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TRENDS IN NEW JERSEY ENVIRONMENTAL AND TOXIC TORT LITIGATION

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This issue:

Class Action, Mass Tort and Consolidated Tort Distinguished in New Jersey Litigation

New Jersey has become something of a favorite venue for plaintiffs seeking to bring multiple actions involving the same issue or product particularly in the pharmaceutical area. There is a distinction, however, between class action lawsuits, mass tort designation and consolidated tort designation. New Jersey Court Rule 4:32 sets forth requirements for certification of a class action. Typically a matter is filed as a potential class action and thereafter, formal certification as a class action must be sought by the party who seeks such a certification. On occasion, an order denying class certification is sought by the defendants in the proposed class action if plaintiffs do not timely move for a resolution of the issue. Class certification is generally appropriate where the number of potential plaintiff is so numerous that joinder is not practical and further, the value of the individual claims makes the litigation of individual claims less than cost effective. Rule 4:32-1 sets forth the requirement for maintaining a class action. The rule provides that certification is appropriate where:

> One or more members of a class may sue or be sued as representative parties on behalf of all only if (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class. Rule 4:32-1.

Only where the requirements of subpart (a) of the rule are met, will the court engage in the second prong of the analysis. Specifically, a class action may only be maintained where the foregoing prerequisites are satisfied in addition to the following:

> (1) The prosecution of separate actions by or against individual members of the class would create a risk of either of:
>
> (a) Inconsistent or varying adjudications with respect to

individual members of the class that would establish incompatible standards of conduct for the party opposing the class, or

(b) Adjudications with respect to individual members of the class that would as a practical matter be dispositive of the interests of the other members not parties to the adjudications or substantially impair or impede their ability to protect their interests; or

(2) The party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole; or

(3) The court finds that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that the class action is superior to other available methods for the fair and effective adjudication of the controversy. Rule 4:32-1(b).

In essence, in addition to the four prerequisites, there are three avenues under which a potential class may seek certification. Subsection (2) pertains typically to those circumstances where the remedy sought is injunctive in nature. The most commonly utilized basis is subsection 3 pertaining to common questions of law or fact. The rule further provides criteria for the court to consider in determining whether a class action may be maintained under subpart (b)(3). Specifically, the court must consider:

a. The interests of members of the class in individually controlling the prosecution or defense of separate actions;

b. The extent and nature of any litigation concerning the controversy already commenced by or against members of the class;

c. The desirability or undesirability in concentrating the litigation of the claims in the particular forum; and

d. The difficulties likely to be encountered in the management of a class action. Rule 4:32-1(3).

Moreover, the rule provides that the court shall make a determination as to whether the class will be certified "at an early practicable time." Rule 4:32-2. This rule further provides that the order may be modified or adjusted at any time prior to entry of final judgment. Accordingly, certification may be subsequently revoked or denial of certification may be reconsidered depending upon changes in circumstances as the litigation progresses.

The first prong or requirement in the four prerequisites is sometimes referred to as numerosity. This relates whether the prospective class is so numerous that joinder is impracticable. The leading case on this issue is In re Cadillac V8-6-4 Class Action, 93 N.J. 412 (1983). While subclasses may be utilized, each subclass must independently meet all of the requirements for the maintenance of a class action under the rule. Right to Choose v. Brandon P. Byrne, 165 N.J. Super. 443 (Ch. Div. 1978). It is not necessary for all class members to share identical claims but a "single common question is sufficient." Delgozzo v. Kenny, 266 N.J. Super. 169, 185 (App. Div. 1993). Where there are unique issues of liability, causation and damages, commonality becomes problematic and certification may not be appropriate. See, Saldana v. City of Camden, 252 N.J. Super. 188, 197 (App. Div. 1991). Typicality pertains to the same type of claim damage or causation and has been referred as requiring an "common nucleus of operative facts." Strawn v. Canuso, 140 N.J. 43 (1995).

Mass tort and consolidated tort designations differ substantially from a class action. In a class action, all of the plaintiff's claims are litigated simultaneously and will result typically in a single determination as to liability, and perhaps even damages. Matters designated as mass torts typically proceed either singularly, or in much smaller groups of cases allowing for individual litigation of claims, defenses and unique damages issues.

Rule 4:38A sets forth the guidelines for mass tort litigation. The rule provides:

> The Supreme Court may designate a case or category of cases as a mass tort to receive centralized management in accordance with criteria and procedures promulgated by the Administrative Director of the Courts upon approval by the Court. Promulgation of the criteria and procedures will include posting in the Mass Tort Information Center on the Judiciary's Internet website. Rule 4:38A.

In fact the New Jersey Judiciary homepage, www.judiciary.state.nj.us. is not only cited in the rule but provides a comprehensive overview to potential litigants and counsel in the form of the "New Jersey Mass Tort (Non-Asbestos) Resource Book." The website likewise provides an asbestos handbook as well as reference to general orders pertaining to asbestos litigation. Parties may seek designation as a mass tort for "centralized management". Matters not designated as mass torts may nevertheless be designated as consolidated tort matters.

Both the non-asbestos and asbestos publications set forth detailed procedures for matters such as case management orders, pro hac vice motions, appointment of special masters and judges will often implement their own unique procedures in order to facilitate efficient handling of voluminous litigation such as abbreviated procedures for addressing discovery disputes, amending complaints, and the filing of either notices of appearances or short form answer.

The Honorable Carol E. Higbee, P.J.Cv. is assigned to preside over a number of pharmaceutical mass torts and consolidated matters venued in Atlantic County, New Jersey. The mass torts include Accutane, Fosamax, Levaquin as well as an environmental action. Additionally,

Judge Higbee presides over centralized management of a number of pharmaceuticals and medical products. Judge Higbee is assisted by a number of designated court staff members in Atlantic County. She utilizes a fairly organized system of case management conferences, case management orders and procedures along with the requirement of electronic service of pleadings to facilitate the management of large volumes of cases.

Judge Martinotti of Bergen County presides over a number of mass torts including pharmaceutical and environmental. The Honorable Ann G. McCormick, J.S.C. has long presided over the asbestos litigation. She also presides over the Ciba-Geigy litigation, the Honorable Jessica R. Mayer, J.S.C. presides over a number of medical and pharmaceutical mass torts also venued in Middlesex County.

The mass torts and consolidated torts often have similar actions filed in other states or in the federal system. New Jersey Superior Court judges are often called upon to coordinate with or at least be cognizant of federal multi-district litigation involving the same products.

As new and emerging environmental and products liability actions continue to be filed in New Jersey, we are likely to see increased applications for mass tort or consolidated tort designation. Additionally, it is likely that we will continue to see ordinary actions involving a handful of plaintiffs filed as prospective class actions.

United States Supreme Court Is Set to Review Federal Preemption in the Context of Generic Drug Warnings

The United States Supreme Court is expected to hear oral argument in PLIVA, Inc. v. Mensing, Nos. 09-993 and 09-1039. Generic manufacturers sought review of the United States Court of Appeals for the Eighth Circuit's decision and the United States Supreme Court has granted certiorari. At the heart of the dispute is whether the Hatch-Waxman Amendments, 21 U.S.C. § 355(j)(2)(A)(ii) by requiring that generic drugs in all essential respects be the "same as" those of their respective brand-name equivalents, has the effect of preempting a claim against the generic manufacturer for failure to warn. Specifically, the Hatch-Waxman Amendments at § 355(j)(2)(A)(iv) essentially requires the generic manufacturer to demonstrate that it has the same labeling as has been approved for the brand name version of the drug. The Eighth Circuit in allowing the plaintiffs to bring a state law cause of action against the generic drug manufacturers held:

> The generic defendants were not compelled to market [the generic drug]. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product. Instead, they are alleged to have placed a drug with inadequate labeling on the market and profited from its sales.

The Eighth Circuit went on to hold that as a result of that conduct, the generic manufacturers could be held liable.

As a result of the Hatch-Waxman Amendments, the FDA can approve a generic drug product without requiring the manufacturer to conduct the same investigational studies and clinical trials as are required before approval of the brand name drug. Such approval requires the generic manufacturer to prove that the product is both pharmaceutically equivalent and a bioequivalent of the brand name FDA approved drug. See 21 U.S.C. § 355(j)(2)(A). The approval process for the generic drug essentially requires the generic manufacturer to replicate the label utilized by the approved brand name manufacturer. 21 U.S.C. § 355(j)(4)(G).

The generic drug manufacturers argue that as a result of the Hatch-Waxman Amendments, any state law claim relating to the labeling or warnings is preempted. The Eighth Circuit based its reasoning on the absence of an expressed provision in the Hatch-Waxman Amendments forbidding generic manufacturers from proposing a label change.

In recent years the United States Supreme Court has issued several decisions including Wyeth v. Levine, 129 S. Ct. 1187 (2009) which have sharply curtailed the federal preemption doctrine. The Court's decision in Mensing will no doubt have far-reaching implications.

EPA Pursues Efforts to Eliminate Lead from Aviation Gasoline

In April, 2010 the United Environmental Protection Agency issued an Advance Notice of Proposed Rulemaking on Lead Emissions from Piston-engine Aircraft Using Leaded Aviation Gasoline. General aviation gasoline is one of the few areas where leaded gasoline continues to be used. It is aviation gasoline or Avgas used in piston-engine aircraft contains tetraethyl lead (TEL) which is used to boost octane. Popular types of Avgas include 100% octane and 100% octane low lead. The primary Avgas used in general aviation presently is 100 LL. See http://www.aopa.org/whatsnew/regulatory/reglead.html.

The EPA's increased efforts to eliminate lead from Avgas stem from concerns over that lead emissions from general aviation aircraft endanger public health and welfare and that a proposed standard should be issued under the Clean Air Act. See Federal Register, Volume 75, No. 81, April 28, 2010, proposed rule. In 1990 Congress added Section 211(n) of the Clean Air Act which made it unlawful after December 31, 1995 to sell any gasoline for use in motor vehicles which contains lead or lead additives. In 1996 the EPA incorporated the Clean Air Act statutory ban on gasoline containing lead and lead additives for highway use into the Agency's existing regulations on lead content. In so doing, an exemption was created which permitted the market gasoline produce with lead additives for all remaining uses which included fuel for use in aircrafts, racing cars and non-road engines such as farm equipment and marine engines. See 61 FR 3832 and 61 FR 3834. In the Advance Notice of Proposed Rulemaking, the EPA notes:

This occurs due to the environmental cycling of this persistent metal

> which, once emitted into the ambient air is distributed to other environmental media and can contribute to human exposures via indoor and outdoor dusts, outdoor soil, food and drinking water, as well as inhalation air. Atmospheric deposition is estimated to comprise a significant proportion of lead in food. See Federal Register, Volume 75, No. 81, April 28, 2010 at 22440.

Citing concerns over the environment, health effects and welfare effects, the EPA notes that lead emissions from piston-engine aircraft contributed a significant portion of the lead emissions. The EPA also raises concerns over lead concentrations in the vicinity of airports.

Aircraft manufacturers have been researching and attempting to develop piston engines which can operate efficiently and safely on unleaded gasoline for a number of years. However, according to Airline Owners & Pilots Association (AOPA), three fourths of U.S. fleet of aircraft "are piston-powered aircraft certified to fly on leaded fuel only". Lead boosts the octane of the fuel used in piston-powered aircraft, thus protecting aircraft engines against early detonation, which can cause an engine to literally tear itself apart during operation. High performance engines are especially susceptible to early detonation/knock.

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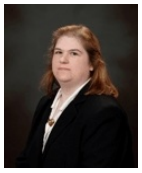

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Copies of any of the cases, statutes or regulations cited above are available by contacting the authors.