

IN THE COURT OF APPEALS OF IOWA

No. 3-129 / 12-0596

Filed April 24, 2013

THERESA HUCK,
Plaintiff-Appellant,

vs.

TRIMARK PHYSICIANS GROUP, BERNADETTE GYANO, M.D., KENNETH ADAMS, M.D., WYETH, INC. d/b/a WYETH, SCHWARZ PHARMA, INC., PLIVA, INC., and BARR LABORATORIES,
Defendants-Appellees.

Appeal from the Iowa District Court for Sac County, Gary L. McMinimee,
Judge.

Plaintiff appeals multiple district court orders granting summary judgment and dismissing its claims. **AFFIRMED.**

Terrence J. Donahue Jr. of McGlynn Glisson & Mouton, Baton Rouge, Louisiana, and James R. Van Dyke of Eich, Van Dyke & Weden, P.C., Carroll, for appellant.

Kevin C. Newsom and Lindsey C. Boney IV of Bradley Arant Boult Cummings L.L.P, Birmingham, Alabama, for appellee Wyeth, Inc., n/k/a Wyeth L.L.C.

Richard J. Sapp and Ryan Koopmans of Nyemaster, Goode, West, Hansell & O'Brien, P.C., Des Moines, for appellees Wyeth, Inc., n/k/a Wyeth L.L.C. and Schwarz Pharma, Inc., n/k/a UCB, Inc.

Henniger S. Bullock and Andrew J. Calica of Mayer Brown L.L.P., New York, New York, and Carl J. Summers of Mayer Brown, L.L.P., Washington, D.C., for appellee Schwarz Parma, Inc. n/k/a UCB, Inc.

Gregory M. Lederer of Lederer Weston Craig, P.L.C., Cedar Rapids and Lina E. Maichl, Jeffrey F. Peck, and Joseph P. Thomas of Ulmer & Berne, L.L.P., Cincinnati, Ohio, for appellee PLIVA, Inc.

Heard by Vogel, P.J., and Vaitheswaran and Bower, JJ.

VOGEL, P.J.

Plaintiff, Theresa Huck, ingested a drug which later caused her serious negative side effects. She appeals from various district court rulings, all of which resulted in judgments for the defendant brand name and generic drug companies.¹ Because we find all of her claims to be either not preserved, controlled by Iowa law, or preempted by federal law, we affirm.

I. Background Facts and Proceedings

From February 11, 2004, until March, 2006, Huck was prescribed Reglan,² a drug first approved by the Food and Drug Administration, (FDA) in 1980. Her physician³ relied upon information published by the brand name manufacturer in the *Physician's Desk Reference*, containing the manufacturer's labeling for the drug. The 2002 FDA labeling, approved at the time Huck began taking metoclopramide, contained a warning about possible side effects, including developing tardive dyskinesia⁴ or irreversible movement disorder. The warning included that tardive dyskinesia was expected to occur in one in every five-hundred patients. Huck never ingested Reglan, the brand named drug, as her

¹ Specifically, she appeals the district court's January 9, 2012 order granting summary judgment to PLIVA, Inc.; the district court's March 2, 2009 order granting summary judgment to Wyeth, Inc. and Schwarz Pharma, Inc. (collectively "Brand Defendants"), and the district court's January 9, 2012 order denying Huck's motion for relief from judgment as to the Brand Defendants as well as the February 23, 2012 order denying Huck's motion for reconsideration.

² Metoclopramide is Reglan's nonproprietary name. It is a drug designed to speed the movement of food through the digestive system.

³ While initially part of this case, on March 25, 2009, the district court granted Trimark Physicians Group, Dr. Bernadette Gyano, M.D., and Dr. Kenneth Adams, M.D. summary judgment. They are not part of this appeal.

⁴ Tardive dyskinesia is a severe neurological disorder resulting in involuntary, repetitive body movements of slow or belated onset.

pharmacy filled the prescription using the generic form, metoclopramide, manufactured by PLIVA.

In July 2004, approximately five months after Huck began taking the drug, the FDA approved the additional label warning language requested by Schwarz⁵ to indicate in bold print in two different locations, “Therapy should not exceed 12 weeks in duration.” While this new language appeared in the label approved by the FDA for Reglan, the generic manufacturer did not provide the updated label, or communicate the new information it contained to Huck or her physician. On June 27, 2008, the FDA reviewers evaluated the onset of “Drug-Induced Movement Disorders” and recommended heightened warnings about the prolonged use of the drug. On February 26, 2009, the FDA imposed the following warning, “prolong treatment (greater than 12 weeks) with metoclopramide should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risks to the patient of developing tardive dyskinesia.”

While the symptoms of tardive dyskinesia had been occurring in Huck for some time, she was not diagnosed with the disease until about June 6, 2006. She filed suit on May 27, 2008, alleging strict liability, negligence, misrepresentation, fraud, and breach of warranties against the “manufacturers.” In her petition she did not distinguish between the Brand Defendants and PLIVA. On March 2, 2009, the district court granted the Brand Defendants’ motion for summary judgment, finding they were entitled to dismissal because they “did not manufacture or sell the generic metoclopramide ingested by [Huck].” This motion

⁵ Wyeth originally held the new drug application for metoclopramide. Schwarz purchased the Reglan application in late 2001.

was unresisted by Huck, no post dismissal motions were filed, and the ruling was not immediately appealed.

On December 14, 2010, PLIVA, the only remaining defendant, moved the district court for a stay of all deadlines and to continue the scheduled trial date as a result of the Supreme Court of the United States' grant of certiorari in the case of *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011). After the Supreme Court handed down its decision in *Mensing*, PLIVA moved for summary judgment,⁶ asserting all of Huck's claims were preempted by federal law. As a result of her interpretation of the *Mensing* decision, Huck filed a "motion for relief" from the March 2, 2009 judgment that dismissed the Brand Defendants. On January 9, 2012, the district court granted PLIVA's motion for summary judgment and denied Huck's motion for relief. After a denied motion for reconsideration, Huck appeals.

II. Standard of Review

We review a district court decision to grant or deny a motion for summary judgment for correction of errors at law. *Kolarik v. Cory Int'l Corp.*, 721 N.W.2d 159, 162 (Iowa 2006). We examine the record to determine whether a material fact is in dispute and, if not, whether the district court properly applied the law. *Robinson v. Fremont Cnty.*, 744 N.W.2d 323, 325 (Iowa 2008). Summary judgment is proper when the plaintiff's claim lacks evidence to support a jury

⁶ This was PLIVA's third time filing for summary judgment. The first was on February 26, 2010, in which PLIVA claimed federal preemption. Huck conceded the dismissal of certain claims in response to this motion, and the remaining claims were for breach of implied warranty of merchantability, negligence, negligent misrepresentation, fraud and misrepresentation, constructive fraud, and fraud by concealment. The second motion for summary judgment was denied without prejudice from the bench, but contained much of the same substance as the third motion.

question on an essential element of the claim. *Parish v. Jumpking, Inc.*, 719 N.W.2d 540, 543 (Iowa 2006).

III. PLIVA

Huck appeals the district court's order granting PLIVA summary judgment. PLIVA's motion for summary judgment sought dismissal of all remaining claims based on *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2572 (2011), a case which held federal regulations applicable to generic drug manufacturers pre-empt state law failure-to-warn claims against generic drug manufacturers. Huck goes to great lengths in her brief to distinguish *Mensing*, however, we agree with the district court, it is indistinguishable.

The plaintiffs in *Mensing* were in much the same situation as Huck. They took generic metoclopramide for extended periods of time and developed tardive dyskinesia. *Id.* at 2573. They sued the generic drug manufacturers that produced the drug they ingested, alleging the manufacturers were liable for failing to provide adequate warning labels. *Id.* Based on identical claims and nearly identical facts to the case at hand, the Supreme Court of United States explained as follows:

If the [generic] Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law. Taking *Mensing* and *Demahy's* allegations as true, state law imposed on the [generic] Manufacturers a duty to attach a safer label to their generic metoclopramide. Federal law, however, demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels. See, e.g., 21 CFR § 314.150(b)(10). Thus, it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same.

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Had *Mensing* and *Demahy* taken *Reglan*, the brand-name drug prescribed by their doctors, *Wyeth [v. Levine]*, 555 U.S. 555

(2009)] would control and their lawsuits would not be pre-empted. But because pharmacists, acting in full accord with state law, substituted generic metoclopramide instead, federal law pre-empts these lawsuits. [citations omitted]. We acknowledge the unfortunate hand that federal drug regulation has dealt Mensing, Demahy, and others similarly situated.

Mensing, 131 S. Ct. at 2578-81. Like the Supreme Court, we appreciate the harsh result for individuals such as Huck. However, based on federal pre-emption, her remedy for injuries sustained from generic medications and labeling lies not with the courts, but with Congress and the FDA. See *id.*, at 2582 (“Indeed, it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public. But different federal statutes and regulations may, as here, lead to different pre-emption results. We will not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme. As always, Congress and the FDA retain the authority to change the law and regulations if they so desire.”). We agree with the district court, all of the state tort claims against PLIVA are pre-empted.

Huck makes multiple other arguments against PLIVA, all of which are merely an attempt to skirt the effect of *Mensing*. First, her argument PLIVA is liable to her because it failed to update its label to conform with the 2004 changes is without merit. The requirement for generic drug labeling to be the same as the “reference listed drug” (RLD) label arises under federal law, which explicitly prohibits private attempts to enforce the Food Drug and Cosmetic Act (FDCA). 21 U.S.C. § 337(A) (“[A]ll such proceedings for the enforcement, or to

restrain violations, of this chapter [the FDCA] shall be by and in the name of the United States.”).⁷

Second, Huck argues PLIVA should be liable to her because it should have disseminated warnings through means other than “labeling” as long as the information was consistent with the approved labeling.⁸ This is directly addressed and rejected by *Mensing*, and further, Huck’s position throughout the litigation has been that the warning, including the post-2004 warning, was inadequate. See *Mensing*, 131 S. Ct. at 2576. Even if *Mensing* did not foreclose on this type of communication, Iowa law does not provide a cause of action for failing to disseminate allegedly inadequate warnings. Huck has not argued these warnings—providing what she argued is faulty information—would have prevented the harm she suffered.

Despite her attempt to plead around the holding of *Mensing*, the only conclusion we can reach is that Huck uses each claim to attack the adequacy of the labeling and each falls within *Mensing’s* sphere.⁹

⁷ Moreover, at oral argument it was explained that when a brand company updates its label with the FDA, the agency then posts the updates on its website. It is unclear if the agency communicates the information to the generic manufacturer through any other means. Regardless of whom is at fault for PLIVA’s failure to update its label, this fault is immaterial to this case.

⁸ The testimony is clear Huck’s physician never read any information from PLIVA. At oral arguments, Huck’s counsel explained for practical purposes a prescribing physician would never see the warning label from PLIVA as it would be contained in the bulk packaging sent to the pharmacy.

⁹ We recognize that, in *Fulgenzi v. PLIVA*, __ F.3d. __ 2013 WL 949096 (6th Cir. 2013), the Sixth Circuit Court of Appeals recently reversed the dismissal of a state law claim premised on the adequacy of PLIVA’s warnings, specifically concluding its prior contrary opinion in *Smith v. Wyeth, Inc.*, 657 F.3d 420, 423 (6th Cir. 2011) was not controlling. However, two other circuits summarily dismissed state law claims following *Mensing*. See *Mensing v. Wyeth*, 658 F.3d 867 (8th Cir. 2011) (vacating on remand those portions of its earlier opinion that concluded *Mensing* stated viable claims against PLIVA); *Demahy v. Actavis, Inc.*, 650 F.3d 1045 (5th Cir. 2011) (vacating its opinion that

IV. Brand Defendants

Under Iowa common law, a plaintiff must prove product identification to maintain suit against a defendant. *Mulcahy v Eli Lilly & Co.*, 386 N.W.2d 67, 76 (Iowa 1986). The district court, in March 2009, entered summary judgment for the Brand Defendants because they did not manufacture or supply the drug Huck ingested—generic metoclopramide. That decision was not immediately appealed. In September 2011, Huck requested the district court to use its “inherent power to correct interlocutory errors . . . to grant relief from its prior judgment for [Brand Defendants].” She claimed by holding the generic manufacturers have no ability to change their labels, the Supreme Court of the United States in *Mensing* overturned prior precedent relied upon by the lower courts that generic manufacturers had the ability to change their labels.

It is important to note, Huck never resisted the Brand Defendants’ motion for summary judgment in 2009. In motions for summary judgment, “if the movant has failed to establish its claim and the court nevertheless enters judgment, the nonmovant must at least preserve error by filing a motion following entry of judgment, allowing the district court to consider the claim of deficiency.” *Bill Grunder’s Sons Const., Inc. v. Ganzer*, 686 N.W.2d 193, 197-98 (Iowa 2004). This follows our general principle we decline to address issues not both raised and decided by the district court. *Meier v. Senecaut*, 641 N.W.2d 532, 537 (Iowa 2002). However, our supreme court has carved out an exception by holding, “If

previously found state-law failure to warn claims were not preempted); see also *See Gaeta ex rel. AIG. V. Perrigo Pharmaceuticals Co.*, No. 09-15001, 2012 WL 605678 (9th Cir. Feb. 27, 2012). Because the United States Supreme Court painted preemption with a broad brush in *Mensing*, we decline to adopt the reasoning of *Fulgenzi*.

the district court considered the issue raised on appeal by the nonmovant in ruling on an uncontested summary judgment motion, the rationale for requiring the nonmovant to file a post judgment motion with the district court to preserve error on appeal is inapplicable.” *Otterberg v. Farm Bureau Mut. Ins. Co.*, 696 N.W.2d 24, 28 (Iowa 2005).

The only issue explicitly decided by the district court in 2009 was that there was no duty owed to Huck under Iowa law because she did not ingest a product manufactured or sold by the Brand Defendants. Therefore, Huck’s appellate claims that the Brand Defendants “designed” the product in question, and that her negligence, misrepresentation, and fraud claims do not require product identification are not preserved for our review.

The only claims properly before us are (1) whether *Mensing* changed Iowa tort law, and (2) whether the principles in *Mulcahy* allow this suit to go forward.¹⁰ We answer both in the negative. It is clear from our reading of *Mensing*, it does not change the state-law principles that require dismissal of a claim brought against a non-manufacturer, such as the Brand Defendants. Furthermore, *Mulcahy* held “under Iowa common law a plaintiff in a products liability case must prove that the injury-causing product was a product manufactured or supplied by the defendant.” *Mulcahy*, 386 N.W.2d at 76. To the minimal extent Huck argues *Mulcahy* is either distinguishable or not applicable, we disagree and find the district court’s application of *Mulcahy* correct. See *id.* at 69 (providing regardless of the theory of liability, such as strict liability, negligence, misrepresentation,

¹⁰ The Brand Defendants dispute whether these issues were properly argued on appeal. However, we find them minimally presented and will address them.

breach of warranties, Iowa law's causation requirements requires the defendant manufactured or supplied the product that caused the injury).

V. Conclusion

We agree with the district court *Mensing* controls and summary judgment is appropriate as to PLIVA. Regarding the Brand Defendants, Huck's claims are either not preserved or controlled by *Mulcahy*. We therefore affirm.

AFFIRMED.