2013 PA Super 215

| IN RE: REGLAN/METOCLOPRAMIDE LITIGATION<br><br>APPEAL OF: MORTON GROVE PHARMACEUTICALS INC., AND WOCKHARDT USA, LLC | IN THE SUPERIOR COURT OF PENNSYLVANIA<br><br>No. 83 EDA 2012 |
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Appeal from the Order November 18, 2011
In the Court of Common Pleas of Philadelphia County
Civil Division at No.: January Term, 2010 No. 01997

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

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

I concur in part and respectfully dissent in part from the decision of the learned Majority, for the reasons set forth here and those already noted more fully in my concurrence and dissent in the companion case of ***Hassett v. Dafoe***, No. 81 EDA 2012.

I concur that we have jurisdiction to review the trial court's order as an appealable collateral order. Otherwise, I respectfully dissent. Specifically, I would conclude that Appellants, Morton Grove Pharmaceuticals, Inc., and Wockhardt, USA, LLC (collectively, Morton Grove) had no additional duties or liability under state law as the FDA designated

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* Retired Senior Judge assigned to the Superior Court.

holder of the RLD (Reference Listed Drug) for liquid syrup metoclopramide, precluding any separate basis for the overrule of the preliminary objections as to these Appellants.

I find no support for the Majority's conclusion that Morton Grove failed to meet its burden of proof to establish pre-emption. (***See*** Majority, at *12-*13). Further, I find the Majority's conclusions unsupported by pertinent caselaw. The Majority's mere identification of inconsistent use of terminology in the caselaw or FDA regulations is, in my view, insufficient to establish the imposition of additional affirmative duties on a successor RLD holder.

Because the Majority also references here its more general conclusions from the companion cases, I include in response my summary discussion from ***In Re: Reglan/Metoclopramide Litigation***, No. 82 EDA 2012, for clarity and completeness, as follows:

In my view, the trial court erred in overruling the preliminary objections, because all of the supposed "carve out" claims still rest on, or derive from, failure-to-warn claims. The clear teaching of ***PLIVA, Inc. v. Mensing***, 131 S. Ct. 2567 (2011) and ***Mutual Pharmaceutical Co., Inc. v. Bartlett***, 133 S. Ct. 2466 (2013) is that failure-to-warn claims are preempted under the Supremacy Clause because it is impossible to comply

with both the assumed state-law based duties to warn and the federal regulatory scheme for generic drug manufacturers.

Similarly, in my opinion, the learned Majority errs in concluding that it is possible to comply with the federal duty of sameness and various assumed (but vaguely defined) state-based duties to warn. The Majority finds merit in Appellee's asserted "viable method of compliance with a state law duty that does not conflict with federal law," (Majority, at *26), but in my reading never spells out what that assumed viable method is. Instead, the Majority cites Appellee's allegations at length, and then concludes generically that his position has merit. (***See id.***). I do not.

"[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).

> "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 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).

Accordingly, I concur in part and dissent in part.