Shook, Hardy & Bacon L.L.P.

NOVEMBER 19, 2009

# PRODUCT LIABILITY LITIGATION REPORT

CONTENTS



## COURT IMPOSES SANCTIONS ON PHARMACEUTICAL CO. FOR BELATED DOCUMENT PRODUCTION

A federal court in New Hampshire has decided to sanction a prescription drug maker for the late production of annual reports submitted to the Food and Drug Administration (FDA) relating to the anti-inflammatory drug that allegedly caused the plaintiff wife's toxic epidermal necrolysis. *Bartlett v. Mutual Pharm. Co., Inc.*, No. 08-cv-358 (U.S. Dist. Ct., D.N.H., filed November 2, 2009). The company had repeatedly assured plaintiffs over the course of discovery that the three periodic reports it produced comprised the total of all adverse event-related documents in its possession.

Just before the discovery period closed, however, the company found more than 4,000 pages of periodic and annual reports in off-site storage and produced them. According to the court, because one employee knew about the existence of these reports and because circumstances suggested that the company should have noticed that they were obviously missing from its production, the failure to produce them in a timely manner justified the imposition of sanctions. Still, the court did not order all of the relief requested, including exclusion of the reports from trial, because it found that the company acted in good faith.

Among other matters, the court noted that the late-produced reports were more voluminous than the other reports produced and their absence "was glaring and should have caused Mutual and its counsel to take the reasonable steps necessary to locate them." The court also observed that the company's reliance on a paralegal's privilege review of the electronic file marked "FDA Correspondence," did not substantially justify the company in assuming that the folder "contained all of the annual and periodic reports, without making a reasonable effort to verify its contents."

Finding the company's failure to produce harmful to the plaintiffs who had been planning to ask for a spoliation instruction to the jury, the court ordered the company to pay certain of plaintiffs' reasonable attorney's fees and costs. The court also ordered the company and its counsel to search for and produce all company documents relating to serious skin reactions in connection with the drug at issue in the litigation as well as with ibuprofen, tolmetin, indomethacin, and Bactrim (both branded and generic).

Shook, Hardy & Bacon L.L.P.

# PRODUCT LIABILITY LITIGATION REPORT

NOVEMBER 19, 2009

*SHB offers expert, efficient and innovative representation to clients targeted by class action and complex litigation. We know that the successful resolution of products liability claims requires a comprehensive strategy developed in partnership with our clients.*

*For additional information on SHB's Global Product Liability capabilities, please contact*


***Gary Long***
*+1-816-474-6550*
*glong@shb.com*

***Greg Fowler***
*+1-816-474-6550*
*gfowler@shb.com*

*or*

***Simon Castley***
*+44-207-332-4500*
*scastley@shb.com*


## U.S. SUPREME COURT ASKED TO SET STANDARD FOR CORPORATE "PRINCIPAL PLACE OF BUSINESS" IN DETERMINING DIVERSITY JURISDICTION

The U.S. Supreme Court has heard **argument** in a case that asks where a national corporation's "place of business" is located for purposes of establishing whether a plaintiff and corporate defendant reside in different states and can pursue their litigation in a federal court under its diversity jurisdiction. *Hertz Corp. v. Friend*, No. 08-1107 (U.S., argued November 10, 2009).

The issue arose in litigation between a nationwide car rental company and its California employees. The employees initially filed their putative class action in a California state court on behalf of California employees. Hertz Corp. removed the action to a federal district court under the Class Action Fairness Act, which allows federal courts to preside over class actions with minimal diversity and an amount in controversy exceeding $5 million. The plaintiffs filed a motion to remand, contending that Hertz was a citizen of California and thus not diverse from any plaintiff.

The district court and the Ninth Circuit Court of Appeals applied a "place of operations" test, which looks to factors such as "the location of employees, tangible property, production activities, sources of income, and where the sales take place" to determine whether the corporation's business in one state "is significantly larger than any other state in which the corporation conducts business." If this inquiry does not answer the question about a corporation's "home," the court then examines where a majority of its executive and administrative functions is performed. Because 17 percent of Hertz's business is in California, a percentage not matched in any other state, the courts determined that the company's principal place of business was California and remanded the case to state court.

Hertz argued on appeal to the U.S. Supreme Court that its principal place of business is where its headquarters are located. With Hertz headquarters in New Jersey, the company claimed that diversity existed and the case, therefore, was improperly remanded. The company contended that applying the Ninth Circuit's test was cumbersome and encourages wasteful litigation just to establish jurisdiction. It also argued that conflicting tests used in other circuits create a situation in which a corporation's principal place of business can vary by circuit. The justices asked a number of questions about the definition of "headquarters" and expressed some concerns about a multifactor test that could end up identifying California as the principal place of business of every national corporation simply by virtue of the size of the state's population and market activity. *See SCOTUS Wiki*, November 11, 2009.

## DEFENDANT WAIVES HAGUE CONVENTION REQUIREMENTS, SPECIAL MASTER NAMED IN CHINESE DRYWALL LITIGATION

The multidistrict litigation (MDL) court in Louisiana presiding over the pre-trial proceedings of some 260 cases filed by homeowners against the makers of allegedly defective drywall has issued an order confirming the agreement of a Chinese company to waive its service-of-process rights under the Hague Convention. *In re: Chinese-Manufactured Drywall Prods. Liab. Litig.*, MDL No. 2047 (U.S. Dist. Ct., E.D. La., filed November 2, 2009). The company, Knauf Plasterboard (Tianjin) Co. (KPT), agreed to accept service of process for those homeowner plaintiffs who will be named in an omnibus class action complaint that will be filed no later than December 9, 2009.

According to the court, eligibility for inclusion in the omnibus class will require submission of "sufficient indicia that the homes in question contain KPT drywall (e.g., photographs, samples, visual inspections or reports identifying KPT markings on drywall in the home)." As to claimants not participating in the omnibus class action, the court "will not consider any requests for extensions of time to effectuate service against KPT" and will dismiss those actions in which the time has expired.

The court has also appointed a special master to preside over the litigation, giving the parties until November 17, 2009, to respond to the notice. The court cited the "complex nature" of the litigation and its "numerous and varied defendants and issues" to justify the appointment. The litigation arises out of property damage and physical injury allegedly caused by the abnormally high sulfur levels in drywall manufactured in China, much of which was imported since the mid-2000s during a housing boom and the new construction required after hurricanes Katrina and Rita. *See Product Liability Law 360*, November 13, 2009.

## AUTO DEFECT CLASS ACTION FILED AGAINST TOYOTA IN CALIFORNIA

California residents have reportedly filed a putative class action against Toyota Motor Corp., alleging that some of its models, manufactured since 2001, are defective and prone to sudden, involuntary acceleration. The action follows a massive recall of nearly 4 million vehicles for what the company has characterized as a floor mat problem. According to Toyota, the floor mats can cause the gas pedal to stick; the company reportedly released a statement claiming that the National Highway Traffic Safety Administration (NHTSA) had confirmed that "no defect exists in vehicles in which the driver's floor mat is compatible with the vehicle and properly secured."

*The action follows a massive recall of nearly 4 million vehicles for what the company has characterized as a floor mat problem.*

NHTSA called that statement inaccurate and misleading, saying that removal of the driver's floor mat is simply the most immediate way to address the alleged safety

risk. According to the agency, this action does not correct the underlying alleged defect which involves the floor pan design and the accelerator. The agency stated that the matter will not be closed "until Toyota has effectively addressed the defect by providing a suitable vehicle based solution." Sudden acceleration of a Toyota vehicle allegedly led to a high-speed crash and four fatalities in August 2009.

The law firm representing the named plaintiffs in the California lawsuit has indicated that the vehicles should be equipped with systems that would allow a driver to "easily put the vehicle in neutral, apply the brakes, or just turn off the ignition." Toyota vehicles also apparently lack "a brake-to-idle failsafe, which many other manufacturers already incorporate in their designs." *See NHTSA Press Release*, November 4, 2009; *Associated Press*, November 6, 2009; *The Orange County Register*, November 9, 2009.

## ALL THINGS LEGISLATIVE AND REGULATORY

### CPSC Continues to Develop Product Safety Incident Database

*Motivated by an unprecedented number of product safety-related recalls in 2007, Congress required, as part of 2008 reforms, that the Consumer Product Safety Commission (CPSC) establish a product safety incident database where consumers can post and review reports of product-related injuries and potential hazards.*

Motivated by an unprecedented number of product safety-related recalls in 2007, Congress required, as part of 2008 reforms, that the Consumer Product Safety Commission (CPSC) establish a product safety incident database where consumers can post and review reports of product-related injuries and potential hazards. The agency's initial **report** to Congress on the implementation of this requirement was filed in September 2009.

CPSC continues to develop the database, which is expected to be released as mandated by March 2011, and recently conducted a **hearing** for stakeholders to provide comments and recommendations. Shook, Hardy & Bacon Public Policy Of Counsel **Cary Silverman** testified during the hearing on behalf of the U.S. Chamber of Commerce's Institute for Legal Reform. He expressed industry's concern about the potential for inaccurate information to be posted on the Web site and suggested that the CPSC provide a way for manufacturers to flag inaccurate information before posting and challenge inaccurate posted information.

A human factors consultant recently provided an analysis of the database requirement and shared research he conducted into the accuracy and utility of online consumer product-safety comments. He focused on comments posted to Amazon.com about the ingestion of magnets from recalled magnetic toys. Among the questions this research raised, according to the consultant, are whether early consumer warnings about product-safety hazards will influence purchasing decisions, lack of contextual detail and other information may limit investigation and scientific analysis, and the extent to which biased reports, underreporting or manufacturer misidentification could limit the database's utility. *See BNA Product Safety & Liability Reporter*, November 9, 2009.

### Workshop on Product Testing, Certification and Labeling Scheduled

The Consumer Product Safety Commission (CPSC) has **announced** a two-day workshop intended to address the requirements for testing, certification and labeling of products under section 14 of the Consumer Product Safety Act. The December 10-11, 2009, meeting will address possible options for implementing section 14.

According to CPSC, "significant differences between consumer products, children's products, manufacturers, and even testing methods and sampling methods" make "it difficult to devise a regulatory approach" general enough to apply to most products subject to section 14, detailed enough for stakeholders to know what tests must be performed and sensitive enough to the needs of small businesses and individuals so as not to impose costs or burdens that drive them out of business.

Workshop topics to be addressed include (i) reasonable testing programs for products such as bicycle helmets; (ii) additional third-party testing requirements for children's products, (iii) issues affecting importers and small businesses, (iv) the Consumer Product Labeling Program, and (v) certification. Public comments must be submitted no later than January 11, 2010. *See Federal Register,* November 13, 2009.

### Seventh Circuit Implements Phase One of Electronic Discovery Pilot Program; Lawyers Adopt Pilot Project Rules to Advance Civil Justice Reforms

The Seventh Circuit Court of Appeals has launched the first phase of its **Electronic Discovery Pilot Program**. It was developed due to continuing concerns about "the rising burden and cost of discovery in litigation in the United States brought on primarily by the use of electronically stored information ('ESI') in today's electronic world." The court also cites the release of a final report of the American College of Trial Lawyers (ACTL) and the Institute for the Advancement of the American Legal System (IAALS) at the University of Denver as impetus for the pilot program.

Among the principles enunciated in support of the program is that "An attorney's zealous representation of a client is not compromised by conducting discovery in a cooperative manner." The principles include the recognition that the meet-and-confer process required by the federal discovery rules "will be aided by participation of an e-discovery liaison(s)" who is prepared to participate in dispute resolution, is knowledgeable about the party's e-discovery efforts, has reasonable access to or familiarity with the party's electronic systems and capabilities, and is knowledgeable about the technical aspects of e-discovery. The principles also include a proposed standing order relating to the discovery of ESI that can be used in the Seventh Circuit's district courts; it calls for the litigants to comport themselves with the principles.

*Among the principles enunciated in support of the program is that "An attorney's zealous representation of a client is not compromised by conducting discovery in a cooperative manner."*

The pilot program is effective from October 2009 to May 2010 and will be evaluated "using objective and subjective measuring tools." The resulting data will be presented during conferences to be held in May 2010. The second phase of the pilot program will be conducted from June 2010 to May 2011.

Meanwhile ACTL and IAALS have released pilot project rules and guidelines for civil caseflow management, that also arise from the joint report the organizations released in March 2009. According to a statement accompanying the rules, "The nation's civil justice system is too expensive, too cumbersome and takes too long. As a result, the price of justice is high and access is being compromised." The 12 pilot rules were apparently developed for use in federal courts which are urged "to use these Rules as a roadmap for consideration in creating and implementing a pilot project." The rules address a range of issues, focusing for the most part on discovery. Similarly, the caseflow management guidelines focus on discovery and other pre-trial issues.

**Department of Justice Releases 2005 Statistics for Tort Bench and Jury Trials in State Courts**

Bench and jury trials in state courts accounted for an estimated 4 percent of all tort dispositions in 2005, with one out of four product liability trials involving asbestos claims, according to a November 2009 report issued by the U.S. Department of Justice's Bureau of Justice Statistics.

The data collected also show that (i) one-half of plaintiff winners in tort trials were awarded $24,000 or less in damages; (ii) punitive damages were sought in 9 percent of tort trials with plaintiff winners, with $55,000 as the median punitive damage award; and (iii) the number of tort trials declined by about one-third between 1996 and 2005 in the nation's 75 most populous counties.

The report further states, "Although less than 5 percent of tort trials involved product liability issues, these cases garnered a great deal of societal interest because of the high degree of publicity surrounding some of them and the perceived potential for very large payouts."

Of the 346 product liability trials in state courts in 2005, defective construction, electrical or manufacturing equipment accounted for 14 percent; and faulty home appliances, food or transportation products each accounted for about 10 percent. Implants, prostheses or other medial devices accounted for 2 percent; sporting goods equipment accounted for about 3 percent; drugs and cosmetics accounted for about 6 percent; and toxic substances accounted for almost 28 percent.

In asbestos cases, one-half of the plaintiff winners were awarded damages of $682,000 or more, with the median damage awards exceeding $100,000 in non-asbestos product liability ($500,000) trials.

According to the report, punitive damages were sought in 9 percent of the approximately 8,763 tort trials with plaintiff winners in 2005. Twenty-three percent of the punitive awards were more than $250,000 and 17 percent were $1 million or more. The median punitive damage awards in tort jury ($100,000) and bench ($54,000) trials were not statistically different. Too few cases occurred to obtain statistically reliable estimates for punitive damages awarded to product/asbestos liability litigants. *See Bureau of Justice Statistics Bulletin,* November 2009.

## LEGAL LITERATURE REVIEW

### Victor Schwartz, et al., "Can Governments Impose a New Tort Duty to Prevent External Risks? The "No-Fault" Theories Behind Today's High-Stakes Government Recoupment Suits," *Wake Forest Law Review*, 2009

Shook, Hardy & Bacon Public Policy Attorneys Victor Schwartz, Phil Goldberg and Christopher Appel discuss the legal theories under which government attorneys have sought to recover damages from product manufacturers for external costs not tied to any wrongdoing. For example, attorneys general have sued "gun makers for harms caused by gun violence, former manufacturers of lead pigment and paint for harms caused by deteriorated lead paint, and automobile and gasoline manufacturers for costs associated with global warming."

According to the article, traditional products liability and tort law principles have taken "a back seat to the desire to advance a public policy agenda and create a new revenue source." The authors conclude that allowing government attorneys to disregard that "externalization-of-risk" actions relate not to the manufacture and sale of products but to consumer conduct and accepted product risks imposes new duties on manufacturers and "creates limitless, unpredictable liability based on the personal beliefs and policy agendas of the government attorneys, not wrongdoing." They contend that legislators, not courts, should make such changes to liability, if society deems this change appropriate.

*According to the article, traditional products liability and tort law principles have taken "a back seat to the desire to advance a public policy agenda and create a new revenue source."*

### Myriam Gilles, "Class Dismissed: Contemporary Judicial Hostility to Small-Claims Consumer Class Actions," *DePaul Law Review*, 2009

Benjamin N. Cardozo School of Law Professor Myriam Gilles contends that "small-claims consumer cases are a—if not *the*—primary reason why class actions exist, and that without class actions many—if not most—of the wrongs perpetrated upon small-claims consumers would not be capable of redress." She explores how federal district courts have consistently declined to certify small-value consumer claims as class actions over the past decade. The courts have, according to Gilles, tended to find that putative class members are not sufficiently ascertainable "to ensure the efficacy of a subsequent distribution of damages." Calling the ascertainability requirement "extra-statutory," Gilles claims that it advances a "private law conception of the class action device" that "will often entail impunity for corporate defendants who perpetrate harms in relatively modest increments upon large numbers of consumers."

### Patricia Hatamyar, "The Tao of Pleading: Do *Twombly* and *Iqbal* Matter Empirically?," *American University Law Review* (forthcoming)

Authored by St. Thomas University School of Law Visiting Professor Patiricia Hatamyar, this article provides a statistical analysis of motions to dismiss in the federal courts since the U.S. Supreme Court adopted the plausibility pleading standard under

*Bell Atlantic Corp. v. Twombly* and *Ashcroft v. Iqbal*. She concludes that these cases "have resulted in a noticeable increase in the granting of 12(b)(6) motions by district courts." Hatamyar recognizes that many legal commentators are calling for a return to fact-based pleading, but she suggests that "such a result, if desirable, should be accomplished by the normal rule-amendment process." According to Hatamyar, a "plausibility" standard "injects too much subjectivity into the ruling, and the very word 'plausible' implies a value judgment on the merits of the case at the pleadings stage." She concludes, "[]t]his was not the original intent of the [Federal Rules of Civil Procedure], and such a profound shift in philosophy should be accomplished by deliberative and representative consensus."

### Brian Fitzpatrick, "The Politics of Merit Selection," *Missouri Law Review*, 2009

Vanderbilt University School of Law Assistant Professor Brian Fitzpatrick contends that when states use merit selection systems to place judges on the bench, because the systems typically rely on panels of lawyers to assess the merit of judicial candidates, liberal judges are apt to be selected more often than in those states relying on public election or selection by elected representatives. He suggests that lawyers are more liberal than the general population and are just as apt as the general public to consider the political affiliation of a candidate when assessing merit.

Fitzpatrick examined the merit-based plans in Tennessee and Missouri and shows that merit-plan nominees in those states voted more often in Democratic primaries (and thus, were presumably Democrats) than voters tended to vote for Democratic candidates in state and federal races for elected office. Fitzpatrick concludes that "proponents of merit selection may need to change the focus of their energies away from the notion that merit selection takes politics out of judicial selection and towards an explanation as to why the judiciary should reflect the political beliefs of lawyers rather than the public."

*Fitzpatrick concludes that "proponents of merit selection may need to change the focus of their energies away from the notion that merit selection takes politics out of judicial selection and towards an explanation as to why the judiciary should reflect the political beliefs of lawyers rather than the public."*

## LAW BLOG ROUNDUP

**Is the Tort System a Litigation Lottery?**

"Suggesting that the error rate of a decision procedure makes it a lottery is a category mistake since the very possibility of identifying an erroneous outcome, by definition, makes the procedure non-random and therefore not a lottery." Albany Law School Professor Timothy Lytton, guest blogging about legal commentators who contend that the U.S. tort system shares features with a lottery, purportedly because many plaintiffs who suffer no harm or have not been treated negligently still receive compensation.

TortsProfBlog, November 16, 2009.

### Public Health Association Calls for Asbestos Ban

"At last, the world's oldest public health organization has joined the funeral dirge-paced parade to ban asbestos in the U.S. The 50,000-member American Public Health Association adopted a resolution at its annual meeting this week calling on Congress to pass legislation banning the manufacture, sale, export, or import of asbestos-containing products including products in which asbestos is a contaminant." Investigative journalist Andrew Schneider, discussing the history of asbestos regulation in the United States, noting that it was banned for only two years following 10 years of study by the Environmental Protection Agency. Apparently, the Fifth Circuit Court of Appeals reversed the agency's action in favor of a Canadian asbestos industry challenge.

The Pump Handle, November 12, 2009.

### Only the Best Clients Need Apply?

"How are law firms like public schools? If you want to do well, you need better clients (or students)." Editorial commentator Milt Policzer, writing about a Ninth Circuit Court of Appeals ruling in stockholder litigation that the lead plaintiff, "chosen for having the most at stake in the case—gets to pick his/her lawyer." The trial court had appointed two lead plaintiffs and two lead counsels, one of whom did not represent either lead plaintiff. "So naturally, the lead plaintiff whose lawyer didn't get picked, appealed." According to Policzer, "if you want to keep your financial scores up, you've got to recruit the very best clients. Think of it as No Client Left Behind."

Courthouse News Service, November 16, 2009.

## THE FINAL WORD

### Research Suggests Some Nanomaterials Can Pass Through Placenta

New **research** suggests that some nanoparticles may pass through the placenta, opening a new area for further toxicological studies on this organ system. Peter Wick, et.al., "Barrier Capacity of Human Placenta for Nanosized Materials," *Environmental Health Perspectives* (November 12, 2009).

A team of 10 Swiss researchers explored whether nanoparticles could pass through the placenta because (i) airborne ultrafine particles, which can be about the same size as nanoparticles, have been shown to affect the fetus; (ii) people are expected to have some nanoparticles injected into them for medical purposes such as vaccinations; and (iii) previous research has not addressed whether nanoparticles may cross the placenta.

Using a human placenta in a laboratory test, the researchers investigated whether fluorescent polystyrene particles measuring 60, 80, 240, and 500 nanometers in diameter would pass through the placenta. They found that those measuring 240 nanometers were taken up and crossed the placental barrier, but that polyethylene glycol-coated gold particles measuring up to 30 nanometers did not. *See Daily Environment Report*, November 13, 2009.

## UPCOMING CONFERENCES AND SEMINARS

American Conference Institute, New York, New York – December 8-10, 2009 – "14th Annual Drug and Medical Device Litigation Conference." Co-sponsored by Shook, Hardy & Bacon, this conference features a distinguished faculty from the bench, bar and industry offering practical insights and strategies for successfully meeting the litigation challenges facing the drug and medical device industry. Shook, Hardy & Bacon Pharmaceutical and Medical Device Litigation Partner Michelle Mangrum will serve on a panel discussing "Successfully Asserting a Preemption Defense and Managing Industry/FDA Relationships in a Post-*Levine* and Post-*Riegel* World." Shook, Hardy & Bacon Pharmaceutical and Medical Device Litigation Partner Eric Anielak joins a panel addressing "Procedural Strategies for Winning Cases." ■

OFFICE LOCATIONS

**Geneva, Switzerland**
+41-22-787-2000

**Houston, Texas**
+1-713-227-8008

**Irvine, California**
+1-949-475-1500

**Kansas City, Missouri**
+1-816-474-6550

**London, England**
+44-207-332-4500

**Miami, Florida**
+1-305-358-5171

**San Francisco, California**
+1-415-544-1900

**Tampa, Florida**
+1-813-202-7100

**Washington, D.C.**
+1-202-783-8400

## ABOUT SHB

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

Shook attorneys have unparalleled experience in organizing defense strategies, developing defense themes and trying high-profile cases. The firm is enormously proud of its track record for achieving favorable results for clients under the most contentious circumstances in both federal and state courts.

The firm's clients include many large multinational companies in the tobacco, pharmaceutical, medical device, automotive, chemical, food and beverage, oil and gas, telecommunications, agricultural, and retail industries.

With 93 percent of our more than 500 lawyers focused on litigation, Shook has the highest concentration of litigation attorneys among those firms listed on the *AmLaw* ***100,*** *The American Lawyer's* list of the largest firms in the United States (by revenue).