2013 PA Super 213

PAUL E. HASSETT,

v.

DONALD DAFOE, M.D., JAMES F. BURKE, JR.., M.D., GEORGE FRANCOS, M.D., RAKESH GULATI, M.D., JEFFERSON UNIVERSITY PHYSICIANS, JEFFERSON RENAL ASSOCIATES, THOMAS JEFFERSON UNIVERSITY HOSPITAL, WYETH INC., WYETH PHARMACEUTICALS INC., SCHWARZ PHARMA, INC., SCHWARZ PHARMA, INC. D/B/A SCHWARZ PHARMA, USA, SCHWARZ PHARMA, USA, PLIVA INC., TEVA PHARMACEUTICALS INDUSTRIES, LTD, TEVA PHARMACEUTICALS INDUSTRIES, LTD D/B/A TEVA PHARMACEUTICAL USA, INC., TEVA PHARMACEUTICAL USA, INC.

APPEAL OF: PLIVA, INC., AND TEVA PHARMACEUTICALS USA, INC.

IN THE SUPERIOR COURT OF PENNSYLVANIA

No. 81 EDA 2012

Appeal from the Order November 18, 2011
In the Court of Common Pleas of Philadelphia County
Civil Division at No.: August Term, 2008 No. 01551

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

CONCURRING AND DISSENTING OPINION BY PLATT, J.**FILED JULY 29, 2013**

I respectfully concur in part and dissent in part.

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* Retired Senior Judge assigned to the Superior Court.

I concur with the learned Majority's conclusion that we have jurisdiction to review the trial court's order, which is appealable as a collateral order. However, in my opinion, this case and all of the similarly situated companion cases are preempted under the Supremacy Clause of the United States Constitution, following the principles set forth by the United States Supreme Court in ***PLIVA, Inc. v. Mensing***, 131 S. Ct. 2567 (2011) and ***Mutual Pharmaceutical Co., Inc. v. Bartlett***, 133 S. Ct. 2466 (2013). I would vacate the decision of the trial court and remand with instructions to sustain Appellants' preliminary objections.

As the ***Mensing*** Court noted:

> The Supremacy Clause establishes that federal law "shall be the supreme Law of the Land ... any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2. Where state and federal law "directly conflict," state law must give way. State law is naturally preempted to the extent of **any** conflict with a federal statute. We have held that state and federal law conflict where it is "impossible for a private party to comply with both state and federal requirements."

Mensing, ***supra*** at 2577 (case citations, some internal quotation marks and other punctuation omitted) (emphasis added).[1]

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[1] The ***Bartlett*** Court further explained:

> As ***PLIVA*** made clear, federal law prevents generic drug manufacturers from changing their labels. ***See*** 564 U.S., at ––– –, 131 S.Ct., at 2577 ("Federal drug regulations, as interpreted by the FDA, prevented the Manufacturers from independently changing their generic drugs' safety labels"). ***See also*** 21

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> It is fundamental that by virtue of the Supremacy Clause, the State courts are bound by the decisions of the Supreme Court with respect to the federal Constitution and federal law, and must adhere to extant Supreme Court jurisprudence. U.S. CONST. art. VI, cl.2; ***Chesapeake & O. Ry. Co. v. Martin***, 283 U.S. 209, 221, 51 S.Ct. 453, 75 L.Ed. 983 (1931). ("The determination by this [C]ourt of [a federal] question is binding upon the state courts, and must be followed, any state law, decision, or rule to the contrary notwithstanding."); ***Commonwealth v. Ware***, 446 Pa. 52, 284 A.2d 700, 702 (1971) ("[A] state court is not free to ignore the dictates of the United States Supreme Court on federal constitutional matters because of its own conclusion that those dictates are 'ill-considered.' ").

Council 13, American Federation of State, County and Mun. Employees, AFL-CIO ex rel. Fillman v. Rendell, 986 A.2d 63, 77-78 (Pa. 2009) (footnote omitted).

Here, the chief allegation of the original suits in the class action under the Philadelphia mass tort program was that manufacturers of the brand name drug Reglan and the generic equivalent metoclopramide did not adequately warn patients or their health care providers of the high risk of

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> U.S.C. § 355(j)(2)(A)(v) ("[T]he labeling proposed for the new drug is the same as the labeling approved for the [approved brand-name] drug"); 21 C.F.R. §§ 314.94(a)(8)(iii), 314.150(b)(10) (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"). Thus, federal law prohibited Mutual from taking the remedial action required to avoid liability under New Hampshire law.

Bartlett, ***supra*** at 2476.

adverse side effects on prolonged or high dosage use of Reglan or metoclopramide.

After the ***Mensing*** Court decided that state tort liability claims based on the failure to provide adequate warning labels (similar to those here) were preempted under the Supremacy Clause, counsel for Appellee and the other plaintiffs again amended their master complaint. The post-***Mensing*** amended complaint presents nine counts pertinent to our review, asserting strict liability for failure to give adequate warnings; strict liability for design defect; negligence (in testing, manufacture, distribution and effective warning); negligence *per se* (alleging failure to exercise reasonable care under "applicable statutes or regulations" and failure "to perform proper pharmacovigilance"); fraud, misrepresentation, and suppression; constructive fraud (asserting knowing assent and passive cooperation by generic manufacturers in brand name defendants' misrepresentations); breach of express and implied warranties; unfair and deceptive trade practices; and civil conspiracy. (***See*** Plaintiffs' Third Amended Master Long Form Complaint, 8/03/11, at 50-77).

Preliminarily, as recognized by the learned Majority, Appellee's argument that Appellants, generic drug manufacturers, could have simply stopped selling was rejected by the United States Supreme Court in ***Bartlett***. (***See*** Majority at *19 n.8); ***see also Bartlett***, ***supra*** at 2470 ("Rather, adopting the . . . stop-selling rationale would render impossibility

pre-emption a dead letter and work a revolution in this Court's pre-emption case law.").

It is also important to note that the ***Mensing*** Court decided that the federal duty of sameness (generic drug labeling must be same as reference listed drug labeling), make it impossible for generic drug manufacturers to strengthen the warnings on drug labels, even assuming they are required to do so under state law. ***See Mensing*** at 2574-75, 2577. It is because of this impossibility that the ***Mensing*** Court concluded that the state law claims at issue (assumed to require strengthened warning labels) conflicted with the federal regulatory scheme for generic drugs and under the Supremacy Clause were preempted.

Here, the learned Majority holds that "only pre-[FDAAA] Act failure-to-warn claims based solely on a label that was in conformity with the RLD label are pre-empted under ***Mensing***." (Majority, at *28). It affirms the trial court's order for all other claims. (***See id.*** at *27-*29).

In effect, the Majority "carves out" a sub-category of claims presumed not to be preempted under ***Mensing*** or ***Bartlett***, or as to which pre-emption is "premature." (Majority, at *28). The Majority arrives at this result by a circuitous route. It largely ignores the impossibility analysis which is at the core of both ***Mensing*** and ***Bartlett***. Instead, it relies on derived analogies from other cases addressing liability for cigarettes, pesticide manufacture, even improper scheduling of Congressional elections,

without reference to the abbreviated procedures and specific restrictions placed on manufacturers under the federal regulatory scheme for generic drugs.

Problematically, in my view, the Majority misinterprets the authority on which it relies. For example, the Majority cites ***Merrell Dow Pharmaceuticals Inc. v. Thompson***, 478 U.S. 804 (1986) for the proposition 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 cause of action for the violation." (Majority, at *27) (without pinpoint citation).

More specifically, the ***Merrell Dow*** Court affirmed the decision of the Court of Appeals for the Sixth Circuit, reversing a grant of removal to federal court. The Supreme Court concluded that "a complaint alleging a violation of a federal statute [FDCA] as an element of a state cause of action, when Congress has determined that there should be no private, federal cause of action for the violation, does not state a claim 'arising under the Constitution, laws, or treaties of the United States.'" (citing 28 U.S.C. § 1331). ***Merrell Dow***, ***supra*** at 817. Put simply, this is a removal case. The issue of whether the plaintiffs had a state cause of action was not before the Supreme Court, and the Supreme Court did not address it.

Similarly, the Majority invokes ***Wyeth v. Levine***, 555 U.S. 555 (2009), in support of its conclusions. (***See*** Majority, at *13, *18). This

reliance overlooks the distinction, apparent from the facts, and plainly drawn in ***Mensing***, between a brand name drug manufacturer's ability to change its warning label and that of a generic drug manufacturer: "The federal statutes and regulations that apply to brand-name drug manufacturers differ, by Congress' design, from those applicable to generic drug manufacturers. And different federal statutes and regulations may, as here, lead to different pre-emption results." ***Mensing***, ***supra*** at 2571.

Additionally, the learned Majority quotes the ***Bartlett*** Court's reservation of the question of **absolute** liability pre-emption analysis (***see*** Majority, at *14), but then, in my opinion, misapplies it to **strict** product liability design defect claims, ignoring the distinction made by the ***Bartlett*** Court, (***id.*** at 18). ***See Bartlett***, ***supra*** at 2474 n.1.

Curiously, while taking Appellants to task for failing to provide state-specific pre-emption issues analysis, (***see*** Majority at *16), the Majority offers virtually no state statutory or caselaw, whether Pennsylvania, Delaware or otherwise, (other than a reference to the Restatement), in support of its conclusion that Appellees have presented allegations of state law tort claims which survive preemption.[2]

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[2] Notably, the Majority appears to assume a cause of action here in "absolute liability" for the sale of an unreasonably dangerous product under Restatement (Second) Torts § 402A, comment f (1965). (Majority at *17). However, the Majority fails to address comment k, Unavoidably unsafe products, which creates an exemption, under specified conditions, from 402A
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In my view, the over-arching defect of the learned Majority's analysis is that no amount of eclectic exegesis will change the reality that where Congress has enacted legislation for the federal regulation of generic drug manufacturers, claims derived from a failure to warn, however framed or re-framed, are preempted. During the time period of the allegations, it would have been impossible to comply with the federal duty of sameness and an assumed state-law based duty to alter the warning label, or distribute some divergent warning in derogation of the required label, on a unilateral basis. The claims are preempted under the Supremacy Clause, ***Mensing***, and ***Bartlett***. The trial court erred in overruling the preliminary objections.

Furthermore, from my review, it is apparent that all of Appellee's relevant allegations of state law tort liability depend on a failure to warn, or to give adequate warning, or otherwise communicate, however denominated, the perceived risks of taking metoclopramide. Under controlling authority, Appellants could not be liable for "defective design" of the generic drug itself. As approved manufacturers of a generic equivalent, Appellants had no duty, and indeed, based on the federal duty of "sameness" were prohibited from altering the "design" or pharmaceutical formulation of the generic drug from the RLD (reference listed drug). The Majority recognizes that the ***Bartlett*** Court held that because federal law

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strict liability for drugs. ***See*** Restatement (Second) Torts § 402A, comment k (1965).

prohibited Mutual, the generic drug manufacturer, from taking the remedial action required to avoid liability under New Hampshire law (redesign of reference listed drug, redesign of drug label), the state law was preempted. (***See*** Majority, at *14); ***see also Bartlett***, ***supra*** at 2476.

Therefore, in my opinion, Appellee's assertions of fraud, negligence *per se*, failure to communicate, and so on, for purposes of this action, could only refer to some variation of the duty to provide an adequate warning label, or some purported substitute, claims preempted by the federal regulatory scheme for generic drug manufacturers.[3] (***See*** Appellee's Brief, at 41).

"[P]re-emption analysis should not involve speculation about ways in which federal agency and third-party actions could potentially reconcile federal duties with conflicting state duties. When the 'ordinary meaning' of federal law blocks a private party from independently accomplishing what state law requires, that party has established pre-emption." ***Mensing***, ***supra*** at 2580 (internal quotation marks in original).

The learned Majority correctly notes that this Court is not bound by the decisions of other jurisdictions. (***See*** Majority, at *15). However, the Majority further chooses to disregard - even for their persuasive value - the

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[3] In particular, as recognized by the Majority, Appellee's argument that generic drug manufacturers could have met state law requirements to provide stronger warnings by sending so-called "Dear Doctor" letters to health care providers was expressly rejected in ***Mensing***, ***supra*** at 2576. (***See*** Majority, at *6).

overwhelming majority of decisions of other courts, both state and federal, which have held that state-law based claims, similar or identical to those alleged here, are preempted by the federal scheme of regulation for generic drugs under ***Mensing***, and now, ***Bartlett***.

"The dreadful injuries from which products liabilities cases arise often engender passionate responses. Today is no exception[.] But sympathy for [the appellee] does not relieve us of the responsibility of following the law." ***Bartlett***, ***supra*** at 2478.

I would vacate the trial court's order and remand with instructions to sustain Appellants' preliminary objections.

Accordingly, I concur in part and respectfully dissent in part.