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MASTER DOCKET NO. 2005-59499

Ruby Ledbetter	§	**IN THE DISTRICT COURT OF**
	§	
v.	§	**HARRIS COUNTY, T E X A S**
	§	
Merck & Co., Inc.	§	**157th JUDICIAL DISTRICT**
	§	(Trial Court: 151st Dist. Court of Harris
	§	County, Cause No. 2005-58543)

Order Granting Defendant's Motion for Partial Summary Judgment And Granting Expedited Appeal

Defendant Merck & Co., Inc. ("Merck") has filed a no evidence motion for partial summary judgment on plaintiff's warning claims. This motion is based on a 2003 Texas statute governing FDA approved warnings. TEX. CIV. PRAC. & REM. CODE ANN. §82.007. Merck argues that §82.007 is preempted by federal law. For reasons stated, the motion is granted.

1. Background

Vioxx (known generically as rofecoxib) is a NSAID (non-steroidal anti-inflammatory drug). This class of drugs includes over the counter medications, such as Advil (ibuprofen) and Aleve (naproxen) and a variety of prescription medicines. NSAIDS work by inhibiting cyclo-oxygenase (COX), an enzyme that stimulates synthesis of prostaglandins, which are chemicals produced in the body that promote certain effects.

In the early 1990s, scientists discovered that the COX enzyme was composed of two forms. COX-1 affects the synthesis or production of prostaglandins responsible for protection of the stomach lining; COX-2 stimulates the prostaglandins that cause pain and inflammation. This belief led to the hypothesis that a selective NSAID, designed to inhibit COX-2, but not COX-1, could offer pain relief without the risk of fatal or debilitating gastrointestinal perforations and

ulcers. This led Merck to begin the development of such a drug, which became known as a COX-2 inhibitor. Vioxx is a COX-2 inhibitor.

In December 1994, Merck submitted an Investigational New Drug Application to the FDA seeking approval to conduct studies to test the safety of Vioxx to treat osteoarthritis, rheumatoid arthritis, and pain. In November 1998 Merck submitted a New Drug Application for Vioxx. The FDA reviewed the Merck submission and, as well, convened an Advisory Committee to review the data and make recommendations. On May 20, 1999, the FDA approved Vioxx for sale in the United States.

Vioxx was subjected to a number of studies and trials, including VIGOR, APPROVe, and others. APPROVe was a randomized clinical trial that compared Vioxx to a placebo. The APPROVe study indicated that the use of Vioxx increased the risk of cardiovascular thrombotic events such as myocardial infarctions.

On September 30, 2004, Merck withdrew Vioxx from the market. Thousands of lawsuits ensued across the country. On September 6, 2005, Texas cases were consolidated into this MDL proceeding. There are currently over 1,000 Vioxx cases in these consolidated Texas proceedings; virtually all of them contain an allegation that Merck failed to provide an adequate warning.

2. Preemption

A. The Texas Act

In 2003, the Texas legislature enacted TEX. CIV. PRAC. & REM. CODE ANN. §82.007, which provides, in part:

> **§ 82.007. Medicines**
>
> (a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical

> product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:
>
> > (1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.), as amended, or Section 351, Public Health Service Act (42 U.S.C. Section 262), as amended; or
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> * * * *
>
> (b) The claimant may rebut the presumption in Subsection (a) as to each defendant by establishing that:
>
> > (1) the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury;
>
> * * * *

TEX. CIV. PRAC. & REM. CODE ANN. §82.007 (hereinafter the "Texas Act"). The Texas Act was one of a number of enactments in 2003 designed to achieve "tort reform" as a result of a perceived lawsuit crisis, particularly involving the medical arena. This statute has yet to be construed by Texas appellate courts.

There is no question but that the FDA approved the general warnings or information provided by Merck with respect to Vioxx. Plaintiffs rely exclusively upon subsection (b)(1) of the Texas Act in order to rebut the Act's presumption that Merck is not liable for failure to provide an adequate warning.

B. Construction of the Texas Act.

In order to determine whether the Texas Act has been preempted, this Court must first construe the various terms contained in the Act.

1. Burden of Proof.

A threshold question confronting this Court concerns the burden of proof under the Texas Act. Section 82.007 states that a claimant may rebut the presumption in the statute by "establishing" that certain required information was withheld. What does "establish" mean? Merck equates "establish" with "prove" and argues that plaintiffs must prove that such information was withheld or misrepresented by a preponderance of the evidence. Plaintiffs argue that the presumption "bursts" merely upon presenting some evidence that information was withheld. Thus, according to plaintiffs, at the conclusion of plaintiffs' case, the Court would rule as a matter of law whether some evidence of withholding or misrepresentation of evidence was presented, and thereafter, the failure to warn question would be presented to the jury. Plaintiffs therefore argue that the court, rather than the jury, decides whether information was withheld.

The Court agrees with Merck. Plaintiffs have the burden to "establish" or prove that required information was withheld from or misrepresented to the FDA by a preponderance of the evidence. This is ordinarily a question for the jury.

2. Required Information

To rebut the presumption, plaintiffs must show that "required information" was withheld or misrepresented. "Required information" means that information which is required to be submitted to the FDA pursuant to federal statute and regulations governing pharmaceutical products.

3. Material Information.

The Texas Act next requires that claimants prove that "material and relevant" information was withheld. Not surprisingly, the parties presented two different definitions of materiality.

- Plaintiffs posit that they must merely show "that the allegedly withheld information, if disclosed, would have a natural tendency to influence, or be capable of influencing, a government function."
- Merck, on the other hand, argues that plaintiffs must show "that the allegedly withheld information, if disclosed, in reasonable probability would have led to a different regulatory outcome such as refusal to approve Vioxx for marketing or requiring a label change."

Plaintiffs proposed definition is erroneous for several reasons. First, the definition would effectively make any relevant information sufficient to eliminate the presumption. Under the plaintiff's definition, virtually any information would qualify. Since the Texas Act was promulgated in an environment of tort reform, the legislature surely meant that the burden on plaintiffs be more than merely finding "some information" that "might" be capable of influencing the FDA. This Court may consider the circumstances surrounding a statute and the goals sought to be achieved by the legislature in construing a statute. *See Lexington Ins. Co. v. Strayhorn*, 209 S.W.3d 615 (Tex. 2005).

Second, the Texas Act requires that the withheld information be "causally related" to the plaintiff's injury. Unless withheld information would have resulted in some definite change by the FDA, either non-approval of the drug, or a labeling change, such with withheld information could not be causally related to a plaintiff's injury.

Thus, plaintiffs must prove by a preponderance of the evidence that required information was withheld from or misrepresented to the FDA, such that the allegedly withheld or misrepresented information, if disclosed or not misrepresented, would have led to a different regulatory outcome such as refusal to approve Vioxx for marketing or requiring a label change.

4. Relevant Information

The allegedly withheld or misrepresented information must relate to the same injury complained of by plaintiff.

C. Preemption of the Texas Act

The starting point of any preemption analysis concerning the Texas Act is *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), where the Supreme Court held that state law "fraud on the FDA" claims are preempted by the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.* ("FDCA"). There, Buckman was a consulting company that assisted a manufacturer to obtain FDA approval for certain medical devices. Plaintiffs were consumers of these devices, who claimed personal injuries; plaintiffs sued Buckman alleging that Buckman made fraudulent representations to the FDA. Plaintiffs claimed that such misrepresentations were a "but for" cause of injuries: had the representations not been made, the FDA would not have approved the device, and plaintiffs would not have been injured. The Supreme Court held that such claims are preempted by the FDCA. The Court reasoned that it is the FDA's exclusive responsibility to "police fraud consistently with the Administration's judgment and objectives." *Id.* at 350. The Court observed that the FDA is empowered to investigate fraud and that citizens may report wrongdoing and petition the agency to take action. *Id.* at 349. Moreover, "fraud-on-the FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court" resulting in a "deluge" of needless information on the FDA, potentially burdening the agency and delaying release of new products. *Id.* at 351.

Since *Buckman*, several courts have considered statutes similar to the Texas Act. In *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961 (6th Cir. 2004), the Sixth Circuit considered

a Michigan law that immunizes a drug manufacturer from products liability suits if the [illegible] approved by the FDA unless the manufacturer intentionally withheld or misrepresented required information.[1] The court held the Michigan law was preempted to the extent that it permitted a state court to determine whether a drug manufacturer committed fraud on the FDA. *Id.* at 966. However, such "inter-branch-meddling concerns that animated *Buckman*" do not arise when the "FDA *itself* determines that a fraud has been committed on the agency during the regulatory-approval process." *Id.* (emphasis in original) Thus, the court held that a plaintiff could only invoke the "fraud on the FDA" exception to the Michigan statute if the FDA itself determines that it was defrauded. Other courts have reached similar conclusions. *See, e.g., Henderson v. Merck & Co.*, 2005 WL 2600220 (E.D. Pa., Oct. 11, 2005); *Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166, 1172-74 (D. Ariz. 2005).

Plaintiffs, however, rely on *Desiano v. Warner-Lambert & Co.,* 467 F.3d 85 (2d Cir. 2006), which reached a different conclusion and suggested three reasons why the *Garcia* analysis is flawed. First, plaintiffs correctly note that there is a presumption against preemption. While such a presumption exists, *see Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992), the Supreme Court in *Buckman* expressly held that no such presumption against preemption existed in that case. "The 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

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[1] The statute provides, in relevant part: "(5) In a product liability action against a manufacturer or a seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. . . .This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:

(a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act. . ., and the drug would have not been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

MICH. COMP. LAWS § 600.2946(5).

according to federal law." 531 U.S. at 347. Because, in that case, the medical device manufacturer's dealings with the FDA were prompted by federal law, "no presumption against preemption obtains in this case." *Id.* The same analysis must apply with no less force to drug manufacturers. Indeed, the State of Texas, by enacting the Texas Act, has placed the relationship between drug manufacturer and FDA in issue.

Second, plaintiffs argue that *Buckman* is inapplicable since it involved a non-traditional suit based entirely on a fraud on the FDA theory, whereas these suits allege traditional products liability theories. This is a distinction without a difference. Under the Texas Act, in order to pursue a failure to warn case, plaintiffs must prove that required and material information was withheld from the FDA. Whether it is an element of plaintiffs' cause of action, or a way to defeat an affirmative defense, the proof is the same. All of the federalism concerns expressed in *Buckman* still apply. The requisite showing under the Texas Act is analogous to and sufficiently equivalent to plaintiffs' asserting a claim of fraud on the FDA that the claim is preempted under *Buckman*.

Finally, plaintiffs argue that the proof required under the Texas Act is different from a "fraud on the FDA" complaint. Plaintiffs argue that mere inadvertent withholding of information is sufficient to puncture the rebuttable presumption of the Texas Act[2], whereas intentional fraud was at issue in *Buckman*, and, indeed, part of the statute in Michigan. This Court is not persuaded by this argument. The logic of *Buckman* was that the FDA promulgates detailed data submission requirements and is fully empowered to investigate wrongful withholding by manufacturers. 531 U.S. at 1017. If anything, the argument that *Buckman* involved a claim with

[2] The Court notes that the Texas Act uses the word "misrepresents" which could imply an element of intent, depending on whether the misrepresentation required is intentional or negligent. However, for purposes of this motion, the Court will assume no scienter is required since the statute disjunctively includes "withheld from" as sufficient to eliminate the statutory rebuttable presumption.

an element of scienter, whereas the Texas Act requires only inadvertent withholding undermines plaintiffs' argument. State courts traditionally adjudicate a party's state of mind, *e.g.,* whether fraud occurs. Indeed, a state court is probably better suited than a federal agency to determine whether an intentional misrepresentation occurred as opposed to an inadvertent omission. The key issue for purpose of presumption analysis is not whether information was intentionally withheld, but whether the federal regulation is so pervasive as to leave no room for state regulation. Given the extent of federal regulation, and the extent to which the FDA is empowered to investigate and regulate drug manufacturers who fail to provide required information, permitting a Texas jury or judge to make the same inquiry would impinge on a uniquely federal issue.

All of the concerns raised by the Supreme Court in *Buckman* would manifest themselves if the motion for summary judgment were denied. *Buckman* noted that manufacturers might "deluge" the FDA with information it neither needed nor wanted in order to defend state tort claims. 531 U.S. at 351. This could potentially impede the regulatory process. The *Buckman* concern of deluging the FDA could well come true if manufacturers were forced to make data submissions defensively in order to ensure that the presumption of the Texas Act remained in place.

There is no question but that the FDA has not made a determination that material and relevant information was either withheld or misrepresented concerning Vioxx.

C. Severability

Plaintiffs argue that if subsection (b)(1) is preempted, then the entirety of section 82.007 must fall, leaving no presumption that Merck's is not liable with respect to the allegations involving failure to provide adequate warnings. This argument fails. First, plaintiffs can still

avail themselves of (b)(1) if the FDA determines that required information was withheld. The issue is who makes the determination—the FDA or a Texas court or jury.

Second, the Texas Act is severable. Texas law currently provides that:

> (c) In a statute that does not contain a provision for severability or nonseverability, if any provision of the statute or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the statute that can be given effect without the invalid provision or application, and to this end the provisions of the statute are severable.

TEX. GOV'T. CODE § 311.032(c). Unless the legislature provides for nonseverability, the Government Code provides that the statute is severable. Even if subsection (b)(1) is invalid, the remaining statute can be given effect.

Finally, in passing the Texas Act, the legislature expressly considered the possibility that the law would not survive a *Buckman* analysis.[3] Yet, notwithstanding this forewarning, the legislature did not insert a nonseverability provision into § 82.007.

D. Conclusion on Preemption

For the forgoing reasons, Merck's motion for partial summary judgment is granted and subsection (b)(1) of TEX. CIV. PRAC. & REM. CODE ANN. §82.007 is preempted to the extent that someone other than the FDA is being asked to make the determination. Plaintiffs cannot rely on subsection (b)(1) unless and until the FDA makes the required findings under (b)(1).

3. Merck's Alternative Motion

Merck argued alternatively that even if the Texas Act is not preempted, a no evidence motion for summary judgment should nevertheless be granted. Merck argues that plaintiffs do not have sufficient evidence to rebut the presumption.

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[3] For example, Baylor Law School Dean Bradley Tobin testified in Senate committee hearings that § 82.007 could very well be challenged on *Buckman* grounds. Hearings on Tex. H.B. 4 Before Senate State Affairs Comm., 78th Leg., R.S. at 23-24 (May 5, 2003).

In response, plaintiffs submit the affidavits of various experts. However, because of this Court's ruling on preemption, it is not necessary to rule on Merck's alternative motion.

Plaintiff's motion to strike Merck's Summary Judgment evidence is Denied.

Plaintiff's claim of failure to warn is hereby severed from this Master Docket and will henceforth be under cause number 2005-59499A and in the original trial court as Cause No. 2005-58543A. The pleadings in this severed cause shall consist of plaintiff's petition(s), defendants' answer(s), Merck's motion for partial summary judgment and all responses, replies, rebuttals and other briefs and memoranda concerning the motion for summary judgment.

This is a final order and is appealable.

It is further ordered that any appeal from this Order be expedited pursuant to Tex. R. Jud. Admin. 13.9(c) as this order is made in MDL pretrial proceedings.

Signed April 19, 2007.

Hon. Randy Wilson