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Iowa High Court Spares Wyeth From Generics Injury Claims

By **Sindhu Sundar**

Law360, New York (July 11, 2014, 1:47 PM ET) -- The Iowa Supreme Court found Friday that Wyeth Inc. and other brand makers of the nausea medication metoclopramide aren't liable for injuries caused by generic versions of the drug, but found the U.S. Supreme Court's Mensing ruling doesn't preempt all state tort law claims against generics makers.

The high court vacated a lower appeals court's decision affirming summary judgment rulings for the defendants including Wyeth and Schwarz Pharma Inc. in the suit brought by plaintiff Theresa Huck, and partly reversed a trial court's finding for the drug's generic manufacturer Pliva Inc. The high court found that Huck's state common law tort claims over the generics maker's allegedly insufficient warnings are not preempted where the maker did not issue the stronger warning that federal regulators had approved in 2004.

A trial court had applied the U.S. Supreme Court's landmark ruling in Pliva v. Mensing, finding that Huck's claims against Pliva to be preempted by federal law that requires generics makers to adopt brand manufacturers' warning labels approved by the U.S. Food and Drug Administration.

But the Sixth Circuit's March 2013 ruling in Fulgenzi v. Pliva Inc. found that Mensing does not preempt claims based on a generics maker's alleged failure to update its label warning with an FDA-approved warning, the Iowa Supreme Court said Friday. In this case, Huck had claimed Pliva had not implemented an updated warning label the FDA had approved in 2004.

"As the Sixth Circuit observed, 'not only could Pliva have independently updated its labeling to match [the warning added in 2004], it had a federal duty to do so,'" the high court said, citing the Sixth Circuit. "We find Fulgenzi persuasive and hold Huck's claims survive preemption to the extent they are based on Pliva's failure to adopt the additional warning language approved by the FDA in 2004."

The high court's ruling affirmed the trial court's summary judgment finding on behalf of the brand-name makers.

"The court's ruling is in line with the large body of decisions holding that a brand name manufacturer cannot be liable for injuries caused by the ingestion of generic drugs," said Henninger Bullock of Mayer Brown LLP, who represents Schwarz.

Huck, who had been treated with generic metoclopramide — sold under the brand name Reglan — claimed she developed the neurological disorder tardive dyskinesia and sued Pliva along with other

branded Reglan makers.

The FDA-approved warning for the drug in early 2004, at the time that Huck began taking the medication for her reflux problem, listed tardive dyskinesia as a possible side effect of the drug, indicating it was expected to occur in one in every 500 patients, according to the opinion.

The ailment, which causes uncontrollable body movements including repetitive grimacing and tongue chewing, has no known treatment or cure, the opinion noted.

In July 2004, the the FDA approved an additional warning label, which stated that patients should not be treated with the medication for longer than 12 weeks. But Pliva did not update its drug packaging to include this updated warning, and neither the defendants nor Pliva provided Huck or her doctor with the new warning information, according to the opinion. Huck continued to refill her prescription for the drug until March 2006.

In February 2009, the FDA then required a black box warning for metoclopramide, warning of its tardive dyskinesia risks especially with long-term use.

“The court affirmed today the dismissal of all claims against Wyeth in the case pending before it," Steven Danehy, a spokesman for Pfizer, of which Wyeth is a subsidiary, said in a statement Friday. "The Supreme Court of Iowa now stands with the vast majority of courts to address the issue – including seven U.S. Circuit Courts of Appeals – in applying the well-established legal principle that a pharmaceutical company may not be responsible for injuries alleged to have been caused by products it did not manufacture or distribute."

An attorney for Pliva could not immediately be reached for comment Friday.

Huck is represented by Terrence J. Donahue Jr. of McGlynn Glisson & Mouton and James R. Van Dyke of Eich Van Dyke Werden & Steger PC.

Pliva is represented by Jeffrey F. Peck, Linda E. Maichl and Joseph P. Thomas of Ulmer & Berne LLP and Gregory M. Lederer of Lederer Weston Craig PLC. Wyeth is represented by Kevin C. Newsom and Lindsey C. Boney IV of Bradley Arant Boult Cummings LLP and Richard J. Sapp and Ryan G. Koopmans of Nyemaster Goode West Hansell & O'Brien PC. Schwarz is represented by Henninger S. Bullock, Andrew J. Calica and Carl J. Summers of Mayer Brown LLP and Richard J. Sapp and Ryan G. Koopmans of Nyemaster Goode West Hansell & O'Brien PC.

The case is Huck v. Wyeth Inc. et al., case number 12-0596, in the Iowa Supreme Court.

--Editing by Andrew Park.

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