowable levels established by the International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, and therefore did not pose harm to consumers. On that basis, Elysium argued that *Noerr-Pennington* immunity did not apply to the petition because it was a sham to cover an attempt to interfere with Elysium's business relationship. However, the Court attributed Elysium's ongoing efforts to improve its methods of production (which ultimately eliminated all toluene from Basis), at least in part, to the petition. Based thereon, the Court concluded that the petition elicited a favorable outcome and therefore was not a sham.

In a further attempt to influence consumers away from Elysium and eliminate Elysium from the market, ChromaDex has engaged in false advertising, federal unfair competition, and deceptive business practices, including, but not limited to, by:

- ChromaDex falsely claiming that it has "3 FDA Safety Reviews" giving consumers the false impression that the FDA made an affirmative determination that Tru Niagen is safe and effective. The FDA has never reviewed Tru Niagen. ChromaDex submitted "new dietary ingredient notifications" to the FDA. In response the FDA stated: "acceptance of this notification for filing is a procedural matter, and thus, does not constitute a finding by FDA that the new dietary ingredient or supplement that contains the new dietary ingredient is safe or is not adulterated under 21 U.S.C. 342."

- ChromaDex falsely claiming that it is the only "authorized" or "legitimate" seller of NR, giving consumers the false impression that all other NR products, like Basis, are "counterfeit" or dangerous. There is no dispute that Basis contains NR. Elysium obtains that NR from a different source and by a different method than ChromaDex. Elysium's NR has undergone safety testing and enjoys that same "Generally Recognized as Safe" ("GRAS") status as Tru Niagen. Furthermore, ChromaDex is not even the exclusive licensee of NR-related patents, as it claims to be.

- ChromaDex also falsely claiming that Tru Niagen is clinically proven to raise NAD levels and is more effective than Basis. However, ChromaDex's own clinical study showed no statistically significant increase in NAD levels among participants taking Tru Niagen. Elysium believes that result is because of the lack of PT in Tru Niagen. ChromaDex then attempted to rig the results of a second study by restricting participants' diets to deprive them of NAD+ in order to give the artificial impression that Tru Niagen raised NAD+ levels.

ChromaDex projects its own bad faith advertising practices onto Elysium, alleging that Elysium misappropriated ChromaDex's "pedigree," falsely claims that Basis is safe and effective, and falsely claims that Basis can treat numerous diseases. As a preliminary matter, ChromaDex mischaracterizes Elysium's advertising. All of Elysium's advertising is supported by facts and scientific research and does not deceive the public.

2. A statement of all existing deadlines, due dates, and/or cut-off dates

The following deadlines have been set by the operative Civil Case Management Plan and Scheduling Order ("CMP") entered on March 21, 2019, ECF No. 77, as extended by the Court on August 22, 2019, ECF No. 92:

- Completion of Document Discovery – February 24, 2020
- Completion of Fact Depositions – April 11, 2020
- Initial Expert Disclosures – April 25, 2020
- Rebuttal Expert Disclosures – May 25, 2020
- Completion of Expert Depositions – June 20, 2020
- Completion of All Discovery – June 20, 2020
- Submission of Joint Pretrial Order – August 28, 2020

3. A brief description of any motions which have been made and decided and a confirmation that there are no pending motions and no pending appeals

a. Motions previously made and decided

On September 27, 2017, Elysium commenced this action and filed a complaint against ChromaDex relating to a citizen petition ChromaDex had filed with the FDA regarding the presence of toluene in Basis. ECF No. 1. On October 26, 2017, ChromaDex commenced an action and filed a complaint against Elysium relating to false and misleading advertising. ECF No. 23. The two actions were consolidated, ECF No. 27, and each side moved to dismiss. ECF Nos. 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. ECF No. 44. The Court later granted summary judgment in favor of ChromaDex and dismissed Elysium's complaint. ECF No. 63.

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. ECF No. 44. Specifically, the Court ruled that ChromaDex had failed to state an actionable Lanham Act claim regarding a statement that Basis is pure and failed to state a claim for tortious interference, but 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. *Id.* 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 25.

Both sides have moved to amend their pleadings twice. Each motion was granted on consent. ECF Nos. 79, 88, 137, 138.

b. No Pending Motions or Appeals

The parties confirm that there are no pending motions or appeals.

4. A statement describing the status of any discovery in the case

The document discovery deadline in this action was February 24, 2020. ChromaDex produced nearly 15,000 non-privileged documents, spanning approximately 95,000 pages, in response to Elysium's requests for production. Elysium has produced approximately 37,000 pages. The parties expect that both sides will identify withheld privileged documents in short order. As set forth above, the deadline to complete depositions is April 11, 2020, and the deadline for completion of all discovery is June 20, 2020.

The parties respectfully leave any extension of the deadlines to the Court's discretion. However, both sides believe that an extension of at least one month of all deadlines would be appropriate. Such an extension would allow the parties to seek limited additional discovery related to the amended pleadings, review all the produced documents, prepare for and complete depositions in an organized manner, and devote resources to a productive mediation (as described below).

5. A statement describing the status of any settlement discussions

The parties are discussing a potential resolution of this action and have scheduled a private mediation on March 17, 2020 before the Hon. Daniel Weinstein (Ret.).

Sincerely,

s/ Joe H. Tuffaha
Joe H. Tuffaha

CC: Via ECF to Counsel of Record

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