Shook, Hardy & Bacon L.L.P.

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PRODUCT LIABILITY LITIGATION REPORT

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LAW FIRM NEWS

McDonough to Discuss Crisis Communication Issues During PCPC Conference

Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Chair **Madeleine McDonough** will join a distinguished faculty in Montreal, Canada, May 22-24, 2013, to discuss crisis communications and reputation management issues during the Personal Care Products Council's (PCPC's) "**2013 Legal and Regulatory Conference**." The firm is a conference co-sponsor.

Newstead Authors Article on EU's System for Reporting Unsafe Products

Shook, Hardy & Bacon Global Product Liability Partner **Alison Newstead** has authored an **article** titled "Unsafe products: identifying risks and notifying the relevant authorities" appearing in the April 2013 issue of *The In-House Lawyer*.Newstead discusses the obligations of businesses and regulatory authorities once a non-food consumer or professional product is deemed a "serious" risk and how that information is disseminated throughout the European Union (EU) via the RAPEX system. Established under Article 12 of the General Product Safety Directive, 2001/95/EC, the RAPEX system was designed to "ensure that information about dangerous products found in one member state was rapidly circulated to other members states and the European Commission." The article explains how it works and how the commission distinguishes between serious and non-serious product risks. Newstead concludes by advising product manufacturers to understand "how to evaluate the risks that a product may pose. The seriousness of the risk directly affects how information about the problem will be disseminated throughout the EU."

CASE NOTES

Fourth Circuit Addresses Taxable ESI Production Costs in Deceptive Trade Practices Suit

The Fourth Circuit Court of Appeals has determined that E. & J. Gallo Winery, Inc., the prevailing party in deceptive trade practices litigation filed by North Carolina wine wholesaler The Country Vintner, was entitled to receive only a small fraction of its costs arising from the production of electronically stored information (ESI) under the

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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federal taxation-of-costs statute, 28 U.S.C. § 1920(4). ***The Country Vintner of N.C., LLC v. E. & J. Gallo Winery, Inc.*, No. 12-2074 (4th Cir., decided April 29, 2013)**.

After the trial court granted its pre-trial motions, Gallo sought more than $100,000 in discovery-related costs for (i) "flattening" and "indexing" ESI, (ii) "searching/review set/data extraction," (iii) "TIFF production" and "PDF production," (iv) electronic "Bates numbering," (v) copying images onto a CD or DVD, and (vi) "management of the processing of electronic data,""quality assurance procedures,""analyzing corrupt documents and other errors," and "preparing the production of documents to opposing counsel." Citing Third Circuit precedent, the trial court allowed recovery of about $200 for "TIFF Production,""PDF Production" and "CD Copy" only. Gallo filed an appeal.

The Fourth Circuit provided an overview of § 1920(4), following its development from 1853 to the most recent version adopted in 2008. The court rejected Country Vintner's argument that the statute applies "only to the costs related to materials attached to dispositive motions or produced at trial," finding that the circuits in which the issue has been considered allow the taxing of the costs of copies in discovery. Emphasizing that "taxable costs are a fraction of the non-taxable expenses borne by litigants for attorneys, experts, consultants, and investigators," the court also rejected Gallo's argument that its ESI processing charges constitute the "costs of making copies … necessarily obtained for use in the case." In this regard, the court was also persuaded by the Third Circuit precedent.

Regarding Gallo's argument that ESI processing charges are taxable as "fees for exemplification," the court noted a circuit split on the matter, but determined it need not interpret this part of § 1920(4), because the processing would not constitute "exemplification" under any interpretation. Thus the court affirmed the lower court's determination that "only the conversion of native files to TIFF and PDF formats, and the transfer of files onto CDs, constituted 'making copies' under § 1920(4)."

Prop. 65 Suit Claims Failure to Warn About DEHP and Lead in Electronics Products

A public interest organization has filed a complaint under California's Proposition 65 (Prop. 65), the Safe Drinking Water and Toxic Enforcement Act of 1986, against manufacturers, distributors and retailers of electronics and other products allegedly containing diethyl hexyl phthalate (DEHP) or lead and sold without providing the consumer warnings required under the law. *Consumer Advocacy Group, Inc. v. Argento SC by Sicura, Inc.*, No. BC506624 (Cal. Super. Ct., Los Angeles Cnty., Cent. Dist., filed April 26, 2013). Companies must provide "clear and reasonable" warnings before exposing consumers to chemicals known to the state to cause cancer or reproductive toxicity. According to the complaint, both DEHP and lead, as such chemicals, have been added to the Prop. 65 list.

The products at issue include the Iwave™ Neptune 2.0 Speaker System; iWave™ OHM + Stereo Headphone; "Portable Design""Air compressor 12 V 300 PSI""Mammoth™ Precision Tools"; TKO® jump ropes; and iWAVE® Laptop Combination Lock, Resettable

Four-Digit, Coil Cable Lock, CLO 003. The plaintiff seeks an order requiring compliance with Prop. 65, civil penalties of up to $2,500 per day per individual exposure, attorney's fees, and costs.

Manufacturer Sues over Contractor's Failure to Dispose of Unusable Tampons

Kimberly-Clark has reportedly filed a Racketeer Influenced and Corrupt Organizations Act (RICO) lawsuit against the recycling company it hired to dispose of more than 1 million tampons that failed to meet Kimberly-Clark's specifications and quality standards, alleging that the recycler fraudulently diverted the products to the "grey market" where they were offered for sale on resellers' Websites. *Kimberly-Clark Global Sales LLC v. Balcones Recycling Inc.*, No. 13-262 (U.S. Dist. Ct., E.D. Ark., filed April 30, 2013).

According to a news source, the materials that Kimberly-Clark provided to Balcones were intended to be recycled into fuel cubes, and Balcones assured the tampon maker that all of the products had been destroyed by means of secure disposal methods. Kimberly-Clark apparently discovered instead that "defendant Balcones facilitated and/or enabled the Doe defendants to sell the tampons to unknowing consumer[s] on the grey market, including over the Internet … [and thus] engaged in a pattern of fraudulent conduct" that defrauded both Kimberly-Clark and consumers "who believed they were purchasing Kotex products that met Kimberly-Clark's demanding safety standards." The company claims that it began purchasing cases of the tampons once it learned of the improper Internet sales to remove them from the market. It seeks at least $2.4 million in actual damages, as well as punitive damages for RICO violations, fraud, breach of contract, and deceptive trade practices. *See Courthouse News Service*, May 2, 2013.

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ALL THINGS LEGISLATIVE AND REGULATORY

ALJ Rules Commission May Add Buckyballs® Maker CEO to Suit

Applying the responsible corporate officer doctrine articulated in *United States v. Dotterweich*, 320 U.S. 277 (1943) and *United States v. Park*, 421 U.S. 658 (1975), an administrative law judge (ALJ) has determined that the Consumer Product Safety Commission (CPSC) may amend its complaint against Maxfield & Oberton Holdings, LLC, the now-defunct company that made high-power magnetic desk toys alleged to be hazardous, by adding its CEO Craig Zucker as a respondent. *In re Maxfield & Oberton Holdings, LLC*, CPSC Nos. 12-1, -2, -3 (C.P.S.C., decided May 3, 2013).

According to the ALJ, courts have continued to apply the doctrine to statutes involving public health, safety and welfare since *Dotterweich* and *Parks* were decided. It allows liability against an individual if it is shown that "the person sought

to be held liable actually participated in the liability-creating conduct." "Here," states the ALJ, "CPSC has alleged Mr. Zucker was responsible for ensuring Maxfield's compliance with applicable statutes and regulations. CPSC has further alleged Mr. Zucker personally controlled the acts and practices of Maxfield, including the importation of Buckyballs and Buckycubes. The Commission did not allege that by virtue of his corporate position Mr. Zucker was automatically liable; on the contrary, CPSC specifically alleged that he assumed responsibility." The ALJ also allowed the agency to add another to product, Neoballs, to its complaint against Zen Magnets, LLC, finding that this would not unduly broaden the issues in the proceeding or cause undue delay.

CPSC Seeks Comments on Injury Information Collection system

The Consumer Product Safety Commission (CPSC) has **requested** comments on its time and cost burden estimates for a continued collection of information from "persons who have been involved in or have witnessed incidents associated with consumer products." Under the Consumer Product Safety Act, CPSC is required to collect information "related to the causes and prevention of death, injury, and illness associated with consumer products." It gathers this information from numerous sources, including its Website, and a surveillance system known as the National Electronic Injury Surveillance System, which is based on "a statistically valid sample from approximately 100 hospital emergency departments." The agency also actively investigates cases of interest with face-to-face interviews and on-site visits. Comments on the burdens associated with this information collection activity—$3.3 million and 160 commission staff months each year—must be submitted by July 8, 2013. *See Federal Register*, May 7, 2013.

Williams-Sonoma Agrees to Penalty for Failure to Report Defective Product

The Consumer Product Safety Commission (CPSC) has provisionally accepted an agreement with Williams-Sonoma, Inc. requiring that the company pay a nearly $1 million civil penalty for failing to report immediately "a defect involving Pottery Barn wooden hammock stands." The company, which neither admits nor denies CPSC's allegations, has also apparently agreed to "maintain and enforce a system of internal controls and procedures" ensuring that it will comply with its reporting obligations.

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The product at issue was sold nationwide for about five years; CPSC staff alleged that the stands could deteriorate and break when used over time outdoors. Williams-Sonoma first filed its full report to the commission in September 2008 despite apparently knowing for some time about numerous incidents involving the hammocks, "including 12 reports of injuries requiring medical attention for lacerations, neck and back pain, bruising, and one incident involving fractured ribs." *See CPSC New Release*, May 6, 2013.

Commissioners Approve Amended Rule on Certificates of Compliance

The Consumer Product Safety Commission (CPSC) has reportedly approved a proposed rule that would amend the existing regulation on certificates of compliance at 16 C.F.R. part 1110. According to CPSC, the proposed amendment seeks "to update the rule to clarify requirements in light of new regulations on testing and labeling pertaining to product certification, and component part testing."

To that end, the proposed amendment would, among other things, (i) "use newly defined terms such as 'finished product certificate' and 'component part certificate'"; (ii) require that regulated, privately labeled finished products be certified by the private labeler for products manufactured in the United States; (iii) "clarify requirements for the form, content, and availability of certificates of compliance"; and (iv) "require that importers of regulated finished products manufactured outside of the United States file the required certificate electronically with U.S. Customs and Border Protection (CBP) at the time of filing the CBP entry or at the time of filing the entry and entry summary, if both are filed together."

According to a news source, additional changes included in an amendment proposed by Commissioner Robert Adler were also adopted during the May 1, 2013, meeting. These changes include (i) "language intended to clarify that replacement parts can be finished products"; (ii) "the inclusion of additional requests for comments"; and (iii) "the addition of a chart to clarify which CSPC bans require compliance certification under the 1110 rule and which do not." *See Draft Record of Commission Action*, May 1, 2013; *Bloomberg BNA Product Safety & Liability Reporter,* May 3, 2013.

Debate over Review of CHAPS Phthalates Report Continues

After Consumer Product Safety Commission (CPSC) Chair Inez Tenenbaum announced that the Chronic Hazard Advisory Panel on Phthalates and Phthalate Substitutes (CHAP) would submit its draft final report to scientific peer reviewers nominated by the National Academy of Sciences, a number of stakeholders continued to debate whether it should instead undergo a public scientific peer review process.

A coalition of groups, including the American Academy of Pediatrics, Consumers Union, Natural Resources Defense Council, and Union of Concerned Scientists submitted a letter to the acting director of the Office of Management and Budget (OMB), asking OMB to reject a call by chemical industry interests to require CPSC to subject the CHAP process to OMB's Final Information Quality Bulletin for Peer Review. According to the groups' April 23, 2013, letter, this process is neither applicable nor consistent with congressional intent under the Consumer Product Safety Improvement Act, which evidently does not contemplate further review of the CHAP report. The letter's signatories were apparently concerned about expediting the completion of CHAP's review.

Voicing concerns about U.S. jobs, Rep. Adam Kinzinger (R-Ill.) claimed in an April 24 blog comment posted on *The Hill* that CPSC "is breaking the rules by refusing to allow its [phthalates] findings to be reviewed in an open process. Instead, the Commission is relying on a closed-door panel to conduct the analysis and make recommendations to the Commission." Kinzinger also complained that CPSC is "marching ahead with new rules without review or comment by those who will be affected by it." Kinzinger contends that $10 billion to $15 billion and 30,000 to 40,000 jobs are at stake.

FDA Proposes Pilot Program to Test Automated Form for NDA Submissions

The Food and Drug Administration (FDA) has **announced** a pilot program "to test an XML (extensible markup language)-enabled Adobe PDF form, Form FDA 3331—Automated to submit new drug application (NDA) and abbreviated new drug application (ANDA) Field Alert Reports (FARs)." According to its May 2, 2013, *Federal Register* notice, FDA ultimately seeks to improve efficiency by allowing "participants [to send] FAR reports simultaneously to the selected FDA district office and to CDER's [Center for Drug Evaluation and Research's] Office of Compliance." FDA said that participation in the pilot program is voluntary and "no additional software or licenses are needed to use the proposed Form FDA 3331—Automated." The agency intends for the program to run between May 1, 2013, and January 1, 2014, and, if it is successful, will "seek to adopt a more permanent, required reporting system."

Maryland Governor Signs Ban on Flame Retardant in Children's Products

Maryland Gov. Martin O'Malley (D) has signed H.B. 99, a bill that, as of October 1, 2013, will prohibit the import or sale of any child care product that contains more than one-tenth of 1 percent of certain flame-retardant chemicals, identified at TCEP (tris (2-choroethyl) phosphate). Additional details about the legislation appear in the April 11, 2013, **Issue** of this *Report*. Child care products are defined as consumer products intended for use by a child younger than age 3, "including a baby product, toy, car seat, nursing pillow, crib mattress, and stroller." The state's health secretary may suspend implementation of the ban, if "the fire safety benefits of TCEP are greater than the health risks associated with TCEP." The Department of Health has until January 1, 2014, to adopt implementing regulations.

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LEGAL LITERATURE REVIEW

Lee Epstein, William Landes & Richard Posner, "How Business Fares in the Supreme Court," *Minnesota Law Review*, 2013

Law professors and Seventh Circuit Court of Appeals Judge Richard Posner explore in this article U.S. Supreme Court decisions since the 1940s involving a business entity on just one side of the case. According to the authors, "Whether measured

by decisions or Justices' votes, a plunge in warmth toward business during the 1960s (the heyday of the Warren Court) was quickly reversed; and the Roberts Court is much friendlier to business than either the Burger or Rehnquist Courts, which preceded it, were. The Court is taking more cases in which the business litigant lost in the lower court and reversing more of these—giving rise to the paradox that a decision in which certiorari is granted when the lower court decision was anti-business is more likely to be reversed than one in which the lower court decision was pro-business. The Roberts Court also has affirmed more cases in which business is the respondent than its predecessor Courts did." The authors further found that "five of the ten Justices who, over the span of our study (the 1946 through 2011 Terms), have been the most favorable to business are currently serving, with two of them ranking at the very top among the thirty-six Justices in our study."

LAW BLOG ROUNDUP

A Hot Topic in Aggregate Litigation: *Parens Patriae* Suits

"[A]ccess to justice in a mass society is the central civil-justice issue of our day. Individual litigation of mass-injury claims is a luxury that neither litigants nor the court system can typically afford. Class actions are shriveling as a realistic alternative in many instances. Non-class aggregate litigation is infected with its own problems, as the ALI's recent *Principles of the Law of Aggregation* shows. And contracts of adhesion increasingly shunt victims into individual arbitration processes that provide little realistic opportunity for relief—and no opportunity for judicial resolution." Notre Dame Law School Professor Jay Tidmarsh, blogging about recent legal scholarship on "the *parens patriae* action, which has emerged as the newest academic darling with the potential to provide victims of mass injury a measure of justice." Tidmarsh also discusses its potential drawbacks.

Individual litigation of mass-injury claims is a luxury that neither litigants nor the court system can typically afford.

Jotwell: Courts Law, May 1, 2013.

THE FINAL WORD

Business Interests Continue Winning Streak Before U.S. Supreme Court

U.S. Supreme Court watchers have opined that its tilt toward business interests is unmistakable. Writing for *The New York Times*, Adam Liptak cites the *Minnesota Law Review* article summarized elsewhere in this *Report* as compelling evidence that "the Roberts court is unusually friendly to business." Liptak also quotes University of California, Irvine, Dean Erwin Chemerinsky, who said, "The Roberts court is the most pro-business court since the mid-1930s. I think this helps understand it far more than traditional liberal and conservative labels." Examining amicus briefs supporting petitions seeking U.S. Supreme Court review during a three-year period, a Justice

Department lawyer reportedly found that "pro-business and anti-regulatory groups accounted for more than three-quarters of the top 16 filers. 'My data indicate that, as the court shapes its docket, it hears conservative voices far more often than liberal ones, and the disparity is growing.'"

Writing for the Constitutional Accountability Center, Founder Doug Kendall and Counsel Tom Donnelly underscored the latter point in the Center's annual assessment of the U.S. Chamber of Commerce's overall success before the high court. According to their May 1 article, "Not so Risky Business: The Chamber of Commerce's Quiet Success Before the Roberts Court—An Early Report for 2012-2013," during the past 30 years, "the Chamber's participation rate has increased six-fold, from 4% in the early 1980s to 24% today. This dramatic increase in participation is a reflection, in part, of the Chamber's success in shaping the Court's docket." Apparently, "since John Roberts took over as Chief Justice and Justice Samuel Alito succeeded Justice Sandra Day O'Connor, the Chamber has prevailed in 69% of its cases overall (66 of 95 cases from 2006-2013)." The article also explores key pro-business decisions from this term and notes that several disputes involving business interests are still pending. *See The New York Times*, May 4, 2013.

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UPCOMING CONFERENCES AND SEMINARS

DRI, New York, New York – May 16-17, 2013 – "29th Annual Drug and Medical Device Seminar." Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner Scott Sayler will deliver opening remarks in his role as current chair of DRI's Drug and Medical Device Committee. Co-sponsored by SHB, the event will feature presentations by judges, in-house and outside counsel, and other professionals on cutting-edge topics such as (i) "How to use your advocacy skills to persuade the toughest audience," (ii) "The latest on consolidated drug and device proceedings in Philadelphia," (iii) "What jurors are thinking about the FDA," (iv) "How to help a jury understand a state-of-the-art case," (v) "The latest on 'judicial hellholes,'" (vi) "How to try a multiple-plaintiff pharmaceutical case," and (vii) "How to take the 'junk' out of junk science."

ACI, New York City – June 5-7, 2013 – "4th Annual Advanced Forum on Biosimilars." Shook, Hardy & Bacon Life Sciences & Biotechnology Partner John Garretson will participate in a panel discussion on "Preparing for the Impending Reality of Biosimilars Patent Litigation: Immediate Action Plans for the First Wave," during this event. Garretson joins a distinguished faculty including in-house counsel for major pharmaceutical companies focusing on biosimilar IP, regulatory, commercial, and policy issues. Shook, Hardy & Bacon is a conference co-sponsor.

ACI, Chicago, Illinois – June 26-27, 2013 – "Consumer Products Regulation & Litigation." Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner Harley Ratliff will join a panel of speakers discussing "Total Recalls: Counsel Perspective on

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Processes for Streamlining the Response to Product Issues and Effectively Working with the CPSC." Designed to provide consumer product manufacturers with a "safety net" in balancing regulatory compliance and litigation risks, this conference brings together a distinguished faculty of judges, regulators and in-house and outside counsel "to give consumer products professionals the most up-to-date, expert tested advice possible on navigating this terse terrain."

DRI, Washington, D.C. – July 25-26, 2013 – "2013 DRI Class Actions Conference." Shook, Hardy & Bacon Class Actions & Complex Litigation Partners Tim Congrove and Jim Muehlberger will participate in this event. Congrove, who is also serving as program vice-chair, will moderate a panel of distinguished in-house counsel discussing "Inside and Out: A Wide-Ranging Discussion of Class Actions from the Client's Perspective." Muehlberger "will discuss the current state of issue classes, techniques for addressing them, and his experience in trying a case involving a Rule 23(c)(4) class" during a presentation titled "Making an Issue Out of It: The Trial of a 23(c)(4) Class." SHB 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 95 percent of our more than 440 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).