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 (NHL) Judge Noel L. Hillman

CHEMNUTRA, INC.'S REPLY IN SUPPORT OF ITS MOTION TO DESTROY RETAINED WHEAT GLUTEN

Defendant ChemNutra, Inc. ("ChemNutra") hereby serves its Reply in Support of its motion to destroy the recalled raw wheat gluten purchased from XuZhou Anything Biologic Technological Development Co. Ltd. ("XuZhou Anying") (collectively "Wheat Gluten") that ChemNutra is currently storing in compliance with preservation orders previously issued by this Court.

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF CHEMNUTRA, INC.'S REPLY MOTION TO DESTROY ITS INVENTORY OF WHEAT GLUTEN

I. <u>INTRODUCTION</u>

ChemNutra, Inc. ("ChemNutra") has incurred great cost and substantial burden as a result of having to store, since April 2007, over 430 metric tons of raw wheat gluten inventory in three warehouses located in Missouri, New Jersey and Pennsylvania. (See Declaration of Steven Miller, ¶ 2, 3, 10 and 11.) At no time since April, 2007 has any party made efforts to sample or test ChemNutra's Wheat Gluten, other than the FDA. The FDA's sampling and testing, the results of which are publically available and were attached to ChemNutra's moving papers, were the result of reliable, independent and valid sampling and testing. The FDA has requested that ChemNutra destroy its Wheat Gluten for public health and safety concerns and has agreed, upon entry of an order by this Court, to make FDA employees available to assist in the destruction of the Wheat Gluten. Plaintiffs fail to provide any good cause to justify the continued storage of ChemNutra's Wheat Gluten and this Court should order its immediate destruction.

In the alternative, if this Court does not authorize the full destruction of ChemNutra's Wheat Gluten, ChemNutra requests that this Court authorize the destruction of its Wheat Gluten *except* for those bags which have been opened, sampled and tested by the FDA.

Alternatively, if the opened bags sampled and tested by the FDA is found insufficient by this Court or plaintiffs, ChemNutra requests that plaintiffs take custody and control of any additional Wheat Gluten bags which they consider necessary for potential future sampling and testing and that this Court order plaintiffs to pay all costs associated with storage of these additional bags.

Good cause supports this cost shifting burden. First, the FDA has already obtained samples and tested ChemNutra's Wheat Gluten. The FDA's sampling and tests resulted in reliable, independent and valid results, all of which are publicly available from the FDA and were attached to ChemNutra's moving papers. ChemNutra has agreed to retain at its cost, if

necessary, these opened bags for any further testing by plaintiffs or any other party. Requiring ChemNutra to retain over 430 metric tons of Wheat Gluten is excessive "of that typically necessary for evidentiary purpose." (See Letter from Department of Health and Human Services regarding ChemNutra's currently stored Wheat Gluten, Exhibit C to Brazil Dec.)

Second, since the recall of ChemNutra's Wheat Gluten (over 1 ½ years) no effort or request by plaintiffs or any other party has been made to sample or test ChemNutra's Wheat Gluten. (See Declaration of Karen Firstenberg ("Firstenberg Dec."), ¶ 2) It is this continued delay in requesting testing of ChemNutra's Wheat Gluten that has caused ChemNutra's financial burden and hardship. Plaintiffs had ample opportunity to sample and test ChemNutra's Wheat Gluten, but have not done so. Requiring ChemNutra to continue, at its expense, to store the Wheat Gluten for an undetermined future amount of time, which plaintiffs equally could do, lacks justification.

Third, the Wheat Gluten stored by ChemNutra is *not* the food ingested by the pets and therefore is not the relevant Wheat Gluten which should be tested to establish causation, if any, to plaintiffs' pets. The key issue is whether the pet food ingested was contaminated since the Wheat Gluten was but one of many ingredients in the finished product. Thus it is the testing of the pet food, rather than one small ingredient (ie Wheat Gluten) that will determine liability.

Finally, the FDA <u>has</u> requested that ChemNutra destroy its Wheat Gluten and has affirmatively agreed to make itself available upon entry of an order by this Court for the destruction of ChemNutra's Wheat Gluten. (See Declaration of Anthony Brazil, ¶¶ 2 and 4; Firstenberg Dec., Exhibit A). The FDA's pubic safety concerns far outweigh any justifications plaintiffs have proferred to justify retention of the Wheat Gluten.

For these reasons, ChemNutra requests that this motion be granted. Alternatively, if this Court orders the continued retention of ChemNutra's Wheat Gluten, ChemNutra requests that this Court order the costs to be shifted to plaintiffs as the financial burden of continued retention by ChemNutra is enormous and ChemNutra has no desire or interest in retaining the material.

II. GOOD CAUSE SUPPORTS THE DESTRUCTION OF CHEMNUTRA'S WHEAT GLUTEN

Good cause supports the destruction of ChemNutra's Wheat Gluten and plaintiffs have failed to provide any justification to oppose this request, over 1 ½ years after this Court's initial preservation order.

The Manual for Complex Litigation is instructive, noting that a "blanket preservation order may be prohibitively expensive and unduly burdensome" and suggesting that after reasonable notice "[a]ny preservation order should ordinarily permit destruction. . ." Manual for Complex Litigation (4th) § 11.442 (Preservation).

Plaintiffs in their opposition argue that complete destruction would prevent "interested parties" (opposition p.3) from future testing and that the "urgency" of ChemNutra's request is not appropriate under the circumstances of anticipated settlement (opposition, pg. 6). Plaintiffs have had over 1½ years to test ChemNutra's Wheat Gluten and have never requested or even suggested a need for such testing. Plaintiffs, even in its opposition, do not even assert this need—plaintiffs state only that "if they so chose" plaintiffs should be able to test the Wheat Gluten (opposition, pg. 4). Yet, plaintiffs have had such a chose for over 1½ years and have never made any effort to sample or test the Wheat Gluten. The urgency, as clearly demonstrated in ChemNutra's moving papers is the great expense ChemNutra continues to incur as a result of storing its Wheat Gluten in three warehouses located in three states. (*Miller*, ¶¶ 2, 3, 10 and 11) This burden is unjustifiable in light of the FDA's testing, the results of which are publically available. This Court should grant ChemNutra's request in its entirety and order the full destruction of its Wheat Gluten.

III. CHEMNUTRA WILL RETAIN THE SAMPLE TESTING CONDUCTED BY THE FDA

If this Court is not inclined to order the full destruction of ChemNutra's Wheat Gluten, ChemNutra requests, in the alternative, that this Court allow ChemNutra to retain only the Wheat Gluten bags which have been opened, sampled and tested by the FDA. The *Manual for Complex*

Litigation, supra, detailing preservation provides guidance. The manual states that any "preservation order should ordinarily permit destruction after reasonable notice . . . The order may . . . exclude specified categories . . . whose cost of preservation outweighs substantially their relevance in this litigation. . . particularly . . . if there are alternative sources for the information. Manual for Complex Litigation (4th) § 11.442 (emphasis added).

Here, retaining only the Wheat Gluten which has already been opened, sampled and tested by the FDA provides sampling for future testing and access to data and information which has already been recorded and published by the FDA. This compromise allows ChemNutra to minimize its costs while preserving, at plaintiffs' request, Wheat Gluten for future sampling and testing, if necessary. ChemNutra agrees to incur these costs, if necessary.

IV. IN THE ALTERNATIVE, CHEMNUTRA REQUESTS THAT PLAINTIFFS TAKE CUSTODY AND CONTROL OF ITS WHEAT GLUTEN AND BE ORDERED TO PAY THE COSTS FOR CONTINUED STORAGE OF ITS WHEAT GLUTEN

ChemNutra, in the alternative, requests that if plaintiffs contend that the Wheat Gluten tested by the FDA is an insufficient sampling for future testing, that plaintiffs take custody and control of any Wheat Gluten plaintiffs deem necessary for future sampling and testing and that this Court order plaintiffs to incur the future storage expenses.

While the general presumption in discovery is that the responding party must bear the expenses of complying with discovery requests, if responding party asks the court for an order protecting it from "undue burden or expense" the court may shift the costs to the non—producing party. *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 358 (1978); Fed. R. Civ. P. 26(c); *see also Rowe Entm't v. The William Morris Agency, Inc.*, 205 F.R.D. 421 (S.D. N.Y. 2002)(finding that courts have ample power under Rule 26 to protect respondent against undue burden or expense either by restricting discovery or requiring that the discovery party pay costs).

In analyzing a request to shift – costs, courts have conducting balancing tests of various factors including: (1) the likelihood of discovering critical information; (2) availability of such

information from other sources; (3) the amount in controversy as compared to the total cost of production; (4) the parties' resources as compared to the total cost of production; (5) the relative ability of each party to control costs and its incentive to do so; (6) the importance of the issue at stake in the litigation; (7) the importance of the requested discovery in resolving the issues at stake in the litigation; and (8) the relative benefit to the parties of obtaining the information. Wiginton v. CB Richard Ellis, Inc., 229 F.R.D. 568 (N.D. Ill., 2004); see also Zubulake v. UBS Warburg LLC, 217 F.R.D. 309 (S.D.N.Y., 2003); Rowe Entertainment, Inc. v. William Morris Agency, Inc., 205 F.R.D. 421 (S.D. N.Y., 2002).

The Supreme Court was instructive in *Oppenheimer Fund v. Sanders*, 437 U.S. 340 (1978). In *Oppenheimer*, defendants sought to reverse a court order compelling defendants to incur the costs of producing evidence to plaintiffs, the costs and burden of which would have been equal for both parties and which benefited only plaintiffs. The Supreme Court held that where good cause supports the shifting of costs, such a shift should be ordered. The Supreme Court found that the costs would be equal to both parties and that the benefit flowed only to plaintiffs and that this justified the shifting of costs to the plaintiffs. *Id.* at 353, 357, 359. *see also Linder v. Calero Portocarrero*, 31 F. Supp.2d 134 (D.D.C., 1998)(ordered cost – shifting to plaintiff, despite minimal financial means, as a means of deterring the requesting party from engaging in fishing expeditions for marginally relevant material)

Here, like in *Oppenheimer* and in balancing factors to assess whether to shift costs, good cause supports ChemNutra's request to shift the burden of costs associated with continued storage of its Wheat Gluten.

First, the FDA has already obtained samples and tested ChemNutra's Wheat Gluten. ChemNutra is not aware of anyone who contests the FDA's findings. The FDA's sampling and tests resulted in reliable, independent and valid results, all of which are publicly available from the FDA and were attached to ChemNutra's moving papers. Thus, there exists the requested information from other sources, i.e. the FDA's final report. Plaintiffs have failed to provide any

justification why the extensive sampling, testing and final results of the FDA are not reliable and sufficient for any future need.

The only argument presented by plaintiffs to oppose this position is the assertion that the FDA's testing is inconsistent with previous sampling orders issued by this Court for defendants Menu and Del Monte. This Court's previous order to allow destruction of all but a limited sample of Menu and Del Monte's wheat gluten are distinguished because the sampling agreement that was the basis for that order were never implemented due to the enormous burden and expense associated with implementing that order. Even more important, testing was never conducted on any of Menu or Del Monte's wheat gluten. This is drastically different from ChemNutra's Wheat Gluten since sampling and testing has been conducted by the FDA, the results of which are publicly available and provide detailed results. Specifically, the FDA's final report consists of 134 pages (See Exhibit 2 to Firstenberg Dec.) the FDA was methodical in documenting its sampling and testing procedures. These test reports 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, ¶ 3; Exhibit 2 to Firstenberg Dec. Plaintiffs have presented no evidence to dispute the adequacy of this testing.

Second, since the recall of ChemNutra's Wheat Gluten in April, 2007, no party has made any effort to sample or test ChemNutra's Wheat Gluten. Significant time has passed. Plaintiffs' delay in conducting any sampling or testing has resulted in ChemNutra incurring great expense and hardship, including the on – going costs that ChemNutra has been compelled to undertake in paying to store its Wheat Gluten at three storage facilities located in New Jersey, Pennsylvania and Missouri. (Miller, ¶ 2, 3, 10 and 11) There is no explanation for this delay nor is their any justification why ChemNutra should continue to incur expenses as a result of plaintiffs' own delay. Significantly, plaintiffs' opposition fails to even confirm their request or need for such

testing – only that plaintiffs wish to preserve such right. Plaintiffs have had such right and their delay should not be justification for ChemNutra's continued burden and expense.

Third, plaintiffs have failed to justify the continued retention of ChemNutra's Wheat Gluten, particularly in light of the fact that the plaintiffs' pets were injured from ingesting the finished product (ie pet food) which may or may not have contained Wheat Gluten supplied by ChemNutra. More importantly, the key issue in the case is not whether ChemNutra's Wheat Gluten was contaminated but rather whether the per food ingested by plaintiffs pets was contaminated. To resolve that issue the plaintiffs need to test the finished product not the raw Wheat Gluten. In addition, no portion of the batch of the Wheat Gluten stored by ChemNutra at the Steven Shannon Warehouse in Bloomsburg, Pennsylvania was *ever* sold, distributed and supplied to any person or entity the estimated 72 metric tons of Wheat Gluten. *Miller*, ¶ 7. Therefore no pets would have been exposed to food containing wheat gluten from this warehouse and continued storage of this wheat gluten lacks any justification since it would not establish causation to plaintiffs' claims.

Fourth, as part of the FDA's active investigation related to ChemNutra's recall of its Wheat Gluten, the FDA specifically informed ChemNutra by letter that ChemNutra should not continue to store its Wheat Gluten for fear of public safety. Specifically, on or about June 29, 2007, the FDA sent to ChemNutra a letter expressing its concerns regarding the "public health risks" associated with ChemNutra's storing of their approximately 430 metric tons of wheat gluten. The FDA stated that "until the product is **destroyed**, there is a risk of reintroduction into interstate commerce, whether intentional or not, and/or risk of expert." The FDA then urged ChemNutra to "seek whatever relief is appropriate from the Court." *Miller*, ¶ 8; *see also* Exhibit A to Miller Dec. (emphasis added). After being informed of plaintiffs' opposition to this motion, the FDA has reiterated this request and has agreed to make its field agents available to oversee ChemNutra's destruction, upon entry of an order from this Court. *Exhibit "A" to Firstenberg Dec.*

ChemNutra seeks to follow the FDA's sound advice. Since ChemNutra's Wheat Gluten has been appropriately sampled, well tested and documented, good cause now supports the destruction of ChemNutra's Wheat Gluten and its Motion should be granted. Both the FDA and the US Attorneys office have approved of this request for destruction by ChemNutra. *Brazil*, ¶5, 6. Other than telling the Court that ChemNutra should wait the plaintiffs have offered no valid reason to force ChemNutra to incur the enormous costs associated with continuing to store the Wheat Gluten. Furthermore, the plaintiffs' justification for retention of the Wheat Gluten is far outweighed by the public safety concerns that the FDA has expressed by the continued storage of this Wheat Gluten.

V. <u>CONCLUSION</u>

ChemNutra respectfully requests that this Court issue an Order allowing ChemNutra to destroy its XuZhou Anying Wheat Gluten in accordance with and under the supervision of the FDA. In the alternative, ChemNutra requests that this Court order the destruction of its Wheat Gluten *except* for those bags which have been opened, sampled and tested by the FDA. In the alternative, ChemNutra requests that if the FDA's sampling and testing lots is insufficient for either this Court or plaintiffs, that plaintiffs take custody and control of its Wheat Gluten and that this Court shift the burden of costs to plaintiffs for continued storage.

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