

In the Supreme Court of Pennsylvania

No. 600 EAL 2010

PATSY LANCE, Administratrix for the Estate of
CATHERINE RUTH LANCE, Deceased,
Respondent,

v.

WYETH, f/k/a
AMERICAN HOME PRODUCTS CORP.,
Petitioner.

RESPONDENT'S ANSWER IN OPPOSITION TO WYETH'S PETITION FOR ALLOWANCE OF APPEAL

On Petition for Allowance of Appeal from the Judgment of the Superior Court of Pennsylvania at No. 2905 EDA 2008, filed August 2, 2010, Affirming in Part and Reversing in Part the Judgment of the Court of Common Pleas of Philadelphia County, Pennsylvania, Civil Trial Division, November Term 2006, No. 926, entered September 19, 2008

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I. INTRODUCTION

Plaintiff/respondent Patsy Lance, administratrix for the estate of Catherine Ruth Lance, deceased, respectfully files this Answer in opposition to the Petition for Allowance of Appeal that defendant/petitioner Wyeth has filed.

Wyeth seeks allowance of appeal on three grounds.

First, Wyeth asserts that plaintiff supposedly failed to preserve for appellate review the issue whether a claim for negligent design defect may be asserted against the manufacturer of a prescription drug.

Second, Wyeth asserts that the panel's decision recognizing that someone injured as the result of ingesting a dangerous prescription drug may assert a claim for negligent design defect against the drug's manufacturer is supposedly contrary to three earlier rulings from this Court and earlier rulings of the Superior Court of Pennsylvania.

Third and finally, Wyeth advances arguments, which are both unripe and waived, that plaintiff's complaint supposedly fails to allege the elements of a negligent design defect claim and that the Superior Court's recognition of a negligent design defect claim supposedly fails to defer adequately to the authority of the federal Food and Drug Administration.

For the reasons explained below, none of the grounds for allowance of appeal that Wyeth advances has any merit. Accordingly, Wyeth's Petition for Allowance of Appeal should be denied.

II. COUNTER-STATEMENT OF THE CASE

This case is one of three appeals that were argued in tandem before the same three-judge panel of the Superior Court of Pennsylvania in Philadelphia on June 22, 2010. The other two cases argued in conjunction with this case were *Cochran v. Wyeth*, 3 A.3d 673 (Pa. Super. Ct. 2010), *petition for alloc. filed*, No. 459 EAL 2010 (filed Aug. 19, 2010); and *Owens v. Wyeth*, No. 185 EDA 2009 (Aug. 2, 2010) (unpublished), *petition for alloc. filed*, No. 572 EAL 2010 (filed Oct. 12, 2010).

The facts that give rise to this lawsuit are as follows. Catherine Lance was 35 years old and the mother of three sons when she died from complications related to treatment of her primary pulmonary hypertension (PPH), a commonly fatal condition caused by ingesting “Fen-phen” weight loss drugs, such as Pondimin and Redux, manufactured by Wyeth. R.17a, 127a.¹ Catherine ingested Redux from January through April 1997. R.17a. She was diagnosed with PPH on November 15, 2004. R.18a. Plaintiff Patsy Lance is Catherine’s mother and the executrix of Catherine’s estate. R.17a, 127a. When this case goes to trial, plaintiff’s expert witness will testify that Catherine Lance’s use of Redux caused her PPH and resulted in her death. R.127a.

The medication Redux was a so-called Fen-phen medication sold to promote weight loss. “Fen-phen” refers to the use of fenfluramine in combination with phentermine. Wyeth was the sole supplier of fenfluramine in the United States, and

¹ Cites herein to “R.” followed by a page number refer to the Reproduced Record filed in the Superior Court.

Wyeth's trade name for fenfluramine was Pondimin. R.143a–44a. Fenfluramine (Pondimin) is 50% dexfenfluramine, which is the active ingredient of Pondimin.

Wyeth knew fenfluramine and dexfenfluramine caused PPH as early as 1993, and possessed additional evidence of that fact in March 1995, but Wyeth took no steps to investigate these disturbing findings. R.148a–50a, 162a–63a, 166a–67a, 171a–74a, 178a–83a. By mid-1995, Wyeth had also received numerous reports of valvular heart disease (VHD) in fenfluramine users, but deliberately chose not to investigate those cases, and did not follow up at all on those reports until the Mayo Clinic forced Wyeth's hand in April 1997. R.204a–349a. Even then, Wyeth intentionally deleted 17 of the 24 Mayo Clinic heart valve disease cases from its database and re-used the report numbers for other products, so that they would be untraceable by the FDA. R.359a–85a. Moreover, Wyeth failed to perform any studies of the potential harmful effects of fenfluramine and Fen-phen and failed to conform to FDA-mandated industry post-marketing surveillance standards.

In late 1995 and early 1996, Wyeth was in the process of seeking FDA approval for Redux, which contained only dexfenfluramine, the potent half of fenfluramine. Wyeth did not want a "black box" warning about PPH or VHD to be attached to the Redux package label, and Wyeth was determined not to make public any bad information about Pondimin and Fen-phen during the approval process, since Pondimin and Redux were the same drug. R.389a–91a, 395a–96a, 401a–02a, 405a–34a, 436a–44a.

Wyeth was successful in getting Redux approved and marketed without the black box warning. The FDA advisory committee approved Redux by only one vote. One of the members who voted to approve, Dr. Illingworth, later testified that he would have voted against approval if he had been fully informed of the risks of the drug. R.448a.

As early as 1994 and 1995, Wyeth knew of far more reports of heart valve disease cases than it reported to the FDA. R.453a, 459a–64a. Wyeth also did not alert the medical community to these potential heart valve disease outcomes in long-term users. As a result, independent investigators made their discovery without the benefit of knowing about these other cases known only to Wyeth. Ultimately, Wyeth delayed public disclosure of the risk of heart valve disease caused by its fenfluramine until July 1997, less than two months before these drugs were taken off the market. R.477a–78a. Most tragically, Wyeth did nothing to investigate the possible association of fenfluramine and heart valve disease for two years after it knew about these reports in 1995.

Wyeth should have conducted an investigation in early 1995, and, if it had, it would have found then what was discovered in August 1997: that a significant portion of long-term Redux users developed serious heart valve disease. Had that happened — had Wyeth acted as a reasonably prudent pharmaceutical company — Wyeth would never have completed its application for FDA approval of Redux, or at least Wyeth would have taken Redux off the market before January 1997, when the medication was first prescribed to Catherine Lance.

Eventually, Wyeth could no longer cover up the PPH/VHD epidemic. The truth percolated to the surface as outside researchers began publishing reports of VHD cases cropping up throughout the United States. Immediately thereafter, the FDA pressured Wyeth to issue a new black box warning for both PPH and VHD. R.477a. The FDA also demanded to see the sizable database of PPH/VHD cases that Wyeth had managed to keep hidden from the agency for several years. R.480a–507a. Faced with these mounting pressures, on September 15, 1997, Wyeth withdrew both Redux and Pondimin from the market. R.510a–11a.

Since then, the FDA added fenfluramine and dexfenfluramine to the list of unsafe products ineligible for compounding exemptions. In other words, the FDA determined that fenfluramine and dexfenfluramine are unsafe and unfit for their intended use regardless of warnings, and the FDA has made it illegal to compound these drugs, effectively preventing their use for any purpose whatsoever.

Patsy Lance, as administratrix of the estate of Catherine Lance, filed this lawsuit on November 13, 2006. R.1a, 12a. In the complaint, plaintiff affirmatively disclaimed any intention to assert a negligent failure-to-warn claim against Wyeth. R.19a–20a. Instead, the complaint makes clear that plaintiff's claims against Wyeth assert negligence in bringing Redux to the market, negligent failure to withdraw Redux from the market sooner, negligent failure to test, and negligent design defect. R.17a–19a, 45a–47a, 134a–35a.

Wyeth filed a motion for summary judgment asserting that plaintiff's claims against Wyeth were not cognizable under Pennsylvania law. R.70a–79a. Plaintiff

filed a timely response in opposition (R.125a–40a), and then Wyeth filed a reply brief (R.512a–19a). On September 19, 2008, the trial court entered an order granting Wyeth’s motion for summary judgment. R.8a.

Thereafter, on October 10, 2008, plaintiff filed a timely notice of appeal. R.8a, 526a. After the trial court ordered plaintiff to file a “Statement of Errors Complained of on Appeal” pursuant to Pennsylvania Rule of Appellate Procedure 1925(b) (R.8a), and after plaintiff filed a timely Rule 1925(b) statement in response to that order, the trial court issued its opinion explaining the basis for its summary judgment order on January 7, 2010.

After briefing and oral argument, a three–judge panel of the Superior Court issued a published, precedential opinion on August 2, 2010 affirming the trial court in part and reversing the trial court in part. With respect to plaintiff’s claims that Wyeth had negligently marketed Redux and had negligently failed to withdraw Redux from the market sooner, the Superior Court ruled that Pennsylvania law would not recognize either of those claims. With regard to plaintiff’s claim that Wyeth had negligently failed to test Redux, thereby failing to ascertain that medication’s actual risks before bringing it to market, the Superior Court ruled that no such claim exists under Pennsylvania law. Lastly, the Superior Court recognized that Pennsylvania law allows a plaintiff to assert a claim for negligent design defect against the manufacturer of a dangerous prescription drug. It is only that last holding that Wyeth is challenging by means of its Petition for Allowance of Appeal. Plaintiff Patsy Lance has separately filed a Petition for Allowance of Appeal,

docketed at No. 610 EAL 2010, in which she is seeking this Court's review of the Superior Court's rulings that are adverse to her in this case.

For the reasons explained below, this Court should deny Wyeth's Petition for Allowance of Appeal.

III. WYETH'S PETITION FOR ALLOWANCE OF APPEAL SHOULD BE DENIED

A. As The Superior Court's Opinion Correctly Recognizes, Plaintiff Has Preserved Her Appellate Challenge To The Trial Court's Grant Of Summary Judgment On Plaintiff's Negligent Design Defect Claim

The Superior Court's opinion recognizes — and Wyeth's Petition for Allowance of Appeal does not dispute — that plaintiff's complaint asserted a claim for negligent design defect against Wyeth. Plaintiff accomplished this both by expressly alleging negligent design defect (R.19a) and by incorporating the negligence count contained in the master long form complaint filed in the underlying Fen–Phen mass tort proceedings pending in the Court of Common Pleas for Philadelphia County (R.17a). The master long form complaint's negligence count included a claim for negligent design defect. R.45a–47a.

Thus, Wyeth's implication throughout its Petition for Allowance of Appeal that this case is somehow unique is incorrect. A design defect claim has been asserted by each and every plaintiff in the Fen–Phen mass tort proceedings who has incorporated the master long form complaint's negligence count. Moreover, such

design defect claims are commonly asserted in prescription drug personal injury cases filed in Pennsylvania and throughout the Nation.

Wyeth maintains in its Petition for Allowance of Appeal that the Superior Court should have found that plaintiff's challenge to the trial court's entry of summary judgment on plaintiff's negligent design defect claim was waived because plaintiff supposedly: (1) failed to argue against dismissal of her negligent design defect claim in opposing Wyeth's motion for summary judgment; (2) failed to raise the issue in her Rule 1925(b) statement of errors complained of on appeal; and (3) failed to raise the issue with sufficient specificity in her statement of issues in the Brief for Appellant filed in the Superior Court.

This ground for allowance of appeal lacks merit, because — as the record in this case reflects — plaintiff did not waive her appellate challenge to the trial court's entry of summary judgment against plaintiff's negligent design defect claim. Plaintiff now responds in turn to each of Wyeth's unsubstantiated allegations of waiver.

(1). At pages 10 and 11 of her brief filed in the trial court in opposition to Wyeth's motion for summary judgment, plaintiff made clear that she incorporated from the master long form complaint a claim against Wyeth for negligent design defect. R.134a–35a. Thus, plaintiff expressly noted for the trial court's benefit that she was asserting a negligent design defect claim against Wyeth, and plaintiff argued in her trial court brief in opposition that Wyeth's motion for summary judgment should be denied as to all of plaintiff's claims. Wyeth's assertion that

plaintiff waived her negligent design defect claim in opposing Wyeth's motion for summary judgment is accordingly incorrect.

(2). Plaintiff also preserved her appellate challenge to the trial court's entry of summary judgment against plaintiff's negligent design defect claim in the Rule 1925(b) statement that plaintiff filed in the trial court. The second numbered specification of error that plaintiff included in her Rule 1925(b) statement filed in this matter stated, in relevant part:

2. The trial court erred or otherwise abused its discretion in granting the Wyeth defendants' Motion for Summary Judgment based on Wyeth's contention that plaintiff, choosing not to pursue a claim of inadequate warning, has no cognizable claim against Wyeth, when no Pennsylvania case requires plaintiffs to prove inadequate warnings as an element of negligence claims against drug manufacturers * * *.

Plaintiff's Rule 1925(b) statement at page 2.

The trial court in this case ruled (as evidenced by its later Rule 1925(a) opinion) that the only type of negligence claim that Pennsylvania law recognized against a prescription drug manufacturer was a claim for negligent failure to warn. In the above-quoted specification of error, plaintiff asserted that the other claims of negligence that she had asserted against Wyeth in this case (including plaintiff's claim for negligent design defect) were cognizable under Pennsylvania law.

(3). The Superior Court's opinion in this case quotes the question presented in plaintiff's Brief for Appellant, and thus Wyeth's assertion that the question presented did not fairly encompass plaintiff's challenge to the trial court's grant of summary judgment on plaintiff's negligent design defect claim is simply not credible. *See Lance v. Wyeth*, 2010 PA Super 137, slip op. at 4 ¶7, 4 A.3d 160, 163

(Pa. Super. Ct. 2010). Stated plainly, plaintiff's negligent design defect claim is encompassed within plaintiff's assertion that "Wyeth was negligent in bringing Redux to the market," and thus Wyeth is incorrect in contending that the question presented in the Brief for Appellant filed in the Superior Court failed to include plaintiff's negligent design defect claim.

The meritless nature of Wyeth's waiver argument is further evidenced by the fact that Wyeth never argued in its Brief for Appellee filed in the trial court that plaintiff's challenge to the entry of summary judgment against her negligent design defect claim was waived, even though that challenge was unquestionably being advanced in plaintiff's opening brief on appeal. *See* Pa. Super. Ct. Brief for Appellant at 8, 16–17. If Wyeth's waiver argument actually had merit, Wyeth's counsel would have and should have advanced that argument in Wyeth's Brief for Appellee filed in the Superior Court, instead of waiting until the reargument and allowance of appeal stages of this proceeding to do so.

Indeed, Wyeth's failure to argue waiver of plaintiff's effort to reinstate her negligent design defect claim in Wyeth's Brief for Appellee filed in the Superior Court gives rise to Wyeth's own irrevocable waiver of any such waiver argument now being advanced against plaintiff. As this Court has repeatedly recognized, arguments that were not properly raised in the Superior Court are not properly considered by this Court on allowance of appeal. *See* Pa. R. App. P. 302(a); *Pentlong Corp. v. GLS Capital, Inc.*, 573 Pa. 34, 48 n.17, 820 A.2d 1240, 1248 n.17 (2003) (holding that argument not presented to intermediate appellate court is waived and

will not be considered by this Court); *Commonwealth v. Piper*, 458 Pa. 307, 309–11, 328 A.2d 845, 847 (1974) (issue not raised in trial court or Superior Court cannot be raised for first time on allocatur).

For the reasons explained above, Wyeth is incorrect in contending that plaintiff waived her challenge to the trial court's grant of summary judgment against plaintiff's negligent design defect claim. No such waiver occurred. Moreover, it is Wyeth that has waived its own belated waiver argument by failing to raise it in Wyeth's Brief for Appellee filed in the Superior Court. For all of these reasons, the first question presented in Wyeth's Petition for Allowance of Appeal lacks merit, and the petition for allowance of appeal should be denied.

B. The Superior Court's Holding That One Who Is Injured As The Result Of Consuming A Dangerous Prescription Drug Can Sue The Manufacturer For Negligent Design Defect Does Not Conflict With Any Ruling Of This Court Or The Superior Court

In its second ground for discretionary review, Wyeth asserts that the Superior Court's recognition of a claim for negligent design defect against the manufacturer of a prescription drug supposedly conflicts with three rulings from this Court and various earlier Superior Court rulings.

The first decision of this Court that Wyeth alleges the Superior Court's ruling conflicts with is *Incollingo v. Ewing*, 444 Pa. 263, 282 A.2d 206 (1971). In *Incollingo*, this Court recognized that the manufacturer of a prescription drug can be held liable for negligent failure to warn but not for strict liability. *See id.* at 287–88, 282 A.2d at 219–20. Yet this Court's ruling in *Incollingo* did not discuss or consider

whether the manufacturer of a prescription drug could be liable on a negligent design defect claim. Moreover, *Incollingo* does not stand for the proposition that the *only* negligence claim that can be asserted under Pennsylvania law against the manufacturer of a prescription drug is a claim for negligent failure to warn.

This Court's ruling in *Incollingo* quoted with approval this Court's even earlier ruling in *Henderson v. National Drug Co.*, 343 Pa. 601, 610, 23 A.2d 743, 748 (1942), for the proposition that "the public interest requires the holding of companies which make and sell drugs and medicine for use in the human body to a high degree of responsibility under both the criminal and civil law for any failure to exercise vigilance commensurate with the harm which would be likely to result from relaxing it." *Incollingo*, 444 Pa. at 287–87, 282 A.2d at 219. Recognizing a claim for negligent design defect against the manufacturer of a dangerous prescription drug is in accord with, rather than contrary to, the public interest as recognized in both *Incollingo* and *Henderson*.

Wyeth next asserts that the Superior Court's ruling is somehow contrary to this Court's ruling in *Baldino v. Castagna*, 505 Pa. 239, 478 A.2d 807 (1984). *Baldino*, however, did not consider whether a claim for negligent design defect could be brought under Pennsylvania law against the manufacturer of a prescription drug. Rather, the *Baldino* case involved a claim for negligent failure to warn.

This Court's statement in *Baldino* that the manufacturer of a prescription drug "is liable only if he fails to exercise reasonable care to inform those for whose use the article is supplied of the facts which make it likely to be dangerous" was

made in the context of this Court's explanation that "a manufacturer of drugs is not strictly liable for unfortunate consequences attending the use of otherwise useful and desirable products which are attended with a known but apparently reasonable risk." *Id.* at 244, 478 A.2d 810. Properly understood in this context, this Court's opinion in *Baldino* merely says that the plaintiff in a failure to warn case must prove negligence because the manufacturer of a prescription drug is not strictly liable for injuries caused by its products.

This Court's decision in *Baldino* does not purport to limit the types of negligence claims that may be asserted against the manufacturer of a prescription drug as the result of injuries caused by ingesting the manufacturer's products, and thus Wyeth's allegation that the Superior Court's decision conflicts with *Baldino* is without merit.

Wyeth further contends that the Superior Court's ruling is somehow in conflict with this Court's ruling in *Hahn v. Richter*, 543 Pa. 558, 673 A.2d 888 (1996), but that assertion is likewise without merit. In *Hahn*, this Court merely held that claims sounding in strict liability cannot be maintained against prescription drug manufacturers for injuries caused by consuming their medications. The Superior Court's opinion in this case faithfully recognized and applied that holding. *See Lance v. Wyeth*, 2010 PA Super 137, slip op. at 7 ¶13, 4 A.3d 160, 164 (Pa. Super. Ct. 2010). This Court's ruling in *Hahn* did not purport to decide or restrict what types of negligence claims may be brought against the

manufacturer of a prescription drug, and therefore Wyeth's contention that the Superior Court's ruling conflicts with *Hahn* is meritless.

Lastly, Wyeth contends that the panel's ruling is somehow in conflict with various earlier rulings of the Superior Court. But those rulings, as with this Court's rulings in *Hahn*, *Baldino*, and *Incollingo*, merely recognized the existence — and discussed the contours of — negligent failure to warn claims against a prescription drug manufacturer whose product was alleged to have injured the plaintiff. None of those decisions limited, or purported to limit, the types of negligence claims that can be brought under Pennsylvania law against the manufacturer of a dangerous prescription drug. Moreover, the Superior Court's denial of Wyeth's application for reargument en banc without recorded dissent demonstrates the absence of any conflict between the decision in this case and earlier Superior Court rulings.

For the reasons explained above, the Superior Court's ruling in this case does not conflict with any of the decisions that Wyeth has identified in its Petition for Allowance of Appeal. Accordingly, the second ground for review raised in Wyeth's petition lacks merit, and the petition should be denied.

C. Wyeth's Remaining, Newly Asserted Challenges To The Merits Of Plaintiff's Negligent Design Defect Claim Are Not Properly Raised For The First Time On Petition For Allowance Of Appeal

The third and final ground on which Wyeth seeks allowance of appeal consists of contentions that Wyeth failed to raise until after the Superior Court issued its opinion in this case. In the aftermath of the Superior Court's opinion,

Wyeth is now seeking to raise for the very first time the argument that plaintiff's complaint supposedly does not adequately allege the elements of a negligent design defect claim. Wyeth further asserts, for the very first time in this litigation, that the recognition of a negligent design defect claim does not adequately defer to the FDA's expertise.

Although plaintiff is confident that neither of Wyeth's two newly raised arguments has merit, it surely is improper for Wyeth to attempt to raise these two merits-related arguments for the first time ever while this case is at the reargument or petition for allowance of appeal stage. The contentions that Wyeth is seeking to advance are arguments that should be considered by the trial court in the first instance, if Wyeth has not already irrevocably waived them.

Before this Court considers what a complaint asserting a claim for negligent design defect against the manufacturer of a prescription drug must allege in order to avoid dismissal, that question should first be advanced by the defendant in the trial court and addressed by both the trial court and the Superior Court. Here, neither the trial court nor the Superior Court have addressed that question, because Wyeth did not argue to either of those courts (until Wyeth filed its petition for reargument in the Superior Court) that plaintiff's complaint does not adequately allege a negligent design defect claim. As a result, Wyeth has failed to preserve that issue for this Court's review. *See* Pa. R. App. P. 302(a); *Pentlong Corp. v. GLS Capital, Inc.*, 573 Pa. 34, 48 n.17, 820 A.2d 1240, 1248 n.17 (2003) (holding that argument not presented to intermediate appellate court is waived and will not be

considered by this Court); *Commonwealth v. Piper*, 458 Pa. 307, 309–11, 328 A.2d 845, 847 (1974) (issue not raised in trial court or Superior Court cannot be raised for first time on allocatur).

In addition to being waived, Wyeth's newly raised argument that the recognition of a claim under Pennsylvania law against a manufacturer of a dangerous prescription drug for negligent design defect fails to afford adequate deference to the FDA is contrary to the U.S. Supreme Court's recent ruling in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009). Therein, the U.S. Supreme Court greatly curtailed the instances when federal law will preempt state law personal injury claims sounding in negligence against prescription drug manufacturers.

Wyeth's argument about the need to defer to the expertise of the FDA also proves too much. That argument, if accepted, would deny a claim under Pennsylvania law for negligent failure to warn, despite this Court's repeated holdings that such a claim exists and may be pursued by plaintiffs injured as a result of ingesting dangerous prescription drugs. Even though the FDA approves the warnings that accompany a prescription drug, Pennsylvania law nevertheless allows claims against the manufacturers of prescription drugs for negligent failure to warn. Thus, the mere fact that the FDA approves a prescription drug for sale should likewise not preclude a claim for negligent design defect against the manufacturer of that prescription drug.

Wyeth's deference argument also overlooks the facts of this very case. Once the FDA became fully informed about the actual risks of Redux, the FDA first

convinced Wyeth to voluntarily withdraw that medication from the market. Soon thereafter, the FDA prohibited Wyeth from continuing to sell Redux or that medication's active ingredient for any purpose whatsoever. Plaintiff is not asking any court to second-guess the FDA's fully informed decision that Redux was too dangerous and never should have reached the market. Rather, the FDA's ultimate findings about Redux provide convincing evidence that the medication was negligently designed.

Because the third and final ground for allowance of appeal that Wyeth seeks to advance lacks merit and is not properly raised for the very first time in this case at this late stage of appellate proceedings, this Court should deny Wyeth's Petition for Allowance of Appeal.²

² Before concluding, plaintiff wishes to note her objection to Wyeth's reliance in seeking allowance of appeal on an article that *The Legal Intelligencer* published reporting on the result in this appeal and in two related appeals that were argued in tandem with this case. The presence or absence of press coverage of a ruling is not a basis on which to seek or obtain allowance of appeal. And, for the reasons explained above, this case does not otherwise qualify for allowance of appeal.

III. CONCLUSION

For the reasons set forth above, Wyeth's Petition for Allowance of Appeal should be denied.

Respectfully submitted,

Dated: November 18, 2010

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