IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

KATHLEEN A. WAGNER, Plaintiff, v. PFIZER INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., WYETH LLC, GREENSTONE LLC, PHARMACIA LLC, WYETH PHARMACEUTICALS INC., ESI LEDERLE, DURAMED PHARMACEUTICALS, INC., PHARMACIA AND UPJOHN LLC, PHARMACIA AND UPJOHN COMPANY LLC, TEVA PHARMACEUTICALS USA. INC., BARR PHARMACEUTICALS, LLC and BARR LABORATORIES, INC., Defendants.	]]]]]]]]]]]]]]]]	UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT AMENDED DOCKETING STATEMENT AND JURISDICTIONAL MEMORANDUM Case No. 13-cv-497-jdp

AMENDED DOCKETING STATEMENT

1. **Trial Court:** U.S. District Court
   Western District of Wisconsin (Madison)
   Case #: 3:13-cv-00497-jdp

2. **Trial Court Judge:**

   Hon. James D. Peterson, presiding

3. **Lead Counsel for Plaintiff**

   Party: Appellant

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7. Date Notice of Appeal Filed: June 13,2015

8. File Date of Judgment in a Civil Case: June 2, 2015.

9. **Date docket record shows notice of final order mailed by clerk:** June 2, 2015

10. Appeal Involves: Judgment on Pleadings

11. Is Transcript of Proceedings to be filed? N/A.

12. Oral Argument Requested: Yes.

13. Nature of Case: General Civil Appeal of Products Liability/Personal Injury (365);

14. Other Activity:

Stay request being filed with this court? No.
Have the parties to this appeal been parties to a previous appeal? No.
Do you know of another case(s) pending before this court or recently decided by this Court which raise the same issue? No, not in the Seventh Circuit Court of Appeals but multiple other U.S. Courts of Appeal, the California Supreme Court, cert. denied. U.S. Supreme Court (Jan., 2015) and other state Supreme Courts.

15. Summary Probable Issues for Review:

a. Is a generic drug Defendant entitled to preemption if said Defendant didn't have an identical warning label as the brand name drug and the failure to include the language was an approximate cause of Plaintiff's injuries? i.e. Bold Black Box warning upfront, including a reference to the Women's Health Initiative Study (WHI) findings, cancer concerns and long-term usage.

b. Does the failure to comply with the Food and Drug Administration Amendments Act of 2007 121 Stat. 823 for claims arising after said Act disqualify the generic Defendants from preemption because there is no longer "impossibility" between federal and state law? [In *PLIVA, Inc. v. s* 131 S. Ct. 2567 (2011 all claims were prior to the Act of 2007 Amendments)? Also see Fulgenzi v. PLIVA, Inc. 711 F.3d 575 (6th Cir. 2013).

c. Are generic Defendants negligent or negligent pro se when they fail to provide a label identical to the brand drugs as mandated by the Drug Price Competition and Patent Term restoration Act of 1984 also known as the 1984 Hatch-Waxman Amendments 21 U.S.C. §355(j) (2)(A)(v) or fail to communicate the already strengthened warnings of a Reference Listed Drug (RLD)? See. Fisher v. Pelstring 2011 U.S. Dist 116162 (DSC 2011). Lyman v. Pfizer, Inc. 2012 WL 2970627 (D. Vermont, 2012).

d. Does failure to comply with the Food and Drug Administration Amendments Act of 2007 standards render the drug misbranded per se under 21 U.S.C. §331(a) and do the changes in the Act of 2007 21 U.S.C. §355(o)(4) and 21. U.S.C. §255 (1)-(3) now shift the burden to a generic defendant to show that the FDA would not have approved a label change (the standard set forth in Wyeth v. Levine, 555 U.S. 555 (2009) post the Amendments? (See *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013) footnote 4.)

e. Is a state by state analysis of a state's defective design liability and negligence requirements necessary to determine whether a generic defendant is preempted per Restatement (second) of Torts § 402A as *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013) did with New Hampshire's law? And if so, would Wisconsin's design defect laws that requires a showing of the existence of an alternative safe product defeat a generic defendant's preemption?

f. Does Wisconsin's design defect legislation that requires a showing of the existence of an alternate safe product meet a negligent design defect claim when a generic defendant sells and markets a drug it knew was unreasonably dangerous or defective when it left the manufacturer's hand's and was expected to reach the consumer without change? See *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013)

g. Does the modification of a natural molecule (human or plant progesterone) which contains an additional segment (synthetic progestin), in order to obtain a patent, that causes unintended consequences-- that is, a change to the natural molecular structure has the effect of blocking the apoptosis of breast cells and results in being the proximate cause of breast cancer, preclude a generic defendant's preemption with respect to Restatement (second) of Torts § 402A because the drug is unreasonably dangerous to a group of individuals?

16. Does the appeal turn on an interpretation or application of a particular case(s) or statute(s)? Yes. *PLIVA, Inc. v. Mensing,* 131 S. Ct. 2567 (2011); *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 364 (Iowa 2014**)** Fulgenzi v. PLIVA, Inc. 711 F.3d 575 (6th Cir. 2013); In Re: Reglan Litigation, No. A-2014-13T4, (N.J. Super., App. Div.); Lyman v. Pfizer, Inc. 2012 WL 2970627 (Vermont, 2012); Fisher v. Pelstring 2011 U.S. Dist 116162 (DSC 2011). Dow Pharmaceuticals, Inc. v. Thompson, et al, 478 .S. 804 (1986). Hassett v. Teva et al, 2013 Pa Super 214 (2011); 217 Cal. App. 4th 96 (2013), *review denied* (Sept. 25, 2013), *cert. denied sub nom. Teva Pharm. USA, Inc. v. Superior Court of Cal., Orange Cnty.*, 2015 WL 231967, *cert. denied*, (U.S.Supreme Court, Jan. 20, 2015). *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 364 (Iowa 2014) *cert. denied* (U.S. Supreme Court, March 30, 2015)

CERTIFICATION

I certify that the information provided on this docketing statement is accurate

Dated: June 14, 2015 at Madison, Wisconsin

/s/Kathleen A. Wagner

Signature of counsel for Plaintiff/Appellant

AMENDED JURISDICTIONAL MEMORANDUM

A. JURISDICTION OF THE DISTRICT COURT

The district court had jurisdiction as a civil action arising under the laws of the United States pursuant to a removal action under 28 U.S.C. §1441 because this action could have originally been filed under 28 U.S.C. §1332. Specifically, the district court had subject matter jurisdiction because there was the requisite diversity of citizenship between plaintiff and each of the defendants and the amount in controversy exceeded $75,000, exclusive of interest and costs.

B. JURISDICTION OF THE COURT OF APPEALS

This appeal is taken from the final decision of the U.S. District Court for the Western District of Wisconsin entered on June 2, 2015 by the Honorable James D. Peterson. The United States Court of Appeals has jurisdiction to decide this case pursuant to 28 U.S.C. §1291.

The Notice of Appeal was filed with the District Court on June 13, 2015.

Dated at Madison, Wisconsin, this 13th day of 2015.

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