Shook, Hardy & Bacon L.L.P.

MARCH 31, 2011

PRODUCT LIABILITY LITIGATION REPORT

CONTENTS

NINTH CIRCUIT REQUIRES LOSING PARTY TO PAY COSTS OF TRANSLATING DOCUMENTS

Adding to a circuit court split on the issue, the Ninth Circuit Court of Appeals has upheld a district court ruling awarding the costs of translating documents to the prevailing party in litigation involving injuries allegedly sustained by a professional baseball player who fell through a wooden deck at a marina and spa property. *Taniguchi v. Kan Pac. Saipan, Ltd.*, No. 09-15212 (9th Cir., decided March 8, 2011). The district court granted the defendant's motion for summary judgment and awarded the company the costs of translating documents from Japanese to English on the basis of 28 U.S.C. § 1920(6), which gives the courts discretion to award fees for the compensation of interpreters in addition to the costs of "special interpretation services under section 1828."

Recognizing that one circuit (the Seventh) has limited the section's "interpretation services" to apply to those translating the spoken word only, the Ninth Circuit found persuasive Sixth Circuit authority allowing an award of costs for the translation of documents necessary for litigation. The Sixth Circuit relied on a dictionary definition of "interpret," which apparently includes "to translate into intelligible or familiar language," and concluded that "translation" services and "interpretation" services are interchangeable. The Ninth Circuit also noted that this analysis is compatible with Federal Rule of Civil Procedure 54, "which includes a decided preference for the award of costs to the prevailing party."

Because the plaintiff alleged that his injuries affected his compensation under negotiated contract deals, the court found that it was necessary for the defendant to have his documents and medical records translated to "adequately prepare its defense." Thus, the court held "that the district court acted within its discretion when it determined that translation services were necessary to render pertinent documents intelligible to the litigants."

U.S. SUPREME COURT HEARS ARGUMENT ON GENERIC DRUG LABELING

The U.S. Supreme Court is considering whether a generic drug maker can be held liable under state law for failing to include on its drug label safety information not yet

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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.

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used by name brand manufacturers or required by the Food and Drug Administration (FDA). *PLIVA, Inc. v. Mensing*, No. 09-993 (U.S., oral argument, March 30, 2011). The product at issue was the generic bioequivalent of a drug prescribed to treat the plaintiff's diabetic gastroparesis. She took the generic drug for four years and then allegedly developed tardive dyskinesia. Generic drug makers generally label their products with the warnings that FDA approves for the name brand versions, and when the plaintiff was taking metoclopramide, no manufacturer had taken steps to change the label warnings despite mounting evidence that long-term use carries a purported tardive dyskinesia risk.

The Eighth Circuit Court of Appeals reversed a lower court's grant of the generic drug makers' motion for summary judgment, finding that the plaintiff had stated a viable claim that was not preempted by federal law. According to the court, the regulatory framework "does not permit generic manufacturers passively to accept the inadequacy of their drug's label as they market and profit from it." The Eighth Circuit rejected the defendants' efforts to establish that it would be impossible for them to comply with both federal law and the state laws the plaintiff sought to enforce. The defendants argued that they are prohibited from implementing a unilateral label change without prior FDA approval, but the court observed that they "could have at least *proposed* a label change that the FDA could receive and impose uniformly on all metoclopramide manufacturers if approved."

Numerous *amicus* briefs were filed, nearly all of them on behalf of the plaintiff, who is the respondent before the U.S. Supreme Court. Among those supporting her are 42 states and the District of Columbia; various medical societies, including the American Medical Association; the U.S. government; Representative Henry Waxman (D-Calif.); and a number of legal scholars. A decision could be handed down before the Court concludes its term in June 2011.

FIRST CIRCUIT REVERSES LOWER COURT'S EXCLUSION OF EXPERT'S BENZENE-CAUSATION TESTIMONY

The First Circuit Court of Appeals has determined that a district court abused its discretion by excluding the general causation testimony of the plaintiffs' toxicologist in a case involving benzene exposure that allegedly caused a refrigeration technician's rare leukemia. ***Milward v. Acuity Specialty Prods. Group, Inc.*, No. 09-2270 (1st Cir., decided March 22, 2011)**. The lower court excluded the evidence on the ground that it lacked "sufficient demonstrated scientific reliability to warrant its admission under Rule 702."

According to the appellate court, the toxicologist based his opinion about a causal link between benzene and the plaintiff's disease on a "weight of the evidence" methodology. The court described the methodology and noted, "The fact that the

role of judgment in the weight of the evidence approach is more readily apparent than it is in other methodologies does not mean that the approach is any less scientific." The court also described how the toxicologist applied the methodology and concluded that his "opinion rests on a scientifically sound and methodologically reliable foundation." The court explained that the district court, in ruling the opinion inadmissible, relied on (i) "its evaluation of the mechanistic and epidemiological evidence on which Dr. Smith based his opinion," and (ii) "its understanding of the scientific concept of 'biological plausibility' as used by Dr. Smith when he explained his conclusions."

The court determined that on both points the district court erred, observing "In the end, the court's exclusion of the testimony was based on its evaluation of the weight of the evidence, which is an issue that is the province of the jury, and on its misperception of the methodology and analysis that provided the basis for Dr. Smith's opinion." Accordingly, the First Circuit reversed the judgment entered for the defendants and the ruling excluding the testimony, and remanded for further proceedings.

CLASS CERTIFIED IN SUIT ALLEGING DEFECTIVE LAPTOP AND FALSE MARKETING

A federal court in California has conditionally granted a motion to certify a nationwide class in litigation alleging that a company's notebook computers were defective because they did not have sufficient memory to support the operating systems with which they were sold. *Wolph v. Acer Am. Corp.*, No. 09-01314 (U.S. Dist. Ct., N.D. Cal., order entered March 25, 2011).

Among other matters, the defendant argued that the plaintiffs could not satisfy the ascertainability requirement of Federal Rule of Civil Procedure 23(a). According to the defendant, the plaintiffs failed to define an ascertainable class "because the proposed class of purchasers who experienced problems is too subjective in that not all purchasers experienced problems such as Plaintiffs did." The company also argued that that "all purchasers" of the allegedly defective notebook computer was too broad a class, because "it includes consumers who already received their remedy by returning the notebook for a full refund."

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The court agreed that the proposed class definition was too broad, but proposed a definition to "make the class more ascertainable," that is, "All persons and entities who reside in the United States who have purchased, and have not returned for refund, a new Acer notebook computer from Acer or an Acer Authorized Reseller, not for resale, that came pre-installed with a Microsoft® Windows Vista Home Premium, Business, or Ultimate operating system, and contained 1 GB of Random Access Memory or less as shared memory for both the system and graphics." Finding

every other Rule 23 requirement for class certification met under its proposed definition, the court granted the plaintiffs leave to amend to conform their class definition to the court-modified definition.

ALL THINGS LEGISLATIVE AND REGULATORY

Legislation Introduced to Improve Children's Football Helmet Safety

Senator Tom Udall (D-N.M.) and Representative Bill Pascrell (D- N.J.) have introduced **legislation** (S. 601/H.R.1127) that would strengthen safety standards for new and reconditioned youth football helmets. Designed to protect the country's 4.5 million youth and high school football players from the dangers of sports-related brain injuries, the Children's Sports Athletic Equipment Safety Act also "increases potential penalties for using false injury prevention claims to sell helmets and other sports equipment," according to the lawmakers.

Noting that football helmet safety technology "has improved since the days of leather helmets," Pascrell said that current standards primarily protect against serious injury from severe, direct blows and not those caused by less severe impacts or by "rotational acceleration resulting from hits that spin the head and brain." As co-founder and co-chair of the Congressional Brain Injury Task Force, Pascrell also noted that standards for reconditioned used football helmets were lax because they did not specify how often the helmets must be recertified.

Although the bill does not set an age limit for helmets or require professional reconditioning, it would require clear risk warning labels that indicate when new helmets were manufactured or when used ones were reconditioned. It would mandate that the Federal Trade Commission impose civil fines on manufacturers making false or misleading claims and would empower state attorneys general to sue companies that violate the bill.

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"This isn't just an issue about football," Udall told a news source. "We have all sorts of athletic equipment that is out there to fulfill the role of safety or protection. So it seems to me if you have a headband or a mouth guard, the same set of issues come up—misrepresentation issues." *See The New York Times,* March 15, 2011; *Representative Bill Pascrell* and *Senator Tom Udall Press Releases*, March 16, 2011.

Senate Proposal Would Restrict Use of Protective Orders in Personal Injury Cases

Senator Herb Kohl (D-Wis.) has introduced the "Sunshine in Litigation Act of 2011" (**S. 623**) to restrict the circumstances under which federal courts enter protective orders or seal cases and settlements in civil actions "in which the pleadings state facts that are relevant to the protection of public health or safety." The proposed measure would require courts to make certain findings before entering such orders and would impose the burden of proof in obtaining these orders on the proponent.

Among other matters, courts would be required to balance "the public interest in the disclosure of past, present, or potential health or safety hazards" with "a specific and substantial interest in maintaining the confidentiality of the information or records in question."

According to Kohl, "This legislation does not prohibit secrecy agreements across the board, and it does not place an undue burden on judges or on our courts. It simply states that where the public interest in disclosure outweighs legitimate interests in secrecy, courts should not shield important health and safety information from the public. The time to focus some sunshine on public hazards to prevent future harms is now." Introduced on March 17, 2011, the bill was referred to the Committee on the Judiciary. *See Senator Herb Kohl Press Release*, March 17, 2011.

FTC Finalizes Settlement over False Claims About Children's Dietary Supplements

The Federal Trade Commission (FTC) has **finalized** an order "settling charges that a major vitamin marketer and its subsidiaries made false and unsupported claims that their Disney and Marvel Heroes line[s] of children's multivitamins contained a significant amount of DHA (docosahexaenoic acid, an Omega-3 fatty acid) and promoted health brain and eye development in children." As part of the agreement, the marketer will not misrepresent any product ingredient or make any representations about DHA or similar ingredients as beneficial for brain or eye health, "unless the representation is non-misleading," and supported by "competent and reliable scientific evidence." The company must also pay $2.1 million to provide refunds for consumers who purchased the products at issue. *See FTC Press Release*, March 29, 2011.

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Federal Judicial Center Releases Data on Motions to Dismiss After *Twombly* and *Iqbal*

Analyzing data from 23 federal district courts, Federal Judicial Center researchers have concluded that while more motions to dismiss were filed in civil litigation after the U.S. Supreme Court adopted a plausibility pleading standard, there was no discernible increase in the rate at which a grant of a motion to dismiss terminated the case. The center's March 2011 **report** is based on a study that compared motion activity in 2006 and 2010 and included "an assessment of the outcome of motions in orders that do not appear in the computerized legal reference systems such as Westlaw. Statistical models were used to control for such factors as differences in levels of motion activity in individual federal district courts and types of cases."

According to the researchers, at first look, it appeared that "motions to dismiss for failure to state a claim were more likely to [result in a] grant [of] all or some of the relief requested in 2010 than in 2006." But a closer look apparently revealed overall "that the increase extends only to motions granted with leave to amend. No

increase was found in motions granted without leave to amend." In tort actions, the rate of grants with amendment increased 7.7 percent between 2006 and 2010, while grants without amendment decreased 5.9 percent in that time. The report cautions that results could include factors unrelated to the U.S. Supreme Court rulings, "such as differences across district courts, differences across types of cases, and differences in the presence of an amended complaint." Still, the study also showed that, in tort cases, courts dismissed all of a plaintiff's claims 4.5 percent more often in 2010 than in 2006.

The authors conclude that this type of assessment is "complicated" and call for further study, noting some of the weaknesses in their data. They are conducting a "follow-up on the outcome of cases in which the plaintiff had an opportunity to amend the complaint" to determine "the extent to which complaints that are amended are challenged by subsequent motions to dismiss, and the extent to which those motions are granted without leave to amend."

Florida Senate Approves Product Liability Reform Bill

With just one Democrat in favor and one Republican against, the Florida Senate has reportedly passed along party lines a **bill** (S.B. 142) that would overturn a 2001 state supreme court ruling that adopted the "crashworthiness doctrine" and imposed liability on a car maker for a design defect that enhanced, rather than caused, injury.

The bill would allow juries to hear about the underlying causes of an accident and would also provide that fault be apportioned among all responsible parties.

The bill would allow juries to hear about the underlying causes of an accident and would also provide that fault be apportioned among all responsible parties. A similar bill is now before a Florida House committee.

Sponsored by State Senator Garrett Richter (R-Naples), the bill would overturn *D'Amario v. Ford Motor Co.*, in which the Florida Supreme Court vacated a jury's defense verdict exonerating a car manufacturer from liability for a passenger's severe injuries in a car crash allegedly involving a drunk driver. The high court ruled that a jury should not consider or be told about the underlying cause of accidents, such as negligent driving or driver intoxication, but should determine whether a vehicle defect caused "enhanced injuries."

Richter told a news source that the bill will allow juries to hear all of the facts leading to an accident. "I believe Lady Justice is blind, but she's not deaf," he said. State Senator Alan Hays (R-Umatilla) was quoted as saying that tort reform was a priority of the state's General Government Appropriations Committee, which he chairs. "It's part of the picture when trying to create an avenue of economic recovery and allow businesses to operate without governmental constraints," he said about the bill. *See Product Liability Law 360,* March16, 2011; *DailyCommercial.com,* March 27, 2011.

LEGAL LITERATURE REVIEW

Madeleine McDonough and Jennifer Stonecipher Hill, "Chapter 5. *Centocor, Inc. v. Hamilton,"* in *Top 20 Cases of 2010 and Cases to Watch*, 2011, Food and Drug Law Institute (April 1, 2011)

Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Attorneys Madeleine McDonough and Jennifer Stonecipher Hill have co-authored a chapter in the second edition of the Food and Drug Law Institute's *Top 20 Cases* book. The case they discuss involves the learned intermediary doctrine, which protects prescription drug makers from liability for claims of inadequate warnings, where accurate information has been provided to physicians about a drug's risks and benefits. An intermediate appellate court in Texas expressly permitted a direct-to-consumer (DTC) marketing exception to the doctrine and upheld a $4.8 million jury award to a woman allegedly injured by a prescription drug. The authors contend that "the learned intermediary doctrine should still apply, despite DTC marketing, as physicians continue to be primarily responsible for communicating risks involving medications to patients." Noting that the ruling is on appeal before the Texas Supreme Court, they conclude, "So long as the physician has the ultimate responsibility for the prescription decision, the learned intermediary doctrine continues to be relevant and applicable in law."

Christopher Appel, "Reigning in New Ways to Sue Where Lawmakers Never Intended," *Inside ALEC*, March 2011

Shook, Hardy & Bacon Public Policy Associate Christopher Appel contends in this article that the new *Restatement (Third) of Torts: Liability for Physical and Emotional Harm* has the potential to expand liability to the extent that it calls on state judges to recognize affirmative duties and create private rights to sue under newly enacted legislation "even where the legislature never stated or intended such a result." Appel observes that the *Restatement* is supposed to "reflect the most sound liability rules," but in this instance represents "rather dramatic departures in the law." The author cites a model law developed by the American Legislative Exchange Council requiring that "any law establishing a new private right to sue must expressly state such legislative intent, and that courts may not 'second-guess' the will of the legislature." He concludes by suggesting that such legislation is needed to curb the *Restatement's* excesses.

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Jay Tidmarsh and Linda Sandstrom Simard, "Foreign Citizens in Transnational Class Actions," *Cornell Law Review* (forthcoming 2012)

Notre Dame and Suffolk University Law School professors consider whether foreign citizens should be included as members of class actions brought in U.S. courts. According to the authors, a general presumption against their inclusion has been tied to *res judicata* and the recognition of judgments, that is, "If a court in the country of which putative class members are citizens will not recognize the judgment of an

American court, then the court should exclude those citizens from the class action." As well, "If a foreign class member could bind the defendant to a result that favored the class member but a defendant could not bind the foreign class member to a result that favored the defendant, the class action was a one-way ratchet that always operated to the detriment of the defendant." The authors provide a framework for courts considering which foreign litigants should be included and note that at the most basic level, the framework's presumptions "divide small-stakes cases from large-stakes cases."

LAW BLOG ROUNDUP

To Live in a Country Where Even Chopsticks Come with Warnings…

"Sushi Maki, a Miami-based Japanese restaurant chain, is kind enough to provide diners with chopsticks. Not uncommon. However, their chopsticks are far more entertaining than average." Widener University School of Law Associate Professor Christopher Robinette, writing about the amusing drawings on the restaurant's chopstick wrappers showing how they can be used to embellish costumes. The wrappers also include warnings that provide, in part, "Professional Chopstick Stunt People were used for the drawings above. In real life, chopsticks are dangerous—even lethal in a ninja warrior's hands. You could poke your eye out, or tear your rotator cuff or something. So our lawyers tell us that we have to warn you that they can be dangerous and cause serious physical harm if you use them for anything but eating."

TortsProf Blog, March 17, 2011.

Legislative Assaults on Safety Standards Continue

"Apparently, Paul does not think that 2007, the year of the recall, was bad enough and would like to make our homes as unsafe as possible." OMB Watch Regulatory Policy Analyst Matt Madia, blogging about a small-business-aid bill amendment offered by Senator Rand Paul (R-Ky.) to abolish the Consumer Product Safety Commission.

OMB Watch, The Fine Print, March 17, 2011.

More Research Needed?

"All in all, the report continues to suggest that we still do not know much about *Twiqbal's* real effects. There is certainly more 12(b)(6) activity, but plaintiffs are not routinely being tossed out of court at the early stages, at least not in significantly greater numbers than under pre-*Twiqbal* pleading rules (whatever they really were)." Florida International University College of Law Associate Professor Howard Wasserman, discussing the Federal Judicial Center's study on the use and granting of Federal Rule of Civil Procedure 12(b)(6) motions since the U.S. Supreme Court

imposed a "plausibility" standard on pleading in *Bell Atlantic Corp. v. Twombly* and *Ashcroft v. Iqbal*, which many legal commentators refer to in the aggregate as "*Twiqbal*."

PrawfsBlawg, March 29, 2011.

THE FINAL WORD

Judicial Conference Committee Updates Guidance on Wireless Communication Devices in Federal Courthouses

The Judicial Conference Committee on Court Administration and Case Management has issued updated **guidance** on the use of portable wireless communication devises in federal courthouses.

Acknowledging the "ever-growing number of wireless communication devices that have the capability of recording and/or transmitting sound, pictures, and video, as well as the ability to instantaneously post content to or through blogs, social media sites (e.g., Facebook, Twitter), and other websites," the guidance is intended to help courts develop or revise their respective policies on "cellular phones (including smartphones), personal digital assistants (BlackBerrys, iPhones, Palm Pilots), laptop computers (including iPads), earpiece devices (such as Bluetooth), and digital or other types of video cameras or audio recorders."

Although federal courts are allowed to "decide on a courthouse-by-courthouse basis" what devices are permissible, the guidance stipulates that the public be given ample notice of the policies, such as signs outside the courthouse and at security posts, and prominent placement on court Websites and in notices provided to attorneys and jurors. The guidance focuses on issues raised by the devices, including security risks, considerations favoring entry or restrictions on entry, types of rules adopted by courts, and the media's possession and use of these devices in the courtroom. *See U.S. Court News,* March 23, 2011.

UPCOMING CONFERENCES AND SEMINARS

ACI, Chicago, Illinois – April 27-28, 2011 – "Reducing the Legal Risks in the Sales and Marketing of Medical Devices: Fortifying Domestic and International Fraud and Abuse Compliance Efforts in the Face of Increasing Scrutiny." Shook, Hardy & Bacon Government Enforcement & Compliance Practice Co-Chair **Carol Poindexter** will conduct a half-day "master class" that will focus on region-specific compliance strategies and best practices in "high-risk emerging markets," such as Latin America, China and India.

DRI, Chicago, Illinois – May 5-6, 2011 – "Drug and Medical Device Seminar." Co-sponsored by Shook, Hardy & Bacon, this 27th annual CLE program will include a presentation by Pharmaceutical & Medical Device Litigation Partner Matthew Keenan, who will discuss "Rambo vs. Atticus Finch: Ethical Consideration and the Preservation of Professionalism in Drug and Medical Device Litigation."

Advanced Medical Technology Association, London, England – May 18-20, 2011 – "2011 International Medical Device Industry Compliance Conference." Shook, Hardy & Bacon Government Enforcement & Compliance Partner Nate Muyskens is scheduled to moderate a panel discussion on "Best Practices in Distributor Risk Management: Pre-Contract Diligence, Training, Auditing and Monitoring." Organized by medical device industry leaders, the conference will feature an array of panel discussions with distinguished speakers from around the world. Shook, Hardy & Bacon is a conference co-sponsor. ■

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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).