IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

VIOLET R. MYERS-ARMSTRONG,

Plaintiff,

v.

ACTAVIS TOTOWA, LLC, a Delaware Limited Liability Corporation, ACTAVIS GROUP hf., an Icelandic Company, ACTAVIS INC., a Delaware corporation, McKesson Corporation, a California corporation, and Does 1 through 50,

Defendants.
_____/

No. C 08-04741 WHA

ORDER RE MOTION FOR JUDGMENT ON THE PLEADINGS

INTRODUCTION

In this putative consumer class action, defendants Actavis Totowa, LLC and Actavis Inc. move for judgment on the pleadings. For the reasons stated below, defendants' motion is **GRANTED IN PART AND DENIED IN PART**.

STATEMENT

This action concerns 107 pharmaceutical products that were recalled in 2008 by defendants. Following the recall, plaintiff Violet R. Myers-Armstrong initiated this action against defendants Actavis Totowa, LLC, Actavis Group hf., Actavis, Inc. (collectively "Actavis"), and McKesson Corporation, alleging: (1) breach of implied warranty of merchantability; (2) violation of California Business and Professions Code Section 17200; (3) fraudulent concealment; and (4) unjust enrichment. Plaintiff seeks relief on behalf of herself

and a class of California purchasers of defendants' products, although a class has not yet been certified.

Actavis produces, manufactures, distributes and sells generic pharmaceutical products. McKesson distributes, markets, and sells products manufactured by Actavis throughout the United States. The 107 drugs in question were manufactured at Actavis' plant in Little Falls, New Jersey. In August 2008, defendants announced a voluntary recall at the retail level — but not the consumer level — of all 107 products and stated in a press release that the recall was due to the company's failure to meet industry or Food and Drug Administration good manufacturing practices ("GMP") at the plant. The FDA had previously warned Actavis on August 15, 2006, that the operations at the Little Falls plant violated FDA statutes and regulations by failing to report and investigate serious and unexpected adverse events, failing to file a periodic safety report, failing to establish appropriate pharmacovigilence procedures to monitor adverse events, and manufacturing numerous prescription drug products without approved applications. On February 1, 2007, the FDA again warned Actavis that the operations at its Little Falls plant were substandard. Although Actavis stated that the recall was not prompted by product complaints or health hazards associated with the products, Myers-Armstrong now alleges that the statement was false (Compl. ¶ 28). According to her, Actavis received dozens of complaints.

Plaintiff Virginia Myers-Armstrong lives in California. She purchased one of the 107 drugs, Chlordiazepoxide with Clidinium Bromide ("CDP"), at a local pharmacy. She alleges that all 107 of the pharmaceutical products manufactured at the Little Falls plant should not have been offered for sale in California because the products were adulterated, were not manufactured according to GMP requirements, and were not otherwise fit for the purposes intended. She seeks economic damages and restitution. Expressly disclaiming any personal injury claims, she "does not seek damages for personal injury or other physical harm, either for herself or any class members" (Compl. ¶ 5).

It is useful to review the role of GMP requirements and recalls. Regulations regarding the manufacture of pharmaceutical products, known as "Current Good Manufacturing Practice" regulations, have been promulgated by the FDA as follows:

> (a) The regulations set forth in this part and in Parts 211 through 226 of this chapter contain the minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.
>
> (b) The failure to comply with any regulation set forth in this part and in Parts 211 through 226 of this chapter in the manufacture, processing, packing, or holding of a drug shall render such drug to be adulterated under section 501(a)(2)(B) of the act and such drug, as well as the person who is responsible for the failure to comply, shall be subject to regulatory action.

21 C.F.R. 210.1 (2009).

A recall is one way that a company's failure to comply with GMP requirements may be addressed by the FDA. Recall is defined by the FDA to mean "a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, *e.g.*, seizure. Recall does not include a market withdrawal or a stock recovery." 21 C.F.R. 7.3(g) (2009). Addressing recall policy, the FDA has stated that:

> Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration. Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective.

21 C.F.R. 7.40(a) (2009). A recall is an "alternative" to a FDA-initiated court action, and the agency, by setting forth specific procedures, can "monitor recalls and assess the adequacy of a firm's efforts in recall." *Ibid.*

Taking into account numerous factors, the FDA evaluates the health hazard presented by a product being recalled or considered for recall. The FDA will assign the recall a

classification, *i.e.*, Class I, Class II, or Class III, to indicate the relative degree of health hazard of the product being recalled or considered for recall:

> (1) Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
>
> (2) Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
>
> (3) Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

21 C.F.R. 7.41 (2009); 21 C.F.R. 7.3(m)(1)-(3) (2009).

After it is decided that a recall should be done, a recall strategy is developed, including considerations regarding public warnings, recall effectiveness checks, and recall level, *i.e.*, consumer or user level, retail level or wholesale level. The manufacturer then proceeds with the recall based on the recall strategy. As stated, in our case, the recall covered all products except those already in the hands of consumers.

ANALYSIS

Actavis asserts that it is entitled to judgment as a matter of law under FRCP 12(c) because (1) plaintiff does not have standing under Article III of the United States Constitution to pursue any of her claims regarding CDP that she purchased and the other 106 drugs she did not purchase; (2) plaintiff does not have standing to pursue her claim for violation of Section 17200 under the heightened statutory standing requirements for unfair competition claims; and (3) plaintiff's claims are preempted under federal conflict preemption principles.[1]

1. RULE 12(C) STANDARD.

"After the pleadings are closed — but early enough not to delay trial — a party may move for judgment on the pleadings." FRCP 12(c). "For purposes of the motion, the allegations of the non-moving party must be accepted as true, while the allegations of the moving party which have been denied are assumed to be false. Judgment on the pleadings is

[1] Defendant McKesson Corporation joins Actavis' motion and, thus, this order applies to McKesson as well.

proper when the moving party clearly establishes on the face of the pleadings that no material issue of fact remains to be resolved and that it is entitled to judgment as a matter of law." *Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542, 1550 (9th Cir. 1989). Although materials outside of the pleadings should not be considered, a court may consider all materials properly submitted as part of the complaint, such as exhibits. *Ibid.* Otherwise, if "materials outside the pleadings are presented to and not excluded by the court," the motion must be treated as a summary judgment motion instead. FRCP 12(c).[2]

2. CDP.

According to Actavis, plaintiff purchased CDP deemed safe by the FDA for consumption. This, Actavis asserts, means she suffered no injury in fact and, thus, she lacks Article III standing. This reasoning tries to import the standing rulings in injunction/declaratory decisions into a different context, the damage context. The reasoning is rejected by this order.

If California law supplies plaintiff with a damage remedy, then she would have a clear stake in the outcome of the litigation and, therefore, would have standing to pursue such a monetary claim. Many decisions cited by counsel regarding standing concern injunction and declaratory relief cases only. In those cases, the Supreme Court has been insistent that the plaintiff have a stake in the outcome of the equitable relief being sought. Those were not damages cases. In contrast, when the relevant law supplies a damage/money remedy to a plaintiff, the plaintiff necessarily has a genuine economic stake in the outcome of the case and Article III standing is satisfied.

The short answer to our immediate problem, however, is that California law does *not* provide plaintiff with a damage remedy. Myers-Armstrong asserts claims for breach-of-warranty, fraud, and unjust enrichment and for a violation of Section 17200 based on the theory that she was harmed because of her purchase of a drug that was "adulterated." Significantly, Myers-Armstrong does *not* allege there was anything ineffective or harmful for the CDP she bought. The complaint merely states that CDP was recalled (at the retail level) because of the plant's failure to meet GMP requirements. Although missing from the complaint, Myers-

[2] Unless otherwise noted, internal citations and quotations have been omitted.

Armstrong's counsel represented at the hearing that she had, in fact, ingested the CDP, which this order accepts as part of the pleading. But there are no allegations that plaintiff ever had a side effect from the CDP or that it did not work as intended. In fact, plaintiff repeatedly disclaims any damages for personal injury or physical harm (Compl. ¶¶ 5, 36, 51; Opp. at 8). To invent an injury, counsel contends that for her breach-of-warranty, Section 17200, fraud, and unjust enrichment claims, reminding us that she purchased a drug that was "adulterated." This is like saying the drug was impure, *i.e.*, mixed with something else, although it must be deemed conceded that the something else was benign, did no harm and the CDP component itself did what it was supposed to do.[3]

Myers-Armstrong's argument essentially boils down to this: Actavis manufactured and sold CDP. CDP was manufactured in a facility not meeting GMP requirements. As required by the FDA, Actavis recalled CDP from the retail level. Myers-Armstrong had already purchased and consumed her CDP. Even though no recall covered it, she wants her money back, despite the fact that the CDP worked as prescribed and any adulteration did her no harm.

As a concession to the shortness of life, California law does not allow a civil lawsuit to recover the purchase price for medicine consumed by the purchaser which performed as intended with no harm or fear of future harm merely because the consumer would not have purchased it had he or she known that the medicine came from a plant whose quality-control had been compromised. That the CDP was adulterated due to a lack of compliance with GMP requirements is not enough, without more, to state a claim. A plaintiff must allege an actual *manifestation* of a defect *that results in some injury or rational fear of future injury* in order to state cognizable claims. *See Khan v. Shiley*, 217 Cal. App. 3d 848, 855 (1990); *see also Am. Suzuki Motor Corp. v. Superior Court*, 37 Cal. App. 4th 1291, 1298–99 (1995). There must be

[3] At the hearing, counsel for Myers-Armstrong disclaimed any relevance of effectiveness vel non, saying: "That our case doesn't depend on whether the drug's effective or ineffective at the time they were sold." After the hearing, the Court reread the complaint and found that for both her breach-of-warranty and fraud claims she used the following language: "Plaintiff and the class purchased pharmaceutical products that were inadequately tested, improperly manufactured, *ineffective*, and potentially dangerous" (Compl. ¶¶ 36, 51) (emphasis added). This order recognizes that one of the adjectives used is "ineffective." This theory, however, was disclaimed at the hearing, as quoted above. Because leave to file a motion to amend the complaint will be allowed, plaintiff is advised to make very clear what theory plaintiff plans to pursue.

at least some physical manifestation such as physical harm, or a failure of the drug to work as intended, or a rational fear of future harm, none of which are alleged.

If the pills had not been consumed, the consumer might possibly have a claim for a refund. But after consuming the pills and obtaining their beneficial effect with no downside, the consumer cannot get a refund on the theory that the pills came from a source of uncertain quality. This does not mean the manufacturer will go scot free. A criminal prosecution might lie. A regulatory shutdown of the plant might be in order. But the civil law should not be expanded to regulate every hypothetical ill in the absence of some real injury to the civil plaintiff.[4]

3. THE OTHER 106 DRUGS.

As to the other 106 drugs, state law does not supply her with a damages remedy for the additional reason that she did not even purchase or ingest any of the other 106 drugs. Plaintiff cites no California decision that shows her extreme theory should go forward. Accordingly, Myers-Armstrong has failed to state a claim as to any of the 107 drugs and this action is **DISMISSED**.

4. PREEMPTION.

On the other hand, Actavis' preemption argument is rejected. The Supreme Court has determined conflict preemption applies in the following two types of situation: (1) where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce; or (2) where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. *See Wyeth v. Levine*, 129 S. Ct. 1187, 1208 (2009). Arguing that Myers-Armstrong's action imposes an impermissible obstacle to the

[4] The extreme theory advanced by plaintiff's counsel seems to be motivated by a desire to obtain class-wide relief in the wake of *Amchem Products, Inc. v. Windsor*, 521 U.S. 591 (1997). There, the Supreme Court affirmed the decertification of a class of present and future asbestos-injury claimants because of the prevalence of individual issues regarding causation and damages. The Supreme Court noted that each plaintiff in an action involving personal injury has a significant interest in individually controlling the prosecution of his case; whereas, class actions are generally suited for the vindication of the rights of groups of people who individually would be without effective strength to bring an action. *Id.* at 616–17. Because individual stakes are high and disparities among class members are great, class certification has been rejected in many product-liability cases. *See Rezulin*, 210 F.R.D. at 66.

FDA's regulation and enforcement of Actavis' manufacturing practices and 2008 recalls, Actavis focuses on the second type of conflict preemption.

According to Actavis, the FDA determined prior to the 2008 voluntary recalls that it could continue manufacturing and selling the drugs manufactured at its Little Falls facility and the FDA concluded that the recalls should reach only to the retail level and consumers should continue taking their drugs. On the other hand, Myers-Armstrong alleges that Actavis' drugs "should never have been offered for sale in California because they were adulterated, were not manufactured using Good Manufacturing Practices, and otherwise were not fit for the purposes for which they were intended" (Compl. ¶ 4). Essentially, Actavis contends that because the FDA did not require a recall at the consumer level (but only the retail and wholesale level) the agency must have performed a balancing of the risks and benefits. This, however, is not clear from the current record.

Actavis' relies on a number of materials outside the four corners of the complaint. While Actavis received warning letters from the FDA on several occasions, Actavis voluntarily recalled the drugs at issue. Contrary to Actavis, this order will not conclude that the drugs were safe for consumers as a matter of law. The Court is unwilling to make this finding, even in light of the additional materials submitted. Actavis, for example, points to its own August 2008 press release, which it refers to as a "FDA-approved recall press release" (Reply at 3). The press release said "[p]atients who may have these medications in their possession should continue to take them in accordance with their prescriptions, as the risk of suddenly stopping needed medication may place patients at risk" (Actavis Exh. A at 1). But this does not go so far as expressly saying the drugs were safe. At most, the statement reflected that the FDA may have considered the downside of continuing to taking the medication as no worse than the downside of discontinuing to take the medication. And, the top of the press release says the "FDA does not endorse either the product or the company." *Ibid*.[5]

[5] Actavis requests judicial notice of the August 2008 press release. FRE 201 allows a court to take judicial notice of a fact not subject to reasonable dispute in that it is capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be disputed. The August 2008 press release, is referenced in the complaint (Compl. ¶¶ 2, 24). Judicial notice of the full text of documents referenced in a

The preemption defense is rejected. Actavis' motion for judgment on the pleadings as to preemption is **DENIED**.

CONCLUSION

For the foregoing reasons, defendants' motion for judgment on the pleadings is **GRANTED IN PART AND DENIED IN PART**. The action is **DISMISSED**. Within **FOURTEEN CALENDAR DAYS**, plaintiff may file a motion on a normal 35-day track seeking leave to amend and appending to the motion a proposed amended complaint. The motion should explain why the foregoing deficiencies would be cured. It should plead plaintiff's best case.

IT IS SO ORDERED.

Dated: April 22, 2009

WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE

complaint is proper under the doctrine of incorporation by reference; such documents are treated as part of the complaint, not extrinsic evidence, and are properly considered on a Rule 12(c) motion. The parties' other requests for judicial notice are **DENIED** as moot.