SUPERIOR COURT OF NEW JERSEY

CHAMBERS OF
JESSICA R. MAYER, J.S.C.

MIDDLESEX COUNTY COURT HOUSE
P.O. Box 964
NEW BRUNSWICK, NJ 08903-0964

NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE ON OPINIONS

Memorandum of Decision on Defendants' Motion for Partial Summary Judgment Dismissing Plaintiffs' Punitive Damage Claims

Skala v. Johnson & Johnson, et al., Docket No. MID-L-6820-06
Laissen v. Johnson & Johnson et al., Docket No. MID-L-6720-06
(In re: Risperdal®/Seroquel®/Zyprexa® Litigation, Case No. 274)

Defendants: Ken Wilbur, Esq., Drinker Biddle & Reath LLP

Plaintiffs: Robert Cowan, Esq., Bailey Perrin Bailey

Dated: November 18, 2011

BACKGROUND

Plaintiffs Gary Skala and Shon Laissen ("Plaintiffs") allege that they developed diabetes as a result of their ingestion of Risperdal®, a second generation antipsychotic approved by the United States Food and Drug Administration ("FDA"). See Plaintiffs' Brief in Opposition to Motion for Partial Summary Judgment ("Pls. Opp.") at 1-2. Plaintiffs contend that Defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc. ("Defendants") failed to warn of weight gain and diabetes associated with Risperdal® despite having knowledge of an association. Id. at 2. Plaintiffs assert causes of action under the New Jersey Products Liability Act ("NJPLA"), N.J.S.A. §§ 2A:58C-1 to -11. Ibid. Plaintiffs also seek punitive damages. Ibid.

Defendants filed a motion for partial summary judgment seeking dismissal of Plaintiffs' punitive damage claims. The parties agree that New Jersey law governs this issue. Id. at 1. On October 25, 2011, during the oral argument of other motions, counsel agreed to waive oral argument on this motion and consented to the court's disposition of the matter on the papers submitted.

Defendants premise the motion to dismiss Plaintiffs' punitive damage claims on the appellate court's decision in McDarby v. Merck & Co., Inc., 401 N.J. Super. 10 (App. Div. 2008). Relying on McDarby, Defendants argue that Plaintiffs' punitive damage claims are preempted by the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C.S. §§ 301 to 399. See Defendants' Brief in Support of the Motion for Partial Summary Judgment ("Defs. Br.") at 16. Plaintiffs respond that their claims are distinguishable from the claims preempted in McDarby. Plaintiffs contend that McDarby dealt solely with claims alleging fraud-on-the-FDA, whereas, Plaintiffs' punitive damage claims in this case are based on Defendants' alleged failure to warn doctors and consumers of potential adverse effects associated with Risperdal®. Pls. Opp. at 3.

Plaintiffs' interpretation of McDarby overlooks the threshold requirement for recovery of punitive damages under the NJPLA. Under the NJPLA, when the product is an FDA-approved pharmaceutical, fraud on the FDA must be shown to recover punitive damages. N.J.S.A. § 2A:58C-5c. Based upon this threshold requirement, the McDarby court held that a punitive damage claim in a pharmaceutical products liability suit is a claim premised on fraud-on-the-FDA, and thus preempted under the United States Supreme Court's decision in Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 121 S. Ct. 1012, 148 L. Ed.2d 854 (2001). See McDarby, supra, 401 N.J. Super. at 93-95.

In opposition to Defendants' motion, Plaintiffs also argue that the United States Supreme Court's decision in Wyeth v. Levine, 555 U.S. 555, 129 S. Ct. 1187, 173 L. Ed.2d 51 (2009), casts doubt on the validity of the McDarby decision. Pls. Opp. at 11-13. However, the Appellate Division's decision in McDarby remains controlling precedent in New Jersey. Thus, this court must dismiss Plaintiffs' claims for punitive damages.

ANALYSIS

SUMMARY JUDGEMENT STANDARD

A moving party is entitled to summary judgment "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact challenged and that the moving party is entitled to a judgment or order as a matter of law." Rule 4:46-2; see also Judson v. People's Bank and Trust Co. of Westfield, 17 N.J. 67, 73-75 (1954). In determining whether summary judgment is

precluded by the existence of a genuine issue of material fact, the court must consider whether the competent evidential materials presented, when viewed in the light most favorable to the non-moving party and examined under the evidentiary standards applicable at trial, are sufficient to permit a rational factfinder to resolve the alleged disputed issue in favor of the non-moving party. Brill v. Guardian Life Ins. Co., 142 N.J. 520, 540 (1995).

PUNITIVE DAMAGES UNDER McDARBY

In McDarby, the plaintiffs sought compensatory and punitive damages under the NJPLA alleging that defendant, the manufacturer of the FDA-regulated drug Vioxx®, failed "to provide both prescribing physicians and consumers with adequate and timely warning of the cardiovascular risks of this drug." See Brief on Behalf of Plaintiffs-Respondents John McDarby and Irma McDarby at 2, McDarby, supra, 401 N.J. Super. 10 (No. A-0076-07T1). Under the NJPLA, punitive damages may not be awarded in product liability suits if the drug received FDA approval. However, the law provides an exception where the "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. . . ." N.J.S.A. § 2A:58C-5c.

The McDarby trial judge concluded that the NJPLA's punitive damages remedy was not preempted by the FDCA, McDarby, supra, 401 N.J. Super at 87-88, and thus the jury considered, and ultimately awarded, punitive damages. See Brief on Behalf of Defendant-Appellant Merck and Co., Inc. at 5, McDarby, supra, 401 N.J. Super. 10 (No. A-0076-07T1). The Appellate Division, reversing the $9 million punitive damages awarded by the jury, found such claims were preempted by the FDCA. McDarby, supra, 401 N.J. Super. at 99.

The Appellate Division's decision in McDarby relied heavily on the United States Supreme Court's decision in Buckman Co. v. Plaintiffs' Legal Comm., in which the Court held that private fraud-on-the-FDA actions are preempted by the FDCA. Buckman, supra, 531 U.S. at 344, 121 S. Ct. at 1015, 148 L. Ed.2d at 858. In McDarby, the Appellate Division explained that the presumption against preemption does not apply to "policing fraud against federal agencies" such as the FDA because:

> [t]he relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law . . . . Accordingly -- and in contrast to situations implicating "federalism concerns and the historic primacy of state regulation of matters of health and

safety," -- no presumption against pre-emption obtains in this case.

> [McDarby, supra, 401 N.J. Super. at 89, (quoting Buckman, supra, 531 U.S. at 347-48, 121 S. Ct. at 1017, 148 L. Ed.2d at 860-61) (citation omitted).]

The McDarby appellate court emphasized that "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Agency, and that, this authority is used by the Agency to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Agency can be skewed by allowing fraud-on-the-FDA claims under state tort law." McDarby, supra, 401 N.J. Super. at 89, (quoting Buckman, supra, 531 U.S. at 348, 121 S. Ct. at 1017, 148 L. Ed.2d at 861).

In McDarby, the Appellate Division expressly distinguished compensatory damages from punitive damages. Relying upon the Appellate Division's discussion of the Punitive Damages Act[1], N.J.S.A. §§ 2A:15-5.9 to -5.17, in Tarr v. Bob Ciasulli's Mack Auto Mall, Inc., 390 N.J. Super. 557 (App.Div. 2007), aff'd, 194 N.J. 212 (2008), the McDarby appellate court explained that punitive damages serve a policing function:

> The Act provides that the purpose of a punitive damage award is "to punish the defendant and to deter that defendant from repeating such conduct." N.J.S.A. 2A:15-5.14. The Act defines punitive damages as "exemplary . . . damages awarded against a party in a civil action because of aggravating circumstances in order to penalize and to provide additional deterrence against a defendant to discourage similar conduct in the future." N.J.S.A. § 2A:15-5.10.

> [McDarby, supra, 401 N.J. Super. at 90, (quoting Tarr, supra, 390 N.J. Super. at 565).]

In contrast, the McDarby appellate court noted that the purpose of compensatory damages in the personal injury context is to make the individual plaintiff whole. McDarby, supra, 401 N.J. Super. at 91. Such compensation serves "neither to reward the plaintiff, nor to punish the defendant, but to replace plaintiff's losses." Id. at 91, (quoting Caldwell v. Haynes, 136 N.J. 422, 433 (1994).)

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[1] In a footnote, the McDarby decision acknowledged that, "[t]he Punitive Damages Act is applicable to the present case in concert with the punitive damage provisions of the PLA." McDarby, supra, 401 N.J. Super. at 90 n.47 (citation omitted).

The McDarby court ultimately reasoned that, because punitive damages inherently serve a policing function, and because policing fraud-on-the-FDA receives no presumption against preemption, punitive damage claims based on fraud-on-the-FDA are preempted under the FDCA. McDarby, supra, 401 N.J. Super. at 90-94. Moreover, as punitive damages claims under the NJPLA are conditioned expressly upon a finding of fraud on the FDA, such claims are within the category of claims preempted. The court wrote:

> Significantly, N.J.S.A. 2A:58C-5c is designed to effectuate the State's interest in punishing unlawful conduct. In that context, a plaintiff bringing a product liability action acts in a fashion akin to a private attorney general, since any damages awarded on his punitive damage claim do not compensate him for his injury, but instead vindicate societal interests. And in this context, the statutory focus, like that in Buckman, is narrowly drawn upon a defendant's act of knowingly withholding from or misrepresenting to the FDA information material to the harm alleged. This limited claim for punitive damages, focused upon deterring a manufacturer's knowingly inadequate response to FDA informational requirements, thus differs from the common law compensatory claims at issue in Desiano as to which a strong presumption against preemption applies.
>
> [Id. at 93 (citation omitted).]

Additionally, framing a claim as one not *merely* based on fraud on the FDA or as a state law tort claim does not overcome the NJPLA's threshold requirement so as to avoid triggering federal preemption. Indeed, similar to the Plaintiffs in this case, the McDarby plaintiffs were *not* asserting purely fraud-on-the-FDA claims, yet the McDarby appellate court held that their claims were tantamount to the fraud-on-the-FDA claims as asserted in Buckman. The Appellate Divison in McDarby held:

> Although there are differences between the fraud-on-the-FDA claim asserted in Buckman and McDarby's punitive damage claim premised on the withholding of information regarding the incidence of myocardial infarctions demonstrated by a meta-analysis, we find the single focus upon fraud on the FDA in each to be sufficiently similar to warrant the application of Buckman to this case.
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> [Id. at 93-94.]

Here, Plaintiffs assert that McDarby is distinguishable from the facts before this court because "Plaintiffs' claims are not fraud-on-the-FDA" and "[i]n contrast to Buckman, Plaintiffs' punitive damages claims are based on Janssen's intentional conduct towards Plaintiffs, other patients, and the medical community, not the FDA." Pls. Opp. at 3. This court finds that

Plaintiffs' claims for punitive damages are not sufficiently distinguishable from those asserted by the plaintiffs in McDarby so as to avoid preemption. Although framed as state tort law claims, Plaintiffs' claims in this case are still subject to the NJPLA's requirement of a threshold showing of fraud-on-the-FDA, and thus fall within the category of claims preempted by the FDCA according to McDarby.

PUNITIVE DAMAGES UNDER LEVINE

Plaintiffs argue that their claims for punitive damages, to the extent that they are preempted under McDarby, can be resuscitated under the Supreme Court's decision in Wyeth v. Levine, supra, 555 U.S. 555, 129 S. Ct. 1187, 173 L. Ed.2d 51. In Levine, the Court held that FDA approval of a drug label does not preempt state tort suits premised on failure to warn. Id. at 555, 129 S. Ct. at 1199-1204, 173 L. Ed.2d at 65-70. The Court reasoned that such suits do not defeat the presumption against preemption:

> If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices, Congress has not enacted such a provision for prescription drugs. Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.
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> [Id. at 555, 129 S. Ct. at 1200, 173 L. Ed.2d at 66 (citation omitted) (footnote omitted).]

In Levine, Justice Stevens noted a fundamental distinction between Vermont's interest in protecting the health and safety of its citizenry (where the presumption against federal preemption would apply), and state-law based fraud on the FDA claims like those in Buckman (which the court deemed preempted). Levine, supra, 129 S.Ct. at 1195 n.3.

Plaintiffs argue that the Levine decision undermines the McDarby holding with regard to the viability of their punitive damage claims. Pls. Opp. at 11-13. Arguments noting a potential tension between the courts' decisions in McDarby and Levine fail to recognize that the McDarby ruling continues to bind this court. The Levine opinion was issued on March 5, 2009. Two months later, on May 7, 2009, the New Jersey Supreme Court withdrew the petition for certification in McDarby as improvidently granted. 200 N.J. 267 (2009). The Appellate Division's McDarby decision, holding that punitive damages under the PLA are preempted, was

left undisturbed. This court is bound by the precedents established by the courts' decisions in Buckman and McDarby. Thus, Plaintiffs' punitive damage claims are preempted.

CONCLUSION

For the foregoing reasons, Defendants' motion for partial summary judgment dismissing Plaintiffs' punitive damage claims is **GRANTED**. The court will sign the order submitted by Defendants.

Jessica R. Mayer, J.S.C.

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IN RE: RISPERDAL/SEROQUEL/ ZYPREXA LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION : MIDDLESEX COUNTY
THIS ORDER APPLIES TO:	CASE NO. 274
Gary D. Skala v. Johnson & Johnson Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P., a/k/a Janssen, Pharmaceutica, Inc.	CIVIL ACTION
Docket No. MID-L-6820-06	**ORDER**
Shon Laissen v. Johnson & Johnson, Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc.	
Docket No. MID-6720-06	

THIS MATTER having been brought before the Court by Drinker Biddle & Reath LLP, attorneys for defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc. (f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.); the Court having heard and considered the moving papers, ~~any~~ opposition papers, ~~any~~ reply papers, ~~and the arguments of counsel~~, and good cause having been shown;

IT IS on this 18th day of November, 2011,

ORDERED that defendants' Motion for Partial Summary Judgment is hereby granted for the reasons set forth in the court's memorandum dated November 18, 2011;

IT IS FURTHER ORDERED that plaintiffs' punitive damages claims are dismissed with prejudice;

IT IS FURTHER ORDERED that a copy of this Order shall be served upon plaintiffs' counsel within seven (7) days of the date of this Order.

OPPOSED

JESSICA R. MAYER, J.S.C.

This motion was:

/ Opposed

____ Unopposed

FP01/6541987.1