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November 15, 2018

VIA ECF AND BY HAND

Honorable Colleen McMahon
Chief United States District Judge
United States District Court
Southern District of New York
500 Pearl Street
New York, N.Y. 10007-1312

Re: In re Elysium Health – ChromaDex Litigation, 17 Civ 7394 (CM*)*

Dear Judge McMahon:

We write on behalf of plaintiff Elysium Health, Inc. in response to the November 13, 2018 letter motion (ECF No. 59) of defendant ChromaDex, Inc. seeking leave to file a second declaration of its executive vice president, Troy Rhonemus, and over 320 pages of new exhibits in connection with the Court's September 27, 2018 Decision and Order (ECF No. 44) that converted ChromaDex's motion to dismiss (ECF No. 19) to a motion for summary judgment on the "single, discrete issue" of "objective baselessness under *Noerr-Pennington's* sham exception" and directed the parties to submit "any and all evidence that may bear on the objective baselessness of [ChromaDex's] Citizen Petition" no later than October 29, 2018.

By way of background, in its Order converting ChromaDex's motion to dismiss, the Court stated that "[m]ost damning on the issue of objective baselessness is Elysium's contention that [ChromaDex's pterostilbene] product, pTeroPure®, also contains toluene in levels comparable to the toluene in Basis," and observed that, "[a]ssuming *arguendo* that [ChromaDex] does not intend to market an adulterated product, it would be objectively baseless for it to argue to the FDA that a competitor's product is adulterated because it contains an ingredient that is found in [ChromaDex's] own competing product." (ECF No. 44 at 13.)

ChromaDex has admitted that it sold pTeroPure to Elysium that contained toluene in levels comparable to those it claimed to have found in Elysium's Basis. (ECF No. 51 at ¶¶ 51-52.) The supplemental filing ChromaDex now seeks to put before the Court does not alter that admission.

Instead, ChromaDex seeks to blunt the impact of its concession by contending it did not sell its toluene-containing pterostilbene directly to consumers.

In a declaration submitted with ChromaDex's initial evidentiary submission, Rhonemus stated that ChromaDex had sold consumer products under the brand BluScience, but omitted to disclose that those products contained pterostilbene. (ECF No. 51 at ¶ 7.) It was Elysium that advised the Court of that latter fact. (ECF No. 53 at ¶¶ 13-14 & Exs. 6-7.) ChromaDex now seeks leave to file a second declaration from Rhonemus (the "Supplemental Declaration") that attaches as exhibits what he describes as results of "[c]ontemporaneous analyses" of the lots of pterostilbene ChromaDex sold to consumers through the BluScience brand to support his assertion that "ChromaDex has never sold a consumer product containing toluene." (ECF No. 59 at Ex. A (Supplemental Declaration at ¶¶ 4, 7).)[1]

In the Supplemental Declaration, Rhonemus directs the Court only to specific pages in each of the attached exhibits. (ECF No. 59 at Ex. A (Supplemental Declaration at ¶ 7).) Although he offers no explanation whatsoever, the pages he cites appear to be reports of gas chromatography performed on the 19 lots of pterostilbene, which Rhonemus claims "disclosed that none [of the samples] contained detectible amounts of toluene." Exhibit 2 to the Supplemental Declaration appears on its face to refute that assertion, because on its seventh page it reveals the presence of toluene in the tested sample. (ECF No. 59 at Ex. A (Supplemental Declaration Ex. 2).)

Even more damning, however, is a document buried among the more than 320 pages of exhibits Rhonemus proffers that he elected ***not*** to draw to the Court's attention. That document is a Certificate of Analysis ("COA") comprising the second and third pages of Exhibit 19. (ECF No. 59 at Ex. A (Supplemental Declaration Ex. 19).) This COA, which Rhonemus admits was for pterostilbene sold to consumers, reveals the results of testing for the presence of seven different residual solvents, including toluene. Four of the seven solvents were "Not detected." The three others, however, ***including toluene***, were detected. ***In particular, the COA reveals that toluene was detected in the sample at 5 parts per million***. For the Court's convenience, we attach this COA, excerpted from Exhibit 19, to this letter as Exhibit A.

This COA puts the lie to Rhonemus' claim that the analyses of the 19 lots of pterostilbene ChromaDex sold to consumers "disclosed that ***none*** contained detectible amounts of toluene." (ECF No. 59 at Ex. A (Supplemental Declaration at ¶ 7 (emphasis added).) It also demonstrates the falsity of Rhonemus' contention that "ChromaDex has ***never*** sold a consumer product containing toluene." (ECF No. 59 at Ex. A (Supplemental Declaration at ¶ 4 (emphasis added).)

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[1] ChromaDex certainly could have put the results of these analyses before the Court when it made its original submission on October 29, 2018, because they date from 2011 and 2012. (ECF No. 59 at Ex. A (Supplemental Declaration Exs. 1-19).) Rhonemus was not employed by ChromaDex when these analyses were conducted, yet he curiously claims personal knowledge of them. (ECF No. 59 at Ex. A (Supplemental Declaration at ¶¶ 1, 6-7).)

And it demolishes ChromaDex's argument in its letter motion that its proposed submission provides "specific evidence which definitively demonstrates that ChromaDex did not sell to consumers products which contained toluene." (ECF No. 59.)

Moreover, the fact that the COA in Exhibit 19 explicitly refutes the conclusion Rhonemus states should be drawn from the gas chromatography results in that same exhibit raises serious doubts about the reliability of the gas chromatography results in each of the other exhibits to which Rhonemus directs the Court, and raises grave questions about the analytical methods used in the testing. These concerns are only heightened by the fact that notably absent from 17 of the 19 exhibits to the Supplemental Declaration are COAs reporting on the presence of residual solvents, including toluene. (Exhibit 18 does contain a COA reporting that toluene was not detected in that lot.)

It bears emphasis that the 19 exhibits to the Supplemental Declaration have been selected by ChromaDex from among the doubtless hundreds, if not thousands, of other documents in its possession that relate to the presence of toluene in its pterostilbene products, and that the discovery stay in place in this action has to date prevented Elysium from having access to any of those other documents to test the assertions ChromaDex has made in connection with this motion. That the documents ChromaDex cherry-picked to put before the Court themselves contain information that belies ChromaDex's contentions is, we submit, powerfully suggestive of the likelihood that many other documents that will be available to Elysium through the discovery process will only further validate Elysium's claims.

In sum, ChromaDex's proposed supplemental submission merely reinforces the evidence Elysium submitted in response to this Court's Order to demonstrate that ChromaDex sold multiple products containing toluene, including directly to consumers. (*See* ECF Nos. 52, 53.) This is precisely the type of evidence this Court characterized as "[m]ost damning on the issue of objective baselessness," and we submit warrants denial of ChromaDex's motion for summary judgment.

Respectfully submitted,

/s/ *Joseph N. Sacca*

Joseph N. Sacca

cc: All Counsel of Record, via ECF

Exhibit A

Drug Substance Manufacturing Unit
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Parawada, Visakhapatnam - 531021. India.
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Certificate of Analysis

Product Name	Pterostilbene (Phenol Alcohols)	A.R.No.	AR/FD/ADPEP/026/0612
		Date of Release	20/06/2012
Batch No.	ADPEPVSP10[redacted]2	Dispatch Qty.	300.00 Kg
Manufacturing Date	May' 2012	Specification No.	FS(R)/ADPEP/01
Retest/~~expiry~~ date	Oct' 2014	Test Procedure No.	FT(R)/ADPEP/01

Sl. No.	Test Parameter	Specification	Result
1.0	Description	Off-white to light brown color solid.	Off white color solid
2.0	Identification by a) IR	The IR spectrum obtained with the sample should be concordant with that of standard.	Complies
	b) HPLC	The retention time of the main peak in the sample chromatogram should match with the retention time of standard as obtained in purity by HPLC	Complies
3.0	Solubility	Soluble in Ethyl acetate, methanol and insoluble in water.	Complies
4.0	Melting Range(°C)	Between 90 to 96	93 – 95
5.0	Loss on drying (%w/w)	Not more than 1.0	0.1
6.0	Heavy Metals by ICP-OES (ppm) a) Lead b) Arsenic c) Cadmium d) Mercury	 <1.0 <1.0 <1.0 <1.0	 <LOQ <LOQ <LOQ <LOQ
7.0	Residue on ignition (%w/w)	Not more than 0.1	0.04
8.0	Purity by HPLC (% area)	Not less than 99.0	99.7

	Prepared by	Reviewed by	Approved by
Name	P. Kalyan Kumar	[illegible]	V. Ramesh
Signature			
Date	29/06/12	29/06/12	29/06/12
Department	Quality Control	Quality Control	Quality Assurance

Form No.: FM/LL/QA/031/01 Rev 3.0

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Certificate of Analysis

Product Name	Pterostilbene (Phenol Alcohols)	A.R.No.	AR/FD/ADPEP/026/0612
		Date of Release	20/06/2012
Batch No.	ADPEPVSP10120612	Dispatch Qty.	300.00 Kg
Manufacturing Date	May' 2012	Specification No.	FS(R)/ADPEP/01
Retest/~~expiry~~ date	Oct' 2014	Test Procedure No.	FT(R)/ADPEP/01

Sl. No.	Test Parameter	Specification	Result
9.0	Residual solvents by GC (ppm)		
	a) Tetrahydrofuran	Not more than 720	Not detected
	b) Methanol	Not more than 3000	Not detected
	c) Ethyl acetate	Not more than 5000	14
	d) Acetone	Not more than 5000	Not detected
	e) Toluene	Not more than 890	5
	f) Dichloromethane	Not more than 600	Not detected
	g) Hexanes	Not more than 290	139
10.0	Microbial tests		
	a) Total Aerobic Microbial Count	≤ 1000 Cfu/g	20
	b) Yeast and Mould	≤ 100 Cfu/g	Less than 10
	c) Salmonella	Should be absent	Negative
	d) Staphylococcus	Should be absent	Negative
	e) Escherichia coli	Should be absent	Negative
	f) Pseudomonas aeroginosa	Should be absent	Negative
*11.0	Bulk density (g/ml) Untapped	For information	0.28
*12.0	Particle size (Microns)		
	d(0.1)	For information	3
	d(0.5)	For information	29
	d(0.9)	For information	712

*As per customer requirement.
Note: LOQ- Limit of Quantification (0.50)
Remarks: The Material complies/~~does not comply~~ as per the above specification.

	Prepared by	Reviewed by	Approved by
Name	P. Kalyan Kumar	P. Srinivasan	V. Ramesh
Signature			
Date	29/06/12	29/06/12	29/06/12
Department	Quality Control	Quality Control	Quality Assurance

Form No.: FM/LL/QA/031/01 Rev 3.0