

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

:
KRISTINA VERCELLONO and DANIEL:
VERCELLONO, individually and on
behalf of all others similarly situated,
:
:
Plaintiffs,
:
v.
:
:

Hon. Dennis M. Cavanaugh

OPINION

Civil Action No. 09-CV-2350 (DMC)

GERBER PRODUCTS COMPANY;:
HELENE CURTIS, INC.; JOHNSON &:
JOHNSON CONSUMER COMPANIES,:
INC.; MZB PERSONAL CARE; M.Z.
BERGER & COMPANY; NESTLE U.S.A.,
INC.; THE PROCTOR & GAMBLE
DISTRIBUTING LLC and WAL-MART
STORES, INC.,

Defendants.

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court upon motion by Johnson & Johnson Consumer Companies, Inc. (“J&J”) and Wal-Mart Stores, Inc. (“Wal-Mart”) (collectively “Defendants”) to reconsider this Court’s February 3, 2010 Opinion and Order in accordance with L. Civ. R. 7.1. Pursuant to Fed. R. Civ. 78, no oral argument was heard. Upon consideration of the parties’ submissions, for the reasons herein expressed, it is the decision of this Court that Defendants’ motion to reconsider is **granted** and Plaintiffs’ Amended Complaint is **dismissed**.

I. BACKGROUND

On July 31, 2009, Plaintiffs filed an Amended Class Action Complaint. On August 7, 2009,

Defendant J&J filed a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6). Subsequently, remaining Defendants filed motions to dismiss on similar and related grounds, in part incorporating by reference the moving papers submitted by J&J. Pursuant to this Court's February 3, 2010 Opinion and Court, Plaintiffs' Amended Class Action Complaint was dismissed in its entirety as it pertained to 1,4-dioxane and formaldehyde for lack of standing. At the same time, this Court concluded that "insofar as Plaintiffs claims pertain to methylene chloride, a chemical explicitly banned for use by the FDA in any cosmetic, this Court declines to dismiss Plaintiffs' claims pursuant to Fed. R. Civ. P. 12(b)(1) for lack of standing."¹ Defendants now move to reconsider that Opinion and Order on the grounds that the presence of methylene chloride in the products at issue does not constitute an ingredient in accordance with the Code of Federal Regulations and accordingly, is not subject to the ban imposed by the FDA.

II. STANDARD OF REVIEW

A motion for reconsideration is governed by Local Civil Rule 7.1(I). Reconsideration is an "extraordinary remedy" and is granted "very sparingly." N.L. Indus. Inc. v. Commercial Union Ins. Co., 935 F. Supp. 513, 516 (D.N.J. 1996). A motion for reconsideration will be granted only if: "(1) an intervening change in controlling law has occurred; (2) evidence not previously available has become available; or (3) it is necessary to correct a clear error of law or fact, or prevent manifest injustice." Database Am., Inc. v. Bellsouth Advert. & Publ'g Corp., 825 F. Supp. 1216, 1220 (D.N.J. 1993). If a party simply disagrees with a court's decision, the appropriate avenue to address that disagreement is "through the appellate process not a motion for reconsideration." Database Am.,

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Proceeding on the ground that Plaintiffs had standing with respect to methylene chloride, in accordance with Nevada State Law, this Court further concluded that Plaintiffs' Amended Class Action Complaint may proceed on Counts I-III.

Inc., 825 F. Supp. at 1220.

III. DISCUSSION

Defendants propose that in addressing the initial motion to dismiss in this matter, this Court overlooked the fact that the contaminant methylene chloride, as it exists in the products at issue, does not constitute an ingredient as defined by the Code of Federal Regulations. See 21 C.F.R. § 700.3(e) (emphasis added). Further, Defendants assert that to the extent methylene chloride is present in the disputed products, the amount of the contaminant is *de minimus*. Additionally, Defendants assert that Plaintiffs' Complaint does not allege that the contaminant in the products at issue was used as an ingredient.

In response, Plaintiffs contend that Defendants' motion for reconsideration fails to comport with the procedural dictates established by Local Civil Rule 7.1. Instead, Plaintiffs assert that Defendants' motion is merely an attempt to have a second bite of the apple, a measure explicitly precluded by Local Civil Rule 7.1. Further, Plaintiffs allege that Defendants' arguments derive from two fundamentally incorrect assumptions. "The first assumption is that the Court based its ruling on the fact that methylene chloride is an 'ingredient' . . . a novel issue that Defendants never raised, or even mentioned, in the 68 pages of briefing they submitted to the Court." Defendants' second assumption is that the Court's ruling pertained to "*personalized* injury-in-fact and ascertainable loss."

A. Relevant Material Before this Court

On August 7, 2009, Defendant J&J filed a motion to dismiss Plaintiffs' Amended Complaint, contending that "[i]n support of each of the causes of action, Plaintiffs allege that the substances purportedly contained in the Defendants' products, according to the testing commissioned and

conducted by their attorneys, are ‘contaminants’ not listed as ingredients on the product labels. . . *See Amended Complaint*, ¶¶ 2-3.” Defendant J&J Brief (“D. J&J Br.”) at 4. Despite Defendants’ present representations to the contrary, the reasonable inference drawn from Defendants’ assertion interpreting Plaintiffs’ allegations that the products contain “‘contaminants’ not listed as ingredients” would be that Defendants have interpreted Plaintiffs’ Complaint as requiring that the purported ‘contaminants’ be listed as ingredients.

Indeed, Defendants’ moving papers fail to address the applicable measure or definition for determining whether the presence of a particular substance rises to the level of an ingredient. Moreover, despite the fact that Defendants now point to the operative regulatory provision in this matter, Defendant J&J’s moving papers fail to reference to the Code of Federal Regulations whatsoever. The moving briefs of the other present and former co-Defendants, including Wal-Mart Stores, Inc., Gerber Proctor & Gamble Distributing, LLC, M.Z. Berger & Co., Inc. and MZB Personal Care., , are equally devoid of any reference to applicable provisions in the Code of Federal Regulations.

In the absence of any argument to the contrary, in reading the Amended Complaint in the light most favorable to Plaintiffs’ - for example, Despite the fact that Defendants knew or should have known that their Children’s Personal Care Products contained methylene chloride, a dangerous and toxic chemical banned by the FDA as an ingredient in any cosmetic, . . . Defendants made numerous representations to Plaintiffs about their products wherein they failed to disclose the presence of these chemicals in their products and/or represented that they were safe for use with children.- the Court proceeded to draw a reasonable inference that Plaintiffs’ Complaint alleged methylene chloride as an ingredient in the allegedly adulterated products. See Plaintiffs’ Complaint (“P. Compl.”), ¶ 16. In a

similar light, for example, Plaintiffs' opposition papers represent that "Johnson's Baby Shampoo and Wal-Mart's Equate Tearless Baby Wash are not merchantable because they are adulterated with methylene chloride, a substance banned as an ingredient by the FDA." Plaintiffs' Brief ("Pl. Br.") at 35-36. In accordance with 21 C.F.R. § 700.19(b), a cosmetic is "adulterated" when "methylene chloride" is an "ingredient" in that product. In the absence of any argument to the contrary, the reasonable interpretation of the foregoing representation, and similar representations, is that Plaintiffs contend that methylene chloride rises to the level of an ingredient.

B. Manifest Injustice

Defendants assert that the presence of methylene chloride in the contaminated products does not rise to the level of an ingredient and therefore, Plaintiffs' Amended Complaint must be dismissed. Plaintiffs, in turn, assert that the Court's conclusion turned on the use of methylene chloride in the contaminated products, rather than the ingredient status.

Pursuant to 21 C.F.R. § 700.19:

(a) Methylene chloride has been used as an ingredient of aerosol cosmetic products, principally hair sprays, at concentrations generally ranging from 10 to 25 percent. In a 2-year animal inhalation study sponsored by the National Toxicology Program, methylene chloride produced a significant increase in benign and malignant tumors of the lung and liver of male and female mice. Based on these findings and on estimates of human exposure from the customary use of hair sprays, the Food and Drug Administration concludes that the use of methylene chloride in cosmetic products poses a significant cancer risk to consumers, and that the use of this ingredient in cosmetic products may render these products injurious to health.

(b) Any cosmetic product that contains methylene chloride as an ingredient is deemed adulterated and is subject to regulatory action under sections 301 and 601(a) of the Federal Food, Drug, and Cosmetic Act.

"The term ingredient means any single chemical entity or mixture used as a component in the manufacture of a cosmetic product." 21 C.F.R. § 700.3. Pursuant to 21 C.F.R. § 701.3, Designation

of ingredients:

(1) The provisions of this section do not require the declaration of incidental ingredients that are present in a cosmetic at insignificant levels and that have no technical or functional effect in the cosmetic. For the purpose of this paragraph, incidental ingredients are:

(1) Substances that have no technical or functional effect in the cosmetic but are present by reason of having been incorporated into the cosmetic as an ingredient of another cosmetic ingredient.

(2) Processing aids, which are as follows:

(i) Substances that are added to a cosmetic during the processing of such cosmetic but are removed from the cosmetic in accordance with good manufacturing practices before it is packaged in its finished form.

(ii) Substances that are added to a cosmetic during processing for their technical or functional effect in the processing, are converted to substances the same as constituents of declared ingredients, and do not significantly increase the concentration of those constituents.

(iii) Substances that are added to a cosmetic during the processing of such cosmetic for their technical and functional effect in the processing but are present in the finished cosmetic at insignificant levels and do not have any technical or functional effect in that cosmetic

As recited above, in permitting Plaintiffs' claims to proceed, the Court concluded that "insofar as Plaintiffs claims pertain to methylene chloride, a chemical explicitly banned for use by the FDA in any cosmetic, this Court declines to dismiss Plaintiffs' claims pursuant to Fed. R. Civ. P. 12(b)(1) for lack of standing." Accordingly, this Court's conclusion turned on the FDA ban of methylene chloride as it pertains to cosmetics. The regulation bans the use of methylene chloride as an ingredient. The regulation does not ban the presence of methylene chloride to the extent that the presence of that chemical does not constitute an ingredient. Although Plaintiffs contend that there is an issue of fact concerning whether the presence of methylene chloride is dangerous in amount,

Plaintiffs do not dispute Defendants' new assertion that methylene chloride is not an ingredient. To the extent that Defendants' contend that the presence of methylene chloride in the products at issue does not constitute an ingredient, and in the absence of an argument to the contrary by Plaintiffs, a manifest injustice would arise in permitting these claims to proceed. In accordance with L. Civ. R. 7.1, in order to prevent manifest injustice, Plaintiffs' Amended Complaint is dismissed in its entirety for lack of standing pursuant to Fed. R. Civ. P. 12(b)(1).

IV. CONCLUSION

For the foregoing reasons, Defendants' motion to reconsider is **granted** and Plaintiffs' Amended Complaint is **dismissed** for lack of standing pursuant to Fed. R. Civ. P. 12(b)(1). An appropriate Order accompanies this Opinion.

S/ Dennis M. Cavanaugh
Dennis M. Cavanaugh, U.S.D.J.

Dated: August 2, 2010
cc: All Counsel of Record
Hon. Mark Falk, U.S.M.J.
File