IADC Committee Newsletter

DRUG, DEVICE AND BIOTECHNOLOGY

August 2013

IN THIS ISSUE

This month Brigid Carpenter and Ceejaye Peters review two recent decisions, one from the United States Supreme Court and one from the Sixth Circuit Court of Appeals, which will likely impact committee members' practice areas.

What you Need to Know about *Bartlett* and *In Re: Whirlpool Corp.*: Two Important Decisions that May Affect Your Practice

ABOUT THE AUTHORS

Brigid M. Carpenter is a shareholder in the Nashville office of Baker, Donelson, Bearman, Caldwell & Berkowitz, P.C., where she focuses on product liability defense, including defense of drug and device manufacturers, and complex commercial litigation. Ms. Carpenter is active in the Drug, Device and Biotechnology and Product Liability Committees of the IADC and currently serves as vice chair of newsletters for the DDB committee. She can be reached at bcarpenter@bakerdonelson.com.

Ceejaye S. Peters is an associate in the Jackson, Mississippi office of Baker, Donelson, Bearman, Caldwell & Berkowitz, P.C. Her main practice areas include defense of drug and device product liability cases, as well as environmental and mass tort litigation involving asbestos, benzene and dioxin exposure. She can be reached at cpeters@bakerdonelson.com.

ABOUT THE COMMITTEE

The Drug, Device and Biotechnology Committee serves as an educational and networking resource for in-house counsel employed by pharmaceutical, medical device and biotech manufacturers and the outside counsel who serve those companies. The Committee is active in sponsoring major CLE programs at the Annual and Midyear Meetings as well as internal committee programs. The Committee also publishes a monthly newsletter that addresses recent developments and normally contributes two or more articles to the *Defense Counsel Journal* annually. In the future, the Drug, Device and Biotechnology Committee will be focusing on increasing its use of technology to make it an even more valuable resource for its members.

Learn more about the Committee at www.iadclaw.org. To contribute a newsletter article, contact:

Brigid M. Carpenter
Vice Chair of Newsletters
Baker, Donelson, Bearman, Caldwell & Berkowitz, PC
(615) 726-7341
bcarpenter@bakerdonelson.com

Drug Device and Biotechnology Committee "Leadership Spotlight"

Joe Cohen
Vice-Chair of Membership Recruitment

Joe Cohen is a partner in the litigation practice group of Porter Hedges LLP in Houston, Texas. His practice focuses on handling catastrophic injury and wrongful death cases arising from allegations of products liability (including pharmaceutical products), exposure to chemicals and asbestos, and general negligence. He also provides individual representation to employees (current and former) of pharmaceutical and medical device manufacturers in both civil and criminal contexts.

Joe has tried cases to jury verdict as both first and second chair counsel and has engaged in an extensive motion practice that has included complex summary judgment issues and intricate challenges to experts in a variety of disciplines. He has handled matters in almost 30 states across the country and in multiple counties throughout the state of Texas.

For IADC's Drug Device and Biotechnology Committee, Joe is currently the Vice-Chair of Membership Recruitment. Our committee is interested in nominating practitioners in our practice area for IADC membership. If you are aware of a potential candidate for membership, please contact Joe at (713) 226 6628 or jcohen@porterhedges.com or complete the nomination process using the forms on IADC's website.

Now, on to our monthly article.

The United States Supreme Court and Sixth Circuit Court of Appeals were busy over the early summer, issuing decisions that members of this committee likely will find applicable to their practice areas. This article summarizes those decisions, one of which defense attorneys will consider helpful and one…well, not so much.

Mutual Pharmaceutical Co. Inc. v. Bartlett

In a 5-4 decision issued June 24, the United States Supreme Court gave generic drug manufacturers another victory when it held that state law design defect claims against such manufacturers are preempted by federal law when the claim hinges on the adequacy of the drug's warning. In *Mutual Pharmaceutical Co. Inc. v. Bartlett*, No. 12-142, (U.S. June 24, 2013), 570 U.S. ___ (2013), the plaintiff argued at trial that the maker of sulindac (a generic form of the nonsteroidal anti-inflammatory drug Clinoril) was liable on a defective design theory because the drug "was unreasonably dangerous and had an inadequate warning." Finding that it would have been impossible for the manufacturer to have complied with both the FDA's regulations promulgated under the Hatch-Waxman Amendments and state tort law duties, the Court reversed the First Circuit's decision affirming a $21 million verdict in favor of the plaintiff based on the premise that the defendant manufacturer could have complied with both federal and state law by choosing not to make the drug.

Because generic drugs must be chemically equivalent and bioequivalent to the brand-name drug and utilize warning labels that are the same as the brand-name's, generic manufacturers are "prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients or in the specifications provided in the approved application'" and they are "prohibited from making any unilateral changes to a drug's label." *Bartlett*, Slip op. at 3-4. To satisfy their duty to provide products that are not "unreasonably dangerous" under New Hampshire law, however, manufacturers must either change the drug's design or its labeling. *Id.* at 9-11. According to the Court, because redesigning sulindac was not possible under the FDCA and because of the drug's simple composition, "New Hampshire's design-defect cause of action imposed a duty on [the defendant] to strengthen sulindac's warnings." *Id.* at 10-11. And, as the Court held in its decision in *PLIVA v. Mensing*, 113 S. Ct. 2567 (2011), "federal law prevents generic drug manufacturers from changing their labels." *Id.* at 13. Federal law thus prohibited the manufacturer of sulindac from taking the action required by New Hampshire law, and the plaintiff's state law design defect claims based on the adequacy of the drug's warnings were preempted. *Id.*

The Court rejected the First Circuit's reasoning that it was not "impossible" for the manufacturer of sulindac to comply with federal and state law because it could have simply stopped selling the drug. *Id.* at 14-16. Indeed, the Court recognized that the adoption of the "stop-selling" theory would mean that *PLIVA* as well as most other cases involving impossibility preemption were wrongly decided. *Id.* at 16.

In a nod to the grave nature of many plaintiffs' injuries in pharmaceutical cases, the Court acknowledged the "passionate responses" engendered from such injuries, but stated that "sympathy for [the plaintiff] does

not relieve [the Court] of the responsibility of following the law." *Id.* at 17.

The *Bartlett* decision further shores up generic manufacturers' preemption defenses and reiterates that, under *PLIVA*, a manufacturer is not required to cease operating altogether in order to comply with federal and state law obligations and avoid liability.

In re: Whirlpool Corp. Front-Loading Washer Products Liability Litigation

Although not a case involving a pharmaceutical or medical device product, the *In re: Whirlpool Corp.* case could have a significant impact on consumer-driven economic-injury only cases in those practice areas. In the opinion issued by the Sixth Circuit on July 18, the court affirmed for the second time certification of a class of plaintiffs claiming that front-loading washers foster mold and mildew growth, leading to a laundry basket full of ruined handkerchiefs and boxer shorts. *In re: Whirlpool Corp. Front-Loading Washer Products Liability Litigation*, No. 10-4188 (6th Cir. July 18, 2013). The Sixth Circuit did so despite the fact that the United States Supreme Court reversed the Circuit's earlier affirmance and directed it to reconsider the issues pursuant to the high Court's decision in *Comcast Corp. v. Behrend*, 133 S. Ct. 1426 (2013). *Whirlpool Corp. v. Glazer*, 133 S. Ct. 1722 (2013).

The district court in this case had certified a class as to all issues of liability on the plaintiffs' claims for tortious breach of warranty, negligent design, and negligent failure to warn. Slip op. at 10. Significantly, damages determinations were not subject to the class certification. *Id.* at 27. In its opinion on remand, the Sixth Circuit first rejected Whirlpool's request to remand the case to the district court for a determination of class certification, based on a finding that the Supreme Court's decision was not a finding in Whirlpool's favor on the merits. *Id.* at 3-5. The court then launched into an analysis of whether Rule 23 prerequisites were met by the district court's decision, particularly in light of *Comcast* and another United States Supreme Court decision, *Amgen Inc. v. Conn. Retirement Plans & Trust Funds*, 133 S. Ct. 1884 (2013).

On the issue of commonality, one which frequently trips up plaintiffs in putative tort class actions, the Sixth Circuit found that the claims for tortious breach of warranty and negligent design rise or fall on whether a design defect causes mold or mildew to develop in the washers, and that the negligent failure to warn claim depends upon whether Whirlpool had a duty to warn consumers about the propensity for mold growth in the washers and breached that duty. Slip. op. at 17. After recounting some of the plaintiff's evidence in the record on the design issue, the court found that "proof in this case will produce a common answer about whether the alleged design defects in the [washers] proximately caused mold or mildew to grow in the machines. Common proof will advance the litigation by resolving this issue 'in one stroke' for all members of the class." *Id.* at 19.

Despite Whirlpool's contention otherwise, the court also found that all washer owners – even those with no complaints about the washers and no evident mold growth – were properly included in the class. "If defective design is ultimately proved, all class members have experienced injury as a result of the decreased value of the product purchased." *Id.* at 21. The court went to find that, under the negligent failure to warn theory, "the plaintiffs need not prove that mold manifested

in every [washer] owned by class members because the injury to all [washer] owners occurred when Whirlpool failed to disclose the [washers'] propensity to develop biofilm and mold growth." *Id*. at 21-22.

Finally, the Sixth Circuit held that the *Comcast* decision, which the Supreme Court had specifically directed it to review and apply, was distinguishable because in *Comcast* the court had certified a class to determine both liability and damages. *Id*. at 27. "Where determinations on liability and damages have been bifurcated . . . the decision in *Comcast* – to reject certification of a liability and damages class because plaintiffs failed to establish that damages could be measured on a classwide basis – has limited application." *Id*.

Perhaps the most unsettling aspect of the Sixth Circuit's re-affirmance of class certification in *Whirlpool* is its readiness to include in the class those consumers who purchased a product, used the product, and had no complaints about the product. Under this theory, a purchaser of an over-the-counter remedy who believes that the remedy is improving her health could then be included in a class of "injured plaintiffs" because other purchasers have decided that the remedy is not effective and is thereby less valuable than the purchase price. It will certainly be interesting to see whether Whirlpool again seeks review of the Sixth Circuit (defense lawyers must agree the odds are good), and whether the United States Supreme Court agrees to take another look.

PAST COMMITTEE NEWSLETTERS

Visit the Committee's newsletter archive online at www.iadclaw.org to read other articles published by the Committee. Prior articles include:

JUNE 2013
THE SUNSHINE ACT: Managing the Glare from Increased Reporting Requirements
Gail Rodgers and Teri H. Peeples

MAY 2013
A New Argument against Preemption under Mensing: The Different Manufacturers Exception
Kara Stubbs and Caroline Tinsley

FEBRUARY 2013
What Do California, Vermont … and Alabama Have In Common?: Innovator-Liability for Brand-Name Prescription Drug Manufacturers
Chris Berdy and Ashley Nader Stubbs

Lessons Learned from a Landmark Denial of Certification in Canada: Martin v. Astrazeneca
Steven F. Rosenhek

DECEMBER 2012
Reliability and Admissibility of Forensic Toxicology Testing in Civil Cases
Mollie Benedict and Tariq M. Naeem

NOVEMBER 2012
Ex Parte Communications with Healthcare Providers in Pharmaceutical Mass Torts – Highlights of Recent Rulings
Lela Hollabaugh

OCTOBER 2012
New Jersey Supreme Court Provides a Mixed Result in a Medical Device Preemption Decision
Kenneth R. Meyer and Brian P. Sharkey

SEPTEMBER 2012
California Limits Liability in Product Cases
Reg Reilly and Rebecca Wardell

AUGUST 2012
Nationwide Flux: Mensing's Impact on State Tort Claim Pre-emption & Generic Pharmaceuticals
Debra M. Perry and Sara F. Merin