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Preemption Dooms Branded, Generic Reglan Suit In 5th Circ.

By **Andrew Westney**

Law360, New York (May 13, 2014, 8:35 PM ET) -- The Fifth Circuit on Tuesday affirmed a lower court's decision to dismiss a Texas man's product liability claims against Wyeth Inc., Schwarz Pharma Inc. and two generic-drug makers over a gastrointestinal drug, saying that federal law preempted certain claims.

The three-judge panel upheld a Texas federal court's dismissal of plaintiff Roy Eckhardt's claims against generic-drug makers Qualitest Pharmaceuticals and Vintage Pharmaceuticals LLC, alleging that prolonged use of the drug metoclopramide — also known by its branded name, Reglan — to treat gastrointestinal problems led to his developing tardive dyskinesia, a severe neurological disorder. Eckhardt's main claim against Qualitest and Vintage was a product liability claim for a failure to warn about the dangers of the drug, even though Eckhardt did not classify it that way, the panel said.

"It is not mind-taxing to discern why Eckhardt shies from labeling his claims as products liability claims: A products liability claim against the brand defendants simply cannot succeed," the panel said.

The district court was right to dismiss Eckhardt's product liability claims, which said the generics manufacturers should have provided stronger warnings under Texas law about the dangers posed by the drug, because federal law prohibits generics makers from changing U.S. Food and Drug Administration-approved warnings unilaterally, the panel said.

The panel also affirmed the lower court's summary judgment in favor of brand-name drugmakers Wyeth and Schwarz, saying that since Eckhardt acknowledged he only used generic versions of the drug, a product liability claim doesn't apply because the brand-name drugmakers didn't produce the actual drugs he took. Eckhardt's negligence and negligent misrepresentation tort claims were rightly dismissed because the brand-name manufacturers had no duty to warn Eckhardt about the potential dangers of a competitor's products, the panel said.

Eckhardt also failed to provide enough evidence to support accusations of fraud against the brand-name drugmakers, the court found.

Wyeth in a statement said the Fifth Circuit "again stood with the vast majority of courts to address the issue, including five other U.S. Circuit Courts of Appeals, in 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 distribute."

Ninety-six decisions under the laws of 26 states have held that brand-name pharmaceutical

manufacturers are not liable for injuries caused by products they did not make, and 74 decisions under the laws of 23 states have used that rule to defeat claims seeking to hold brand-name Reglan manufactuers responsible for injuries allegedly caused by taking competitors' generic versions of the drug, the company said.

A strict liability design defect claim and a breach of warranty claim brought against the generic-drug makers also were preempted because the state-law claims directly conflicted with federal law, the panel said. Similar claims under the Texas Deceptive Trade Practices Consumer Protection Act were also preempted, the panel said.

An allegation that the generic-drug makers failed to provide the plaintiff or his doctor with any of the FDA-approved warnings for the drug would be a parallel claim not preempted by federal law, the panel said. But Eckhardt alleged in a filing that he had, in fact, been provided with such warnings by the generic-drug makers, the panel said.

Terrence Donahue of McGlynn Glisson & Mouton, an attorney for Eckhardt, told Law360 on Tuesday that the Fifth Circuit's ruling may have left an opening for future parallel claims in similar cases.

"There's clear indication there that there are still viable claims against generic manufacturers that would have to be actions that violate both federal and state law," Donahue said.

The court might also have left a back door open for fraud claims against brand-name drugmakers not based on the manufacturers' duty toward a purchaser, such as for putting out false information relied upon by a consumer in using a drug, Donahue said.

Representatives for Schwarz, Qualitest and Vintage were not immediately available for comment late Tuesday.

Circuit Judges E. Grady Jolly, Patrick E. Higginbotham and Leslie H. Southwick sat on the panel for the Fifth Circuit.

Eckhardt is represented by Daniel J. McGlynn and Terrence J. Donahue Jr. of McGlynn Glisson & Mouton; William B. Curtis and Michael S. Wilson of Curtis Law Group; John T. Flood of Flood & Flood; and Filemon B. Vela and Rebecca W. Bailey of Filemon Vela Law Group PLLC.

Qualitest and Vintage are represented by Marjory C. Batsell and Norton A. Colvin Jr. of Colvin Chaney Saenz & Rodriguez LLP.

Schwarz is represented by Charles S. Kelley, Andrew J. Calica and Henninger S. Bullock of Mayer Brown LLP.

Wyeth is represented by Michael R. Klatt and Leslie A. Benitez of Gordon & Rees LLP.

The case is Eckhardt et al. v. Qualitest Pharmaceuticals Inc. et al., case number 13-40151, in the U.S. Court of Appeals for the Fifth Circuit.