UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF NORTH CAROLINA CHARLOTTE DIVISION 3:09-cv-210-RJC-DSC

MARY CLEO COUICK,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	**ORDER**
WYETH, INC. et al.,	)	
	)	
Defendants.	)	
	)	

THIS MATTER comes before the Court on a motion to dismiss by defendants Actavis, Inc. and Actavis-Elizaeth LLC (collectively "Actavis") (Doc. No. 12). The Court has considered the arguments in support and opposition (Doc. Nos. 13, 14, 24, 25), the Magistrate Judge's Memorandum and Recommendation ("M&R") (Doc. No. 26), and Actavis's objections to the M&R (Doc. No. 34).

I. BACKGROUND

Plaintiff filed her complaint on May 28, 2009, asserting multiple state law claims. The claims focus on the defendant drug manufacturers' failure to adequately warn of the potential serious side-effects of the drug Reglan and its generic equivalent metoclopramide. Actavis does not object to the facts as set forth by the Magistrate Judge, and this Court adopts the facts as stated in the M&R with the following supplementation.

All prescription drugs must be approved by the Food and Drug Administration ("FDA") before a company may market or sell them. Name-brand manufacturers must submit a New Drug Application ("NDA") to the FDA, which must contain extensive information regarding the safety

of the drug based on clinical trials that the manufacturer conducts. 21 U.S.C. §§ 355(a)-(b), (d). Generic drug manufacturers, on the other hand, may submit an Abbreviated New Drug Application ("ANDA"). The ANDA procedure obviates the need to conduct the clinical trials already completed by the name-brand manufacturers, 21 U.S.C. § 355(j), as long as the generic drug is essentially the same as the name-brand drug and the generic drug's label is identical in relevant part to the name-brand drug's label. 21 C.F.R. § 314.94(a)(8). The ANDA procedure was created when Congress passed the Drug Price Competition and Patent Term Restoration Act in 1984, seeking to allow the entry of affordable generic drugs into the market soon after the patents of name-brand drugs expire. This Act amended the Food, Drug, and Cosmetic Act ("FDCA"), and it became known as the "Hatch-Waxman Amendments" to the FDCA.

Drug manufacturers have a duty to revise a drug's label if they find "reasonable evidence of an association of a serious hazard with a drug." 21 C.F.R. § 201.57(e). There are two main ways that a label may be revised. "Major changes" may be implemented through a prior approval supplement, where the FDA must approve the change that a manufacturer recommends before the change can be implemented. 21 C.F.R. § 314.70(b). "Moderate changes" may be made via a Changes Being Effected ("CBE") supplement, which does not require pre-approval by the FDA. 21 C.F.R. § 314.70(c)(6)(iii)(A)-(D).

Defendant Actavis contends that because the federal statutory and regulatory scheme administered by the FDA requires generic drug manufacturers to label their product identically to the name-brand drug, it could not use a CBE supplement to add to the warnings on its label for metoclopramide. Actavis therefore argues that since it could not initiate a label change under federal law, a state-law claim for failure to warn conflicts with the federal law and is preempted.

II. STANDARD OF REVIEW

The Federal Magistrate Act provides that "a district court shall make a de novo determination of those portions of the report or specific proposed findings or recommendations to which objection is made." 28 U.S.C. § 636(b)(1); Camby v. Davis, 718 F.2d 198, 200 (4th Cir.1983); Keeler v. Pea, 782 F. Supp. 42, 43 (D.S.C.1992). De novo review is not required by the statute when an objecting party makes only general or conclusory objections that do not direct the court to the specific error in the magistrate judge's recommendations. Orpiano v. Johnson, 687 F.2d 44, 47 (4th Cir.1982). Further, the statute does not on its face require any review at all of issues that are not the subject of an objection. Thomas v. Arn, 474 U.S. 140, 149 (1985); Camby, 718 F.2d at 200. Nonetheless, a district judge is responsible for the final determination and outcome of the case, and accordingly the Court has conducted a careful review of the Magistrate Judge's M&R.

In its review of a Rule 12(b)(6) motion, "the court should accept as true all well-pleaded allegations and should view the complaint in a light most favorable to the plaintiff." Mylan Labs, Inc. v. Matakari, 7 F.3d 1130, 1134 (4th Cir. 1993). The plaintiffs' "[f]actual allegations must be enough to raise a right to relief above the speculative level." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007). "[O]nce a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint." Id. at 563. A complaint attacked by a Rule 12(b)(6) motion to dismiss will survive if it contains "enough facts to state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 129 S. Ct. 1937, 1960 (2009) (quoting Bell Atlantic, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. at 1949.

III. DISCUSSION

The M&R found that the plaintiff's state law claims do not conflict with federal law and recommends denying Actavis's motion to dismiss. Actavis objects to the M&R on four grounds. First, it objects to the alleged failure to analyze the generic preemption issue within the context of the specific statutory and regulatory framework applicable to generic drug manufacturers. Second, Actavis contends the Magistrate Judge failed to accord the FDA's interpretations of its own regulations the proper level of deference. Third, it objects to the Magistrate Judge's adoption of another court's reasoning in recommending denial of the motion. Fourth, Actavis argues that the Magistrate Judge failed to address its preemption arguments under Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001).

A. Whether the state-law claims are preempted by federal law

Actavis contends plaintiff's claims are subject to conflict preemption.[1] Conflict preemption exists where state law "actually conflicts with federal law." Anderson v. Sara Lee Corp., 508 F.3d 181, 191 (4th Cir. 2007). In determining "whether an actual conflict exists between state and federal law," the Court must "resolve the more specific inquiries of whether it is impossible to comply with both state and federal law or whether the state law stands as an obstacle to the accomplishment of the full purposes and objectives of federal law." Id. at 192 (quoting Worm v. Am. Cyanamid Co., 970 F.2d 1301, 1305 (4th Cir. 1992)). The Court "start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." Wyeth v. Levine, 129 S. Ct. 1187, 1194-95 (2009) (citation omitted). Thus the analysis begins with a presumption against preemption.

[1] Defendants do not assert that the claims are subject to express or field preemption.

While the Hatch-Waxman Amendments focus on generic drugs, they are a part of the larger FDCA statutory scheme. Actavis argues that the Magistrate Judge failed to recognize that generic drugs are subject to a distinct statutory and regulatory framework from that of name-brand drug manufacturers. Yet, while highlighting the separate and distinct nature of generic drug regulation, Actavis would have the Court ignore the reality that both name-brand and generic drugs are regulated pursuant to the larger statutory scheme of the FDCA. The Hatch-Waxman Amendments "provided for cheaper, expedited approval of generic drugs, not relief from the fundamental requirement of the FDCA that all marketed drugs remain safe." Mensing v. Wyeth, Inc., No. 08-3850, 2009 WL 4111209, at *7 (8th Cir. Nov. 27, 2009). Thus the Hatch-Waxman Amendments must be analyzed as an integral part of the larger FDCA, and not viewed in a vacuum as their own statutory universe.

The Supreme Court in Wyeth v. Levine recently made clear that "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." 129 S. Ct. at 1197. Actavis attempts to distinguish Levine in that it dealt with a name-brand manufacturer rather than a manufacturer of generics. However, the Eighth Circuit has noted that the premise underlying the Levine decision "carries important implications for [generic drug manufacturers'] situation as well. Mensing, 2009 WL 4111209, at *4 (citing Levine, 129 S. Ct. at 1197-98).[2] Thus, "[a]fter [Levine], we must view with a questioning mind the generic defendants' argument that Congress silently intended to grant the manufacturers of most prescription drugs blanket immunity from state tort liability when they market inadequately labeled products." Id. at *3.

[2] The Eighth Circuit issued its opinion in Mensing on November 27, 2009, after this motion to dismiss had already become ripe for this Court's determination.

The Court need not look far to determine that Actavis's main argument is misplaced. Actavis sets forth in detail the statutory and regulatory framework governing generic drug manufacturers. It argues that a generic drug manufacturer is prohibited from changing its label via a CBE supplement, pursuant to 21 C.F.R. § 314.97. Yet, in focusing its energy and argument on whether a generic drug manufacturer can change its label without prior approval, Actavis has failed to explain how – even if correct – this legal conclusion creates a conflict between state and federal law. Actavis has not shown that it was prohibited by federal law from warning customers such as plaintiff of the dangers of long-term use of metoclopramide by means other than a CBE supplement.

It is not impossible for Actavis to comply with both state and federal law. The Eighth Circuit in Mensing recently rejected this same argument presented by Actavis in nearly identical litigation regarding the same drug. See 2009 WL 4111209, at *4-7. No other circuit court has ruled on the issue. While there are strong arguments on both sides regarding whether a generic drug manufacturer can use a CBE supplement to change its label, Actavis provides no compelling argument why resolving the CBE issue in its favor would cause a conflict between state and federal law. As the Mensing court recognized, "[t]he regulatory framework makes clear that a generic manufacturer must take steps to warn its customers when it learns it may be marketing an unsafe drug." Id. at *5 (citing 21 C.F.R. § 201.57(e)). This required warning is not limited to a CBE supplement to a label. The Mensing court explained: "In this case we need not decide whether generic manufacturers may unilaterally enhance a label warning through the CBE procedure because the generic defendants could have at least *proposed* a label change that the FDA could receive and impose uniformly on all metoclopramide manufacturers if approved." Id. at *4 (emphasis in original). It was thus possible for Actavis to comply with both state and federal law, because it could

have proposed a label change through the prior approval process rather than changing the label through the CBE process. In addition, Actavis has not articulated why under federal law it could not have complied with state law by using means other than a label change to warn customers of the risks of long-term use of metoclopramide.

Further, the state claims do not obstruct the purposes and objectives of federal law. Actavis points to the goal of the Hatch-Waxman Amendments to bring affordable generic drugs to the marketplace as quickly as possible. It argues that the research and costs involved in implementing or proposing a label change would thwart this goal. The Mensing court convincingly rejected this argument by giving an example of how label changes may be proposed in a cost-effective and efficient manner. The court pointed to the fact that the FDA, when it recently mandated a heightened warning for metoclopramide, relied on published scientific studies rather than its own studies. Id. at *7. It explained there is "nothing to indicate" that the scientifically substantiated information supporting a request for a label change "must be acquired through a manufacturer's own clinical tests," which can be costly and time-consuming. Id. Thus Actavis need not conduct its own expensive and lengthy trials in order to propose a label change or otherwise warn customers, and if state law should require such measures, it would not obstruct the purposes and objectives of the Hatch-Waxman Amendments. The Court adopts the reasoning of Mensing in holding that the plaintiff's state law claims do not obstruct the purposes and objectives of federal law. Rather, these failure to warn claims "lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." Levine, 129 S. Ct. at 1202.

As our own Circuit stated fifteen years ago, "The statutory scheme governing premarketing approval for drugs simply does not evidence Congressional intent to insulate generic drug

manufacturers from liability for misrepresentations made regarding their products, or to otherwise alter state products liability law." Foster v. Am. Home Prods. Corp., 29 F.3d 165, 170 (4th Cir. 1994). While these comments came in a case involving a name-brand manufacturer, their force is evident and persuasive. Plaintiff's state law claims are not conflict-preempted.

B. Actavis's second and third objections

Actavis argues that the Magistrate Judge failed to accord proper deference to the FDA's interpretations of its own regulations. It rests this argument on the FDA's statements to the effect that a generic manufacturer cannot make a unilateral change via a CBE supplement. Since the Court declines to reach the issue of whether a generic manufacturer can use the CBE provision, the Court need not address the proper deference to accord the FDA's statements regarding this issue.[3]

Actavis also argues that the Magistrate Judge erred in adopting wholesale the reasoning of the Kellogg case from the District of Vermont. Kellogg v. Wyeth, 612 F. Supp. 2d 437 (D. Vt. 2009). A Magistrate Judge is free to adopt the reasoning of any court it finds persuasive, as long as that reasoning demonstrates a proper interpretation of the law. This Court does not comment upon the Kellog case any further, except to reiterate that the Court does not today reach the question whether the CBE process is available to generic drug manufacturers as a matter of law.

C. Preemption under Buckman

Actavis objects to the fact that the Magistrate Judge did not address its Buckman preemption argument. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001). It argues that plaintiff's claims are simply a "fraud-on-the-FDA" claim and thus preempted under Buckman. In

[3] The Court notes that the most direct statement on which defendants rely is contained in a footnote to the "Supplementary Information" section of a notice of proposed rule making that did not even pertain to generic drugs. 73 Fed. Reg. 2848, 2849 n.1 (Jan. 16, 2008) ("CBE changes are not available for generic drugs.").

support of this argument, Actavis extracts one sentence from the plaintiff's brief stating that the defendants kept the practice of long-term use of metoclopramide from consideration by the FDA because they knew such use would not pass FDA scrutiny.

In Buckman, the plaintiffs claimed that a medical device would not have been approved by the FDA but for the defendant's fraudulent statements to the FDA, and that these statements in turn caused their injuries. Id. at 343. The federal act in question that required these statements, the Medial Device Amendments of 1976 (amending the FDCA), was thus a "critical element" to the plaintiff's case. Id. at 353 (citing 90 Stat. 539, 21 U.S.C. § 301 (1994 ed. and Supp. V)). The Court held that since enforcing the FDCA is the exclusive province of the federal government, a private litigant is preempted from enforcing the FDCA. See Riley v. Cordis Corp., 625 F. Supp. 2d 769, 776 (D. Minn. 2009) (citing Buckman, 531 U.S. at 349). Further, a private litigant may not sue a defendant under state law where "the state-law claim is in substance (even if not in form) a claim for violating the FDCA – that is, when the state claim would not exist if the FDCA did not exist." Id. at 777 (citing Buckman, 531 U.S. at 352-53). Alternatively, however, simply because conduct violates the FDCA does not mean a state-law claim based on that same conduct depends on the FDCA's existence.

Plaintiff asserts claims for state-law negligence, breach of undertaking special duty, misrepresentation, constructive fraud, fraud by concealment, infliction of emotional distress, unfair trade practices, and breach of warranties. These claims involve multiple overlapping allegations. The constructive fraud and fraud by concealment claims come the closest to raising a Buckman issue, as they sound in fraud. However, both claims focus on fraud that is allegedly perpetrated against patients and doctors rather than the FDA. The constructive fraud count alleges defendants

made misrepresentations in advertisements, promotional materials, and other communications. The fraudulent concealment count alleges defendants concealed from physicians the serious side effects caused by prolonged use of metoclopramide. Such allegations, while potentially in violation of the FDCA, would exist as state-law claims absent the FDCA. These claims "rely[] on traditional state tort law which . . . predate[s] the federal enactments in question." Buckman, 531 U.S. at 353. Thus plaintiff's fraud claims arise from state law, and "not solely from the violation of FDCA requirements." Id. at 352. Therefore, plaintiff's claims are not preempted under Buckman.

IV. CONCLUSION

IT IS, THEREFORE, ORDERED that:

1. The motion to dismiss by defendants Actavis, Inc. and Actavis-Elizabeth LLC (Doc. No. 12) is **DENIED**; and

2. After de novo review of the M&R (Doc. No. 39) pertaining to PLIVA USA, Inc.'s motion for judgment on the pleadings, that motion (Doc. No. 35) is **DENIED**, as it raises the identical legal issues addressed in this Order and offers no argument that the Court has not already considered.

SO ORDERED.

Signed: December 7, 2009

Robert J. Conrad, Jr.
Chief United States District Judge