UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

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IN RE YASMIN AND YAZ (DROSPIRENONE) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	**3:09-md-02100-DRH-PMF** **MDL No. 2100**

This Document Relates to: *Gail Gannon v. Bayer Healthcare Pharmaceuticals, Inc., et al.* No. 3:13-cv-10143-DRH-PMF	**Judge David R. Herndon**

ORDER

HERNDON, Chief Judge:

I. INTRODUCTION

Before the Court is defendant Teva Pharmaceuticals USA's ("Teva") motion to dismiss under Fed.R.Civ.P. 12(c) (Doc. 23). Teva moves for judgment on the pleadings and dismissal of plaintiff Gail Gannon's ("plaintiff") claims against it. Plaintiff has filed a response in opposition (Doc. 28), to which defendant has replied in accordance with Local Rule 7.1(c) (Doc. 29). Teva contends that the plaintiffs allegations fail under *Iqbal/Twombly* and/or are pre-empt under federal law. The Court finds that the plaintiff's claims are adequately pled. Accordingly, the Court's order focuses on the issue of federal pre-emption. For the following reasons, defendant's motion is **GRANTED IN PART AND DENIED IN PART**.

II. BACKGROUND AND ALLEGATIONS

Plaintiff, a citizen of Illinois, directly filed her complaint in this Court on February 15, 2013, based on diversity of citizenship (Doc. 1). The plaintiff filed her first amended complaint on September 30, 2013 (Doc. 20). According to the pleadings, plaintiff purchased and ingested the brand-name combination oral contraceptive Yaz (drospirenone; ethinyl estradiol) in November 2009. Shortly thereafter, in June 2010, the plaintiff began using Gianvi, a generic iteration of Yaz (drospirenone; ethinyl estradiol) (Doc. 20 ¶ 3). Plaintiff contends that as a result of using Gianvi she suffered an acute bilateral pulmonary embolus on or about March 12, 2011 (Doc. 20 ¶ 3).

Plaintiff asserts claims against Bayer Healthcare Pharmaceuticals, Inc., Bayer Pharma AG (collectively, "Bayer") and Teva Pharmaceuticals USA ("Teva"). In her complaint, the plaintiff alleges that Bayer is the designer, developer, manufacturer, and seller of YAZ (Doc. 20 ¶¶ 3-21, 25, 60). The plaintiff further alleges and Teva admits that it is the distributor of Gianvi (Doc. 20 ¶ 24, 61).

The question of which entity manufactured the Gianvi ingested by the plaintiff is not a question that can be resolved by the Court at this stage in the litigation. The allegations appropriately considered by the Court at this time indicate the Gianvi ingested by the plaintiff was manufactured by either Bayer or a third entity not named as a defendant in this complaint – Barr Laboratories Inc ("Barr"). Barr is an entity that has entered into agreements with Bayer pursuant to

which Bayer supplied Barr with generic versions of both Yaz (Gianvi) and Yasmin.[1] Barr has been a wholly owned subsidiary of Teva since December 2008 (Doc. 63 ¶ 64). Barr submitted an Abbreviated New Drug Application ("ANDA") for a generic version of Yaz (distributed under the trade-name Gianvi), which was approved on March 30, 2009 (Doc. 23 p. 14 citing publically available records on the FDA's website). The Gianvi under Barr's ANDA is associated with national drug code numbers 0093-5661-58 and 00093-5661-28 (Doc. 23 p. 14 citing publically available records on the FDA's website).

Bayer has also manufactured Gianvi. The authorized generic version of YAZ (sold under the trade-name Gianvi) manufactured by Bayer is associated with national drug code numbers 0093-5423-58 and 0093-5423-28 (Doc. 20 ¶ 67, Doc. 22 ¶¶ 68-70).

Teva has distributed Gianvi under Barr's ANDA (i.e. associated with national drug code numbers 0093-5661-58 and 00093-5661-28) and under Bayer's NDA for the authorized generic version of Yaz (i.e. associated with national drug code numbers 0093-5423-58 and 0093-5423-28). Teva announced the introduction and availability of Gianvi under Barr's ANDA in June of 2010 (Doc. 20 ¶ 64). The "start marketing date" associated with Teva's distribution of

[1] In June of 2008, Bayer and Barr entered into an agreement pursuant to which Bayer would supply an authorized generic version of Yasmin to Barr (Doc. 20 ¶ 62). In June 2010 (after acquiring Barr), Teva announced the availability of Gianvi (the generic version of Yaz) (Doc. 20 ¶ 64). Thereafter, litigation between Bayer and Teva/Barr ensued regarding patent infringement and the distribution of Gianvi (Doc. 20 ¶ 65). The litigation eventually settled and, according to the complaint, an agreement was reached pursuant to which Bayer would supply Barr with the product for Gianvi (Doc. 20 ¶ 65). Plaintiff contends that Bayer has supplied Barr with the product for Gianvi since December 2010 (Doc. 20 ¶ 65).

Gianvi under Bayer's NDA for Yaz is March 30, 2011 (Doc. 23 p. 14 citing publically available records on the FDA's website).

Based on the above, Teva contends that it did not distribute an authorized generic version of drospirenone; ethinyl estradiol under Bayer's NDA prior to April 2011 and therefore, the Gianvi ingested by the plaintiff was necessarily Gianvi distributed by Teva under Barr's ANDA for drospirenone; ethinyl estradiol.[2] The plaintiff has alleged that some Gianvi prescriptions filled before April 1, 2011 contain national drug code numbers 0093-5423-28 and 0093-5423-58, the national drug code numbers associated with Gianvi manufactured by Bayer and distributed by Teva (Doc. 20 ¶ 69). Accordingly, the plaintiff contends, it is possible that Bayer-manufactured Gianvi was available prior to April 1, 2011.

The plaintiff has also alleged that the Gianvi distributed by Teva under Barr's ANDA for drospirenone; ethinyl estradiol was made with drospirenone supplied by Bayer (*See* Doc. 20 ¶¶ 61-66) (alleging that pursuant to an agreement, Bayer supplied Barr with the product for Gianvi since December 2010). The plaintiff contends that this alleged agreement establishes that Bayer and Teva acted in concert to market, manufacture and supply Gianvi.

[2] In addition to pointing to the above publically available records, Teva notes that the pharmacy records accompanying the plaintiff's fact sheet indicate her Yaz prescriptions were filled with Gianvi with National Drug Code Numbers 0093-5661-58 (generic Gianvi distributed by Teva under Barr's ANDA for drospirenone; ethinyl estradiol) (Doc. 23 p. 15). This is a matter outside the pleadings that cannot be considered by the Court without converting the current motion into a motion for summary judgment. Accordingly, for purposes of this motion, the Court disregards this assertion.

Based on the above the Court finds that a question of fact exists with regard to which entity manufactured the Gianvi ingested by the plaintiff. However, in any of the alternative scenarios presently before the Court, Teva's involvement amounts to that of a generic distributor.[3] Accordingly, the Court's analysis proceeds under the assumption that Teva is the entity that *distributed* the Gianvi ingested by the plaintiff.[4]

III. LEGAL STANDARD

Federal Rule of Civil Procedure 12(c) allows a party to move for judgment on the pleadings, which include the complaint, the answer, and any written instruments, including contracts, that are attached as exhibits. *N. Ind. Gun & Outdoor Shows, Inc. v. City of S. Bend*, 163 F.3d 449, 452–53 (7th Cir. 1998). In reviewing a Rule 12(c) motion, a court applies the same standards applicable to a Rule 12(b)(6) motion seeking dismissal for failure to state a claim. *See Buchanan–Moore v. County of Milwaukee*, 570 F.3d 824, 827 (7th Cir. 2009). Thus, a court accepts as true all well-pled factual allegations and draws all reasonable inferences in the plaintiff's favor. *See Rujawitz v. Martin*, 561 F.3d 685, 688 (7th Cir. 2009). Only when it appears beyond a doubt that the plaintiff cannot prove any facts to support a claim for relief and the moving party

[3] The plaintiff's complaint contains at least one allegation that Teva may have manufactured the Gianvi ingested by the plaintiff. Any such allegations, however, amount to mere speculation. Further, even if sufficiently alleged, the contention would merely establish that Teva was a generic manufacturer. For reasons discussed below, the assertion that Teva is a generic manufacturer (as opposed to a generic distributor) does not help the plaintiff's case and does not alter the Court's analysis.

[4] The plaintiff argues that the alleged agreement involving Bayer and Barr/Teva establishes that Teva and Bayer were acting in concert and are jointly and severally liable for the plaintiff's alleged injuries. The Court addresses this issue below.

demonstrates that there are no material issues of fact to be resolved will a court grant a Rule 12(c) motion. *Brunt v. Serv. Employees Int'l Union*, 284 F.3d 715, 718-719 (7th Cir. 2002) (*citing N. Indiana Gun & Outdoor Shows, Inc. v. City of South Bend*, 163 F.3d 449, 452 (7th Cir.1998)). Although the court should accept as true all well-pleaded allegations and should view the complaint in a light most favorable to the plaintiff, the "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555.

If the Court considers evidence outside the pleadings, a motion for judgment on the pleadings is treated as one for summary judgment. FED. R. CIV. P. 12(d). However, a district court may take judicial notice of matters of public record without converting a Rule 12 motion into a motion for summary judgment. *Gen. Elec. Capital Corp. v. Lease Resolution Corp.*, 128 F.3d 1074, 1080 (7th Cir.1997). Further, a court may consider "documents attached to a motion to dismiss * * * if they are referred to in the plaintiff's complaint and are central to his claim." *Brownmark Films, LLC v. Comedy Partners*, 682 F.3d 687, 690 (7th Cir.2012) (internal quotation omitted).

IV. DISCUSSION

A. Preemption

Teva asserts that it is entitled to judgment on the pleadings because the plaintiff's state tort claims are preempted by federal law. The Supremacy Clause states that federal law "shall be the supreme Law of the Land ... and any Thing in

the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Implied preemption, the type of preemption at issue in this motion, occurs when it is "impossible for a private party to comply with both state and federal requirements." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287, 115 S.Ct. 1483, 131 L.Ed.2d 385 (1995). In other words, when state law requires what federal law forbids, state law must give way. *See Wyeth v. Levine*, 555 U.S. 555, 583, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009).

Federal preemption is an affirmative defense upon which the defendants bear the burden of proof. *Village of DePue, III v. Exxon Mobil Corp.*, 537 F.3d 775, 786 (7th Cir. 2008).

B. The Hatch-Waxman Act

The labeling of prescription drugs is governed by the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301, *et seq*. Pursuant to the FDCA, before bringing any new drug to market, approval must be obtained by filing a New-Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA"). To secure the approval of the FDA, a manufacturer of a new drug must file an application demonstrating the drug is safe, effective, and adequately labeled. 21 U.S.C. § 355(b), (d); 21 C.F.R. § 314.1 et seq. The NDA process is time consuming, arduous and expensive.

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, 98 Stat. 1585, commonly known as the Hatch-Waxman Act. The

Act amended the FDCA to permit generic drug manufacturers to bypass the approval practice by submitting an "abbreviated new drug application" ("ANDA")—an application showing the proposed generic drug to be the same as a reference listed drug ("RLD") that has already gained FDA approval. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94. This abbreviated process allows generic drug manufacturers "to gain FDA approval simply by showing that its drug is equivalent to an already-approved brand-name drug, and that the safety and efficacy labeling proposed for its drug is the same as that approved for the brand-name drug." *PLIVA Inc. v. Mensing*, 131 S.Ct. 2567, 2574, 180 L.Ed.2d 580 (2011).

Under this streamlined approach, the generic must be bioequivalent to and have the same labeling as the RLD. 21 U.S.C. § 355(j)(2)(A)(iv), (v); 21 C.F.R. § 314.94(a)(7), (8). The Supreme Court recently provided the following summary with regard to the ANDA process:

> First, the proposed generic drug must be chemically equivalent to the approved brand-name drug: it must have the same "active ingredient" or "active ingredients," "route of administration," "dosage form," and "strength" as its brand-name counterpart. 21 U.S.C. §§ 355(j)(2)(A)(ii) and (iii). Second, a proposed generic must be "bioequivalent" to an approved brand-name drug. § 355(j)(2)(A)(iv). That is, it must have the same "rate and extent of absorption" as the brand-name drug. § 355(j)(8)(B). Third, the generic drug manufacturer must show that "the labeling proposed for the new drug is the same as the labeling approved for the [approved brand-name] drug." § 355(j)(2)(A)(v).

Mutual Pharmaceutical Co., Inc. v. Bartlett, 133 S.Ct. 2466, 2471 (2013).

After a generic or brand-name drug is approved, "the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.' " *Bartlett*, 133 S.Ct. at 2471 (*quoting* 21 C.F.R. § 314.70(b)(2)(i)). Generic manufacturers (but not brand-name manufacturers) "are also prohibited from making any unilateral changes to a drug's label," thus "approval for a generic drug may be withdrawn if the generic drug's label is no longer consistent with that for the brand name drug." *Id*. (quotation and alteration omitted) (*citing* 21 C.F.R. §§ 314.94(a)(8)(iii), 314.150(b)(10)).

C. *Levine, Mensing* and *Bartlett*

Three decisions of the United States Supreme Court, *Wyeth v. Levine*, 555 U.S. 555, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009), *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567, 180 L.Ed.2d 580 (2011), and *Mutual Pharm. Co. v. Bartlett*, 133 S.Ct. 2466 (2013) are at the center of recent products liability actions alleging inadequate warnings by drug manufacturers, including this one.

In *Levine*, the plaintiff developed gangrene after using the intravenous form of Phenergan, an antihistamine used to treat nausea. The plaintiff filed an action against the brand-name manufacturer alleging negligence in connection with the drug's warning label. Ultimately, the Supreme Court considered and rejected the brand-name manufacturer's claim that it would have been impossible to comply with its state law duty to warn without violating FDCA and FDA regulations. The

Supreme Court concluded that the brand-name manufacturer could have unilaterally strengthened its warnings without prior FDA approval through the "changes being effected" process, 21 D.F.R. § 314.70(c)(6)(iii), which enables certain labeling changes to be implemented simultaneous to submitting the changes to the FDA for review.

The fact that the manufacturer in *Levine* was a brand-name manufacturer, with the ability to "unilaterally strengthen its warning", was critical to the Supreme Court's decision on preemption. *See Levine*, 555 U.S. at 573. *See also Mensing*, 131 S.Ct. at 2581 (no preemption in *Levine* because federal regulation allowed brand-name manufacturer to unilaterally strengthen its warning without prior FDA approval). Two years later, in *Mensing*, the Supreme Court would reach a different result with regard to generic manufacturers.

In *Mensing*, the plaintiffs were prescribed brand-name metoclopramide, a drug commonly used to treat digestive tract problems. *Mensing*, 131 S.Ct. 2572-73. The plaintiffs alleged that their use of the drug caused them to develop tardive dyskinesia, a severe neurological disorder. *Id.* at 2573.

Although the plaintiffs were prescribed brand-name metoclopramide, their prescriptions were ultimately filled with generic metoclopramide. *Id.* The plaintiffs brought failure to warn claims against the generic manufacturers. *Id.* The plaintiffs alleged the generic manufacturers violated state tort laws by failing to change the labels for metoclopramide to adequately warn of the risk of tardive

dyskinesia. *Id.* The state tort laws involved required manufacturers that are "or should be aware of [their] product's danger to label that product in a way that renders it reasonably safe." *Id*. at 2573

The Supreme Court concluded that the plaintiffs' claims were preempted by federal law, specifically, the Hatch-Waxman Act. *Id.* at 2577-78. In so ruling, the Supreme Court deferred to the FDA's interpretation of its regulations that, under the Hatch-Waxman Amendments, the labeling of a generic drug must be the same as the labeling of the RLD. *Id.* at 2574-76 (accepting the FDA's interpretation that changes unilaterally made by a generic manufacturer would violate federal requirements that the generic label be the same as the brand-name label). The Supreme Court explained that this ""federal duty of 'sameness' " requires "generic drug labels be the same at all times as the corresponding brand-name drug labels." *Id*. at 2574–75, 2578. Accordingly, "[i]f the [generic] Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law." *Id.* at 2578. In other words, unlike brand-name manufacturers, generic manufacturers have no ability to unilaterally alter a drug's warning label.[5]

[5] The plaintiff alleges in her complaint that she "was injured years after the implementation of the Food and Drug Administration Amendment Act of 2007 ("FDAAA") Pub. L. No. 110-85" (Doc. 20 ¶ 98). As such, she contends, Teva had the power to unilaterally seek a label change to Gianvi (Doc. 20 ¶ 98). The Court notes that in *Mensing* the Supreme Court relied on pre–2007 FDA statutes and regulations and "express[ed] no view on the impact of the 2007 Act." *Mensing,* 131 S.Ct. 2572. The plaintiff, however, fails to address this issue in her briefing. Further, The Court has reviewed the 2007 Amendments to the FDCA, and the statutes and regulations cited in *Mensing* appear to be unaltered. Accordingly, the Court finds that the 2007 FDCA Amendments do not remove this case from *Mensing*'s scope.

Shortly thereafter, in *Bartlett,* the Supreme Court again addressed the tension between state tort law and the federal regulatory scheme governing prescription drugs in a case involving generic manufacturers. *Bartlett* involved a generic manufacturer and state-law design-defect claims that turned on the adequacy of a drug's warnings. The Supreme Court held that the reasoning of *Mensing* extends to "warning-based design-defect cause[s] of action" asserted against generic manufacturers. *Bartlett*, 133 S.Ct. at 2477.

The Supreme Court also extended the reasoning in *Mensing* to claims asserting that a generic drug is ineffective or unreasonably dangerous. "In the drug context, either increasing the 'usefulness' of a product or reducing its 'risk of danger' would require redesigning the drug: A drug's usefulness and its risk of danger are both direct results of its chemical design and, most saliently, its active ingredients." *Bartlett*, 133 S.Ct. at 2475. But "the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based." *Id*. (*citing* 21 U.S.C. §§ 355(j)(2)(A)(ii)-(v) and (8)(B); 21 C.F.R. § 320.1(c)).[6]

Levine, Mensing and *Bartlett* establish a distinction between generic and brand manufacturers that is critical to the instant case. In a nutshell, the brand manufacturer has the ability to make unilateral changes to a drug's warning label. Accordingly, failure-to-warn claims against brand manufacturers are *not*

[6] Under *Bartlett,* there is some room for argument relating to state law claims that impose a duty to make changes to the qualitative or quantitative formulation of a drug product (including active ingredients, or in the specifications provided in the approved application) that do not constitute "major" changes. This, however, does not appear to be a matter in issue in the present case.

preempted by federal law. Generic manufacturers, on the other hand, have no such ability. When it comes to strengthening a drug's warning label, generic manufacturers' hands are tied because the "ongoing federal duty of 'sameness'" precludes manufacturers of generic drugs from unilaterally strengthening their labeling. *Mensing*, 131 S.Ct. at 2575–82. Accordingly, in *Mensing,* the Supreme Court concluded that state law failure to warn claims involving generic manufacturers are preempted. In *Bartlett* the Supreme Court held that the reasoning of *Mensing* extends to "warning-based design-defect cause[s] of action" asserted against generic manufacturers. *Bartlett*, 133 S.Ct. at 2477. The *Bartlett* decision also extends the reasoning of *Mensing* to claims asserting that a generic drug is ineffective or unreasonably dangerous – at least to the extent that such claims impose a duty to redesign the drug in issue that conflicts with federal regulations. *Id.* at 2474-2475.

D. Preliminary Consideration – Applicability of *Mensing* and *Bartlett* to Generic *Distributors*

The Court notes that both *Mensing* and *Bartlett* involved generic *manufacturers* and not generic *distributors.* Thus, as an initial matter, the Court must consider whether *Mensing* and *Bartlett* are applicable to Teva – the distributor of a generic drug. As noted above, the rationale for excusing generic manufacturers from liability is that generic manufacturers do not have the ability to unilaterally effectuate a label change. *Mensing,* 131 S.Ct. at 2575-76. Only brand manufacturers have the ability to take unilateral action to strengthen a drug's warning label. *Id.* This rationale is equally applicable to generic

distributors. Under applicable federal regulations, generic distributors have no more authority than generic manufacturers to alter a drug's composition, label, or design. Accordingly, the principles announced in *Mensing* and *Bartlett* are equally applicable to generic distributors.

E. Joint Liability

Plaintiff contends that regardless of whether *Bartlett* or *Mensing* would preempt Illinois tort claims, neither decision applies here, because Bayer and Teva are subject to joint and several liability (Doc. 28 pp. 5-10). Plaintiff contends that the Gianvi she ingested was produced in accord with a December 2010 licensing agreement between Bayer and Barr/Teva pursuant to which Bayer agreed to supply Barr with the product for Gianvi. As such, the plaintiff argues, the Gianvi she ingested was manufactured, licensed, and sold pursuant to an agreement between Bayer and Teva. The plaintiff reasons as follows with respect to this agreement and the alleged joint liability of Bayer and Teva:

> In *Mensing*, the dissent explained that Mensing did not bar claims against a brand name manufacturer that produces generic drugs. *Mensing*, 131 S. Ct. at 2589, n.12 (Sotomayor, J., dissenting). "In that case, the manufacturer could independently change the brand-name label … triggering a corresponding change to its own generic label." *Id*. Thus, when a brand name manufacturer is involved in the production of a generic drug, Mensing and Bartlett are inapplicable.
>
> … Bayer, as the brand-name manufacturer, had the ability to make changes to Yaz without violating the "sameness" requirement of the FDCA. A change to Yaz would have triggered a corresponding change in Gianvi pursuant to the very same "sameness" requirement upon which Teva bases its purported right to judgment. (Def. Mem. at 4.) Accordingly, impossibility preemption does not apply to Plaintiff's

> claims against Bayer. As Bayer and Teva jointly participated in the manufacture, marketing, and sale of Gianvi, they are joint tortfeasors who acted in concert to cause Plaintiff's injuries, and are jointly and severally liable for her damages.

(Doc. 28 p. 5).

The plaintiff's argument fails as a matter of law for two reasons. First, the fact that *Mensing* does not bar claims against a brand-name manufacturer that produces generic drugs only speaks to Bayer's liability. Second, the existence of the alleged supply and distribution agreement between Bayer and Teva does not change the fact that Teva had no authority to make unilateral changes to Gianvi's label. At most, Teva could have sought assistance from the FDA in convincing Bayer to adopt a stronger label for Yaz so it could do the same with regard to Gianvi. The same is true with regard to Teva's ability to alter Gianvi's design or composition. Considering the above, the Court finds that the plaintiff's joint liability argument does not remove this case from the scope of *Mensing* or *Bartlett*.

F. Analysis of Specific Counts

In light of the Court's conclusion that both *Mensing* and *Bartlett* are applicable to the instant case, the Court will now assess whether Teva has established preemption with regard to the relevant counts of the plaintiff's complaint.

1. Count II Strict Products Liability – Design Defect

a. Illinois Design Defect Claims and Duty

The plaintiff notes that in *Bartlett* the design defect claim in issue "place[d] a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling." *Bartlett,* 133 S. Ct. at 2479. According to the plaintiff, Illinois' design defect law "imposes no affirmative duty [on manufacturers], and instead serves to spread risk" (Doc. 28 p. 12). Accordingly, the plaintiff argues, *Bartlett* does not preempt Illinois design defect claims. The plaintiff misconstrues Illinois' strict liability law, and in so doing she actually forwards the very argument that was rejected by the Supreme Court in *Bartlett*.

In 2012, the Appellate Court of Illinois reaffirmed the principle that "in a strict liability cause of action, 'a manufacturer is under a nondelegable duty to produce a product which is reasonably safe.'" *Baley v. Fed. Signal Corp.*, 982 N.E.2d 776, 798 (Ill. App. 2012) (quoting *Rios v. Niagara Machine & Tool Works*, 319 N.E.2d 232, 235-36 (Ill. 1974)). *Baley* involved a number of strict liability claims against a manufacturer, including design defect claims. *Id.* at 789-90. The Court acknowledged that "duty is typically an element of negligence," but pointed to a line of Appellate Court decisions "recogniz[ing] that in strict liability actions a manufacturer has a duty to produce a reasonably safe product." *Id.* at 798-99.

In a 1990 strict liability case brought against a drug manufacturer, the Illinois Supreme Court was even more explicit that duty is an element of *both*

negligence and strict liability in Illinois: "Both negligence and strict liability require proof that [a] defendant breached a duty owed to a particular plaintiff. Each manufacturer owes a duty to plaintiffs who will use its drug or be injured by it." *Smith v. Eli Lilly & Co.*, 560 N.E.2d 324, 343 (1990) (internal citations omitted).

To refute these authorities, the plaintiff offers an argument from silence. She points to a 2008 Appellate Court decision involving a strict liability claim against an automobile dealer, *Murphy v. Mancari's Chrysler Plymouth, Inc.*, 887 N.E.2d 569 (Ill. App. 2008), and notes that "[t]he word 'duty' is mentioned nowhere in the *Murphy* decision." (Doc. 28 at 12). But *Murphy* does not hold, or even suggest, that duty is not an element of strict liability claims in Illinois. Instead, *Murphy* focuses on the difference between strict liability and negligence, noting that *fault* is an element of the latter but not the former. *Id.* at 574-75.[7] Fault and duty are distinct concepts. By conflating them, the plaintiff makes the same error that the Supreme Court addressed in *Bartlett*.

The plaintiff argues that, because strict liability in Illinois does not require a finding of *negligence*, "Teva's liability is not based on a breach of duty…." (Doc. 28 at 12-13). But the Supreme Court considered, and rejected, this very argument in *Bartlett*. 133 S.Ct. at 2473-74. The respondent in *Bartlett* argued that New Hampshire's strict liability law imposes no affirmative duties on manufacturers.

[7] Plaintiff's citations to *Connelly v. Uniroyal, Inc.*, 389 N.E.2d 155, 163 (Ill. 1979), and *Liberty Mut. Ins. Co v. Williams Mach. & Tool Co.*, 338 NE.2d 857, 860 (Ill. 1975), likewise do not support her conclusion that duty is not an element of strict liability, as those cases, like *Murphy*, only repeat the principle that strict liability is distinct from negligence. (Doc. 28 at 13).

Id. at 2473. The Court's subsequent discussion of the relationship between strict liability and duty is just as applicable to the law of Illinois as to the law of New Hampshire.

> [The] respondent's argument conflates what we will call a "strict-liability" regime (in which liability does not depend on negligence, but still signals the breach of a duty) with what we will call an "absolute-liability" regime (in which liability does not reflect the breach of any duties at all, but merely serves to spread risk). New Hampshire has adopted the former, not the latter. Indeed, the New Hampshire Supreme Court has consistently held that the manufacturer of a product has a duty to design his product reasonably safely for the uses which he can foresee.

Id. (internal quotation marks omitted). Just as in New Hampshire, Illinois' strict liability does not mean that manufacturers have no affirmative duties. As discussed above, Illinois manufacturers have a duty "to produce a product that is reasonably safe." *Baley*, 982 N.E.2d at 798.[8]

Bartlett also helps answer the plaintiff's contentions with regard to *Halperin v. Merck, Sharpe & Dohme Corp.*, 2012 WL 1204728 (N.D. Ill. Apr. 10, 2012). In *Halperin*, a United States district court interpreted Illinois' strict liability law as imposing liability "regardless of culpability, duty, knowledge, or fault." *Id.* at *3.[9] But *Halperin* was decided before the Supreme Court decided *Bartlett*. Referring to *PLIVA, Inc. v. Mensing*, 131 S.Ct 2567 (2011), the *Halperin*

[8] As the defendant points out, *Baley*'s description of an Illinois manufacturers' duty is remarkably similar to how *Bartlett* defined the duty of New Hampshire manufacturers: "New Hampshire tort law…requires manufacturers to ensure the products they design, manufacture, and sell are *not unreasonably dangerous*." *Bartlett*, 131 S.Ct. at 2474 (emphasis added).

[9] At the outset it must be noted that a federal district court's interpretation of state law must give way to a contrary interpretation by the state supreme court. *Allstate Ins. Co. v. Menards, Inc.*, 285 F.3d 630, 633 (7th Cir. 2002) ("[T]he ultimate responsibility of the district courts is to apply the law of the state in which the court sits").

court noted that "[n]either the *Mensing* opinion, nor the underlying proceedings in the Fifth and Eighth Circuits, directly address strict liability design defect claims." *Id.* In other words, *Mensing* left open the question of whether preemption concerns are avoided where a state imposes strict liability for design defects. But *Bartlett did* directly address strict liability design defect claims, and explicitly held that the state law claim was preempted. 133 S.Ct. at 2468. Thus, the reasoning of *Halperin* does not survive *Bartlett*.

b. Consumer Expectation Test and Risk-Utility Test

The plaintiff also contends that *Bartlett* is not controlling because Illinois assesses the unreasonableness of the danger of a product using a consumer-expectations test while the state whose tort laws *Bartlett* interprets, uses a risk-utility approach. The Court concludes that this is a distinction without a difference.

In Illinois, "unreasonable dangerousness" can be established using either the risk-utility test or the consumer expectation test. *See Mikolajcyzyk v. Ford Motor Co.,* 901 N.E.2d 329, 348 (Ill. 2008). Importantly, the two tests are not separate theories of liability, but rather two different ways whereby a plaintiff can prove the same ground of liability – unreasonable dangerousness. The plaintiff's implicit argument is that the *content* of the duty imposed by Illinois law is different from the law at issue in *Bartlett* because Illinois uses the consumer expectations test. However, because the two tests are simply alternative methods

of proof, the content of the underlying duty is the same. Moreover, the Fourth Circuit Court of Appeals has considered and rejected the very argument raised by the plaintiff. In *Drager v. PLIVA USA, Inc*., 741 F.3d 470 (4th Cir. 2014), the Fourth Circuit reasoned as follows:

> To the extent that there is a difference in approach between the two states, it is immaterial. The Court in *Bartlett* did not determine that the New Hampshire law was preempted because it applied the risk-utility approach. Instead, it concluded that there was no action that the defendant could take under that approach to increase the safety of its product without violating the restrictions of the [Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 301 et seq.]. We have no trouble concluding that the same is true under either the risk-utility or the consumer-expectations approach in Maryland. PLIVA cannot be required to stop selling its product, but at the same time it is prohibited from making any changes to the product itself or the accompanying warnings. Regardless of the way in which Maryland assesses the unreasonableness of a product's risks, if PLIVA's metoclopramide is unreasonably unsafe, there is no apparent action that PLIVA can take in compliance with FDCA restrictions to avoid strict liability.

Id. (footnotes omitted). The plaintiff urges the Court to look to the Eighth Circuit's opinion in *Fullington v. Pfizer, Inc.,* 720 F.3d 739 (8th Cir. 2013). In *Fullington,* the Eighth Circuit remanded the design defect claims brought under the consumer expectation test for further consideration in light of *Bartlett.* On remand, however, the district court agreed with the Fourth's Circuit's analysis in *Drager See Fullington v. Pliva, Inc.* 2014 WL 806149, 3 (E.D. Ark. Feb. 28, 2014*)* (Holmes, J) ("The Fourth Circuit is Correct, whether a state follows the risk-utility approach or the consumer-expectations approach does not affect the application of *Bartlett*."). The undersigned also agrees with the Fourth Circuit's conclusions as to the consumer expectation test.

c. Federal Misbranding Statute

In *Bartlett,* the Supreme Court expressly noted an exception for state law claims that parallel the federal misbranding statute. *Bartlett* 133 S.Ct. 2477 n.4 ("We do not address state design-defect claims that parallel the federal misbranding statute."). The federal statute requires a manufacturer to pull a drug from the market (even though approved by the FDA) if it is "dangerous to health" even when used in accordance with the FDA-approved directions. *Id.; cf.* 21 U.S.C. § 352(j). This exception only applies where the plaintiff's claim is based on scientific information that was not available when the drug was approved by the FDA. *Bartlett,* 131 S.Ct. 2477 n.4.

In the instant case, the plaintiff alleges that "the Gianvi birth control pills, as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, were dangerous to health when used in the dosage, manner, or with the frequency or duration prescribed, recommended and/or suggested in its labeling, in violation of 410 ILCS § 620/3, *et seq.* As such, the sale of such drugs in this state was strictly prohibited" (Doc. 20 ¶ 134). The plaintiff also sets forth allegations regarding Gianvi's allegedly dangerous design that purportedly was not available to the FDA (Doc. 20 ¶¶ 38-48). The plaintiff contends that "unlike in *Bartlett,* the jury will be asked to find whether new evidence concerning Gianvi that had not been made available to the FDA rendered Gianvi so dangerous as to be misbranded under the federal misbranding statute" (Doc. 28 p. 15).

Considering this argument, the Court finds that, to the extent the plaintiff's design defect claim parallels the federal misbranding statute, it is not foreclosed by *Bartlett.*

d. Conclusion

Accordingly, as to Teva, Count II Strict Products Liability – Design Defect – the motion for judgment on the pleadings is DENIED. The plaintiff's design defect claim may proceed to the extent that the claim parallels the federal misbranding statute.

2. Count III Defect Due to Inadequate Warning

The plaintiff admits that, if the Court does not accept her joint liability argument, this claim is preempt as to Teva under *Mensing* (Doc. 28 p. 18). For reasons already discussed, the court finds that *Mensing* applies to preempt failure-to-warn claims asserted against Teva, a generic distributor, despite the plaintiff's joint liability argument.

Accordingly, as to Teva, Count III Defect Due to Inadequate Warning is Dismissed with prejudice.

3. Remaining Claims

As previously noted, federal preemption is an affirmative defense upon which the defendants bear the burden of proof. *Village of DePue, III v. Exxon Mobil Corp.*, 537 F.3d 775, 786 (7th Cir. 2008). A proper inquiry into the issue of

federal preemption requires a separate analysis of each state law claim to determine whether preemption applies. The Court finds that, as to the remaining counts, Teva has not met its burden of proof with regard to federal preemption. Teva merely asks the Court to construe all of the plaintiff's claims as failure to warn claims and to conclude that the claims are preempt under *Mensing*. This is not sufficient. In order to meet its burden, Teva must identify the state law duties associated with the remaining causes of action and provide the Court with an analysis of how those duties conflict with federal law.

Therefore, the motion for judgment on the pleadings as to the following counts is DENIED:

- **Count I Strict Products Liability – Defective Manufacturing**
- **Count IV Negligence and Negligent Misrepresentation**
- **Count VI Fraud and Misrepresentation**
- **Count VIII Breach of Express Warranty**
- **Count IX Violation of the Illinois Consumer Fraud and Deceptive Business Practices Act**

SO ORDERED:

Digitally signed by
David R. Herndon
Date: 2014.04.23
17:20:19 -05'00'

Chief Judge **Date: April 23, 2014**
United States District Court