Merck Wins Partial Victory in Vioxx Litigation

NJ Appellate Division Reverses Punitive Damages Award, But Expands Exception to State PLA’s Presumption of Adequacy

The New Jersey Appellate Division has reversed a jury award of punitive damages against pharmaceutical manufacturer Merck & Co., Inc., for its marketing of the pain reliever Vioxx, holding that federal laws partially preempt the New Jersey Product Liability Act (PLA). *McDarby v. Merck & Co., Inc.*, A-0076-07T1 (App. Div. May 29, 2008). At the same time, however, the Court held that Merck’s “economically-driven manipulation of the post-market regulatory process” warranted an expansion of the exception to the PLA’s presumption of adequacy where the FDA has approved the warning label for a drug. Under the Court’s decision, a drug manufacturer can be held liable for compensatory damages even absent a showing that it deliberately concealed material information about the risks of using its drug.

Merck marketed a cyclooxygenase-2 (COX-2) inhibitor called rofecoxib, under the trade name Vioxx. Merck marketed Vioxx as a pain reliever for symptoms of osteoarthritis and management of acute pain, with fewer concerns of associated gastrointestinal toxicity than other types of pain relievers.

Prior to its entry on the market, Vioxx had undergone an array of trials in order to obtain federal Food and Drug Administration (FDA) approval. During the course of these trials, questions were raised regarding a potential increase in the risk of cardiovascular and thromboembolic events, such as heart attacks, in patients taking Vioxx, but the data were generally viewed as inconclusive. The FDA approved Vioxx in May 1999, and the labeling which the FDA required did not contain any warnings or precautions regarding possible cardiovascular risks.

Meanwhile, beginning in mid-1998, Merck had launched a large-scale study of the efficacy of Vioxx on patients with rheumatoid arthritis, named the Vioxx Gastrointestinal Outcomes Research study (VIGOR). In March 2000, the VIGOR study confirmed that Vioxx had a comparable efficacy with its competitor naproxen, but with significantly fewer adverse gastrointestinal events. However, the data also demonstrated a significant increase in the incidence of non-acute myocardial infarctions in patients taking Vioxx.

Merck reported the results of the VIGOR study to the FDA in March 2000, and simultaneously issued a news release which stressed the gastrointestinal safety of Vioxx. Although it noted the relative incidence of
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Following the VIGOR study, Merck submitted a supplemental new drug application to the FDA in June 2000, to add the results of the VIGOR study to the Vioxx label. Throughout the process, the McDarby Court found that Merck sought to de-emphasize the concerns of cardiovascular risk in the revised labeling. The McDarby Court also found that Merck challenged several articles in medical journals which suggested that Vioxx increased the risk of adverse cardiovascular events, and trained its sales personnel to stress the positive gastrointestinal aspects of the drug in marketing it to physicians.

The revised label was approved in April 2002, and as explained by the McDarby Court, while the label did set forth details regarding the cardiovascular data of the VIGOR study, “Merck successfully obtained the FDA’s consent to use of a revised label that contained no mention of cardiovascular risks in the ‘Warnings’ section, but instead, contained a ‘Precaution’ that limited use of Vioxx only among patients ‘with a medical history of ischemic heart disease’—patients whose already-diagnosed coronary artery disease was symptomatic.” Merck continued to market Vioxx under the new label until September 2004, when evidence of adverse cardiovascular effects in another study led Merck to withdraw the drug voluntarily from the market.

Plaintiff John McDarby had been prescribed Vioxx in March 2000—prior to FDA approval of the revised label but after the initial VIGOR results were known—to treat osteoarthritis in the hands and knee, and had taken it daily until suffering a heart attack in April 2004. He brought suit against Merck under the PLA and Consumer Fraud Act (CFA), alleging that Merck had failed to provide adequate warning of the drug’s cardiovascular risks. A jury awarded him $15.7 million in compensatory punitive damages and attorneys’ fees, and Merck appealed, arguing first that the federal Food Drug and Cosmetic Act (FDCA) preempted plaintiff’s challenges to the adequacy of the FDA-approved Vioxx labels, and second that the FDA’s approval of its label shielded it from attack by virtue of the PLA’s presumption of adequacy.

Federal Preemption of the NJ Product Liability Act

A unanimous appellate panel rejected Merck’s argument that plaintiff’s claim for compensatory damages was preempted by federal law. The Court held that plaintiff’s PLA claim did not conflict with federal regulations. To the contrary, plaintiff’s claim “is consistent with, and indeed relies upon, FDCA regulations that, at the time, required labeling to be revised ‘to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.’”

The Court agreed that federal law implicitly preempted the award of punitive damages under the PLA, however. The PLA generally precludes an award of punitive damages where a drug or medical device has been approved pre-market by the FDA, except “where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency’s regulations, which information was material and relevant to the harm in question.”

The Court relied on the different purposes of compensatory and punitive damages in its ruling. Compensatory damages merely replace the plaintiff’s losses, not punish the defendant. The Court held that the PLA’s punitive damages provision “is designed to effectuate the State’s interest in punishing unlawful conduct.” Because the Court stressed that a manufacturer would
be subject to such punishment only where it “knowingly withheld or misrepresented” material information which must be submitted to the FDA, the PLA’s punitive damage provision focused solely on fraud on the FDA. The Court held that the PLA punitive damages provision was essentially, an effort by the state to police a drug manufacturer’s dealings with the FDA. The court held that the punitive damages provision thus “impinge[s] upon federal statute and regulation” and was therefore preempted by the FDCA and its regulations.¹

The Presumption of Adequacy

Additionally, the Court addressed the scope of the PLA’s presumption of adequacy provisions. The PLA defines an adequate product warning as “one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, … in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.” Where a particular product warning is approved or prescribed by the FDA, the PLA creates a rebuttable presumption that the warning is “adequate” under the statute.

Relying on earlier New Jersey Supreme Court case law, Merck argued that this presumption of adequacy could be overcome only by a showing that it had deliberately concealed information of the cardiovascular risks revealed by the VIGOR study. The Court rejected this argument, finding that the record in this case warranted recognition of an additional basis for overcoming the presumption: economically-driven manipulation of the post-marketing regulation process. The Court reasoned that “flaws” in the FDA’s post-marketing oversight processes while Vioxx was on the market rendered the deliberate concealment exception to the presumption of adequacy “too narrow.” The Court noted evidence that “Merck actively, and to an extent successfully, sought to dilute the labeling required as a result of the VIGOR study” and that its marketing personnel “engaged in strenuous efforts to ensure that the results of the VIGOR study were not communicated to prescribing physicians by sales persons.” The Court held that this was evidence of Merck’s economically driven manipulation of the post-marketing regulation process that was sufficient to overcome the PLA’s presumption of adequacy.

The Court acknowledged that it was creating “a hitherto unrecognized legal basis for an award of compensatory damages under the PLA.” In doing so, the Court stressed its focus on what it termed “Merck’s economically-driven manipulation of the post-market regulatory process” and on “the dominant power of drug companies in a regulatory process that permitted, and indeed required, efforts to resolve scientific disputes through conciliatory processes.”

The McDarby decision represents only a partial victory for the pharmaceuticals industry in New Jersey, and simultaneously continues the state’s historical expansion of consumer protection law. While it affords pharmaceutical manufacturers protection from punitive damages under New Jersey’s Product Liability Act, it expands potential liability to a manufacturer whose drug label was approved by the FDA even where there is no showing of deliberate concealment of the drug’s risks, at least for drugs manufactured before the 2007 amendments to the FDCA.

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If you have any questions about McDarby v. Merck & Co., Inc., or similar issues, please contact Sheila A. Woolson in the Newark office, at (973) 639-8268 or swoolson@ebglaw.com. Michael J. Slocum, an Associate in the Newark office, assisted with the preparation of this Alert.

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¹ The Court also held that plaintiff’s Consumer Fraud claim was preempted by the PLA.