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"),	
Appellant	No. 84 EDA 2012

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

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

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

Wyeth LLC, Wyeth Pharmaceuticals, Inc. and Wyeth Holdings Corporation (hereinafter "Wyeth"), appeal from the November 18, 2011 order overruling their preliminary objections in the nature of a demurrer to a master complaint filed by Plaintiffs, persons who were allegedly injured after ingesting metoclopramide.[1] Wyeth, a former name-brand manufacturer of metoclopramide known as Reglan, seeks to avoid liability for all claims

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* Retired Senior Judge assigned to the Superior Court.

[1] Mr. Hassett's claims against generic manufacturers are representative of the claims of more than two thousand other plaintiffs pending in the Court of Common Pleas of Philadelphia County. The preliminary objections were filed to the Third Amended Master Long Form Complaint.

arising after 2001 based on the rationale underlying the United States Supreme Court's holding in ***PLIVA, Inc. v. Mensing***, 131 S.Ct. 2567 (2011), namely, that it no longer had the ability to unilaterally change the label. Wyeth premises jurisdiction to entertain this interlocutory appeal on the collateral order doctrine. For the reasons that follow, we hold that the trial court's order as to Wyeth is not immediately appealable under the collateral order doctrine, and we grant Plaintiffs' motion to quash the appeal.

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 facts pertinent to Wyeth are as follows. In 1980, the FDA approved Wyeth as the New Drug Application (NDA) holder for metoclopramide tablets, and permitted it to sell the drug under the brand-name Reglan. The patent for Reglan expired in 1985, and generic manufacturers entered the market. It is undisputed that both Reglan and generic metoclopramide are both marketed today. Wyeth transferred the NDA for Reglan tablets to Schwarz in 2001. Admittedly, under the transfer agreement, Wyeth retained some control over Reglan for some period, the nature and extent of which is disputed.

The Plaintiffs in this mass tort litigation commenced civil actions against both the name-brand manufacturers, including Wyeth, 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.[2] 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 (5th Cir. 2010) (under Louisiana law), to determine whether state failure to warn claims 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 Reference Listed Drug ("RLD") holders, and those pertaining to generic drug manufacturers, many of which 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

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[2] 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.

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 already approved RLD. In addition, the legislation also 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 Food and Drug Administration Amendments Act of 2007, 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 warnings via Dear Doctor letters. 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 reliance upon ***Mensing***, Wyeth filed preliminary objections to Plaintiffs' third amended long form master complaint seeking dismissal of all claims against it arising after 2001 on pre-emption grounds. The trial court overruled the preliminary objections and denied Wyeth's motion for reconsideration. The trial court initially granted Wyeth's motion 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)). It subsequently reversed itself in an order dated February 18, 2012, explaining that its certification was inadvertent. The court concluded that the appeal should be quashed as the order was not final, the issue was not collateral to the central issue, and that there remained material issues of fact. Trial Court Opinion, 2/28/12, at 1.

Wyeth filed both a timely petition for permission to appeal, which this Court denied by order of March 12, 2012, and an appeal as of right 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.

Wyeth presents one issue for our review:

> Does federal law preempt state-law labeling claims asserted against Wyeth by Plaintiffs who were prescribed Reglan or metoclopramide after Wyeth relinquished control of Reglan and its labeling in 2001?

Wyeth's brief at 2.

Before we can reach the pre-emption issue, we must first determine whether this Court has jurisdiction to entertain this interlocutory appeal. Plaintiffs 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).

Wyeth relies largely upon our Supreme Court's decision in ***Pridgen v. Parker Hannifin Corp.***, 905 A.2d 422 (Pa. 2006), in support of collateral order jurisdiction. Therein, the Court addressed the question whether the court's interlocutory order denying summary judgment based upon the eighteen-year statute of repose contained in the General Aviation Revitalization Act of 1994 ("GARA"), 49 U.S.C.S. § 40101, was immediately appealable as a collateral order. In resolving the issue, our High 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 ***Johnson***, the plaintiff, a diabetic, suffered an insulin-related seizure. Five police officers arrested him, believing that he was intoxicated, and transported him to the police station. He was subsequently diagnosed with several broken ribs and hospitalized. The plaintiff commenced a constitutional tort action against the officers pursuant to 42 U.S.C. § 1983, claiming that they used excessive force when they arrested him and that they later beat him at the station. Three of the officers sought summary judgment based on qualified immunity, arguing that the plaintiff could point

to no evidence that they had beaten him or were present while others did so. In opposition to the motion, Mr. Jones pointed to his own deposition testimony in which he swore that officers had used excessive force, as well as the three officers' own depositions, in which they admitted they were present at the arrest and in or near the booking room when Mr. Jones was there. The district court denied summary judgment, finding potential liability if the officers watched and allowed others to beat the plaintiff, and that the plaintiff's deposition provided evidence of those circumstances.

The officers appealed to the Court of Appeals for the Seventh Circuit, which held that it lacked jurisdiction and dismissed the appeal. The Supreme Court framed the issue as whether, in a case involving qualified immunity, the portion of a district court's summary judgment order that determined only a question of "evidence sufficiency," *i.e.*, which facts a party may, or may not, be able to prove at trial, was appealable as a collateral order. The Court concluded that it was not, as the issue was not separate from the fact-related legal issues underlying the merits of the plaintiff's claims.

The facts in ***Pridgen*** are instructive. A thirty-one-year-old Piper PA-32-260 airplane crashed on departure from a local Ohio airport in 1999, killing or seriously injuring all aboard. Representatives of the victims commenced civil actions in negligence, strict liability and breach of warranty against the designer, manufacturer, seller, overhauler, and repairer of the

Lycoming engine that was installed in the aircraft. Defendants asserted GARA's statute of repose as a bar to the action. That statute provided that claims for death and injury against aircraft or component manufacturers were barred if the accident occurred more than eighteen years after delivery of the aircraft to the first purchaser. However, GARA also contained an express "rolling provision" which provided that the eighteen-year period commenced upon the date when component parts were installed and an exception denying manufacturers repose in the event of misrepresentation, concealment, or withholding of essential information regarding performance, maintenance, or operation of an aircraft.

At summary judgment, it was undisputed that the original engine assembly was installed more than eighteen years before the accident. However, plaintiffs maintained that the 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. However, as the basis for avoiding the statute, plaintiffs pointed to defendants' status as the holder of the FAA certificate for the engine model in the aircraft, evidence that defendants supplied the specifications for the replacement components and marketed the parts under

their own classification system, and the fact that these parts were installed within eighteen years of the crash.

The trial court denied summary judgment without opinion. Defendants filed notices of appeal seeking to appeal as of right under Pennsylvania's collateral order doctrine. In its Rule 1925(a) opinion, the trial court held that the three prongs of the collateral order test were not satisfied. As to the separability prong of the test, the court found that the age of the airplane engine, and hence the issue of whether GARA operated to bar the action, was a central issue and inseparable from its merits.[3]

Defendants appealed to this Court and we quashed the appeal. The Supreme Court allowed discretionary review and, after several remands, addressed the collateral order issue. In order to avoid the factual issues identified by the trial court and viewed as inseparable from the merits, defendants recast 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. The focus was thus on the terms of the statute, not on determinations of fact or the scope of liability. Our High Court found this legal issue separable from the merits of the underlying case. Additionally, in furtherance of the policy

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[3] The trial court also held that defendants failed to establish that the rights involved went beyond the particular litigation and found that the inconvenience occasioned by postponing review and proceeding to trial was not "irreparable loss."

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. 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 as framed by Wyeth herein is whether it should be compelled to defend claims arising from ingestion of metoclopramide after it transferred the New Drug Application for Reglan in December 2001. As to the post-2001 claims, Wyeth asserts that ***Mensing*** dictates that it be treated the same as a generic manufacturer because it no longer had the right to unilaterally change the Reglan label. Wyeth maintains that because it raised a dispositive federal-law defense, namely pre-emption, in all cases where plaintiffs were prescribed or ingested Reglan after 2001, a collateral order appeal will lie under ***Pridgen*** and Pa.R.C.P. 313(b).

As in ***Johnson***, Plaintiffs focus on the factual issues that would preclude disposition of the pre-emption issue on purely legal grounds. They point to evidence that Wyeth contractually retained labeling and reporting responsibilities and was responsible for the content of the insufficient warning labels that generic manufacturers were using after 2001. Moreover, Wyeth-manufactured Reglan conceivably remained in circulation and available for consumption for years after Reglan sold the license and thus, the alleged cut-off date was in dispute. Plaintiffs argue that these are the

precisely the types of genuine issues of material fact that rendered the order inseparable from the merits in ***Johnson***. This was also the rationale of the trial court's holding that Wyeth's responsibility for updating the content of its label post-2001 was a central issue rather than a collateral one.

The parties dispute whether Wyeth contractually retained labeling and regulatory reporting duties after December 2001. Furthermore, Wyeth's conduct, *i.e.* failure to warn, misrepresentations of risks, deceptive and fraudulent practices prior to 2001, may have caused injury after that date by impacting the content of warnings post-December 2001. Finally, drugs manufactured by Wyeth pre-December 2001 likely remained on pharmacy shelves after that time and were dispensed after Wyeth transferred the NDA for the drug to Schwarz Pharma. While Wyeth attempts to recast its issue on appeal as purely a legal one, we find that, as in ***Johnson***, we are not dealing with the application of clearly established law to a given set of facts. We agree with Plaintiffs that Wyeth has not met the separability prong of the collateral order test.

Additionally, Wyeth has not satisfied the irreparable harm prong of the test. Wyeth acknowledges that it was a name-brand manufacturer prior to 2001 and concedes that it is subject to liability for failure to warn and other claims based on the adequacy of its labeling during that time. Thus, regardless of our disposition of the pre-emption issue, Wyeth will remain a defendant. Even a successful appeal would result in dismissal of only some

claims against it. Certainly, Wyeth cannot credibly argue that bearing the burden of defending the instant claims equates to an irreparable loss of a right to avoid the burden entirely, the situation in ***Pridgen***, ***supra***.

For these reasons, we grant Plaintiffs' motion to quash the appeal.

Appeal quashed. Jurisdiction relinquished.

Judge Platt files a Dissenting Opinion.

Judgment Entered.

Prothonotary

Date: 7/29/2013