J-A31029-12

2013 PA Super 216

IN RE: REGLAN LITIGATION	IN THE SUPERIOR COURT OF PENNSYLVANIA
APPEAL OF: WYETH LLC, WYETH PHARMACEUTICALS, INC. AND WYETH HOLDINGS CORPORATION (COLLECTIVELY "WYETH")	No. 84 EDA 2012

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

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

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

Wyeth appeals from the order overruling its preliminary objections to the "Third Amended Master Long Form Complaint" filed by Appellees, plaintiffs in a mass tort action involving Reglan and the generic bioequivalent, metoclopramide. It argues that the claims against it are preempted under ***PLIVA, Inc. v. Mensing***, 131 S. Ct. 2567 (2011). The trial court overruled the preliminary objections, and certified the ruling for interlocutory appeal, but then reversed itself and now urges this Court to

* Retired Senior Judge assigned to the Superior Court.

quash the appeal. The learned Majority grants the motion of Plaintiffs/Appellees to quash the appeal. I would find that the order is properly appealed as an appealable collateral order. However, I conclude that the claims against Wyeth are not preempted. Therefore, I would affirm the trial court's original overrule of the preliminary objections.

Appellant Wyeth represents that it purchased the rights to Reglan from A.H. Robins after its bankruptcy in 1989, then marketed and sold Reglan between 1990 and 2001, when it sold the rights to Schwarz Pharma Inc. (Schwarz) in December, 2001. (***See*** Appellant's Brief, at 3). Wyeth states that "Schwarz assumed all control over the content of tablet Reglan's labeling, and, although the transfer agreement required Wyeth to maintain some limited transitional responsibilities for Reglan after December 27, 2001, Wyeth no longer sold Wyeth-brand tablet Reglan after that date." (***Id.*** at 6).[1]

Wyeth argues that after it sold the NDA for Reglan tablets to Schwarz, it had no ability to change the Reglan label unilaterally or independently, and therefore under ***Mensing*** any claimed state law duty is preempted by federal law. (***See*** Appellants' Brief, at 10-11).

> A preliminary objection in the nature of a demurrer is properly granted where the contested pleading is legally insufficient. ***Cardenas v. Schober***, 783 A.2d 317, 321 (Pa. Super. 2001)

[1] Wyeth added in a footnote that "[a] former division of Wyeth, ESI Lederle, marketed generic metoclopramide until 2002." (***Id.*** at 6 n.3).

(citing Pa.R.C.P. 1028(a)(4)). "Preliminary objections in the nature of a demurrer require the court to resolve the issues solely on the basis of the pleadings; no testimony or other evidence outside of the complaint may be considered to dispose of the legal issues presented by the demurrer." ***Id.*** at 321–22. (citation omitted). All material facts set forth in the pleading and all inferences reasonably deducible therefrom must be admitted as true. ***Id.*** at 321.

> In determining whether the trial court properly sustained preliminary objections, the appellate court must examine the averments in the complaint, together with the documents and exhibits attached thereto, in order to evaluate the sufficiency of the facts averred. The impetus of our inquiry is to determine the legal sufficiency of the complaint and whether the pleading would permit recovery if ultimately proven. This Court will reverse the trial court's decision regarding preliminary objections only where there has been an error of law or abuse of discretion. When sustaining the trial court's ruling will result in the denial of claim or a dismissal of suit, preliminary objections will be sustained only where the case i[s] free and clear of doubt.
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> ***Brosovic v. Nationwide Mutual Insurance Co.,*** 841 A.2d 1071, 1073 (Pa. Super. 2004) (citation omitted).

Cooper v. Frankford Health Care Sys., Inc., 960 A.2d 134, 143–144 (Pa. Super. 2008) (quoting ***Hess v. Fox Rothschild, LLP,*** 925 A.2d 798, 805–06 (Pa. Super. 2007)). Thus, "the question presented by the demurrer is whether, on the facts averred, the law says with certainty that no recovery is possible. Where a doubt exists as to whether a demurrer should be sustained, this doubt should be resolved in favor of overruling it." ***Bilt–Rite Contractors, Inc. v. The Architectural Studio,*** 581 Pa. 454, 866 A.2d 270, 274 (2005) (citation omitted).

Weiley v. Albert Einstein Med. Ctr., 51 A.3d 202, 208-09 (Pa. Super. 2012).

"Issues of preemption comprise pure questions of law, of which the standard of review is *de novo* and the scope of review plenary." ***In re Estate of Sauers***, 32 A.3d 1241, 1248 (Pa. 2011)(citation omitted).

Here, the trial court, reversing itself,[2] concluded that Wyeth's appeal should be quashed. (***See*** Trial Ct. Op., 2/28/12, at 1). It reasoned that (1) the order was not final pursuant to Pa.R.A.P 341(a); (2), the issue on appeal is not collateral to the central issue; and (3) that there remains material issues of fact. (***See id.*** at 2).

> As a general rule, an appellate court's jurisdiction extends only to review of final orders. ***See*** Pa.R.A.P. 341 ("[A]n appeal may be taken as of right from any final order.") Final orders are those which either (1) dispose of all claims and all parties, (2) are explicitly defined as final orders by statute, or (3) are certified as final orders by the trial court or other reviewing body.

Rae v. Pennsylvania Funeral Directors Ass'n., 977 A.2d 1121, 1125 (Pa. 2009).

In this appeal, there is no dispute that the subject order was not final. Rather, as noted in the trial court's second point, the issue is whether the order is properly appealable as a collateral order. (***See id.*** at 3-5); ***see also*** Pa.R.A.P. 313, Collateral Orders, which provides:

[2] The trial court explains that its certification was inadvertent. (***See*** Trial Ct. Op., 2/18/12, at 2).

> **(a) General rule.** An appeal may be taken as of right from a collateral order of an administrative agency or lower court.
>
> **(b) Definition.** A collateral order is 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.

> Accordingly, where an order satisfies Rule 313's three-pronged test, we may exercise appellate jurisdiction where the order is not final. If the test is not met, however, and in the absence of another exception to the final order rule, we have no jurisdiction to consider an appeal of such an order.

Rae, ***supra*** at 1125 (citation omitted).

I would conclude that the issue of federal preemption is appropriate for determination under the collateral order doctrine, as indeed, the Majority concluded in the other three companion cases. I would also conclude that the legal issue of federal preemption is readily separable from the underlying factual issues determining state law tort liability. The trial court posits that Appellees' "failure to warn claim against Wyeth is a central issue rather than one 'separable from and collateral to the main cause of action.'" (Trial Ct. Op., 2/18/12, at 5). However, the legal issue of federal preemption can be addressed without deciding whether there is liability for the underlying state law tort issue of failure to warn.

Appellees also argue that resolution of the preemption issue would require comparison of federal versus state duties, which directly implicates the merits of claims in the litigation, precluding collateral review because the inquiry "is neither separable from nor collateral to the merits of plaintiffs' lawsuit." (Appellees' Brief, at 12). However, this argument has been effectively rejected by our Supreme Court in ***Pridgen v. Parker Hannifin Corp.*** 588 Pa. 405, 428-429, 905 A.2d 422, 433 (Pa. 2006) ("As to separability, this Court 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.") (citations omitted).

Similarly, ***Pridgen*** held that the operation of a federal statute of repose to preclude state based tort claims was too important to be denied review on collateral appeal. ***See id.*** Also notable is our Supreme Court's conclusion in ***Pridgen*** that the substantial cost that appellants would "incur in defending this complex litigation at a trial on the merits comprised a sufficient loss to support allowing interlocutory appellate review as of right, in light of the clear federal policy to contain such costs in the public interest." ***Id.***

Here, similarly, it is undisputed that the Hatch-Waxman Amendments were enacted for the purpose of effecting cost savings in the delivery of

generic drugs "to provide a safe, effective, low cost alternative to the American public," as described by the FDA; ***see also Mensing***, ***supra*** at 2583 (Sotomayor, J., dissenting) (acknowledging that Congress enacted the Hatch–Waxman Amendments to "make available more low cost generic drugs by establishing a generic drug approval procedure" (citing H.R.Rep. No. 98–857, pt. 1, p. 14 (1984))). The issue of federal preemption implicates public policy and is too important to be denied review.

Finally, the trial court maintains that Wyeth's appeal should be quashed because "there remain material issues of fact which make Wyeth's request premature." (Trial Ct. Op., 2/28/12, at 2). However, under our standard of review, whether there are unresolved material issues of fact is not relevant because all well-pleaded allegations of material facts must be admitted as true.

Accordingly, I would conclude that the instant collateral order overruling preliminary objections asserting federal preemption is properly appealable under ***Pridgen***, ***supra*** at 434 and Rule 313. Accordingly, I would decline to quash, and review the appeal on the merits.

In its brief, Wyeth posits that in its preliminary objections, "the **sole question** presented was whether ***Mensing*** foreclosed—as a matter of federal law—claims by Plaintiffs who were prescribed and ingested

metoclopramide after 2001." (Wyeth's Brief, at 9) (emphasis added). Similarly, in its summary of the argument, Wyeth asserts that:

> "Wyeth's Preliminary Objections do not turn on the interpretation of state law, but rather on the application of federal law, and federal law is clear. In ***Mensing***, the Supreme Court held that federal law preempted state-law failure-to-warn claims brought against generic metoclopramide manufacturers because federal law prohibited generic manufacturers from 'unilaterally' changing the labeling for metoclopramide."

(***Id.*** at 10) (citation omitted).

To support its claim of federal preemption, Wyeth maintains that after it assigned the NDA for Reglan (tablets) to Schwarz in 2001, "it was in the same position as the generic manufacturers at issue in ***Mensing*** — it was no longer the 'applicant' because it no longer owned the NDA, and it could no longer independently and unilaterally revise the labeling."[3] (Appellant's Brief, at 24) (internal quotation marks in original). Wyeth maintains that "[a]s a matter of federal law, [it] cannot be found to have a duty to any plaintiff with respect to the content of Reglan's labeling after 2001." (Appellant's Reply Brief, at 9).

To review the trial court's ruling, we assume Appellees' well-pleaded factual allegations are true. Wyeth's entire argument assumes that the

[3] Applicant means any person who submits an application or abbreviated application or an amendment or supplement to them under this part to obtain FDA approval of a new drug or an antibiotic drug and any person who owns an approved application or abbreviated application.

21 CFR § 314.3.

holding in ***Mensing*** preempts state law liability for it as a one-time NDA holder which subsequently sold it. But ***Mensing*** plainly and unequivocally addressed **generic** drug manufacturers. Wyeth, except for its former division, ESI Lederle,[4] is not a manufacturer of generic metoclopramide. Divesting its NDA for Reglan tablets to Schwarz did not transform Wyeth into a generic drug manufacturer. ***Mensing*** does not apply.

Appellees do **not** allege liability against Wyeth as a generic manufacturer. To the contrary, they deny it:

> Wyeth, however, is not being sued in the capacity as a manufacturer of a generic prescription drug, and thus ***Mensing***'s holding is simply inapplicable to Wyeth. Rather, all of plaintiffs' claims against Wyeth seek to hold Wyeth liable either in Wyeth's capacity as manufacturer of brand name Reglan, or in in Wyeth's capacity as a corporation that has retained labeling responsibilities for brand name Reglan in a contract with the successor manufacturer of brand name Reglan.

(Appellees' Brief, at 8).

Appellees insist that evidence obtained in discovery demonstrated that "Wyeth had contractually retained labeling and regulatory reporting responsibilities applicable to Reglan tablets even after the nominal sale of ownership of the product occurred in late 2001." (Appellees' Brief at 6).

Whether Appellees can prove this at trial (or prevail against a motion for summary judgment) is another matter, and one not before us in this review. We only note that Wyeth's assertion that it could not change the

[4] ***See supra*** at 3, n.3.

warning label "independently" and "unilaterally," even if accepted at full face value, is not inconsistent with the possibility that the retained responsibilities in the contract of sale of Reglan to Schwarz provided for some form of joint or cooperative responsibility for labeling, marketing, and so on. (***See*** Appellant's Brief, at 11). Wyeth does not address whether it could be liable under **state** law for failing to fulfill these residual duties, or duties which arose previously in its capacity as NDA holder. (***See id.*** at 10).

In ***Mensing***, the United States Supreme Court concluded that because of the federal requirement of sameness for generic manufacturers (who are required to keep their warning labels the same as those of the reference listed drug), it was impossible for generic manufacturers to comply with state law which presumptively required stronger warnings (taking respondents' allegations to be true for the purpose of its analysis). ***See Mensing***, ***supra*** at 2577-78.

Here, Wyeth itself (except for its former division, ESI Lederle) was never a generic manufacturer; rather, it was the holder of a Reglan NDA acquired from the original applicant and divested by sale to a subsequent purchaser. These voluntary transactions do not implicate any of the "sameness" requirements federal law imposes on generic manufacturers, as analyzed in ***Mensing***. Taking Appellees' well-pleaded allegations of fact as true for this review, Wyeth could have retained duties under state law.

Failure to perform these duties could result in state law tort liability. Wyeth did not acquire the duties of a generic manufacturer, particularly the sameness requirement, by virtue of its sale to Schwarz. Therefore, Wyeth did not lose the capacity to comply with any applicable state law duties. The impossibility analysis in ***Mensing*** for generic manufacturers does not apply to Wyeth.

Accordingly, under our *de novo* standard of review and plenary scope of review, taking all well-pleaded allegations of fact as true for purposes of the review, we cannot say "with certainty that no recovery is possible. Where a doubt exists as to whether a demurrer should be sustained, this doubt should be resolved in favor of overruling it." ***Weiley v. Albert Einstein Medical Center***, 51 A.3d 202, 209, 218 (Pa. Super. 2012) (citation omitted). The trial court properly overruled Wyeth's preliminary objections. Accordingly, I would affirm the trial court's order.

Therefore, I respectfully dissent.