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Branded Drug Cos. Not Liable For Generics, 5th Circ. Rules

By **Jeff Overley**

Law360, New York (October 25, 2012, 5:36 PM ET) -- The Fifth Circuit refused Thursday to revive claims by a woman alleging neurological harm from a generic form of heartburn medicine Reglan, saying the U.S. Supreme Court's ruling in *Pliva Inc. v. Mensing* doesn't make brand-name drugmakers liable for generic versions of their products.

The appeals court rejected arguments from Louisiana resident Julie Demahy, who said last year's *Mensing* decision undermined legal immunity for branded drug companies because the immunity was grounded in the ability of consumers to hit generic-drug makers with state failure-to-warn claims, an ability *Mensing* eliminated.

Demahy — who was targeting Pfizer unit Wyeth LLC and Schwarz Pharma, now known as UCB Inc. — misread the state of case law before *Mensing*, the Fifth Circuit said. Previous rulings that blocked generics users from suing brand-name drugmakers were not premised on consumers' ability to sue the generics companies, but rather on interpretation of state law, the Fifth Circuit found, specifically referencing the Fourth Circuit's ruling in *Foster v. American Home Products Corp.*

"We do not view *Mensing* as overruling *Foster* because the court in *Foster* did not reach its holding by relying on the ability of a plaintiff to sue generic manufacturers," the Fifth Circuit said. "Instead, the court's holding was based on its interpretation of Maryland law and the conclusion that a name-brand manufacturer has no duty of care to consumers that are not using the manufacturer's product."

The Fourth Circuit's 1994 ruling assumed that generic-drug makers could be sued — something that's no longer true after *Mensing* — "but this fact does not impose on name-brand manufacturers a duty of care to customers using generic products," the Fifth Circuit said.

As a result, decisions in Louisiana that relied on the *Foster* decision remain valid, the Fifth Circuit said.

"[But] even were we of the view that *Mensing* undermined *Foster*, the implicit reversal of a Fourth Circuit decision about Maryland law would have no effect on Louisiana law," the Fifth Circuit added.

Pfizer issued a statement lauding the decision for applying "the well-established legal principle that a pharmaceutical company should not be responsible for injuries alleged to have been caused by products it did not manufacture or sell."

"While we have great sympathy for the plaintiff, we believe the court appropriately

determined that the law of Louisiana does not allow for claims against brand companies for injuries allegedly caused by the ingestion of a generic version of the medication," Pfizer said.

Counsel for Demahy could not immediately be reached for comment.

Demahy is among many patients who claimed Reglan or its generic equivalent caused them to develop tardive dyskinesia, a condition characterized by involuntary movement of body parts. Her case was one of three consolidated before the Supreme Court as part of the Mensing ruling, which said generics manufacturers can't face state failure-to-warn lawsuits because they lack authority under federal law to make labeling changes.

Thursday's outcome mirrored an Ohio federal court ruling last month. In that case, U.S. District Judge Michael Watson said that Mensing "has no bearing whatsoever on the issue [of] whether the brand defendants may be held liable under Ohio product liability law for injuries arising from the ingestion of generic [Reglan] they did not manufacture."

Separately, the Fifth Circuit also rejected Demahy's attempt to revive her case against generic-drug maker Actavis Inc., joining other courts across the country — the First Circuit being one notable exception — that have characterized design defect claims as failure-to-warn claims by another name that are therefore also preempted.

Richard Alan Dean, counsel for Actavis, said the decision represented a "powerful precedent" and predicted it would lead to the dismissal of many pending cases in lower courts within the Fifth Circuit.

Judges Fortunato P. Benavides, Priscilla R. Owen and Leslie H. Southwick sat on the panel for the Fifth Circuit.

Demahy is represented by Terrence J. Donahue Jr. of McGlynn Glisson & Mouton as well as by Brian Leonard Glorioso, Kristine K. Sims and Richard Alvin Tonry II of Tonry Brinson & Glorioso LLC.

Schwarz is represented by Henninger Simons Bullock and Andrew Jonathan Calica of Mayer Brown LLP as well as by Megan Haggerty Guy, Gregory Fortier Rouchell and Martin A. Stern of Adams & Reese LLP.

Wyeth is represented by Kannon K. Shanmugam and James Michael McDonald of Williams & Connolly LLP.

Actavis is represented by Richard Alan Dean, Irene Childress Keyse-Walker and Kristen Lepke Mayer of Tucker Ellis LLP and Elizabeth Haecker Ryan of Coats Rose Yale Ryman & Lee PC.

The case is Julie Demahy v. Wyeth Inc. et al., case number 11-31073, in the U.S. Court of Appeals for the Fifth Circuit.

--Additional reporting by Greg Ryan. Editing by Eydie Cubarrubia.

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