IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

KATHLEEN A. WAGNER,

Plaintiff,

v.

PFIZER, INC. AND GREENSTONE LTD.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA USA, TEVA INDUSTRIES; WYETH, WYETH PHARMACEUTICALS INC., AND ESI LEDERLE; PHARMACIA AND UPJOHN COMPANY, PHARMACIA CORPORATION; BARR PHARMACEUTICALS, INC. AND BARR LABORATORIES,

Defendants.

OPINION and ORDER

13-cv-497-jdp

For more than ten years, plaintiff Kathleen Wagner took both brand-name and generic hormone therapy drugs as prescribed by her gynecologist to treat her post-menopausal endometrial hyperplasia. After taking the drugs, she developed breast cancer.

Wagner has sued a number of pharmaceutical companies that she alleges designed, manufactured, promoted, and distributed the drugs she took. Wagner seeks damages under multiple state-law theories, all based on the underlying allegations that defendants knowingly sold dangerous products and did not adequately warn of their risks.

Three of the defendant pharmaceutical companies manufactured only the generic form of the drug she took: defendants Teva Pharmaceuticals USA, Inc., Barr Pharmaceuticals, LLC (f/k/a Barr Pharmaceuticals, Inc.), and Barr Laboratories, Inc., which the court will refer to collectively as the Generic Defendants. The Generic Defendants have answered Wagner's amended complaint and they now move for judgment on the pleadings.

The Generic Defendants contend that all of Wagner's claims against them are preempted by federal law. Wagner alleges, in essence, that the Generic Defendants should have altered their drug labels, their formulas, or both to avoid liability. However, the Food, Drug, and Cosmetics Act (FDCA), requires that generic drugs exactly match their brand-name counterparts. The FDCA prohibits unilateral changes of either the generic drug label or the formula, even to strengthen the warning or lower the risk of the drug. Because it would be impossible for the Generic Defendants to do either of these actions and comply with both state and federal law, the Generic Defendants contend that Wagner's state-law claims are preempted. The court agrees, and the Generic Defendants' motion for judgment on the pleadings is granted.

ALLEGATIONS OF FACT

For the purpose of judgment on the pleadings, the court accepts Wagner's version of the facts and any reasonable inferences drawn from them.

Following menopause, Wagner experienced endometrial hyperplasia, which is a build-up of the uterine lining. The build-up is usually the result of too much estrogen and not enough progesterone, and the condition increases the risk of endometrial cancer. One common treatment for endometrial hyperplasia is hormone therapy. Hormone therapy attempts to correct the imbalance using synthetic progestin, which helps to reduce the uterine lining build-up.

To treat her endometrial hyperplasia, Wagner's gynecologist prescribed her various synthetic progestins, including the brand-name versions Provera and Cycrin, and the generic Medroxyprogesterone Acetate (MPA). Wagner took these drugs, as prescribed, for more than

ten years. In 2010, Wagner developed infiltrating lobular breast cancer. She has had multiple surgeries and radiation treatments and continues to undergo cancer treatment.

Pfizer, Inc., which now owns both Pharmacia Upjohn Company LLC and Wyeth LLC, makes Provera and Cycrin. The Generic Defendants make generic MPA. These companies, along with other government and research organizations, conducted studies on the drugs and their effects over the course of decades. As they learned of new risks and effects, the companies updated the drug labels. Despite the dangers, the companies continued to manufacture, market, and sell the drugs.

In 2013, Wagner sued both the brand name and generic manufacturers of the drugs in Dane County Circuit Court. The defendants timely removed the case to this court on the basis of diversity. The court has jurisdiction under 28 U.S.C. § 1332 because the parties are diverse and the amount in controversy exceeds $75,000.

After the defendants answered her complaint, Wagner filed an amended complaint, Dkt. 34, which the defendants have also answered. Dkts. 36, 37, 38 (Generic Defendants); Dkts. 39, 40 (others). The Generic Defendants now move for judgment on the pleadings.

OPINION

A. Standard of Review

A motion for judgment on the pleadings under Fed. R. Civ. P. 12(c) is governed by the same standard as a Rule 12(b)(6) motion to dismiss, except that the court considers both the complaint and the answers to it. *N. Ind. Gun & Outdoor Shows, Inc. v. City of South Bend*, 163 F.3d 449, 452 (7th Cir. 1998). The court will assume the truth of all plausible factual allegations in the complaint, and draw all reasonable inferences in her favor, but the court

will grant the motion if there is no set of facts that Wagner could prove that would entitle her to relief. *Id.*

B. The FDCA preempts state tort laws as applied to generic drugs.

The Generic Defendants assert that Wagner's state law claims against them are preempted by federal law under to two recent Supreme Court cases: *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011); and *Mutual Pharmaceutical Co. Inc. v. Bartlett*, 133 S. Ct. 2466 (2013). These cases hold that the FDCA, 21 U.S.C. §§ 301 *et seq.*, preempts state laws that would require generic drug companies to improve the labeling or change the chemical makeup of their drugs. The reasoning for these decisions is based on the particular requirements that federal law has created for generic drug companies, which differ significantly from those imposed on brand-name drug companies, and are intended to foster the availability of generics.

The process of acquiring federal approval to market a new drug is extensive and involves lengthy and expensive clinical testing. 21 U.S.C. § 355. In 1984, Congress passed the Hatch-Waxman Amendments (formally referred to as the Drug Price Competition and Patent Term Restoration Act, 98 Stat. 1585). The purpose and effect of the amendments were to create a different standard for generic drugs, as the Supreme Court noted, to allow "the generic market to expand, bringing more drugs more quickly and cheaply to the public." *Mensing*, 131 S. Ct. at 2582.

Following the Hatch-Waxman Amendments, generic drugs have not been held to the same rigorous testing requirements as brand-name drugs. Rather, they must demonstrate only equivalence to a brand-name drug that has already been approved. 21 U.S.C. § 355(j). Thus,

the generic drug must have the same active ingredients, route of administration, dosage form, strength, and rate and extent of absorption as the brand-name drug. 21 U.S.C. §§ 355(j)(2)(A)(ii), (iii), and (iv). The generic must also have the same labeling as the brand-name version. 21 U.S.C. § 355(j)(2)(A)(v). Because of this requirement of sameness, after the FDA approves a generic drug, the generic drug company is prohibited from unilaterally changing either the formula or the label for the drug. 21 C.F.R. §§ 314.94(a) and 314.150(b).

In *Mensing*, the Supreme Court held that the FDCA preempts any state law that would require companies to improve generic drug labels. *Mensing*, 131 S. Ct. at 2577-78. The Court reasoned that it would be impossible for those companies to both change the generic drug label and maintain sameness with the corresponding brand-name drug label. *Id.* In *Bartlett*, the Court extended the principles in *Mensing* to cover state defective-design laws. *Bartlett*, 133 S. Ct. at 2470. To comply with the defective-design tort law, the Court determined that generic drug companies would have to either change the drug's formula or change its label. *Id.* at 2474. Alternatively, generic drug companies could choose to stop selling the generic drug. *Id.* at 2477. The Court held that the first two options were impossible because of the FDCA and the last option, withdrawal of the product from the market, was unreasonable. *Id.* at 2470. Thus, under *Mensing* and *Bartlett*, where a generic company faces only these three options to satisfy a state law duty and avoid liability, that state law is preempted by the FDCA.

C. Wagner's claims against the Generic Defendants are preempted by the FDCA.

Wagner's amended complaint alleges many different Wisconsin state law claims, including: varieties of negligence; strict products liability; misrepresentation; breach of warranty; consumer fraud; assault and battery; and infliction of emotional distress. The factual allegations underlying each of Wagner's claims are that the Generic Defendants should have either improved the safety of MPA by changing the formula or strengthened the warnings on the label. But the Generic Defendants could not comply with the FDCA and avoid liability under Wagner's state-law theories. These claims are thus preempted by the FDCA because the Generic Defendants cannot change the formula or the label of MPA without violating federal law. *See Bartlett*, 133 S. Ct. 2466. Nor should the Generic Defendants be expected to stop selling the generic drugs to avoid liability. *Id.* Wagner's opposition to the Generic Defendants' motion criticizes the policy underlying the FDCA and the Supreme Court's rulings in *Mensing* and *Bartlett*. Dkt. 49, at 4-5. But Wagner recognizes the authority of these Supreme Court rulings, and she cannot distinguish her case in any way that avoids their impact.

Most of Wagner's claims (negligence, strict products liability, misrepresentation, breach of warranty, and consumer fraud) can be characterized as failure-to-warn claims, defective-design claims, or both. These claims plainly fall within the scope of *Mensing* and *Bartlett* and are preempted. Although her other claims (infliction of emotional distress and assault and battery) do not fit so obviously into the defective-design box or the failure-to-warn box, they are also preempted. Just like for the failure-to-warn and defective-design claims, the only way for the Generic Defendants to have avoided liability for the remaining

claims would have been to improve the safety of MPA by changing its formula, strengthening the warning on the label, or removing MPA from the market. Again, these options were rejected by the Court in *Mensing* and *Bartlett*. Accordingly, all Wagner's claims are preempted by federal law.

D. Wagner's claims alleging that the Generic Defendants failed to timely update their labels are precluded.

In her opposition to the Generic Defendants' motion, Wagner raises a new allegation that the Generic Defendants failed to timely update the label of MPA to match changes to the brand-name label, as required under the FDCA. Dkt. 49, at 7. She contends that such a claim would not be preempted under *Mensing* and *Bartlett* because failing to timely update the label would violate both the FDCA and state tort law. It would thus be possible for the Generic Defendants to comply with both the FDCA and state tort law by updating MPA's label to match its brand-name counterparts. The weight of authority is against Wagner, but whether such a claim is preempted is still an open question. *See Teva Pharm. USA, Inc. v. Superior Court of Cal., Orange Cnty.*, 217 Cal. App. 4th 96, *petition for cert. filed*, (U.S. Feb. 7, 2014) (No. 13-956).

Nevertheless, this theory has two flaws. First, Wagner has not alleged this claim in her amended complaint. On a motion for judgment on the pleadings, the court may only consider allegations included in the pleadings; it may not consider claims raised in Wagner's opposition brief. To defeat the motion for judgment on the pleadings, Wagner would have to further amend her complaint to allege the Generic Defendants' failure to update. But that leads to a second flaw, and this one is irreparable.

Amending Wagner's complaint to add the failure-to-update claims would be futile for two reasons. First, the FDCA does not provide a private cause of action for its enforcement. 21 U.S.C. § 337(a); *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001)). The FDA exclusively, not private citizens, has the authority to enforce the FDCA labelling requirement on generic drugs. As mentioned above, the question of whether Wagner could use state tort law to effect the same enforcement result to her private benefit is not entirely settled, but most courts that have addressed the issue have decided against allowing it. *See, e.g. Morris*, 713 F.3d at 777. Second, even if her private claim were not barred, it is inconsistent with Wagner's theory of the case. Wagner alleges that the brand-name labels are themselves inadequate. Thus, even if the Generic Defendants had timely updated their labels, Wagner would not have been adequately warned of the dangers of the drugs she was taking. Under Wagner's own theory of the case, the Generic Defendants' failure to timely update their labels to a different but still deficient form could not be a cause of Wagner's injuries. If Wagner were to move to amend her complaint to allege that Generic Defendants failed to timely update the MPA label, the court would have to deny such a motion on the grounds that it was futile.

ORDER

IT IS ORDERED that:

1. The motion for judgment on the pleadings by Defendants Teva Pharmaceuticals USA, Inc., Barr Pharmaceuticals, LLC (f/k/a Barr Pharmaceuticals Inc.), and Barr Laboratories, Inc., Dkt. 46, is GRANTED.

2. Defendants Teva Pharmaceuticals USA, Inc., Barr Pharmaceuticals, LLC (f/k/a Barr Pharmaceuticals Inc.), and Barr Laboratories, Inc. are DISMISSED from this case with prejudice.

Entered this 11th day of July, 2014.

BY THE COURT:
/s/
JAMES D. PETERSON
District Judge