

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

**In Re: Methyl Tertiary Butyl Ether ("MTBE")
Products Liability Litigation**

**Master File C.A. No.
1:00-1898 (SAS)
MDL 1358**

This document refers to:

City of New York v. Amerada Hess Corp., et al., 04 Civ. 3417

**MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANTS' MOTION IN LIMINE TO EXCLUDE
EVIDENCE AND ARGUMENT REGARDING ALLEGED
POTENTIAL HUMAN HEALTH EFFECTS ASSOCIATED WITH MTBE**

Introduction

There is no allegation or evidence in this case that anyone has been or fears being injured as a result of drinking water containing trace levels of MTBE. The Fourth Amended Complaint contains no prayer for damages relative to personal injury or feared illness. Nevertheless, in order to justify its purported intention to treat its water below the level required by state regulations, Plaintiff City of New York intends to tell the jury – in its case in chief – that there is no proven safe level of MTBE and that MTBE is a probable or at least a possible human carcinogen. Not only is the scientific evidence regarding MTBE's potential human health effects extremely weak and speculative, no such evidence has relevance to the claims at issue here, which are solely concerned with property damage. Rule 402 of the Federal Rules of Evidence permits only relevant evidence to be admitted. Moreover, even if the evidence were relevant, Rule 403 counsels that the tremendous danger of unfair prejudice to the Defendants, coupled with the risk of jury confusion, would require exclusion of all evidence or argument with respect to human health effects, given its minimal probative value.

The City apparently wants to tell the jury that it feels morally compelled to remove all traces of MTBE from the wells in Queens. But the City's true motivation undoubtedly relates to the fact that the potential capital costs and future maintenance expenses associated with removing every last part per billion of MTBE from the well water are as much as \$300 million higher than those associated with simple compliance with New York's Maximum Contaminant Limit ("MCL"). The City may also specifically intend to inflame the jury in order to assure a finding that MTBE-gasoline is a defective product. Despite the fact that New York law declares water to be potable containing as much as 10 parts per billion MTBE, which New York State's own public health experts have determined to be low enough to ensure a large margin of safety for the consuming public; and despite the fact that neither the U.S. E.P.A., the U.S. National Toxicology Program, the European Union, or the International Agency for Research on Cancer (IARC") of the World Health Organization believes MTBE to be a human carcinogen or a chronic human health risk; and despite the fact that there has never been a documented case of chronic disease attributable to MTBE exposure – at any dosage level – anywhere in the world; and despite the fact that the City has itself assured its consumers that water containing levels of MTBE at or below the state MCL is perfectly safe; and despite the fact that the City does not (and probably will never) expend funds to remove any other contaminants – including known human carcinogens such as TCE – to levels below their state or federal MCL's – the City intends to present evidence, including the opinion testimony of putative expert Kathleen M. Burns, Ph.D., to the effect that MTBE at any level "can" cause human health effects, including sub-cellular DNA adducts and cancer.

CANCER. Is there any more provocative word to use in front of a jury at a trial involving drinking water and chemicals? **CANCER.** Could any word be more alarming to

jurors who may themselves have been consumers, or are potential future consumers, of the drinking water at issue? As the Court has itself said, in discussing the potential presentation by Plaintiff of a putative expert toxicology researcher: “We don’t have a risk of cancer case here and we don’t want to have one. We’ve got a complicated enough property damage case. . . . That would be a real sideshow to start talking about risk of cancer, fear of cancer and all that.” *See* Transcript of Court Conference of October 31, 2007 (Exhibit A to Declaration of Inbal Paz in Support of Motion (“Declaration of I. Paz”)) at p. 76, lines 3-5, 19-21. “Is she (i.e., the researcher, Ms. Belpoggi) going to say in this trial, that MTBE can cause cancer in humans, based on her animal studies? Are you [i.e., the City] really offering that at this trial? Because I’m not going to allow that anyway.” *Id.* at p. 75, lines 4-7 (emphasis supplied).

With this motion, the Defendants merely ask the Court to apply the above-quoted reasoning, undoubtedly rooted in both Rule 402 and the Rule 403 balancing test, to formally exclude evidence and argument relative to MTBE’s alleged potential chronic human health effects. Such an Order will ensure that only probative evidence of relevant facts are submitted to the jury, and will avoid an extraordinary danger of unfair prejudice to the Defendants.

Facts/Procedural History

The sole Plaintiff in this case is the City of New York. It has not brought this action as a representative of a group of its citizens, but as a water utility operator. Its Fourth Amended Complaint does not request damages with respect to any existing or potential personal injuries or human illnesses. It seeks only damages (or equitable relief) pertaining to harm allegedly suffered (or to be suffered) to its usufructory property rights, i.e., an impingement upon its right to draw and distribute groundwater from certain existing wells. *See* Fourth Amended Complaint (Exhibit B to Declaration of I. Paz) at pp. 2-3, 37. There are no private citizens involved in this

litigation in any way. There have never been any illnesses or injuries, acute or chronic, ever described in the City's pleadings or responses to discovery. Indeed, the Plaintiffs cannot point to any evidence or allegations linking any chronic illnesses or injuries, either among citizens of the City or anywhere else, to the consumption of MTBE-tainted water.

The City has nevertheless listed as an expert witness, for presentation in its case-in- chief, one Kathleen M. Burns, Ph.D. And the City's Exhibit List contains a host of scientific documents and government papers which discuss various toxicological studies performed with respect to MTBE. Dr. Burns, relying in part upon the (highly controversial) research work performed and reported upon by an Italian research organization, intends to present the following opinions to the jury:

Based on substantial scientific evidence, MTBE in drinking water is likely to pose health hazards (defined as including birth defects, developmental abnormalities, cancer and damage to organ systems and basic physiological functions) to some members of the public. MTBE caused cancer in animal models that are relied upon by the U.S. Government to predict cancer in humans. MTBE damages genetic material and caused other serious health problems in multiple species that the U.S. Government relies upon to evaluate the potential for birth defects and other types of damage. There is no credible or proven "safe" level of MTBE exposure and there is substantial . . . evidence that no safe level exists.

Expert Report of Kathleen M. Burns, Ph.D., dated February 6, 2009 (excerpts attached as Exhibit C to Declaration of I. Paz) at p. 5.

Dr. Burns is neither a board certified toxicologist nor a medical doctor. She relies heavily upon a few animal studies in which extremely high levels of administered MTBE (thousands of times greater than the highest reported levels in any of Plaintiff's wells) have been shown to induce specific tumors in rodents. This simplistic and outdated approach, that animal

studies are presumptively relevant to humans, is directly contrary to the U.S. Environmental Protection Agency's recently issued, revised guidelines for carcinogen risk assessment. Those guidelines require more thoughtful analyses from a toxicologist when attempting to draw conclusions from animal studies. *See* EPA Guidelines for Carcinogen Risk Assessment, March 2005, EPA/630/P-03/001F ("EPA Guidelines") (Exhibit D to Declaration of I. Paz) at §2.4. When attempting to extrapolate the human relevance of animal studies, the EPA Guidelines instruct that the essential questions are whether (1) the weight of evidence is sufficient to establish the physiological and biological mechanism for the tumor(s) to form; (2) the key events in how the animal's body created the tumor(s) are relevant to humans; and (3) these key events are plausible in humans. *Id.* at 2-47-49. Contrary to contemporary toxicology and risk assessment procedures, Dr. Burns does not answer or address these questions but blindly accepts the mistaken premise that rodent tumors necessarily predict cancer in humans.

The inherent problems with Dr. Burns' presumption, and the reason in which the EPA Guidelines dictate otherwise, can be distilled to a few key points. First, the amount of MTBE required to generate a response in rodents is extreme, as is the method and duration of exposure. Second, certain tumor types are physiologically and biologically unique to rodents and, in some instances, to rodents of one gender. Dr. Burns does not explain how she has accounted for these factors in order to make a reasonable connection between animal studies and human exposure. Indeed, she does not even acknowledge that these factors exist. Her failure to substantiate the relevance of MTBE animal studies to human exposure is contrary to generally accepted principles and scientific methods used in analysis of carcinogenicity.

Dr. Burns' testimony is based in large measure upon the long-term carcinogenicity study performed by the Ramazzini Foundation, as reported by Fiorella Belpoggi, et al. There have

been numerous problems identified with respect to the reliability of the Ramazzini/Belpoggi work, however. Such problems have led IARC and NTP to refrain from reliance upon it. *See* Expert Report of Douglas McGregor, Ph.D. (Exhibit E to Declaration of I. Paz) at pp. 21-22.

Under the federal Safe Drinking Water Act, 42 U.S.C. § 300g-1 et. seq. (2006), the EPA has full authority to impose a federal Maximum Contaminant Limit (“MCL”) for any chemical compound which it believes to present substantial toxicological risk. In 1987, the EPA agreed with representatives of the refining and petrochemical industry upon a Consent Order which laid out a full battery of health effects testing for MTBE. EPA certainly knew that MTBE’s primary use was as an additive to gasoline. It is likewise undeniable that EPA believed, being in the throes of issuing relevant regulations at the time, that a significant number of underground gasoline storage tanks (“USTs”) around the country were corroded and leaking. EPA therefore fully understood that the American public would be exposed to MTBE both by inhalation (while pumping their own gasoline) and via ingestion in drinking water (should their water supply be affected by UST leaks). *See* Federal Register Notice of Testing Consent Order regarding MTBE (Exhibit F to Declaration of I. Paz) at p. 10392, column 3. Tests conducted by industry pursuant to the Consent Order have long been completed. With those test results in hand, the EPA has never found it necessary to impose a MCL with respect to MTBE in water. *See* generally U.S. EPA Drinking Water Advisory: Consumer Acceptability Advice and Health Effects Analysis on MTBE (Exhibit G to Declaration of I. Paz) (suggesting only an optional level of 20-40 ppb to avoid taste and odor acceptability problems).

Analyses done by numerous other national and international health agencies are in agreement with the EPA’s judgment. The U.S. National Toxicology Program, the World Health Organization’s International Agency for Research on Cancer, the European Union and

California's Proposition 65 Commission have all decided that the robust existing science cannot support a conclusion that MTBE poses a risk of cancer or other chronic health effects to humans. *See* Expert Report of Douglas B. McGregor, Ph.D. (Exhibit E to Declaration of Inbal Paz) at pp. 6-7.

It cannot be denied New York State's MCL for MTBE is health-based. *See* New York State Register Notice of Proposed Rulemaking, dated Sept. 10, 2003 (Exhibit H to Declaration of I. Paz) at p. 12. Indeed, the New York Department of Health specifically considered numerous health studies and effects on sensitive sub-groups when determining the current MCL. *See Toxicological Review and Criteria for Evaluation of Exposure to Methyl Tert-Butyl Ether in Drinking Water*, New York State Department of Health, dated Aug. 2000 (Exhibit I to Declaration of I. Paz) at ii.

Plaintiff's water treatment experts, David K. Cohen and Marnie A. Bell of Malcolm Pirnie, Inc., indulge the assumption that for some reason New York City must/should treat its water such that MTBE cannot be detected, i.e., to a level below 1 ppb. On that basis they intend to opine that New York City's total capital and maintenance treatment costs pertaining to so-called Station 6 wells alone would be \$238.5 million. Those experts also opine that capital costs for the remaining focus wells would be no less than \$12 million per well, with annual O&M costs of as much as \$1.6 million per well per year. *See* excerpts of Cohen and Bell Expert Report (Exhibit J to the Declaration of I. Paz) at pp. 10-3 thru 10-5, 10-7 thru 10-15. By contrast, Defendants' water treatment expert, David Hand, who assumed that the City of New York would not suffer treatment costs associated with MTBE levels below 10 ppb, the New York State MCL, will opine that none of the focus wells other than Well 6D will require the City to expend any monies for treatment. His calculation is that the maximum capital costs for

installation of treatment on Well 6D would be \$6.8 million dollars and the total O&M costs would not exceed \$1.9 million, for a total of \$8.7 million. *See* excerpt of Expert Report of David Hand, Ph.D. (Exhibit K to Declaration of I. Paz) at pp. 16, 18. As can be seen by this comparison, the difference (for the focus wells alone) between simple adherence to the New York State MCL and unnecessary treatment to non-detect could exceed \$300 million dollars.

Applicable Law

Under Rule 402 of the Federal Rules of Evidence, a Court should only admit evidence that is relevant. FED. R. EVID. 402. Rule 401 assists in interpreting Rule 402 by defining relevant evidence as evidence “having the tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.” FED. R. EVID. 401; *In Re: MTBE Products Liability Litigation*, 2009 U.S. Dist. Lexis 37331 (S.D. N.Y. May 7, 2008).

But the admission of relevant evidence is limited by the gatekeeper function of Rule 403. Rule 403 states that even relevant evidence “may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.” FED. R. EVID. 403. Trial courts are given wide latitude to exclude evidence under the balancing test of Rule 403. *Triola v. Snow*, 289 Fed. Appx. 414, *10-11 (2d Cir. 2008) (citing *PRL USA Holdings, Inc. v. United States Polo Ass’n*, 520 F.3d 109, 119 (2d Cir. 2008) and *Madeira v. Affordable Housing Found., Inc.*, 469 F.3d 219, 250 (2d Cir. 2006)).

The balancing test of 403 allows the Court to exclude evidence based on concerns of “prejudice, confusion of the issues, the witness’ safety, or interrogation that is repetitive or only

marginally relevant” to name only a few. *United States v. Holmes*, 44 F.3d 1150, 1157 (2nd Cir. 1995) Courts have recognized that the “unfair prejudice” contemplated by FED. R. EVID. 403 is that a jury may “base its decision on an improper basis.” *United States v. Siegel*, 717 F.2d 9, 17 (2nd Cir. 1983). Further, the discretionary function of 403 allows Courts to exclude evidence that is highly prejudicial and would cause a jury to consider entirely collateral issues. *ESPN, Inc. v. Office of the Commissioner of Baseball*, 76 F. Supp. 2d 383, 408 (S.D. N.Y. 1999).

In evaluating expert evidence, the Court must not only determine that the evidence is relevant and that the witness is qualified “by knowledge, skill, experience, training, or education,” but it must also find that the probative value added by the expert’s testimony is not outweighed by the numerous, and justified, concerns of Rule 403. *In re MTBE Products Liability Litigation*, 2008 U.S. Dist. Lexis 37331, at *11 (S.D.N.Y. May 7, 2008). As this Court has itself noted, an increased level of control must be exercised as to the admission of expert evidence after weighing the possible prejudice against probative force because expert evidence “can be both powerful and misleading because of the difficulty in evaluating it.” *Bonton v. City of New York et al.*, 2004 U.S. Dist. Lexis 22105, at *9 (S.D. N.Y. Nov. 3 2005).

Application of Law to the Facts at Bar

The introduction of evidence as to MTBE health effects in this case would open an irrelevant Pandora’s Box. First, Dr. Burns would testify for the Plaintiff, discussing at length the minute details of genotoxicity, carcinogenicity and mutagenicity testing, the details and the rationale behind animal testing, the supposed applicability of animal testing for human health risk assessment, the comparative details the Belpoggi/Ramazzini work in contrast to alternative study protocols, and the conclusions/discussions of the various state, national, and international health organizations who have considered these questions. Then in Defendants’ case, the jury

will be obliged to hear counter-testimony from three designated experts – Drs. Elizabeth Anderson, Joseph Rodricks and Douglas McGregor, each with slightly different pedigrees and perspectives, and each discussing the inherent mistakes being made by Dr. Burns. Documentary evidence such as EPA decision papers, IARC Monographs, the Belpoggi reports, EPA Risk Assessment Guidelines, and the like will need to be given to the jury for consideration.

One is forced to ask whether or not any of this evidence is at all relevant to the elements of Plaintiff's case. There have been no reported illnesses or injuries in New York or elsewhere associated with MTBE exposure. The citizenry of New York has not been clamoring for protection from any contaminant compounds beyond that already provided by the State of New York's public health regulations. The City has on numerous occasions itself proclaimed that its duty is to comply with state MCLs, and to do so means that water delivered to its consumers is completely healthful. The City probably had no intention of consulting independent health experts upon which to make its treatment decisions until it hired lawyers and engaged in this MTBE litigation, which lawyers no doubt introduced them for the first time to witnesses Dr. Burns and the Belpoggi work. Defendants submit that there is no legitimate or genuine issue of fact to which the proffered health effects evidence could be relevant. Rule 402 allows the admission of only relevant evidence.

Plaintiffs will no doubt claim that Dr. Burn's opinion gives them justification for going "above and beyond" the MCL regulatory requirements, even if they have never done so with respect to any other chemical and even if doing so would cost them \$300 million more than compliance with the state MCL. Presuming that such a claim passes the commonly applied "red face" test, the evidence ought nevertheless be excluded because of the grave danger of unfair prejudice and jury confusion which it will present. This is especially so because the opinions of

Dr. Burns are so speculative and so completely contradicted by the pronouncements and conclusions of every independent health organization that has ever considered MTBE's effects as to have little if any probative value. Not only are the words "cancer," "birth defects," and the like certain to alarm and inflame the jury, the testimony of Dr. Burns has been so carefully crafted as to subtly swap the burden of proof on the issue of health to the Defendants. Dr. Burns avoids the word "risk" in stating her opinions, but instead states that MTBE "can" cause human effects. She states that there is "no proven safe level" of MTBE, a phrase which specifically invites the jury to assume that health effects will result unless the Defendants can present testimony which convinces them that such effects will never occur. Stating opinions in this way fairly invites the jury to disregard the assigned burdens of proof under the law and impose upon the Defendants a burden of insuring that minimal levels of MTBE will portend no harm. This is completely unfair and prejudicial.

The Court may recall the long dispute which occurred in focus cases in 2007 pertaining to the need to visit the Ramazzini laboratory in Italy and/or depose the principal researcher Fiorella Belpoggi. During the course of that discussion, the Court expressed its gut (judicial) instinct by saying that in a property damage case such as this, the jury should not be asked to consider the possibility that MTBE is a human carcinogen. Moreover, the Court properly focused on the highly controversial question of the linkage of animal studies to human health risks. Indeed, during the course of discussion on the Belpoggi issue, the Court indicated that *Daubert* questions were raised by any expert who would suggest that animal studies were indicative of human health risk. See Transcript attached as Exhibit A to I. Paz Declaration at p. 76.

The Court may also recall the motion filed by Defendants in 2006 seeking to limit Plaintiff's damages to those associated with compliance with the state-imposed MCL. At that time, the allegation was that certain taste or odor complaints associated with water served containing MTBE could justify the Plaintiff's decision to remove MTBE to levels below the MCL. But the Court was careful to require direct evidence that consumer complaints were actually caused by the presence of MTBE. Unless such direct causal connection was established, the Court indicated that summary judgment would be appropriate. *In re MTBE Products Liability Litigation*, 458 F.Supp. 2d 149, 159 (S.D.N.Y. 2006).

That same level of and nature of evidence as to consumer health problems ought to be required for health effects evidence to be admitted.

The fact that evidence is going to be presented through expert testimony heightens the potential for unfair prejudice. A pedigreed expert's opinion that there is no safe level of MTBE will be hard for any juror to ignore. If an expert says that some humans can get cancer from ingestion of even trace amounts of MTBE, even if that expert's testimony was appropriately couched in terms of risk evaluation and is contrary to conclusion of every world expert body, the jury will undoubtedly attach great significance to it. In a case involving drinking water and chemicals, in which jury panel members may themselves be potential consumers of that water, any juror will be exceedingly alarmed, inflamed and frightened by such testimony and will attach extraordinary significance to it.

These facts require the Court's careful exercise of its gatekeeper function to assure fairness. When the Plaintiff's evidence is barely relevant, is incredibly weak, is dealing with frightening subject matter, and is being presented by a seemingly-respectable expert, it will be

impossible for the Defendants to obtain fair and unbiased treatment. Rule 403 simply and absolutely requires that any and all evidence pertaining to MTBE's potential chronic human health effects be excluded from the record.

CONCLUSION

For the reasons set forth above, the Defendants request entry of an Order precluding the presentation of evidence or argument pertaining in any way to the alleged chronic human health effects of MTBE.

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