IN RE: PET FOOD PRODUCTS LIABILITY LITIGATION Doc. 317

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE PET FOODS PRODUCTS LIABILITY LITIGATION	MDL DOCKET NO. 1850 Case No. 07-2867 (NLH) Judge Noel L. Hillman **DEFENDANTS' MOTION FOR ISSUANCE OF ORDER TO SHOW CAUSE FOR AN ORDER ALLOWING FOR THE DESTRUCTION OF RECALLED WHEAT GLUTEN, RECALLED RICE PROTEIN CONCENTRATE AND OTHER INGREDIENTS ALLEGEDLY CONTAINING MELAMINE BEING STORED BY DEFENDANTS IN THE POSSESSION OF SUCH INGREDIENTS**

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR ISSUANCE OF ORDER TO SHOW CAUSE FOR AN ORDER ALLOWING FOR THE DESTRUCTION OF RECALLED WHEAT GLUTEN, RECALLED RICE PROTEIN CONCENTRATE AND OTHER INGREDIENTS ALLEGEDLY CONTAINING MELAMINE BEING STORED BY DEFENDANTS IN THE POSSESSION OF SUCH INGREDIENTS

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I. INTRODUCTION AND SUMMARY OF ARGUMENT

Pursuant to Fed. R. Civ. P. 26(b) and (c) and for good cause shown, Defendants request that this Honorable Court issue an Order to Show Cause, in the form annexed hereto as Exhibit "A", for an Order allowing for the destruction of recalled raw wheat gluten ("Wheat Gluten"), recalled raw rice protein concentrate ("RPC") and/or other ingredients allegedly containing melamine ("Work-in-Progress" or "WIP") being stored by those Defendants that are in the possession of such ingredients.

As this Honorable Court is aware, certain components and/or ingredients allegedly used in the manufacture of the recalled pet foods that are the subject of this litigation, specifically Wheat Gluten, RPC and/or WIP, have been preserved by certain defendants. In order to alleviate the burden on Defendants that were storing vast quantities of recalled products, on December 18, 2007, this Court issued an Order permitting those Defendants who sought relief from the Court to: (1) execute the sampling and general retrieval plan for organized recalled product as recommended by their expert statistician, Dr. George P. McCabe; (2) execute the sampling and retrieval plan for Wheat Gluten as recommended by Dr. McCabe; and (3) execute the sampling and general retrieval plan for WIP as recommended by Dr. McCabe. (D.E. 106). This Court further Ordered that "prior to the execution of the sampling and retrieval plans for organized [recalled] product, raw wheat gluten and work-in-progress recipes, the moving Defendants shall provide Plaintiffs with more specific details concerning the retrieval plans." (D.E. 106). Finally, this Court Ordered that "moving Defendants are permitted to dispose of any organized recalled product, unorganized inventory [unorganized recalled product], raw wheat gluten or work-in-progress recipe that is unnecessary to implement or execute Dr. McCabe's sampling and retrieval plans." (D.E. 106).

On April 14, 2008, this Court issued another Order allowing the Defendants who sought relief from this Court to implement the specific retrieval plans for "organized recalled product stored on pallets and/or within cardboard cases as recommended by Dr. George P. McCabe in his March 26 and April 8, 2008 Declarations." (D.E. 140). Thus, as a result of this Honorable Court's Order, adequate samples of finished products containing Wheat Gluten – those products that were actually on store shelves for purchase by consumers and consumption by pets at the time of the recalls – have been preserved by those defendants that previously sought relief from this Honorable Court.[1]

For the reasons set forth below, Defendants now request that this Court issue an Order to Show Cause, in the form attached hereto as Exhibit "A", allowing for the destruction of Wheat Gluten, RPC and WIP being stored by Defendants who possess such ingredients and, if granted, issue an Order, in the form attached hereto as Exhibit "B", allowing for the destruction of Wheat Gluten, RPC and WIP being stored by them.

II. ARGUMENT

A. GOOD CAUSE SUPPORTS THE ISSUANCE OF AN ORDER TO SHOW CAUSE ALLOWING FOR THE DESTRUCTION OF WHEAT GLUTEN, RPC AND WIP

This Court has broad power to limit discovery when good cause is shown. Fed. R. Civ. P. 26(b)(2), 26(C)(2) and 26(C)(4); *United States v. Princeton Gama-Tec*, 817 F.Supp. 488, 493 (D.N.J. 1993)(granting motion to limit discovery). This Court may limit discovery when "the burden or expense of the proposed discovery outweighs the likely benefit" to the party seeking discovery. *Maertin v. Armstrong Indus., Inc.* No. 01-5321, 2007 U.S. Dist. LEXIS 20561, at *4, 6 (D.N.J. Mar. 8, 2007)(Schenider, J.)(internal quotations omitted)(rejecting request for insurer's

[1] Some defendants have implemented Dr. McCabe's sampling plan while at least one defendant continues to store virtually all of its recalled finished product.

claims files that were located in 27 offices, because of the "burden and expense to obtain the requested discovery.") Moreover, discovery should be limited if there exists an "adequate substitute" to the proposed discovery, *Donohue v. Am. Isuzu Motors*, 157 F.R.D. 238, 246 (M.D. Pa. 1994), or if the "discovery sought can be obtained through less burdensome process," *In re Auto Refinishing Paint Antitrust Litig.*, MDL Dkt. No. 1426, 2004 U.S. Dist. LEXIS 29160, *17 (E.D. Pa. Oct. 29, 2004).

In the case at bar, the destruction of Wheat Gluten, RPC and WIP is warranted for the reasons set forth below.

1. THE FDA HAS CONDUCTED ITS OWN INDEPENDENT RELIABLE SAMPLING AND TESTING OF RECALLED WHEAT GLUTEN

Commencing in March 2007, the FDA developed and implemented a detailed sampling, inspection and testing program of ChemNutra's Wheat Gluten stored at its MoKan Container Service, Inc.'s warehouse located in Kansas City, Missouri. *See* Declaration of Stephen S. Miller ("*Miller Dec.*"), ¶5. As this Honorable Court is aware, it is the ChemNutra Wheat Gluten that is the focus of this litigation.

The FDA's methodology and plan for sampling and testing the Wheat Gluten was thorough and consistent with the plans previously proposed by Defendants' retained expert, Dr. McCabe, and previously approved by this Court in connection with its Orders pertaining to retained inventory of finished products. *See* Declaration of Anthony G. Brazil ("*Brazil Dec.*"), ¶ 5; *See* Declaration of Karen M. Firstenberg ("*Firstenberg Dec.*"), ¶ 4.

As evidenced by the FDA's final report consisting of 134 pages (*See* Exhibit 2 to *Firstenberg Dec.*), the FDA methodically documented its sampling and testing procedures. The test reports prepared by the FDA contain, *inter alia*, the following information: (a) the date of collection, (b) product code, (c) FIS sample number, (d) hours spent related to each sampling, (e) country of origin for each sample, (f) a product description, (g) batch identification, (h) reason

for each sampling, (i) lot size, (j) description of sample, (k) method of collection, (l) preparation procedures for each sampling, (m) remarks, and (n) lab conclusions. *See Firstenberg Dec*, ¶ 3; Exhibit B to *Firstenberg Dec.*

Pursuant to Fed. R. Evid. 201(b), Defendants request that this Court take judicial notice of the FDA's final report attached as Exhibit B to *Firstenberg Dec. See Noble Asset Management v. Allos Therapeutics, Inc.* 2005 WL 161977, *2 (D. Colo. 2005) (holding that a court may take judicial notice of FDA documents that are publicly available).

The FDA's testing and sampling results generated reliable, independent and valid results, all of which are publicly available and were obtained by request to the FDA by means of the Freedom of Information Act. *See Firstenberg Dec,* ¶ 2; *See also* Exhibit A to *Firstenberg Dec.*

Since the FDA conducted its sampling plan and tests as an independent, federal agency, these results are reliable and valid. *See Reference Manual on Scientific Evidence* 98 – 102 (2d ed. 2000)(expressly approving analytical testing on sample units to measure the larger population, as long as the sampling is not biased). Courts consistently use results from analytical testing of representative samples, even in criminal cases that "warrant[] special concern." *See* e.g., *United States v. Shonubi*, 895 F.Supp.460, 465, 518, 519-521, 524 (E.D.N.Y. 1995) (for sentencing purposes, relying on statistical data from representative samples, in part, in finding that Defendant "smuggled between 1,000 and 3,000 grams on his eight trips"). *See also NutraSweet Co. v. X-L Eng'g Co.,* 227 F.3d 776, 782, 787, 792 (7th Cir. 2000)(affirming the District Court's conclusion that defendant was liable to NutraSweet for polluting NutraSweet's property where NutraSweet's expert tested soil samples to measure the amount of contamination).

Accordingly, since the FDA has already conducted independent, reliable and valid sampling and testing, the results of which have been well documented, provided herein and are publicly available, it is respectfully submitted that good cause supports the destruction of the Wheat Gluten.

2. THE FDA HAS INDICATED THAT THE CONTINUED RETENTION OF RECALLED PRODUCTS AND INGREDIENTS CONSTITUTES A PUBLIC HEALTH HAZARD AND SHOULD BE DESTROYED

At various times throughout this litigation certain Defendants storing allegedly contaminated products received communications from the FDA requesting that they destroy such allegedly contaminated products due to, *inter alia*, the FDA's concerns about the potential public health risks associated with the retention of such products. *See Miller Dec.; see also* Declaration of Michael Hayes previously submitted in support of *Del Monte Food Company's Motion to Limit the Retention of Recalled Pet Treats and Food, Raw Wheat Gluten and Ingredients Including Recalled Wheat Gluten* (D.E. 88), annexed hereto as Exhibit "C". The FDA has also expressed concern that until the allegedly contaminated products are destroyed, there exists a risk of their reintroduction into interstate commerce. See Attachment 2 to Exhibit "C".

The FDA has the authority to issue such communications, as the Federal Food, Drug and Cosmetic Act requires the FDA to keep foods "for man or other animals...safe, wholesome, [and] sanitary." 21 U.S.C. §§ 321, 393. It is respectfully submitted that this Court should take judicial notice of the FDA's communications and defer to its conclusions that the current quantity of recalled product is creating health risks to the public and to its recommendations that Defendants destroy their inventory of same. *See In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp.2d 751, 755 n.2 (E.D. Pa. 2003) (taking judicial notice of an FDA report published on its website). *See also Sandoz Pharms, Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230-31 (3rd Cir. 1990)(holding that, because agency decisions are frequently of a discretionary nature or frequently require expertise, the agency should be given the first chance to exercise that discretion or to apply that expertise) (*quoting McKart v. United States*, 395 U.S. 185,

194(1996)). *See also Wells Fargo Bank of Tex. NA v. James*, 484 F.Supp.2d 289, 308-17 (E.D. Pa. 2006) (giving "significant deference" to the FDA).

3. THE FINANCIAL COSTS AND EXPENSE ASSOCIATED WITH THE STORAGE OF WHEAT GLUTEN, RPC AND WIP FAR EXCEED ANY POTENTIAL BENEFITS TO PLAINTIFFS

Defendants storing Wheat Gluten, RPC and WIP have incurred and, if the proposed Order to Show Cause and proposed Order are not granted, will continue to incur substantial expenses associated with the storage of those ingredients.

Thus, it is respectfully submitted that this Honorable Court should carefully consider the substantial economic expenses and public health risks associated with the continued storage of Wheat Gluten, RPC and WIP against the nominal benefits, if any, that the continued storage of such ingredients may bestow upon the Plaintiffs. *See McPeek v. Ashcroft*, 202 F.R.D. 31, 34 (D.D.C. 2001) (limiting additional discovery to a sampling or test run of data on backup tapes). *See also Powell v. S. Jersey Marina, Inc.,* No. 3:CV-04-2611, 2007 U.S. Dist. LEXIS 55849 at *18-20 (M.D. Pa. Aug. 1, 2007) (denying motion to compel deposition testimony of defendant's president because plaintiffs already had discovery on the issue, holding that the "benefit to [p]laintiffs' case appear[ed] non-existent.").

In light of the fact that significant quantities of finished products have been preserved by those Defendants that previously sought relief from this Court and that the FDA has already tested and prepared detailed analyses of statistically relevant samples of the ChemNutra Wheat Gluten at issue in this litigation, it is respectfully submitted that this Court can come to only one conclusion, *to wit*, that there exist no good reason for Defendants in the possession of Wheat Gluten, RPC and WIP to continue to store such ingredients.

4. ADEQUATE REPRESENTATIVE SAMPLES OF FINISHED RECALLED PRODUCT ARE ALREADY BEING STORED BY DEFENDANTS

As previously stated, on April 14, 2008 this Court issued an Order allowing certain Defendants to implement the sampling plans for finished pet food products as recommended by Dr. George P. McCabe. (D.E. 140). Thus, as a result of this Honorable Court's Order, statistically adequate samples of the products most relevant to this litigation, *to wit*, those pet food products containing Wheat Gluten that were recalled from store shelves, have been preserved. Courts have agreed to limit discovery to statistical samples where, like here, the burden of full production outweighs its potential benefits. *E.g. Benson v. St. Joseph Reg'l Health Ctr.*, No. H-04-04323, 2006 U.S. Dist. LEXIS 34815, at *4-7 (S.D. Tex. May 17, 2006). The preserved samples are a more than adequate substitute for the continued storage of one or more component ingredients that may be contained in such finished products, but were never available directly to consumers for consumption by their pets. *See Donohue*, 157 F.R.D. at 246.

B. CONCLUSION

As stated, when determining if the continued storage of Wheat Gluten, RPC and WIP is appropriate, this Court should weigh the burdens and expenses associated with the continued storage of such ingredients against the potential benefits derived by Plaintiffs, if any. *Maertin v. Armstrong Indus., Inc.* No. 01-5321, 2007 U.S. Dist. LEXIS 20561, at *4, 6 (D.N.J. Mar. 8, 2007). Here, the continued storage of these ingredients and related expenses imposes a significant financial burden upon a select number of Defendants. More importantly, as stated by the FDA in its communications to Del Monte, the continued storage of these ingredients pose a real risk to the public exists no matter how carefully the Defendants act in storing the ingredients. See Attachment 2 to Exhibit "C." Finally, because statistically relevant quantities

of finished product containing Wheat Gluten are being stored and because the FDA has conducted its own independent testing of the Wheat Gluten – the ingredient that is the focus of this litigation – the destruction of such ingredients will not prejudice plaintiffs in any way.

Dated: March 5, 2009

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