FOLEY HOAG LLP

Product Liability **Update**

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Foley Hoag LLP publishes this quarterly Update concerning developments in Product Liability and related law of interest to product manufacturers and sellers.

United States Supreme Court Holds State Law Rule Mandating Classwide Arbitration of Consumer Claims Stands as Obstacle to Purposes of Federal Arbitration Act and Is Therefore Preempted

In *AT&T Mobility LLC v. Concepcion*, --- U.S. ---, 131 S. Ct. 1740 (2011), consumers purchased mobile phone services advertised as including "free" phones. The seller did not charge for the phones, but did collect sales tax on their retail value. The consumers sued in the United States District Court for the Southern District of California, alleging false advertising and fraud, among other claims. The consumers' complaint later was consolidated with a putative consumer class action asserting similar claims.

Defendant moved to compel individual arbitration of each of the plaintiffs' claims pursuant to its sales and service agreements. Plaintiffs opposed the motion on the ground that the agreements prohibited classwide arbitration, and the California Supreme Court in *Discover Bank v. Superior Court*, 36 Cal. 4th 148 (2005), had held that class arbitration waivers in consumer contracts of adhesion are unconscionable and unenforceable. The trial court denied the motion to compel individual arbitration, the United States Court of Appeals for the Ninth Circuit affirmed and the United States Supreme Court granted certiorari to address whether the *Discover Bank* rule was preempted by the Federal Arbitration Act ("FAA").

Under section 2 of the FAA, agreements to arbitrate are valid and enforceable "save upon such grounds as exist at law or in equity for the revocation of any contract," thus preserving all generally applicable contract defenses. Plaintiffs argued the *Discover Bank* rule was saved by section 2 because the case was simply an application of a generally applicable rule invalidating unconscionable contract provisions. The Court, however, held that section 2's savings clause would not avoid preemption of a state law rule of general applicability where it was applied in a fashion that would stand as an obstacle to accomplishment of the FAA's objectives.

The Court then observed that, although the *Discover Bank* rule does not by itself require classwide arbitration, it allows any party to a consumer contract to demand it pursuant to the contract and the demand is thereby enforceable. The Court concluded that such mandatory classwide arbitration interfered with several fundamental attributes of arbitration and thus conflicted with the FAA's objectives. Specifically, mandatory classwide arbitration would: (1) sacrifice the informality inherent in arbitration, making it slower and more costly; (2) require a high level of procedural formality, essentially equivalent to that of class action litigation, to adequately bind absent class members;

and (3) increase the risk of arbitration to defendants because of the lack of appellate review for legal error, thereby pressuring defendants to settle questionable claims and ultimately discouraging arbitration. The Court specifically rejected the argument that classwide arbitration was necessary to ensure that small-value consumer claims are prosecuted, reasoning that the mere desirability of a procedure does not authorize a state to require it when it is inconsistent with the FAA.

The *Concepcion* decision calls into question the holding of the Massachusetts Supreme Judicial Court in *Feeney v. Dell Inc.*, 454 Mass. 192 (2009) (*see* ***August 2009 Foley Hoag Product Liability Update***), that a sales agreement mandating individual arbitration of claims violates Massachusetts public policy favoring classwide resolution of small-value consumer claims and is unenforceable. Attorneys at Foley Hoag LLP are currently litigating this question on remand in the Massachusetts Superior Court.

United States Supreme Court Holds State Court General Jurisdiction Over Claims Against Corporation Unrelated to Its Contacts with State Proper Only Where Corporation Has "Continuous and Systematic" Contacts with State; Specific Jurisdiction Over Claims Arising from State Contacts Proper Only Where Corporation Deliberately Directed Activity Toward State

In *Goodyear Dunlop Tires Operations, S.A. v. Brown*, No. 10-76, --- U.S. --- (June 27, 2011), and *J. McIntyre Machinery Ltd. v. Nicastro*, No. 09-1343, --- U.S. --- (June 27, 2011), decided the same day, the United States Supreme Court clarified and reinforced the limits imposed by due process on state courts' exercise of personal jurisdiction over a foreign corporation.

In *Goodyear*, two thirteen-year-old boys died in a bus accident outside Paris, France after one of the bus' tires failed. The boys' parents sued three foreign tire manufacturers, and the American tire company of which they were indirect subsidiaries, in the family's home state of North Carolina, alleging negligent design and manufacture of the tire. The three foreign companies moved to dismiss for lack of personal jurisdiction, arguing that they: (1) were not registered to do business in North Carolina; (ii) had no place of business, employees or bank accounts there; (iii) did not design, manufacture or advertise their products there; and (iv) did not themselves sell or ship tires there or otherwise solicit business there. The trial court denied the motion, and the North Carolina Court of Appeals affirmed, on the ground that some of defendants' tires, different from those involved in the accident, had made their way to North Carolina through the "stream of commerce," in an "organized" distribution system involving other affiliated corporations, and defendants had taken no action to prevent sales there.

The Supreme Court reversed. The court noted the important distinction between "general jurisdiction," a state's power to resolve any claim against a defendant, even if unrelated to its contacts with the state, and "specific jurisdiction," the ability to resolve claims arising out of defendant's contacts with the state. Because the claims here were unrelated to defendants' tires that were indirectly sold in North Carolina, the case involved general jurisdiction, which may be exercised consistent with due process only where a corporation has "continuous and systematic contacts" such that the state is the corporation's principal place of business, or it is otherwise "at home" there. Under this standard, the sale of products through the "stream of commerce," and even regular commerce directly in the state, does not suffice. The court declined to address plaintiffs' argument that the activities of defendants' affiliated corporations in North Carolina, rather than merely of defendants themselves, should be considered, as plaintiffs had failed to raise this argument in the state court.

In McIntyre, a New Jersey plaintiff seriously injured his hand using a metal-shearing machine manufactured by defendant in England, where defendant was incorporated. Defendant sold its machinery in the United States through an independent distributor in Ohio, and it had sold between one and four machines, including the one at issue, in New Jersey. The New Jersey Supreme Court concluded the state could exercise specific jurisdiction over defendant because it distributed its products through a nationwide distribution system, knew or reasonably should have known they might be sold in any of the fifty states and failed to take reasonable steps to prevent sales in New Jersey.

The Supreme Court reversed. A four-justice plurality noted the Court's prior rulings that, absent an intentional tort, a state may exercise specific jurisdiction only where the defendant

"purposefully avails itself of the privilege of conducting activities within the forum State." In the plurality's view, a defendant's transmission of goods through the stream of commerce would permit the exercise of specific jurisdiction only where the defendant actually targeted the forum. Foreseeability is not the test; "as a general rule, it is not enough that the defendant might have predicted that its goods will reach the forum State." Moreover, because the states are sovereign entities separate from each other and from the United States, a defendant's purposeful contacts with the United States generally are irrelevant. Here, while defendant did have purposeful contacts with the United States generally by engaging an American distributor, there was no evidence of activities by defendant that specifically targeted New Jersey.

Two justices concurred in the judgment but noted that, because the case did not implicate "modern concerns" such as the solicitation of world- or nationwide sales through the Internet, it was unnecessary to fashion a rule of broad applicability without full consideration of its consequences. These justices found it sufficient to reverse that none of the Court's prior decisions had sustained specific jurisdiction where a defendant had made only an isolated sale in the forum state through the stream of commerce, or had not engaged in some purposeful activity specifically directed at the state.

United States Supreme Court Holds Failure-to-Warn Claims Against Generic Drug Manufacturers Preempted by Food, Drug and Cosmetic Act Because Act Requires Generic Drug's Warnings to Be Same as Branded Drug's and Thus Prohibits Generic Manufacturers from Unilaterally Changing Warnings

In *PLIVA, Inc. v. Mensing*, 2011 U.S. LEXIS 4793 (June 23, 2011), two plaintiffs were prescribed a brand name drug commonly used to treat digestive tract problems and received a generic form of the drug from their pharmacists. After taking the drug for several years, both plaintiffs developed tardive dyskinesia, an irreversible neurological condition. Separately, plaintiffs sued the generic manufacturers under state tort law for alleged failure to provide adequate warnings.

Under the 1984 Hatch-Waxman Amendments to the federal Food, Drug, and Cosmetic Act ("FDCA"), the United States Food and Drug Administration ("FDA") may approve a generic drug for marketing if the manufacturer can show the drug's equivalence to an already approved branded drug. Under the FDCA, the generic drug's warning label must be the "same" as the brand name's label.

In both suits, defendants argued the FDCA preempted plaintiffs' tort claims because the statute forbade defendants to change their warning labels as plaintiffs contended state tort law required. The Courts of Appeals for the Fifth and Eighth Circuits each rejected defendants' arguments. The United States Supreme Court granted certiorari, consolidated the cases and reversed.

The Court first rejected plaintiffs' argument that the FDA's "changes-being-effected" ("CBE") labeling regulations allowed defendants to unilaterally change their labels, while simultaneously requesting FDA approval of the changes. The applicability of these regulations to branded drug manufacturers had led the Court in *Wyeth v. Levine*, 555 U.S. 555 (2009) (*see* ***May 2009 Foley Hoag Product Liability Update***), to hold that failure-to-warn claims against branded drug manufacturers were not preempted.

The Court deferred to FDA's interpretation of its own regulations to the effect that the CBE regulation allowed a generic drug manufacturer to change its labels only to match an updated brand-name label, or to follow FDA's instructions. The Court also rejected plaintiffs' argument that defendants could have used "Dear Doctor" letters to send additional warnings to prescribing physicians and other healthcare providers. Again, the Court deferred to FDA, which interpreted "Dear Doctor" letters as "labeling," so that such a letter with substantial new warnings would have violated the FDCA's mandate that a generic drug's labeling be the same as the branded drug's.

In its amicus brief, FDA nonetheless argued against preemption, asserting that under the FDCA generic manufacturers had a duty at least to propose stronger warning labels to the agency if they believed such warnings were needed and, if defendants had done that, the branded manufacturer and/or FDA might have agreed to the changes.

The Court, however, held that preemption would be avoided only if defendants had the ability under the FDCA unilaterally to effect the labeling changes contended for by plaintiffs under state law, which they did not. Although the Court noted the apparent anomaly that failure-to-warn claims against branded manufacturers were not preempted while such claims against generic manufacturers were, this was a consequence of the relevant statutory and regulatory provisions, which could be changed by Congress or FDA.

Massachusetts Federal District Court Again Denies Class Certification for Third Party Payors Alleging Prescription Drug Manufacturer Fraudulently Promoted Drug, Holding Need for Doctor-by-Doctor Proof of Reliance on Fraud Caused Individual Issues to Predominate Over Common Ones and Rendered Class Action Unmanageable

In *In re Neurontin Marketing and Sales Practices and Products Liability Litigation*, 2011 WL 1048971 (D. Mass. Mar. 18, 2011), numerous plaintiffs sued the manufacturers of an anti-epilepsy drug in various courts alleging defendants had engaged in a fraudulent campaign to market and sell the drug for "off label" indications for which defendants knew the drug was ineffective. The cases were consolidated for pre-trial purposes in a multi-district litigation in the United States District Court for the District of Massachusetts. After the court denied class certification for all third-party payors ("TPPs"), such as health plans, that paid for the drug for off-label uses (see ***August 2009 Foley Hoag Product Liability Update***), plaintiffs moved for reconsideration solely as to a subclass of TPPs that had paid for the drug to treat bipolar and mood disorders.

Defendants argued that class certification was now moot, as the court had recently granted summary judgment for defendants as to all class TPP plaintiffs, holding they could not establish causation because they did not directly rely on defendants' misrepresentations and there was no evidence as to which physicians who prescribed the drug to the TPPs' members had so relied. Because reconsidering class certification would also require reconsidering summary judgment, the court observed that to prevail, plaintiffs must prove: (1) that the prescribing physicians relied on fraudulent communications or suppression of evidence by the manufacturers regarding clinical trials which showed the drug was ineffective for bipolar and mood disorder; and (2) the amount of damages caused by each TPP's physicians' reliance.

In attempting to meet their burden, plaintiffs relied heavily on their expert's analysis, which used national prescription data correlated with information about the manufacturer's promotional spending to conclude that 99.4% of prescriptions of the drug for bipolar disorder were "caused" by the manufacturer's off-label promotion, all of which the expert assumed was fraudulent. The court found that while the expert's testimony demonstrated the likelihood of some injury to TPPs from the fraudulent off-label promotion, a factfinder would have to perform a "granular doctor-by-doctor analysis" to differentiate between prescriptions "caused" by fraud and those that were attributable to non-fraudulent off-label marketing or other independent factors. Because that process would be unmanageable, the court found that certifying a nationwide class of TPPs, even as narrowed, was not a superior way of managing the litigation as required by Rule 23(b)(3). Moreover, because of the complex individualized issues related to calculating damages, plaintiffs could not satisfy the requirement of Rule 23(b)(3) that common issues must predominate over individual ones.

Massachusetts Federal Court Excludes Causation Testimony of Plaintiff's Expert and Grants Summary Judgment for Drug Manufacturer Because Expert Report Failed to Adequately Disclose Basis for General and Specific Causation Opinions

In *Kerlinsky v. Sandoz*, 2011 U.S. Dist. LEXIS 49327 (D. Mass. May 9, 2011), plaintiff's heart stopped beating shortly after he was treated for the first time with terazosin HCL, a drug used to treat high blood pressure and prostate enlargement. He spent four days in the hospital and incurred substantial medical expenses. Plaintiff sued the drug manufacturer, among other defendants, in the United States District Court for the District of Massachusetts for breach of warranty and negligent failure to warn of the possible side effects of the drug.

As evidence of causation, plaintiff initially submitted a two-sentence letter written by his daughter, a family medicine practitioner, stating her opinion that plaintiff's injuries resulted from use of terazosin. After being informed by the court that he had failed to comply with the expert disclosure requirements of Fed. R. Civ. P. 26, plaintiff submitted a three-page supplemental statement, also written by his daughter. Defendants moved to strike the disclosure as inadequate and for summary judgment on the ground that plaintiff lacked expert evidence of causation.

Defendants argued the expert disclosure was insufficient because it did not: (i) contain a complete statement of all opinions the witness would express and the bases for those opinions; (ii) disclose the facts or data considered in arriving at her conclusions; and (iii) adequately describe the proposed expert's qualifications. The court agreed on all counts and struck the report. Specifically, the court found that although plaintiff's expert clearly stated her opinion that plaintiff's heart stoppage was caused by terazosin, her report did not describe her bases for opining as to either general causation (that exposure to terazosin can cause heart stoppage in humans) or specific causation (that plaintiff's exposure to terazosin caused his heart stoppage). For example, although the report stated that "there is no other reasonable cause" for plaintiff's heart stoppage, it did not give any consideration as to whether other factors, including numerous different medications plaintiff was taking at the time, could have caused the stoppage. The report further suffered from a failure to disclose the facts or data relied upon in forming the expert's opinion, and a failure to adequately describe the expert's relevant qualifications other than her general experience as a medical doctor.

With respect to summary judgment, the court first agreed that the issue of medical causation requires expert testimony. Because the court had excluded the report of plaintiff's sole expert on the issue, the court granted summary judgment against plaintiff on all of his claims.

This Update was prepared by Foley Hoag's Product Liability and Complex Tort Practice Group, which includes the following members:

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