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## 5th Circ. Won't Revive Claims Tying Generic Drugs To Disease

By **Rachel O'Brien**

Law360 (February 5, 2021, 9:55 PM EST) -- The Fifth Circuit on Friday upheld a Texas federal judge's May decision that a man claiming two generic drugs caused his Peyronie's disease can't pursue claims that five pharmaceutical companies printed misleading labels.

In an unpublished opinion, the three-judge panel agreed with the district court judge that Ramon D. Johnson II couldn't sue two of the defendants, Novartis Pharmaceuticals Corp. and Bausch Health US LLC, because the drugs he claims caused his illness were not made by those companies.

"Because Mr. Johnson alleges that he only ingested the generic defendants' drugs and not the brand defendants' drugs, he has failed to state a products liability claim against the brand defendants," Circuit Judge W. Eugene Davis wrote for the court.

The circuit judges also affirmed the lower court's decision that state law claims against the three generic-drug manufacturers regarding the adequacy of the drug's label are preempted by federal law.

In light of Supreme Court decisions in [Mensing](#) and [Bartlett](#), "this court has twice held that strict liability, breach of warranty, negligence, and products liability claims under Texas law against generic-drug manufacturers are preempted."

U.S. District Judge Orlando L. Garcia **ruled in May** that the bulk of the claims against Novartis, Bausch, Taro Pharmaceuticals USA Inc., Sun Pharmaceutical Industries Ltd. and Torrent Pharma Inc. are preempted by federal and state law.

He dismissed with prejudice the claims brought by Johnson, who alleged that two generic drugs he took for an unrelated condition — minocycline and carbamazepine — caused his Peyronie's disease, which causes painful erections.

Taro, Sun and Torrent make the generic drugs Johnson took, while Novartis and Bausch make the name-brand versions for which the generics' labeling was based, according to court documents.

Johnson argued that the companies withheld information from the U.S. Food and Drug Administration about the drugs' link to Peyronie's disease. But Judge Garcia ruled that the FDA would need to find fraud for Johnson's claims to stand, and it hasn't.

Judge Garcia said in May that Texas law has rejected the "innovator liability" theory that Johnson argued. Because Johnson didn't allege that he took the name brand drugs Novartis or Bausch made, he couldn't pursue his claims that they were liable simply because they created the drugs and labels that the other companies copied for their generic versions.

As for the claims against Sun, Taro and Torrent, Judge Garcia said Texas law assumes no liability for generic-drug manufacturers that use U.S. Food and Drug Administration-approved labels, and

nothing in Johnson's filings disputes that.

Johnson **appealed the decision** to the Fifth Circuit in September.

"Had Mr. Johnson's suit involved an over-the-counter drug or a brand-name prescription drug that he actually ingested, we would apply Texas's presumption statute," the Friday decision said. "Because we do not reach the issues surrounding the presumption statute, we do not consider Mr. Johnson's arguments regarding rebuttal of the statute."

In a statement to Law360 on Friday, Torrent counsel Neal Seth of Wiley Rein LLP said the company "is pleased with the outcome that comports with the well-established legal principles applicable in this case."

Johnson is representing himself and couldn't be immediately reached for comment Friday.

Counsel for the other pharmaceutical companies didn't immediately respond to requests for comment Friday.

Circuit Judges W. Eugene Davis, Leslie H. Southwick and Gregg Costa heard the case for the Fifth Circuit.

Novartis is represented by Matthew J. Malinowski, Gregory S. Chernack, Robert E. Johnston and Shannon N. Proctor of Hollingsworth LLP.

Sun and Taro are represented by Elizabeth F. Griffin of Clark Hill PLC and Jason Reefer of Pietragallo Gordon Alfano Bosick & Raspanti LLP.

Bausch is represented by David S. Waxman of Saul Ewing Arnstein & Lehr LLP.

Torrent is represented by Neal Seth of Wiley Rein LLP.

The case is Johnson v. Novartis Pharmaceuticals Corp. et al., case number 20-50462, in the U.S. Court of Appeals for the Fifth Circuit.

--Additional reporting by Mike Curley. Editing by Michael Watanabe.

*Note: This story has been updated to add additional counsel for Novartis.*