

In the Superior Court of Pennsylvania

No. 84 EDA 2012

IN RE: REGLAN LITIGATION

Appeal of: Wyeth LLC, Wyeth Pharmaceuticals, Inc., and Wyeth Holdings Corp.

BRIEF FOR PLAINTIFFS–APPELLEES IN OPPOSITION TO WYETH’S APPEAL

On Appeal from the November 18, 2011 Order of the Court of Common Pleas of
Philadelphia County, Mass Tort Program, January Term 2010, No. 1997

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I. INTRODUCTION

In *Wyeth v. Levine*, 555 U.S. 555 (2009), the Supreme Court of the United States held that the federal Food and Drug Administration's approval of a prescription drug's warning label does not preempt a state law claim against the manufacturer of the prescription drug for negligent failure to warn alleging that the drug's warning label should have more clearly and adequately warned of the drug's risks.

Approximately two years later, in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), the U.S. Supreme Court ruled that because federal law requires the manufacturer of a generic prescription drug to use the identical warning label that the FDA has approved for the brand name version of that drug, federal law preempts a negligent failure to warn lawsuit against the manufacturer of a generic prescription drug if the plaintiff is claiming that the generic medication should have contained a warning label that differed from the label that the FDA approved for use on the brand name version of the medication.

Defendant-appellant Wyeth was the manufacturer of brand name Reglan. All of the claims being asserted in this litigation against Wyeth seek to hold it liable either directly in its capacity as the manufacturer of brand name Reglan or 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. Thus, none of plaintiffs' claims against Wyeth seek to hold Wyeth liable on

the ground that Wyeth was the manufacturer of the generic form of Reglan, known as metoclopramide.

Consequently, this Court may be puzzled concerning how Wyeth, sued only in its capacities as the brand name manufacturer of Reglan or as a company having continuing contractual responsibilities for the correctness and accuracy of the warning label for brand name Reglan, maintains that the U.S. Supreme Court's decision in *Mensing* — a decision limited to addressing an issue of federal preemption pertaining to one specific type of failure to warn claim against only generic prescription drug manufacturers — necessitates the dismissal of any of plaintiffs' claims against Wyeth on the basis of federal preemption.

The short answer is that *Mensing* does not compel the dismissal of any of plaintiffs' claims against Wyeth, because none of plaintiffs' claims allege that Wyeth was, or should be held liable as, the manufacturer of generic metoclopramide. Wyeth's attempt to employ *Mensing* in seeking the dismissal of only a small subset of the claims asserted against Wyeth in these lawsuits arises from Wyeth's misbegotten attempt to expand *Mensing's* actual holding into something far more expansive that bears little resemblance to what the U.S. Supreme Court actually decided in that case.

Moreover, Wyeth's appeal improperly attempts to gloss over the important unresolved genuine issues of material fact at the heart of the claims that Wyeth is now seeking to have dismissed. These factual issues have thus far prevented even the trial court from addressing the merits of Wyeth's arguments for dismissal of

those claims. Wyeth asserts, in a nutshell, that once Wyeth sold the rights to manufacture brand name Reglan to a third-party, Wyeth can no longer be liable to anyone who was injured as the result of consuming brand name Reglan after the sale date, even if following the sale Wyeth retained continuing contractual responsibilities for the correctness and accuracy of the warning label for brand name Reglan. Neither the *Mensing* decision nor any of the other opinions on which Wyeth relies lend any actual support for the specific argument that Wyeth is now asking this Court to adopt.

Here, the pertinent facts that will determine whether Wyeth can be held liable on plaintiffs' claims in Wyeth's capacity as manufacturer of brand name Reglan or in Wyeth's capacity as the former manufacturer of brand name Reglan which contractually retained responsibility for the continued adequacy of Reglan's labeling remain actively in dispute and have yet to be addressed or decided at the trial court level. Consequently, not only does Wyeth's appeal fail to implicate the U.S. Supreme Court's actual holding in *Mensing*, but the facts critical to determining under applicable law whether Wyeth may be held liable to plaintiffs in the capacities in which Wyeth actually has been sued remain unresolved. As a result, any appellate consideration of those questions is premature.

Even more importantly, appellate review of Wyeth's arguments must be denied for an entirely separate but interrelated reason: Wyeth's appeal is not a proper collateral order appeal. Because the collateral order doctrine is the sole basis

for appellate jurisdiction that Wyeth invokes, and because that jurisdictional basis does not exist for the reasons explained below, this appeal must be dismissed.

Wyeth's appeal asserts that federal law conflicts with, and thus preempts, certain state law causes of action that plaintiffs have asserted against Wyeth in plaintiffs' Third Amended Master Long Form Complaint. It is well-established, however, that the defense of federal conflict preemption is not the equivalent of an immunity from suit, and therefore a trial court's refusal to find the existence of conflict preemption fails to satisfy the strict requirements for appeal under the collateral order doctrine.

II. STATEMENT OF JURISDICTION

As explained herein, plaintiffs believe that Wyeth's appeal must be dismissed because the order from which Wyeth has appealed does not qualify as an immediately appealable collateral order under Pennsylvania law.

III. COUNTER-STATEMENT OF THE QUESTIONS PRESENTED

1. Whether this Court may address the merits of Wyeth's appeal from an interlocutory order of the trial court when: (a) the sole basis for jurisdiction that Wyeth has invoked is the collateral order doctrine; and (b) Wyeth is incapable of establishing that the order appealed from satisfies any of the criteria for collateral order jurisdiction?

2. Whether the trial court correctly held that disputed issues of fact prohibited the trial court's resolution at the preliminary objections stage of Wyeth's argument that the U.S. Supreme Court's ruling in *Mensing* somehow necessitates the dismissal of certain of plaintiffs' claims against Wyeth, notwithstanding that Wyeth has not been sued in the capacity of a generic prescription drug manufacturer?

IV. COUNTER-STATEMENT OF THE CASE

Wyeth is the one and only brand name manufacturer of Reglan that is pursuing a collateral order appeal requesting immediate appellate review of the trial court's decision correctly recognizing that the precise claim against the manufacturers of a generic prescription drug that the U.S. Supreme Court held was preempted in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), is not among the claims being asserted against the manufacturers of generic prescription drugs in plaintiffs' Third Amended Master Long Form Complaint.

Although *Mensing* did not address or purport to resolve the liability of any brand name prescription drug manufacturers, it is Wyeth's contention that the rationale of *Mensing* should result in a holding that Wyeth cannot be held liable to anyone who consumed brand name Reglan tablets after the date on which Wyeth sold its ownership rights in brand name Reglan tablets to a third-party in late 2001. According to Wyeth, as of that date Wyeth would no longer have possessed

any ability to change or strengthen the warning label found on brand name Reglan tablets.

In opposing Wyeth's *Mensing*-based preliminary objections in the trial court, plaintiffs advanced three arguments. First, plaintiffs pointed out that *Mensing* did not address or purport to limit the potential liability under state law of the manufacturers of brand name prescription drugs, such as Wyeth. R.553a-54a. Second, plaintiffs cited to specific evidence obtained in discovery demonstrating that Wyeth had contractually retained labeling and regulatory reporting responsibilities applicable to Reglan tablets even after the nominal sale of ownership of the product had occurred in late 2001. R.348a-49a, 351a-53a. Third and finally, plaintiffs reminded the trial court that the trial court had already recognized that under the laws of various states, Wyeth could be held liable under a failure to warn theory to plaintiffs who had consumed generic metoclopramide, because Wyeth was the manufacturer of brand name Reglan tablets whose insufficient warning label, devised at a time when Wyeth did control the content and nature of those warnings, was also found on the generic versions of that medication. R.353a-55a. *See, e.g., Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 315 (Cal. App. Ct. 2008) ("We hold that Wyeth's duty of care in disseminating product information extends to those patients who are injured by generic metoclopramide as a result of prescriptions written in reliance on Wyeth's product information for Reglan."). In its Brief for Appellant, Wyeth acknowledges that it is not seeking the dismissal of this third category of claims by means of its current appeal. *See* Brief for Appellant at 9.

In an order issued November 18, 2011, the trial court denied Wyeth’s preliminary objections. R.366a. The trial court’s order stated that the denial was “without prejudice to raise this issue in a motion for summary judgment.” *Id.* On December 19, 2011, Wyeth filed its supposed collateral order appeal. R.401a–02a. Thereafter, on February 28, 2012, the trial court issued an opinion in accordance with Pennsylvania Rule of Appellate Procedure 1925(a) recommending that this Court quash Wyeth’s appeal because the appeal fails to satisfy the criteria for collateral order review. R.409a–14a. Plaintiffs then filed a motion to quash Wyeth’s appeal, but a motions panel of this Court deferred the jurisdictional issue to this merits panel.

V. SUMMARY OF THE ARGUMENT

Two critical flaws plague Wyeth’s appeal.

First, the order from which Wyeth has appealed fails to qualify as an immediately appealable collateral order. Consequently, Wyeth’s appeal should be dismissed for lack of jurisdiction. Even if Wyeth could establish that the U.S. Supreme Court’s ruling in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), compelled the conclusion that federal law preempted plaintiffs’ state law failure to warn claims against Wyeth — which, as explained below, Wyeth cannot establish — the law governing appellate jurisdiction is nevertheless clear that a trial court’s rejection of a defendant’s conflict preemption defense does not give rise to a decision that is immediately appealable under the collateral order doctrine. Moreover, the

trial court's rejection of Wyeth's misbegotten federal preemption defense was grounded in the existence of unresolved disputed issues of material fact, making Wyeth's appeal particularly unsuitable for interlocutory appellate review under the collateral order doctrine. R.413a–14a.

Second, on the merits, Wyeth seeks to vastly and improperly expand the U.S. Supreme Court's holding in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), to stand for the proposition that federal law preempts any failure to warn lawsuit involving a prescription drug where the defendant asserts an inability to alter the drug's warning label. In actuality, the U.S. Supreme Court's holding in *Mensing* was limited to only one type of failure to warn claim asserted against only one type of manufacturer — the manufacturer of a generic prescription drug.

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 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. Wyeth has failed to show that federal law precluded Wyeth from ensuring that brand name Reglan contained a warning label that clearly and adequately warned of Reglan's actual risks in either capacity in which Wyeth actually has been sued in this lawsuit.

Moreover, as the trial court recognized, Wyeth's claimed inability to change Reglan's warning label after Wyeth's sale of that product to a third-party directly implicates disputed issues of fact that have yet to be addressed or resolved by the trial court concerning the effect of a written contract in which Wyeth agreed to retain labeling responsibilities for Reglan even after the sale occurred. An appropriate record concerning these factual issues and a decision on them from the trial court needs to, but does not yet, exist before these questions may properly be considered on appeal.

Thus, were this Court to reach the merits of Wyeth's appeal, this Court should hold that the U.S. Supreme Court's decision in *Mensing* does not stand for the sweeping proposition that Wyeth asserts, but that even if *Mensing* had held that federal law would preempt any failure to warn claim against any defendant that lacked the ability to change a prescription drug's warning label, Wyeth's ability to change Reglan's warning label following Wyeth's sale of manufacturing rights is an issue that remains actively in dispute as a factual matter.

For these reasons, which are explained in more detail below, this Court should either dismiss Wyeth's collateral order appeal for lack of jurisdiction or should affirm the trial court's dismissal of Wyeth's preliminary objections.

VI. ARGUMENT

A. **Wyeth's Appeal Should Be Dismissed Because The Order From Which Wyeth Has Appealed Fails To Satisfy Any Of The Three Prongs Of The Collateral Order Doctrine**

Pennsylvania Rule of Appellate Procedure 313(b) contains the following definition of a “collateral order”:

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. App. P. 313(b).

The Supreme Court of Pennsylvania has recognized that Rule 313(b) imposes three separate requirements, which must all be satisfied in order for collateral order review to be available. Those requirements are: (1) the order must be “separable from and collateral to the main cause of action”; (2) the appeal must involve a right that “is too important to be denied review”; and (3) “if review is postponed until final judgment in the case, the claim will be irreparably lost.” *See Vaccone v. Syken*, 587 Pa. 380, 384, 899 A.2d 1103, 1106 (2006). As Pennsylvania’s highest Court explained in *Vaccone*:

As an exception to the rule of finality, the doctrine is to be interpreted narrowly, and each prong of the collateral order doctrine must be clearly present before an order may be considered collateral.

Id. (internal quotations omitted); *see also Rae v. Pennsylvania Funeral Directors Ass’n*, 602 Pa. 65, 73, 977 A.2d 1121, 1126 (2009) (“To buttress the final order rule, we, too, have concluded the collateral order doctrine is to be construed narrowly,

and we require every one of its three prongs be clearly present before collateral appellate review is allowed.”).

Thus, under Pennsylvania law, Wyeth must clearly satisfy all three of these prerequisites for this collateral order appeal to be proper. Here, Wyeth can satisfy none of these prerequisites, and therefore the Court should dismiss Wyeth’s appeal for lack of appellate jurisdiction.

1. The order from which Wyeth has appealed is not separable from and collateral to the merits of this case

In its so-called “collateral order” appeal, Wyeth argues that certain of the claims asserted against it in plaintiffs’ Third Amended Master Long Form Complaint are preempted by federal law in accordance with Wyeth’s mistaken and plainly incorrect understanding of the U.S. Supreme Court’s ruling in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

What is most important at this juncture, however, is that the U.S. Supreme Court’s approach to determining whether federal law conflicted with state law in *Mensing* — which would thereby result in “conflict preemption” whereby federal law would preempt the state law claim — necessitated a careful evaluation of the elements of the claims that the plaintiffs were asserting against the defendants. In other words, the U.S. Supreme Court’s ruling in *Mensing* recognizes that before one can decide whether federal law preempts a state law cause of action under principles of conflict preemption, it is necessary to ascertain under state law the precise duties that the plaintiff is seeking to impose on the defendant. After those

duties are determined, it is then possible to examine whether imposing those duties would unavoidably conflict with the obligations that federal law places on that same defendant. *See Mensing*, 131 S. Ct. at 2573 (“Pre–emption analysis requires us to compare federal and state law. We therefore begin by identifying the state tort duties and federal labeling requirements applicable to the Manufacturers.”).

Determining the duties that plaintiffs’ various state law claims against Wyeth are predicated on directly implicates the merits of plaintiffs’ state law claims. First, this Court would need to separately analyze each claim that the plaintiffs have asserted against Wyeth. Next, this Court would need to determine what duties each claim seeks to impose on Wyeth under applicable state law. Finally, this Court would then need to ascertain whether the federal law applicable to Wyeth prohibits Wyeth from complying with the state law duties that plaintiffs’ claims seek to enforce. Unquestionably, this inquiry necessitated by Wyeth’s assertion of conflict preemption directly implicates the merits of plaintiffs’ claims in this litigation.

As a result, the inquiry that Wyeth would require this Court to engage in to resolve its collateral order appeal demonstrates that Judge Moss’s order, as demonstrated by the briefs now before this Court, is neither separable from nor collateral to the merits of plaintiffs’ lawsuit. Accordingly, the Court should dismiss this appeal.

Wyeth’s supposed collateral order appeal is also plagued by an additional fatal flaw. The question of *Mensing*’s applicability, if any, to Wyeth involves

disputed issues of material fact. In opposing Wyeth's *Mensing*-based preliminary objections in the trial court, plaintiffs drew to the trial court's attention specific evidence that plaintiffs obtained in discovery revealing that even though Wyeth may have nominally sold its Reglan tablet product line to a third-party effective December 27, 2001, Wyeth affirmatively agreed in its contract of sale with that third-party to "provide continued regulatory assistance" and to continue to work with the third-party purchaser thereafter "to redraft labeling documentation." R.327a (Attachment 5, ¶¶ 6-7). Thus, purely as a matter of fact, plaintiffs brought to the trial court's attention that Wyeth had contractually retained continuing labeling and regulatory reporting responsibilities for brand name Reglan tablets even after nominally selling the product to a third-party in late 2001. Wyeth offers a differing interpretation of this evidence, but the trial court has yet to directly address these contested factual issues or their consequences. Because the factual predicate for Wyeth's liability is legitimately in dispute, that issue is not properly the subject of a collateral order appeal. *See Johnson v. Jones*, 515 U.S. 304, 313-18 (1995) (holding that the existence of genuine issues of material fact underlying the issue of qualified immunity precluded collateral order jurisdiction on appeal).

The purpose of the collateral order doctrine is to treat as a final order a ruling which the trial court has issued that meets all of the various collateral order criteria. To qualify as a collateral order, however, the trial court's order must, at a minimum, have resolved on the merits the issue that the losing party wishes to challenge on appeal. Here, that has not happened, as Judge Moss cogently explains

in her Rule 1925(a) opinion urging this Court to quash Wyeth’s improper collateral order appeal. R.413a–14a.

Because the order that Wyeth seeks to challenge on appeal is not separate from the merits and involves genuine issues of material fact, this Court should dismiss Wyeth’s appeal for lack of appellate jurisdiction.

2. Wyeth’s appeal should be dismissed because the appeal does not assert a right that is too important to be denied review

The second requirement that Wyeth must satisfy in order to establish that its appeal is proper under the collateral order doctrine is that “the right involved is too important to be denied review.” Pa. R. App. P. 313(b). In *Gunn v. Automobile Ins. Co.*, 971 A.2d 505 (Pa. Super. Ct. 2009), this Court examined in detail what the “too important to be denied review” requirement of the collateral order doctrine requires the appellant to establish in order for the appeal to be proper.

In *Gunn*, this Court explained:

For purposes of defining an order as a collateral order under Rule 313, it is not sufficient that the issue be important to the particular parties. Rather it must involve rights deeply rooted in public policy going beyond the particular litigation at hand. In analyzing the importance prong, we weigh the interests implicated in the case against the costs of piecemeal litigation.

Id. at 509.

Pennsylvania courts routinely follow federal rulings in deciding the scope and proper application of the collateral order doctrine. *See Rae*, 602 Pa. at 71–72, 977 A.2d at 1125; *Vaccone*, 587 Pa. at 385, 899 A.2d at 1106.

Wyeth maintains that the “importance” prong of the collateral order doctrine is established by the fact that whether or not federal law preempts certain of plaintiffs’ state law causes of action against Wyeth in this lawsuit necessarily satisfies the “importance” requirement. In advancing this argument, Wyeth cites to the Supreme Court of Pennsylvania’s ruling in *Pridgen v. Parker Hannifin Corp.*, 588 Pa. 405, 905 A.2d 422 (2006), as an example of a case in which Pennsylvania’s highest court held that collateral order review was proper because the issue presented was whether federal law precluded the plaintiffs’ claims.

Unfortunately for Wyeth, the Pennsylvania Supreme Court’s ruling in *Pridgen* fails to establish that Wyeth’s supposed collateral order appeal is proper. At issue in *Pridgen* was whether the 18-year period of repose under the federal law known as the General Aviation Revitalization Act (GARA) operated to bar the plaintiffs’ claims. As the Supreme Court of Pennsylvania explained, “GARA created an explicit right not to stand trial * * * .” *Id.* at 413, 905 A.2d at 427. In so ruling, Pennsylvania’s highest court relied on the decision of the Ninth Circuit in *Estate of Kennedy v. Bell Helicopter Textron, Inc.*, 283 F.3d 1107, 1110 (9th Cir. 2002), holding that GARA “creates an explicit statutory right not to stand trial * * * .”

In addressing whether or not particular collateral order appeals are proper, federal appellate courts recognize a sharp distinction between a so-called “immunity from suit” — in which the defendant can establish that it is the beneficiary of an explicit right not to stand trial — and a mere defense to liability that might ultimately result in the defendant’s victory on appeal from the final

judgment in a case. As the U.S. Supreme Court has explained, “[o]ne must be careful * * * not to play word games with the concept of a ‘right not to be tried,’” *Midland Asphalt Corp. v. United States*, 489 U.S. 794, 801 (1989), as “virtually every right that could be enforced appropriately by pretrial dismissal might loosely be described as conferring a right not to stand trial,” *Digital Equip. Corp. v. Desktop Direct, Inc.*, 511 U.S. 863, 873 (1994).

Federal courts — which exist among other reasons to adjudicate claims arising under federal law and which would thus be expected to have a keen interest in upholding valid assertions of federal preemption of state law causes of action — have repeatedly recognized that a defendant’s contention that federal law preempts a plaintiff’s state law cause of action is not the equivalent of an immunity from suit establishing the defendant’s right not to stand trial.

Thus, in *Martin v. Halliburton*, 618 F.3d 476, 486 (5th Cir. 2010), the U.S. Court of Appeals for the Fifth Circuit explained that “[w]e have previously determined that the denial of a claim that state law is preempted by federal law is not an order that may be immediately appealed under the collateral order doctrine.” In a footnote that cited to the rulings of five other federal appellate courts, the Fifth Circuit in *Martin* wrote that “[w]e are not alone in treating denials of claims of preemption as not subject to immediate review under the collateral order doctrine.” *Id.* at 486 n.16; *see also Jordan v. AVCO Fin. Servs. of Ga., Inc.*, 117 F.3d 1254, 1258 (11th Cir. 1997) (dismissing for lack of appellate jurisdiction a collateral order appeal from the denial of a motion to dismiss after concluding that “the [McCarran–

Ferguson] Act is a statute of preemption rather than one granting immunity”); *Wood v. United States*, 995 F.2d 1122, 1130 (1st Cir. 1993) (en banc) (holding that “interlocutory appeal did not lie from the district court’s decision” on “whether or not federal law preempted certain of Wood’s state law claims”), *abrogated on other grounds by Osborn v. Haley*, 549 U.S. 225 (2007).

Most recently, and perhaps most persuasively, the en banc U.S. Court of Appeals for the Fourth Circuit, in *Al Shimari v. CACI Intern., Inc.*, 679 F.3d 205 (4th Cir. 2012) (en banc), held that federal “preemption falls squarely on the side of being a defense to liability and not an immunity from suit.” *Id.* at 217. Consequently, the en banc Fourth Circuit ruled that collateral order jurisdiction did not exist to consider by means of an interlocutory appeal the defendants’ argument that federal law preempted the plaintiffs’ state law claims at issue in that case.

The en banc Fourth Circuit’s decision in *Al Shimari* discussed in the preceding paragraph overruled the now–vacated Fourth Circuit case that Wyeth cites to and relies on in its Brief for Appellant at page 20 (*Al–Quraishi v. L–3 Services, Inc.*, 657 F.3d 201 (4th Cir. 2011) (vacated on rehearing en banc and thereafter overruled by *Al Shimari v. CACI Intern., Inc.*, 679 F.3d 205 (4th Cir. 2012) (en banc)). Thus, the decision on which Wyeth relies in arguing that “the Fourth Circuit Court of Appeals recently held that an order by a district court denying motions to dismiss state–law claims based on federal preemption are immediately reviewable as collateral orders” (Brief for Appellant at 20) no longer

constitutes good law and had already been vacated and then overruled long before Wyeth submitted its Brief for Appellant to this Court.

Neither Pennsylvania courts nor federal courts allow immediate collateral order review of an order denying the defense of federal preemption, and this Court should not expand the collateral order doctrine to allow such appeals. Because appellate courts have repeatedly rejected the argument that the denial of federal preemption equates to an immunity from suit, it is evident that the denial of the defense of federal preemption fails to satisfy the collateral order doctrine's "importance" prong. Accordingly, this Court should dismiss Wyeth's purported collateral order appeal.

3. Wyeth will not suffer the irreparable loss of any cognizable right if review is postponed until final judgment

For all of the same reasons discussed in the preceding subsection of this Brief for Appellee, Wyeth likewise cannot satisfy the third and final prong of the collateral order doctrine, which requires Wyeth to establish that its claim of federal preemption will be "irreparably lost" "if review is postponed."

Once again, this issue implicates the distinction between an actual immunity from suit, which is irreparably lost if the defendant is forced to defend against a claim at trial, and a mere defense to liability, which can be vindicated on appeal from a final judgment. As explained above, the defense that Wyeth has asked this Court to review by means of its purported collateral order appeal is described as

“conflict preemption,” which requires a defendant to establish that it is impossible for it to comply with the state law duties that plaintiffs are seeking to enforce while simultaneously complying with the obligations that federal law places on that same defendant.

This case thus does not involve any express preemption, whereby the U.S. Congress enacts a law directly precluding any state law claims against a certain category of defendants. Wyeth therefore lacks any plausible basis for asserting that it was the intention of federal lawmakers to confer on Wyeth any immunity from suit on any of plaintiffs’ state law causes of action. *See also Wyeth v. Levine*, 555 U.S. 555, 570–71 (2009) (holding, with regard to the manufacturer of a brand name prescription drug, that “it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market.”)

Moreover, by Wyeth’s own admission, Wyeth’s collateral order appeal only seeks the dismissal of some, rather than all, of plaintiffs’ claims against Wyeth asserted in the underlying litigation. *See* Brief for Appellant at 9. Accordingly, Wyeth would remain as a defendant in this lawsuit even if this Court permitted Wyeth’s supposed collateral order appeal to proceed and then ruled completely in Wyeth’s favor. The fact that Wyeth’s supposed collateral order appeal, even if successful, would not achieve Wyeth’s complete dismissal from this case provides strong additional support for the conclusion that Wyeth will not suffer irreparable

harm as the result of having to await the entry of a truly final judgment before seeking appellate review of the issue of federal conflict preemption under *Mensing*.

As the federal appellate court rulings cited above in *Martin*, *Jordan*, *Wood*, and *Al Shimari* establish, federal appellate courts — which can be expected to have the greatest level of sympathy for an argument that federal law preempts state law claims — have repeatedly recognized that the defense of federal preemption is not an immunity from suit and thus is not irreparably lost if appellate consideration of the defense is postponed until after entry of a final judgment. Because Wyeth is unable to point to any Pennsylvania or federal appellate court rulings which hold that a trial court’s denial of federal conflict preemption is immediately appealable under the collateral order doctrine, this Court should dismiss Wyeth’s purported collateral order appeal.

B. Plaintiffs Exclusively Seek To Hold Wyeth Liable As A Brand Name Manufacturer Of Reglan Possessing The Power To Alter Reglan’s Warning Label, And Thus The U.S. Supreme Court’s *Mensing* Ruling Does Not And Cannot Defeat Plaintiffs’ Claims

To determine how the U.S. Supreme Court itself understood the precise question presented in the *Mensing* case, it is useful to begin with the very first paragraph of the Court’s majority opinion in that case:

These consolidated lawsuits involve state tort-law claims based on certain drug manufacturers’ alleged failure to provide adequate warning labels for generic metoclopramide. The question presented is whether federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus pre-empt, these state-law claims. We hold that they do.

131 S. Ct. at 2572. Later in the majority opinion, the Court made clear that the precise failure to warn claim at issue in *Mensing* involved the assertion that a generic drug manufacturer should have altered the generic medication's warning label to clearly and adequately warn of the drug's risks in ways that the warning label approved for use on the brand name version of the drug failed to communicate. *See id.* at 2574. The U.S. Supreme Court proceeded to hold that federal law preempted this type of state law failure to warn claim against the manufacturer of a generic medication because federal drug regulations applicable to generic drug manufacturers require that the generic medication's warning label be identical in all relevant respects to the brand name medication's warning label. *See id.* at 2578.

Some two years before the U.S. Supreme Court issued its 5-to-4 decision in *Mensing*, the Court ruled by a vote of 6-to-3 in *Wyeth v. Levine*, 555 U.S. 555 (2009), that the federal Food and Drug Administration's approval of a prescription drug's warning label *does not preempt* a state law claim against the manufacturer of a brand name prescription drug for negligent failure to warn alleging that the drug's warning label should have more clearly and adequately warned of the drug's risks. It is the U.S. Supreme Court's ruling in *Levine* that allows state law claims for negligent failure to warn against the manufacturers of brand name prescription drugs to proceed forward without any threat of federal preemption.

Notwithstanding the distinction reflected in the U.S. Supreme Court's preemption jurisprudence between labeling-change based failure to warn claims against brand name versus generic drug manufacturers, and notwithstanding that

Wyeth has only been sued in this litigation in its capacity as a brand name manufacturer of Reglan (R.167a–68a), Wyeth argues for the substance of its appeal that Wyeth should be regarded as identical to a generic manufacturer with respect to the time period after Wyeth sold the rights to manufacture brand name Reglan to a third-party.

One central flaw in Wyeth’s argument is that it improperly seeks to elevate a background assumption concerning the underlying state law claim at issue in *Mensing* — an assumption shared by the opposing parties in *Mensing*, but not actually decided by the U.S. Supreme Court in that case — into a supposed holding of the U.S. Supreme Court. The background assumption in question is that a corporation that lacks the ability to change a prescription drug’s warning label to clearly and adequately warn of the medication’s actual risks cannot be held liable under applicable state law on a failure to warn claim asserting that the drug’s warning label should have been different.

The U.S. Supreme Court’s actual holding in *Mensing* was that a generic drug manufacturer is precluded, under federal law, from affixing a warning label that differs from the FDA-approved warning label for the brand name version of the drug. *See* 131 S. Ct. at 2578. The U.S. Supreme Court, contrary to Wyeth’s argument on appeal, did not announce the far more sweeping holding that federal law would preempt any failure to warn lawsuit against any defendant that could establish as a matter of fact that it lacked the ability to change the warning label of the medication in question. The reasons why such a more sweeping holding did not

issue should be obvious: (1) that was not the question that the U.S. Supreme Court had granted review to decide; and (2) state law does not and would not impose liability in a warning label case on a defendant that as a matter of fact lacked any ability to change the warning label alleged to have resulted in harm to the plaintiff.

For example, if somehow the Hallmark greeting card company were sued as a defendant in a prescription drug inadequate warning label lawsuit, no doubt all would agree that Hallmark should be dismissed as a defendant once Hallmark established that it never manufactured or distributed any prescription drugs. However, the reason for such a dismissal would not be as a result of the U.S. Supreme Court's holding in *Mensing* that federal law preempts one specific type of failure to warn claim against the manufacturer of a generic prescription drug. Rather, the reason for the suit's dismissal against Hallmark would simply be that, because Hallmark could not change the drug's warning label as a matter of fact, liability cannot be imposed against Hallmark as a matter of state law.

The second central flaw in Wyeth's argument is that the argument improperly ignores that all of plaintiffs' various claims against Wyeth are being asserted against that defendant either in Wyeth's capacity as manufacturer of brand name Reglan or in Wyeth's capacity as the former manufacturer of brand name Reglan which contractually retained responsibility for the continued adequacy of Reglan's labeling. R.167a–68a, 348a–49a, 351a–53a. All that *Mensing* held was that a claim that a generic drug's label should have been different from the brand name drug's label is preempted under federal law. *See* 131 S. Ct. at 2578.

Mensing did not hold, contrary to Wyeth's incorrect argument on appeal, that federal law in any way preempts labeling claims pertaining to the brand name version of a medication.

The third and final central flaw in Wyeth's arguments on appeal flows directly from the narrow argument on which Wyeth is actually hoping to prevail in this appeal. According to Wyeth, as of the date on which Wyeth sold the rights to manufacture brand name Reglan to a third-party, Wyeth no longer possessed any ability as a matter of fact to change the warning label for brand name Reglan, and therefore the same general principles that produced the preemption holding in *Mensing* should apply to preclude Wyeth's liability on claims arising after that date. Wyeth's argument in this regard, however, is directly embroiled in disputed questions of material fact that the trial court has not yet even attempted to address. In particular, specific evidence that plaintiffs obtained in discovery demonstrates that Wyeth contractually retained labeling and regulatory reporting responsibilities applicable to brand name Reglan tablets even after the nominal sale of ownership of the product had occurred in late 2001. R.348a–49a, 351a–53a.

Wyeth sweepingly asserts that these factual issues are immaterial because it is seeking to invoke a federal preemption defense supposedly arising from *Mensing* that would enable Wyeth to escape from liability regardless of how these factual disputes are resolved. Wyeth once again, however, ignores a critical distinction between this case and *Mensing*. In *Mensing*, the generic manufacturers of the medication had the factual ability to change the label because they were still

making the drug. What the generic manufacturers lacked in *Mensing*, according to the majority opinion, was the legal ability to alter the warning label from the version that the FDA had approved for the brand name version of the drug. *See* 131 S. Ct. at 2578.

Here, by contrast, Wyeth is arguing that because (according to Wyeth) it no longer had the ability as a factual matter to change the brand name drug's label after it sold manufacturing rights to a third-party, Wyeth likewise lacked the legal ability to change that label. However, plaintiffs dispute the correctness of Wyeth's assertion that Wyeth lacked the ability to change the brand name drug's label as a factual matter following the sale date. R.348a–49a, 351a–53a. If these disputed facts are resolved in plaintiffs' favor, and the trial court concludes that Wyeth retained the factual ability to change the label's warning after the sale date due to the specific provisions of the contract between Wyeth and the purchaser, then Wyeth would also have retained the legal ability to change the warning label as well. Thus, Wyeth is absolutely incorrect in arguing that resolution of this critical factual dispute has no bearing on Wyeth's attempt to invoke *Mensing* to assert federal preemption of certain of plaintiffs' claims.

Moreover, Wyeth has not cited to any case law actually establishing that a corporation cannot have any liability for failure to warn claims pertaining to products on the market that arise after the corporation has sold the right to manufacture the product in question to a third-party. Wyeth in its Brief for Appellant (at pages 11 and 16) relies solely on the U.S. Supreme Court's opinion in

Mensing for this proposition, but once again Wyeth seeks to rely on the *Mensing* decision for a proposition that the ruling in fact fails to support. The manufacturers of generic drugs whose preemption defense the U.S. Supreme Court sustained as to one of the *Mensing* plaintiffs' specific claims were generic drug manufacturers at all relevant times. Thus, *Mensing* did not hold, nor did it have any reason to hold, that a brand name manufacturer's sale of rights to manufacture a medication curtails liability as of any particular date.

Not only does Wyeth's contention that only the brand name manufacturer at the time plaintiff was prescribed the drug can be held liable for the drug's inadequate label fail to gain any support from *Mensing*, but the contention also lacks any basis in common sense. For example, suppose that Wyeth had manufactured, packaged, and shipped a large supply of Reglan to wholesalers in the days before its transfer of manufacturing rights to the product occurred. The medication would then end up on the shelves of pharmacies weeks and months later and still remain available for consumption for quite some time, since the medication has a two-year approved shelf-life. Thus, Reglan medication that Wyeth actually manufactured and failed to adequately warn about would remain available on the market causing harm for years to come. As a result, Wyeth's proposed liability cut-off at the date of sale of manufacturing rights does not seem either sensible or legally compelled.

Wyeth also relies heavily on three federal district court decisions in support of its argument that Wyeth should be regarded as equivalent to a generic drug

manufacturer under *Mensing* once Wyeth sold the rights to a third-party to manufacture brand name Reglan. To begin with, federal appellate courts, including the U.S. Supreme Court, have recognized that a federal district court's opinion does not constitute precedent and in fact binds no one beyond the opposing parties to the very case being decided. *See, e.g., Camreta v. Greene*, 131 S. Ct. 2020, 2033 n. 7 (2011) ("A decision of a federal district court judge is not binding precedent in either a different judicial district, the same judicial district, or even upon the same judge in a different case.") (quoting 18 J. Moore, *et al.*, *Moore's Federal Practice* §134.02[1][d], p.134–26 (3d ed. 2011)); *Flying J, Inc. v. J.B. Van Hollen*, 578 F.3d 569, 573 (7th Cir. 2009) (recognizing that "the decision of a district court has no authority as precedent"); *United States v. One TRW, Model M14, 7.62 Caliber Rifle*, 441 F.3d 416, 423 n.10 (6th Cir. 2006) ("a district court opinion * * * is not binding precedent on any court").

A look at the district court decisions on which Wyeth most heavily relies reveals that they lend little if any support to Wyeth's argument that *Mensing* somehow precludes the liability of a brand name prescription drug manufacturer on a failure to warn claim. For example, a Kentucky federal district court's unreported ruling in *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 2012 WL 3109424 (E.D. Ky. 2012), involved a drug manufacturer that at an earlier time produced both the brand name version of the drug and a generic version of the drug. When the plaintiff consumed the drug in question, she ingested the generic version of the drug after that manufacturer had ceased being the drug's brand name

manufacturer. Thus, *Mensing* was directly relevant to that manufacturer's liability, because the defendant was only a generic drug manufacturer at the time in question, and plaintiff alleged she was injured as the result of ingesting only the generic version of the drug. In short, the facts of *Darvocet* are readily distinguishable from the facts of plaintiffs' claims against brand name manufacturer Wyeth in this case.

Another federal district court decision on which Wyeth relies, *Lyman v. Pfizer, Inc.*, 2012 WL 2970627 (D. Vt. 2012), is also easily distinguished, because that decision issued at the summary judgment stage. When this case is at the summary judgment stage, no doubt the currently disputed and thus far judicially unexamined facts concerning Wyeth's continuing contractual responsibilities for the correctness and accuracy of the warning label for brand name Reglan will have been more clearly established by the parties and directly considered and addressed by the trial court. Moreover, Wyeth's own description of the outcome of *Lyman* is that the federal district court's ruling was based on proximate cause rather than federal preemption. See Brief for Appellant at 13. Thus, the federal district court in *Lyman* did not even invoke *Mensing* in granting summary judgment with respect to the plaintiff's claim against Wyeth in that case.

Lastly, Wyeth relies on a New Jersey federal district court's ruling in *In re Fosamax (Aledronate Sodium) Prods. Liab. Litig.*, 2012 WL 181411 (D.N.J. 2012), which dismissed claims against the distributor of a brand name medication that was manufactured by an entirely separate company. The district court in *Fosamax*

ruled that because a drug's distributor has no power to change a drug's labeling, the plaintiffs' failure to warn claims against the distributor should be dismissed. The district court's ruling in *Fosamax* actually lends support to plaintiffs' argument in favor of affirmance here, as the court expressly recognized that "[t]he *Mensing* decision, however, does not apply to brand manufacturers." *Id.* at *3. Here, of course, Wyeth is exclusively being sued in its capacity as manufacturer of brand name Reglan and in Wyeth's capacity as the former brand name manufacturer of Reglan that expressly retained continuing contractual responsibilities for the correctness and accuracy of the warning label for brand name Reglan after Wyeth sold the manufacturing rights for Reglan to a third-party. Thus, as the *Fosamax* decision recognized, *Mensing* simply has no application to plaintiffs' claims against Wyeth in this case.

In sum, the U.S. Supreme Court's *Mensing* decision does not control or limit Wyeth's liability in the capacities in which Wyeth has actually been sued in this case, which are as the brand name manufacturer of Reglan and as the former brand name manufacturer of Reglan that expressly retained continuing contractual responsibilities for the correctness and accuracy of the warning label for brand name Reglan. Moreover, the extent and duration of Wyeth's continuing labeling responsibilities under the terms of the agreement of sale present factual disputes that have not yet been addressed by the trial court and that are not amenable to resolution in the first instance by this Court on appeal. Accordingly, in the unlikely event that this Court were to rule that collateral order jurisdiction exists over

Wyeth's appeal, this Court should affirm the trial court's denial of Wyeth's *Mensing*-based preliminary objections.

VII. CONCLUSION

For the reasons explained above, this Court should dismiss Wyeth's collateral order appeal for lack of jurisdiction. However, if this Court were to reach the merits, this Court should affirm the trial court's denial of Wyeth's *Mensing*-based preliminary objections.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was served on all parties in the above captioned matter and/or their counsel of record by e-mail with the agreement for the party being served, pursuant to the case management orders governing service in the litigation.

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