2013 PA Super 214

IN RE: REGLAN/METOCLOPRAMIDE LITIGATION,	IN THE SUPERIOR COURT OF PENNSYLVANIA
APPEAL OF: TEVA PHARMACEUTICALS USA, INC., PLIVA ET AL.,	
Appellants	No. 82 EDA 2012

Appeal from the Order Entered November 18, 2011
In the Court of Common Pleas of Philadelphia County
Civil Division at No(s): January Term, 2010 No. 01997

BEFORE: STEVENS, P.J., BOWES, and PLATT,* JJ.

OPINION BY BOWES, J.: **FILED JULY 29, 2013**

PLIVA, Inc. and Teva Pharmaceutical USA, Inc., ("Generic Defendants") appeal from the November 18, 2011 order overruling their preliminary objections in the nature of a demurrer to a master complaint filed by Plaintiffs, who are persons allegedly injured after ingesting metoclopramide.[1] The Generic Defendants assert that all of Plaintiffs' claims against generic manufacturers of metoclopramide, regardless of the legal

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* Retired Senior Judge assigned to the Superior Court.

[1] The claims herein are representative of the claims of more than two thousand claims pending in the Court of Common Pleas of Philadelphia County. The preliminary objections were filed to their third amended master long form complaint.

theory advanced and without consideration of the applicable state law, are failure-to-warn claims. They continue that all causes of action are indistinguishable from those held pre-empted by the United States Supreme Court in ***PLIVA, Inc. v. Mensing***, 131 S.Ct. 2567 (2011), and that the trial court erred in not dismissing them. In addition, Generic Defendant Hospira Inc. ("Hospira") presents a discrete pre-emption issue on appeal: that any claim prior to 2009 premised on its failure to update its label to conform to that of the Reference Listed Drug holder ("RLD"), referred to as a ***Mensing*** carve-out claim,[2] is also pre-empted because the RLD did not update its warning until 2009. After careful review, we reverse in part and affirm in part.

Generic Defendants premise jurisdiction to entertain this interlocutory appeal on the collateral order doctrine. We accept jurisdiction on that basis. For the reasons that follow, we reject Generic Defendants' characterization of all claims herein as ***Mensing*** failure-to-warn claims as well as their proposed blanket application of impossibility pre-emption without any regard

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[2] After ***Mensing***, courts have referred to failure-to-warn claims that were not addressed in ***Mensing*** and which may escape pre-emption as "carve-out" claims. Examples of carve-outs include claims that a generic defendant did not update its label to conform to the updated label of the brand-name drug manufacturer; claims that generic manufacturers should have more effectively communicated their FDA-approved updated label to the medical community; failure-to-warn claims arising after the enactment of the FDAAA; and claims that generic manufacturers should have suspended drug sales until a label change could be effected.

for the applicable state law. Since all of the ***Mensing*** claims pre-dated the Food and Drug Administration Amendments Act of 2007 (hereinafter the "FDAAA" or the "Act"), 121 Stat 823, the Court expressed "no view on the impact of" that legislation. ***Mensing***, ***supra*** at 2574 n.1. Thus, we decline to find post-Act claims pre-empted unless there is a thoughtful and careful examination of the federal law and state law applicable to ascertain whether state law compels what is impossible under federal law.[3] However, we do find pre-empted under ***Mensing*** those failure-to-warn claims arising prior to the 2007 Act that are premised solely on the content of generic drug labels that conform to the name-brand label. Since pre-Act failure-to-warn carve-out claims against Hospira fall within the ambit of this holding, they are pre-empted.

The within appeal is one of four related appeals arising from mass tort litigation in Philadelphia County involving the name-brand drug Reglan and its generic bioequivalent, metoclopramide. The Food and Drug Administration ("FDA") approved metoclopramide under the brand name Reglan in 1980, and five years later, generic manufacturers started producing the drug. The drug stimulates digestive function by speeding up the movement of food through the system, and it is prescribed to treat

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[3] Generic Defendants and Hospira do not address the impact of the 2007 Act on the pre-emption of state law failure-to-warn claims arising after the Act.

chronic digestive problems such as diabetic gastroparesis and gastroesophageal reflux. In the years following FDA approval, long-term use of metoclopramide was linked to tardive dyskinesia, a severe and usually permanent neurological disorder characterized by involuntary and uncontrollable movements of the head, neck, face, arms, and trunk including facial grimacing and tongue thrusting. Third Amended Master Long Form Complaint at ¶82. Studies showed that as many as twenty-nine percent of those people who took the drug for several years developed tardive dyskinesia. Changes to the label were made in 1985, 2004, and 2009, to strengthen warnings of the dangers associated with use of the drug for more than twelve weeks.

Plaintiffs in this mass tort litigation commenced civil actions against both the name-brand manufacturers and generic manufacturers seeking damages for personal injuries and deaths due to their ingestion of either the name brand metoclopramide, Reglan, or its generic bioequivalent.[4] While such claims were pending, the United States Supreme Court granted *certiorari* in two cases: ***Mensing v. Wyeth, Inc.***, 588 F.3d 603 (8th Cir. 2009) (under Minnesota law) and ***Demahy v. Actavis, Inc.***, 593 F.3d 428

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[4] A.H. Robins Company, Inc. received FDA approval for injectable Reglan in 1979, and in tablet form in 1980. It subsequently merged with Wyeth, which was then acquired by Pfizer, Inc. Schwarz Pharma purchased the formula for Reglan from Wyeth and Alaven Pharmaceuticals subsequently purchased the formula from Schwarz. Third Amended Master Long Form Complaint, ¶¶90-95.

(5th Cir. 2010) (under Louisiana law), to determine whether state failure-to-warn cause of action based upon inadequate drug labeling could be maintained against generic drug manufacturers. The precise question was "whether federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus pre-empt, these state-law claims." ***Mensing***, 131 S.Ct. at 2572.

The ***Mensing*** Court thoroughly discussed the differences in the federal regulations governing name-brand drug manufacturers, *i.e.*, the RLD holders, and those regulations pertaining to generic drug manufacturers. Many of the latter regulations originated with the passage of the 1984 Hatch-Waxman Amendments. That legislation streamlined the process whereby generic drug manufacturers could receive FDA approval to market their drugs. Rather than requiring generic manufacturers to file a New Drug Application ("NDA") with the FDA, and to conduct extensive clinical trials to prove that their drugs were safe and effective, the Amendments permitted generic manufacturers to submit Abbreviated New Drug Applications ("ANDA") demonstrating that the generic drug contained the same active ingredient, in the same dosage, with the same therapeutic effect as the previously approved RLD. In addition, the legislation mandated that the generic drug's labeling be identical to the RLD's labeling. 21 U.S.C. § 355(j)(2)(A)(v). While an RLD could change the warning on its label by utilizing a process known as "Changes Being Effected" ("CBE"), 21 C.F.R.

§ 314.70(c)(6)(iii)(C), that procedure was not available to generic manufacturers. Rather, a generic manufacturer could only change its label to conform to an updated RLD label or in response to an FDA directive.

The FDAAA, 121 Stat. 823, was enacted on September 27, 2007. The ***Mensing*** Court noted that its holding "express[ed] no view on the impact of the 2007 Act." ***Mensing*** at 2574 n.1. The Court concluded that federal law applicable at the time the relevant events occurred in ***Mensing*** and ***Demahy*** precluded generic drug manufacturers from unilaterally changing their labels to strengthen a warning, which was the duty imposed in state failure-to-warn cases. It rejected the plaintiffs' assertions that generic manufacturers could use the CBE procedure to change their labels or issue Dear Doctor letters conveying additional warnings. The fact that generic manufacturers could take steps to urge the FDA to change the warnings on the drug's label did not mandate a different result. The ***Mensing*** Court reasoned that "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." ***Mensing***, at 2581-82. State law yielded to federal law. Thus, Minnesota and Louisiana tort-law claims based on generic drug manufacturers' failure to provide adequate warning labels for generic metoclopramide were pre-

empted by federal law. In both cases, the generic labels were the same as the label of the name-brand manufacturer.

In reliance upon ***Mensing***, Generic Defendants filed preliminary objections to Plaintiffs' Third Amended Long Form Master Complaint seeking dismissal of all claims against generic manufacturers of metoclopramide on pre-emption grounds. The trial court overruled the preliminary objections and held that Generic Defendants failed to sustain their heavy burden of proving with certainty that no legal recovery was possible. The court recognized the rebuttable presumption that under Pennsylvania's choice of law rules, the law of the domiciles of the various Plaintiffs would apply, and that blanket pre-emption was premature absent a state-by-state analysis.

Generic Defendant Hospira filed additional preliminary objections arguing that as to it, the ***Mensing*** carve-out claims based on a generic manufacturer's failure to update its label to conform with the updated label of the brand-name manufacturer also were pre-empted. The facts peculiar to the issue raised by Hospira are as follows. Hospira is a generic manufacturer of metoclopramide in an injectable form, which is administered in hospitals and clinics generally for acute conditions. Hospira's brief at 14. It is undisputed that Baxter Healthcare ("Baxter") remains the RLD holder for injectable Reglan since it filed an NDA in 2002, and that, under federal regulations, Hospira was required to conform its label to that of the RLD holder. There is also apparently no dispute that Baxter did not include a

warning of the increased risks associated with use of metoclopramide beyond twelve weeks until the FDA mandated changes to all metoclopramide labeling in 2009. Thus, Hospira maintained that it was impossible for it to update its label to conform to an updated RLD label because the RLD did not update its label until the FDA forced it to in 2009.

The court denied Generic Defendants' and Hospira's motion for reconsideration, but granted their motions to certify the order as one involving "a controlling question of law as to which there is a substantial ground for difference of opinion" and for which "an immediate appeal . . . may materially advance the ultimate determination of the matter." Order, 12/16/11, at 1 (quoting 42 Pa.C.S.A. §702(b)). Hospira and Generic Defendants then filed both a timely petition for permission to appeal, which this Court denied by order of March 12, 2012, and a direct appeal under Pa.R.A.P. 313. Plaintiffs moved to quash the appeal. By order of April 11, 2012, this Court denied the motion without prejudice to reassert the issue before this panel, which Plaintiffs have done.

Generic Defendants raise one issue for our review:

> Did the trial court err in refusing to dismiss Plaintiffs' claims against the Generic Defendants as preempted by federal law in light of the United States Supreme Court's holding in ***PLIVA, Inc. v. Mensing***, 131 S.Ct. 2567 (2011)?

Appellants' brief at 2.

Hospira's additional issue on appeal is:

> Whether plaintiffs' argument that *Mensing* does not preempt claims against a generic manufacturer who failed to adopt or effectively communicate a warning that was added to the labeling for brand-name Reglan® *Tablets* applies to Hospira, which manufactured and sold only the injectable form of generic metoclopramide and therefore was required by federal law to follow and copy the labeling of its reference listed drug – Baxter Healthcare's ("Baxter") brand-name Reglan® *Injection* – which did not include the alleged warning.

Hospira's brief at 7 (emphasis in original).

Prior to reaching the pre-emption issue, we must first address Plaintiffs' contention that this Court lacks jurisdiction to entertain this interlocutory appeal. They maintain that the collateral order doctrine supplies the only possible basis for jurisdiction, but that the order appealed from does not meet the three-pronged test for its application.

A collateral order is defined as "an order separable from and collateral to the main cause of action where the right involved is too important to be denied review and the question presented is such that if review is postponed until final judgment in the case, the claim will be irreparably lost." Pa.R.A.P. 313(b). Our High Court has delineated three requirements that must be satisfied in order for the doctrine to apply. The order must be "separable from and collateral to the main cause of action;" it must involve a right that "is too important to be denied review;" and, "if review is postponed until final judgment, the claim will be irreparably lost." ***Vaccone v. Syken***, 899 A.2d 1103, 1106 (Pa. 2006). The doctrine is to be narrowly interpreted as it

is an exception to the rule of finality. ***Id***.; ***see also Rae v. Pennsylvania Funeral Directors Association***, 977 A.2d 1121, 1126 (Pa. 2009).

Plaintiffs argue that Generic Defendants cannot satisfy any of the three prongs. They contend that pre-emption requires an examination of underlying state-law duties, and a determination as to whether those duties conflict with federal law. Such analysis, according to Plaintiffs, necessarily involves the merits of the underlying claims. Further, Plaintiffs maintain that it does not involve a right "too important to be denied review." ***Gunn v. Automobile Ins. Co.***, 971 A.2d 505 (Pa.Super. 2009). They urge us to follow federal precedent to the effect that an order that a state claim is not pre-empted is not the equivalent of an immunity from suit and hence, not immediately appealable as a collateral order. ***See Martin v. Halliburton***, 618 F.3d 476 (5th Cir. 2010), and cases cited therein. Finally, Plaintiffs attempt to distinguish pre-emption from immunity from suit and asserts that the right is not irreparably lost if appellate review is postponed.

Generic Defendants rely upon our Supreme Court's decision in ***Pridgen v. Parker Hannifin Corp.***, 905 A.2d 422 (Pa. 2006), as the basis for collateral order jurisdiction. In resolving the issue of whether an order denying summary judgment premised on the General Aviation Revitalization Act's eighteen year statute of repose was appealable as a collateral order, the Court adopted and applied the United States Supreme Court's legal/factual approach to collateral orders espoused in ***Johnson v. Jones***,

515 U.S. 304 (1995). In that case, the district court denied the police officers' motion for summary judgment premised on qualified immunity, finding sufficient evidence in the record that the officers watched and allowed others to beat the plaintiff to support liability. The officers appealed the order denying summary judgment as a collateral order. The ***Johnson*** Court concluded that the order was not appealable as the legal issue, qualified immunity, was not separate from the fact-related legal issues underlying the merits of the plaintiff's claims.

In ***Pridgen***, plaintiffs maintained that the airplane crash was caused by a failure of engine and fuel system components that were replaced and overhauled within eighteen years of the date of the accident. Defendants countered that they did not manufacture or supply any of the allegedly defective replacement parts within eighteen years of the accident, an assertion that plaintiffs did not dispute. The rolling provision of the statute of repose provided that the eighteen-year period commenced to run when component parts were installed. Defendants framed the issue on appeal as a legal one: whether an original manufacturer was liable under GARA's rolling provision for the alleged failure of airplane replacement parts that it did not physically manufacture. Thus, the focus was on the terms of the statute, not on determinations of fact or the scope of liability. Our High Court, acknowledging that it "has adopted a practical analysis recognizing that some potential interrelationship between merits issues and the question

sought to be raised in the interlocutory appeal is tolerable[,]"concluded that this legal issue was separable from the merits of the underlying case. ***Pridgen***, at 433 (citations omitted). Additionally, in furtherance of the policy of cost control, the Court found the federal interest underpinning GARA to be sufficiently important to allow appellate courts to weigh in on the issue. Finally, the Court viewed the substantial cost that manufacturers would incur in defending complex litigation at trial "a sufficient loss" to support the third element of the collateral order test.

The issue before us is whether all claims asserted by Plaintiffs against generic drug manufacturers are failure-to-warn claims pre-empted by ***Mensing***. Thus, our analysis focuses largely on the scope of ***Mensing*** and the nature of the allegations contained in the Third Amended Long Form Master Complaint. We need not examine the merits of the underlying claims or resolve factual disputes. Hence, we find the pre-emption issue as phrased sufficiently separable from the merits of the underlying claims to satisfy the first prong of the collateral order doctrine.

With regard to the second prong, implicated herein is the role of state tort law in the federally regulated realm of generic drugs. The public policies surrounding comity and the Hatch-Waxman Amendments, designed to promote access to low-cost alternatives to name-brand drugs, are characteristic of rights "too important to be denied review." Finally, cognizant of the substantial cost that Generic Defendants would incur in

defending more than two thousand lawsuits, we find sufficient loss to satisfy the third prong of the test.

Having concluded that we have jurisdiction to entertain the within appeal pursuant to the collateral order doctrine, we turn to the pre-emption issue. In reviewing the overruling of preliminary objections in the nature of a demurrer, we apply the same standard as the trial court. ***See De Lage Landen Services, Inc. v. Urban Partnership, LLC***, 903 A.2d 586, 589 (Pa.Super. 2006). "All material facts set forth in the complaint as well as all inferences reasonably deducible therefrom are admitted as true for the purpose of this review. The question presented by the demurrer is whether, on the facts averred, the law says with certainty that no recovery is possible." ***Soto v. Nabisco, Inc.***, 32 A.3d 787, 790 (Pa.Super. 2011). Any doubt is resolved by refusing to sustain the demurrer. ***Insurance Adjustment Bureau, Inc. v. Allstate Ins. Co.***, 905 A.2d 462, 468 (Pa. 2006); ***Butler v. Charles Powers Estate***, 29 A.3d 35 (Pa.Super. 2011) *(reversed on other grounds by* ***Butler v. Charles Powers Estate ex rel Warren***, 65 A.3d 885 (Pa. 2013)). The trial court applied the proper legal standard and concluded that it was not certain that recovery was impossible. Our review is plenary, and we reverse only if the trial court has committed an error of law or an abuse of discretion. ***Id***.

We recognize a presumption against federal pre-emption of state law. ***Dooner v. DiDonato***, 971 A.2d 1187 (Pa. 2009) (citing ***Altria Group, Inc.***

v. Good, 555 U.S. 70 (2008)). In ***Kiak v. Crown Equipment Corp.***, 989 A.2d 385, 390 (Pa.Super. 2010), this Court noted that the presumption flows from existence of "dual jurisdiction" and arises "from reasons of comity and mutual respect between the two judicial systems that form the framework of our democracy." ***Fetterman v. Green***, 689 A.2d 289, 292 (Pa.Super. 1997); ***see also Cipollone v. Liggett Group, Inc.***, 505 U.S. 504, 516 (1992)). As the United States Supreme Court noted in ***Altria Group, Inc.***, ***supra***:

> When addressing questions of express or implied pre-emption, we begin our analysis "with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." ***Rice v. Santa Fe Elevator Corp.***, 331 U.S. 218, 230, 67 S. Ct. 1146, 91 L. Ed. 1447 (1947). That assumption applies with particular force when Congress has legislated in a field traditionally occupied by the States. [***Medtronic Inc. v.***] ***Lohr***, 518 U.S., at 485, 116 S. Ct. 2240, 135 L. Ed. 2d 700; ***see also Reilly***, 533 U.S., at 541-542, 121 S. Ct. 2404, 150 L. Ed. 2d 532 ("Because 'federal law is said to bar state action in a field of traditional state regulation,' namely, advertising, we 'work on the assumption that the historic police powers of the States are not to be superseded by the Federal Act unless that is the clear and manifest purpose of Congress'" (citation omitted)). Thus, when the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily "accept the reading that disfavors pre-emption." ***Bates v. Dow Agrosciences LLC***, 544 U.S. 431, 449, 125 S. Ct. 1788, 161 L. Ed. 2d 687 (2005).

Altria Group, Inc., 555 U.S. at 77.

At issue herein is impossibility pre-emption, the type of implied conflict pre-emption that arises when it is impossible to comply with both federal and state law.[5] ***Kiak***, ***supra***. As the Supreme Court recognized in ***Wyeth v. Levine***, 555 U.S. 555, 573 (2009), "[i]mpossibility pre-emption is a demanding defense." Therein, the Supreme Court held that state claims based upon the failure to warn of the risk of gangrene from delivery of Phenergan via IV-push method were not pre-empted on such a theory because the name-brand manufacturer of the drug could have complied with both federal and state law by unilaterally strengthening the drug's warning in order to comply with the latter.

In ***Mensing***, the Court reasoned that since a generic manufacturer is required under federal law to maintain the same label as the name brand label, it cannot unilaterally change its label to attach a stronger label as required by state law. The Court therefore held that it was impossible for generic drug manufacturers to comply with both federal and state law, and state law must yield where state and federal law directly conflict. ***Mensing***, ***supra***. Thus, the claims were held to be pre-empted.

In its recent decision in ***Mutual Pharmaceutical Co. v. Bartlett***, 133 S. Ct. 2466 (U.S. 2013) (decided June 24, 2013), the United States Supreme Court revisited ***Mensing*** impossibility pre-emption in reviewing a

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[5] The FDAAA was signed into law on September 27, 2007. Notably, Congress did not include an express preemption provision.

$21 million judgment against the manufacturer of a generic form of sulindac based on a design defect theory. The ***Bartlett*** Court concluded that New Hampshire's version of § 402A liability did not impose absolute liability on manufacturers, but instead, a "duty to design [their products] reasonably safely for the uses which [they] can foresee." ***Id***. at *16. Under that state's risk-utility approach, increasing the usefulness of the drug or reducing its risks could only be accomplished by; 1) redesigning the drug, which was an option foreclosed by the FDCA as well as by the fact that the drug was composed of only one molecule; or 2) strengthening the warning on its label. The Court concluded that, since a design change was impossible, New Hampshire's law ultimately required the generic manufacturer to change sulindac's labeling, which was prohibited under federal law. By imposing a duty that mandated non-compliance with federal law, state law violated the Supremacy Clause, and hence, was pre-empted. However, the Court expressly reserved "for another day the question whether a true absolute-liability state-law system could give rise to absolute-liability pre-emption." ***Id***. at *17 n.1.

Against this backdrop, Generic Defendants contend that all of Plaintiffs' claims are essentially failure-to-warn claims requiring them to change the label and that the pre-emption issue herein is indistinguishable from that in ***Mensing***. They compare portions of the master complaint herein with the ***Mensing*** complaint and argue that they present similar claims. They rely

upon the persuasive impact of the "tsunami of cases" applying ***Mensing*** to pre-empt virtually all state tort claims against generic manufacturers. Appellants' brief at 17 quoting ***Bowman v. Wyeth, LLC***, 2012 WL 684116, at *7 (D. Minn. 2012).

Notably, with the exception of the United States Supreme Court, we are not bound by those federal court decisions. ***NASDAQ OMX PHLX, Inc. v. Pennmont Secs.***, 52 A.3d 296, 303 (Pa.Super. 2012). Nor do we find the sheer weight of these authorities persuasive.[6] Absent from the vast majority of these cases is the identification of state law duties associated with various causes of action and a cogent analysis of how they conflict with federal law, which is the hallmark of an impossibility pre-emption determination. Furthermore, as the ***Bartlett*** Court's analysis of New Hampshire law illustrates, pre-emption issues are state-law specific, a nuance not appreciated by Generic Defendants.[7] Additionally, Generic Defendants gloss over critical distinctions between strict liability and negligence for defective products, breach of warranty, misrepresentation and fraud theories of liability, without examining the state-law duty allegedly

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[6] Appellants direct our attention to numerous cases decided after ***Mensing***, in which dismissal was predicated upon that decision. However, Appellants fail to distinguish between those involving pre-***Mensing*** complaints and complaints, like the master complaint herein, that were amended in light of ***Mensing***.

[7] In this mass tort litigation involving more than two thousand plaintiffs, many different states' laws are potentially implicated.

violated. Finally, in urging us to give a sweeping effect to ***Mensing***, Generic Defendants fail to compare the pleadings herein with the arguments actually advanced in the Supreme Court in ***Mensing***, all of which implicated the adequacy of the warning on the product label.

Plaintiffs contend that the complaint herein does not frame every issue in terms of a failure to strengthen the warnings on the label. In counts I, II, and III, Plaintiffs asserted strict liability and negligence for defective design, where liability is premised upon Generic Defendants' sale and marketing of a drug they knew was unreasonably dangerous or defective. Third Amended Long Form Master Complaint ¶¶132, 133. The product was alleged to be unreasonably dangerous when it left the manufacturer's hands, and was expected to and did reach the consumer without substantial change. ***Id***. at ¶¶145-147. Plaintiffs pled that the drug was never shown "to be either efficacious or safe when used for long-term treatment." ***Id***. at ¶88. Moreover, Plaintiffs pled that the generic manufacturers continued to market their dangerous drugs despite the fact that there were safer and less expensive alternatives available. ***Id***. at ¶159.

These allegations suggest that the drug, even when used as recommended and with appropriate warnings, was defective and unreasonably dangerous. Such averments do not necessarily implicate labeling, but assert absolute liability based on the sale of a defective or unreasonably dangerous product. The ability or duty to redesign a product

is not an element of this cause of action. ***See*** Restatement (Second) of Torts § 402A cmt. f (1965) ("The rule stated in this Section applies to any person engaged in the business of selling products for use or consumption. It therefore applies to any manufacturer of such a product, to any wholesale or retail dealer or distributor, . . ."). Thus, according to Plaintiffs, Generic Defendants can comply with federal law, which does not permit them to unilaterally alter a drug's design, and state law, which extends liability to a manufacturer of a defectively designed drug without regard to whether it may redesign its drug.

We observe that the ***Wyeth*** Court found no impossibility pre-emption on a similar rationale. The Court found no demonstration therein that it was impossible to comply with both federal and state requirements where "the CBE regulation permitted Wyeth to unilaterally strengthen its warning, and the mere fact that the FDA approved Phenergan's label [did] not establish that it would have prohibited such a change." ***Wyeth***, ***supra*** at 573. There was no impossibility conflict because state law did not require what federal law forbade. ***See Wyeth v. Levine***, ***supra***.

The ***Bartlett*** Court expressly left open the issue of whether § 402A strict products liability design defect claims would be pre-empted. It did not address the argument Plaintiffs asserts herein: that under § 402A strict products liability, it is unnecessary for a plaintiff to demonstrate that a

defendant should or could have altered the design or the warnings.[8] The ***Bartlett*** Court concluded that under New Hampshire's law, §402A imposed a duty upon a product manufacturer to "design his product reasonably safely for the uses which he can foresee." ***Mutual Pharmaceutical Co. v. Bartlett***, ***supra*** at *16. That duty was satisfied either by changing the design or the labeling. Since Mutual, a generic manufacturer of sulindac, had no ability to change the design, the Court concluded that it was required to change the labeling to avoid liability under state law, an impossibility after ***Mensing***. Thus, Plaintiffs' argument that ***Mensing*** does not pre-empt strict liability design defect claims under those states' laws which subject distributors and retailers of defective products to strict liability even though they have no control over the design of the product appears to have some vitality after ***Mensing*** and ***Bartlett***.[9]

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[8] It is undisputed that FDA approval of a name-brand drug and/or its label does not preclude a state law tort claim against that manufacturer based on defective design. ***See Wyeth v. Levine***, 555 U.S. 555 (2009).

[9] Plaintiffs' argument that Generic Defendants can comply with state law simply by not selling their defective drugs, a decision that they can make independently of the FDA, and one that does not run afoul of federal law, was largely rejected in ***Bartlett***. The Supreme Court found that argument "incompatible with our pre-emption jurisprudence." ***Bartlett***, ***supra*** at *28 ("leaving aside the rare case in which state or federal law actually requires a product to be pulled from the market — our pre-emption cases presume that a manufacturer's ability to stop selling does not turn impossibility into possibility. ***See, e.g., Florida Lime & Avocado Growers, Inc. v. Paul***, 373 U.S. 132, 143, 83 S. Ct. 1210, 10 L. Ed. 2d 248 (1963)").

In support of their contention that strict liability, negligence, and breach of warranty claims are not necessarily failure-to-warn claims, Plaintiffs direct our attention to three United States Supreme Court cases concluding just that in the context of federal labeling statutes. In ***Cipollone v. Liggett Group***, 505 U.S. 504 (1992), a plurality of the Supreme Court distinguished failure-to-warn claims from claims alleging negligence in the manner in which defendants' cigarettes were tested, sold, and advertised. Only the former were pre-empted by the 1969 amendments to the (cigarette) Labeling Act of 1965. ***Id***. at 525.

More recently, in ***Bates v. Dow Agrosciences, LLC***, 544 U.S. 431 (2005), the Supreme Court addressed whether state strict liability design defect and warranty claims were preempted by the Federal Insecticide, Fungicide, and Rodenticide Act's ("FIFRA") labeling and packaging requirements. Texas farmers asserted claims in strict liability, negligence, breach of warranty, fraud, and violations of the Texas Deceptive Trade Practices-Consumer Protection Act for damages to their peanut crops caused by application of Dow's pesticide, "Strongarm." The farmers claimed that Dow knew or should have known that Strongarm stunted the growth of peanuts growing in soils with pH levels of 7.0 or greater, but the company's agents and the product label recommended its use in all areas where peanuts were grown. Dow maintained that the farmers' state-law claims were pre-empted by FIFRA's labeling requirements.

The district court granted summary judgment in favor of Dow, finding all claims but one to be expressly pre-empted by 7 U.S.C. § 136v(b), which provided that "Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C.S. § 136v(b). The court of appeals affirmed, holding that § 136v(b) pre-empted any state-law claim in which a judgment against Dow would induce it to alter its product label. The strict liability, negligent testing and manufacturing claims were viewed by that court as disguised failure-to-warn claims, and all were found pre-empted. The Supreme Court granted certiorari to resolve a conflict among the circuits on the pre-emption issue.

The ***Bates*** Court carefully traced the history of the statute, noting that FIFRA was a comprehensive statute conferring upon the EPA the authority to regulate the use, sale and labeling of pesticides. However, in order to be pre-empted, the Supreme Court concluded that the state law requirement had to be one for labeling or packaging and it had to be different from or in addition to those required under the federal statute. If the state requirement was consistent or equivalent to the FIFRA requirement, it was not pre-empted. The Court rejected the Fifth Circuit Court of Appeals' supposition that claims based on defective design or manufacture, breach of warranty, or negligent testing implicated labeling or packaging, and found that none of the common law rules upon which these claims were based

required that manufacturers label or package their products in any particular way. The Court held that "Rules that require manufacturers to design reasonably safe products, to use due care in conducting appropriate testing of their products, to market products free of manufacturing defects, and to honor their express warranties or other contractual commitments plainly do not qualify as requirements for 'labeling or packaging'." 544 U.S. at 444.[10] We note that the ***Bartlett*** Court expressly affirmed the ***Bates*** holding in the prescription drug arena.

Finally, in ***Altria Group, Inc.***, ***supra***, the Supreme Court rejected the argument that fraud and unfair trade practice claims under Maine's law were pre-empted by the Labeling Act, finding that such claims were predicated on the duty not to deceive, not a failure to warn.

These decisions support Plaintiffs' position in several respects. First, they clarify that federal labeling regulations pre-empt state law labeling and packaging requirements only to the extent that they are different from or in addition to those mandated by the federal statute. Second, they highlight that a proper pre-emption analysis is dependent upon a comparison of the

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[10] The Court remanded issues of fraud and negligent failure to warn, which it found to be premised on labeling requirements, to determine if under Texas law, they were in addition to or different from FIFRA's labeling requirements, citing ***Medtronic, Inc. v. Lohr***, 518 U.S. 470, 495 (1996) (holding nothing in the medical device statute "denied Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.")

federal statute or regulation and the particular state law applicable. ***See Foster v. Love***, 522 U.S. 67, 71 (1997) (holding preemption must turn on whether state law conflicts with the text of the relevant federal statute or regulation). Third, and most importantly, they illustrate that while federal labeling statutes may pre-empt state failure-to-warn claims, they do not pre-empt claims based upon the marketing of defective products, a lack of due care in testing, or a product's failure to conform to express and implied warranties, all of which are alleged herein.

In Count VII, breach of express and implied warranties, Plaintiffs seek to impose liability against Generic Defendants for failing to deliver products that conformed to the properties described in the label and promotional materials. Third Amended Master Long Form Complaint, ¶¶ 193-196. Such a claim is not premised on the inadequacy of the label but rather on the product's failure to live up to or conform to its label and advertising. The only warranties identified in ***Mensing*** were those contained in labeling, *i.e.*, package inserts shipped with the drug from the factory. The claims asserted herein implicate warranties arising from advertising and promotional materials that arguably do not fall within the definition of labeling under the Act. ***See*** 21 USCS § 321(m) (defining the term labeling as "all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article"). A label is "a

display of written, printed, or graphic matter upon the immediate container of any article." 21 USCS § 321(k).

Similarly, Counts V, VI, and VIII of the Complaint contain allegations of fraud and misrepresentation in the advertising and promotion of both name brand and generic drugs. Third Amended Long Form Master Complaint, ¶¶ 171, 174, 182, 189-190, 199-201. Plaintiffs pled that both name-brand manufacturers and Generic Defendants intentionally, knowingly, and fraudulently misrepresented material facts regarding the safety of the drugs in their advertising and promotional materials, not just their labels, and that physicians and the public relied upon those misrepresentations. ***Id***. at ¶171. Additionally, Generic Defendants participated and passively cooperated in the dissemination of these misrepresentations in order to induce physicians to prescribe their generic drugs. ***Id***. at ¶182.

We agree with Plaintiffs that such allegations of false advertising and promotion are not failure-to-warn claims based on the label pre-empted by ***Mensing***. ***See Cippolone***, ***supra*** (claims of fraudulent misrepresentation and/or concealment based on state law duties to disclose by other means, as well as breach of warranty claims, were not preempted under the Labeling Act); ***Altria Group, Inc.***, ***supra***. (rejecting the argument that fraud and unfair trade practice claims under Maine's law were preempted by the Labeling Act, finding that they were not failure-to-warn claims but rather, claims predicated on the duty not to deceive).

Count IX seeks the disgorgement of profits stemming from deceptive practices, such as concealing the risks associated with the drug and misrepresenting its safety. Count XI asserts claims of civil conspiracy based upon the concealment and withholding of information. Such claims are not ***Mensing*** failure-to-warn claims but state remedies for tortious business practices.[11]

Generic Defendants contend that the so-called ***Mensing*** carve-outs offer no basis for relief from pre-emption. They allege: 1) that the failure-to-communicate theory is not viable; 2) that pre-emption cannot be circumvented by claiming that the generic manufacturers should have simply stopped selling their defective products; and 3) that failure to conform a generic label to the label of the RLD is not a viable cause of action.

Plaintiffs counter that claims that Generic Defendants were negligent because they did not communicate the already strengthened warnings of the RLD are not pre-empted, a claim that at least one court determined survives ***Mensing***. ***See Lyman v. Pfizer, Inc.***, 2012 WL 2970627 (D. Vermont, 2012). Furthermore, they maintain that negligence and negligence *per se* claims premised upon Generic Defendants' failure to update their warning

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[11] Count XII is a derivative claim for loss of consortium. Counts XIII and XIV are wrongful death and survival actions seeking damages on behalf of the decedent's survivors and estate, respectively.

labels to comply with those of the RLD are not pre-empted by ***Mensing***.[12] Plaintiffs allege that failure to comply with the FDCA standards renders the drug misbranded *per se.* 21 U.S.C. §331(a). Plaintiffs pled that they are within the class of persons these regulations are designed to protect, and their injuries are the type of harm the statutes are intended to prevent. Third Amended Long Form Master Complaint ¶166. Thus, according to Plaintiffs, Generic Defendants' non-compliance with federal law serves as evidence of negligence, requiring only proof of causation and damages in order to prevail under many states' laws.[13] Given this viable method of compliance with a state law duty that does not conflict with federal law,

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[12] Failure to timely update generic labeling to incorporate certain FDA-approved warnings added to the labeling for Reglan in 2003 and July 2004 was held to affect the ***Mensing*** pre-emption analysis in ***Fisher v. Pelstring***, 2011 U.S. Dist. LEXIS 116162 (D.S.C. 2011), as no federal law prevented the generic manufacturer from adding the warnings.

[13] Pennsylvania recognizes that the standard of care may be prescribed by legislative enactment so that "a **violation** of the statute or ordinance may serve as the basis for negligence *per se."* ***Wagner v. Anzon, Inc***., 684 A.2d 570, 574 (Pa.Super. 1996). The plaintiff must show: (1) that the purpose of the statute is "at least in part, to protect the interest of a group of individuals, as opposed to the public generally;" (2) that the statute clearly applies to the conduct of the defendant; (3) that the defendant violated the statute; and (4) that the violation was the proximate cause of the plaintiff's injuries. 684 A.2d at 574. ***See*** RESTATEMENT (SECOND) OF TORTS § 286 (1965); ***see also Phelps v. Wyeth, Inc***., 2013 U.S. Dist. LEXIS 49422 (D. Or. Apr. 2, 2013) (holding that plaintiffs' use of the FDCA to inform the standard of care owed under Oregon law was not "enforcing" the FDCA).

Plaintiffs maintain that impossibility pre-emption is defeated as to these claims. Appellees brief at 41.

We find merit in Plaintiffs' position. A federal regulation may establish the standard of care appropriate to the underlying tort of negligence *per se* under state tort law. The Supreme Court held in ***Merrell Dow Pharmaceuticals, Inc. v. Thompson, et al***, 478 U.S. 804 (1986), that pre-emption was no impediment to the pursuit in an Ohio state court of presumptive negligence claims based on misbranding of a drug in violation of the FDCA where there was no private federal cause of action for the violation. ***See*** 28 U.S.C. § 1331. Hence, we agree that state negligence claims based upon the misbranding of drugs under the federal statute or failure to conform the generic label to the updated RLD label, a form of misbranding, are not foreclosed by ***Mensing***. ***See also Bartlett***, ***supra*** *******27 n.4 (declining to address state design-defect claims that parallel the federal misbranding statute).

Finally, Plaintiffs contend that the ***Mensing*** Court specifically limited its pre-emption holding to negligent failure-to-warn claims prior to the promulgation of the FDAAA. We agree with Plaintiffs that until post-Act

claims are subjected to a thorough pre-emption analysis, dismissal of those failure-to-warn claims is premature.[14]

We turn now to Hospira's position that since the RLD for injectable Reglan did not update its label until 2009 to include a warning of the increased risk of tardive dyskinesia with use exceeding twelve weeks, it could not have conformed its label to that of the RLD until after that time without violating federal law. Hence, Hospira contends that any pre-2009 claims premised on its failure to update its label to conform to the RLD's label are pre-empted. It maintains further that the trial court relied upon what it characterized as a factual dispute, *i.e.*, whether injectable Reglan

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[14] Plaintiffs suggest that the ***Mensing*** rationale will not apply to such claims, pointing to the deference afforded the FDA's acknowledgment in ***Mensing*** that post-Act, generic manufacturers are required to propose stronger labeling if it is warranted, and the FDA can unilaterally order it pursuant to 21 U.S.C. § 355(o)(4). Thus, they argue, Congress removed at least one of the impediments relied upon in support of impossibility preemption: the requirement that the FDA negotiate with the RLD in order to strengthen the warning label. Furthermore, they contend that the 2007 Act mandates that the FDA withdraw approval of a drug found to be unsafe or ineffective, such as where the "potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit." Appellee's brief at 58 (quoting 21 U.S.C. §§ 255(e)(1)-(3)). Plaintiffs conclude that the Act removes much of the discretion afforded RLDs that made it impossible for generic manufacturers to comply with both state and federal law. Thus, they maintain that the landscape for generic manufacturers will more closely resemble that of name-brand manufacturers, and that the ***Wyeth*** standard will likely govern: claims will be pre-empted only if generic manufacturers demonstrate that the FDA would not have approved the labeling change at the time.

was administered for more than twelve weeks, to overrule Hospira's preliminary objections when these objections related to pre-emption.

The facts as pled herein do not support liability against Hospira based on a ***Mensing*** carve-out theory as to claims arising prior to the 2007 FDAAA. With regard to pre-Act claims, since the RLD did not update its label, Hospira could not have failed to conform its label to an updated label. Our holding that pre-2007 Act failure-to-warn claims involving generic labels that conformed to those of the RLD are pre-empted encompasses these claims against Hospira. Post-2007 carve-out claims against Hospira are not pre-empted because the ***Mensing*** Court did not express any view on the impact of the Act on the pre-emption of failure-to-warn claims. Accordingly, we find it far from certain that, after the effective date of the 2007 Act, federal law prohibited Hospira or other generic manufacturers from unilaterally updating their labels to strengthen warnings regardless of whether the RLD did so. ***See*** discussion of post-Act failure-to-warn claims *infra* at 27-28.

In conclusion, we find that the master complaint contains some negligent failure-to-warn claims that pre-date the FDAAA of 2007 and that are premised upon the generic manufacturers' failure to strengthen the warnings on their labels. Where those pre-2007 generic labels conformed to the RLD labels, those claims are pre-empted by ***Mensing***. The design defect claims may be of the type held pre-empted in ***Bartlett***. However,

without a careful analysis of the applicable state law, pre-emption of all design defect claims is premature. The remaining claims either do not sound in failure to warn, arose after the passage of the 2007 Act, or involve a generic manufacturer's failure to conform its label to that of the name brand, none of which is pre-empted under our reading of ***Mensing***. Thus, we agree with the trial court that blanket dismissal of all claims on pre-emption grounds, which was the remedy sought by Generic Defendants herein, is unwarranted.

We hold that only pre-Act failure-to-warn claims based solely on a label that was in conformity with the RLD label are pre-empted under ***Mensing***. As to all remaining claims, we affirm the trial court's overruling of preliminary objections in the nature of a demurrer and remand for further proceedings.

Order affirmed in part, reversed in part. Application to quash denied. Jurisdiction relinquished.

Judge Platt files a Concurring and Dissenting Opinion.

Judgment Entered.

Prothonotary

Date: 7/29/2013