UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

KIMBERLY HARTMAN

Plaintiff,

v.

Civil Action No. 2:10-1319

CARACO PHARMACEUTICAL LABORATORIES, LTD., a corporation, and TRIVILLIAN'S PHARMACY OF KANAWHA CITY, INC., a corporation,

Defendants

MEMORANDUM OPINION AND ORDER

Pending are plaintiff's motion to remand filed December 17, 2010, and the motion to dismiss of defendant Trivillian's Pharmacy of Kanawha City, Inc. ("Trivillian's"), filed January 17, 2011.

I.

Hartman is a West Virginia citizen. Caraco is a Michigan citizen. Trivillian's is a West Virginia citizen. Caraco manufactures Zolpidem, a generic substitute for the sleep medication Ambien. Hartman was prescribed Zolpidem by her physician. She filled her prescription at Trivillian's. During a period of time when Hartman was taking the medication, she lost control of her vehicle and sustained serious personal injuries. She alleges as follows:

Among the known side effects of Zolpidem is that persons taking it will engage in various activities while they are asleep, including the operation of motor vehicles. While under the influence of Zolpidem persons who experience such side effects will have no recollection of the events, which were taken in the absence of any voluntary control or action on the part of the person engaged in the activity. Plaintiff operated her motor vehicle while asleep and under the effect of Zolpidem, said actions being a side effect of the medication.

(Compl. ¶ V).

On September 16, 2010, Hartman instituted this action. She alleges in Count One that "[d]efendants failed to properly warn . . [her] of the dangerous side effects of Zolpidem, including the hazard posed to her by attempted operation of motor vehicles while sleeping." (Id. ¶ VI). In Count Two, she alleges that "[d]efendants negligently designed, tested and marketed Zolpidem." (Id. ¶ II). Hartman elaborates upon the nature of these two claims:

The Plaintiff alleges negligence and strict liability against the pharmacy for its failure to warn her of the dangerous side effects associated with consumption of the prescription drug Zolpidem. Hence, the Plaintiff's claims against the pharmacy are based on a theory of use defectiveness.

The West Virginia Supreme Court has explained that a use defectiveness claim is based "not so much on a flawed physical condition of the product, as on its unsafeness arising out of the failure to adequately

label, instruct, or warn." Morningstar v. Black & <u>Decker Mfg. Co.</u>, 253 S.E.2d 666, 682 (W. Va. 1979). "Use defectiveness covers situations when a product may be safe as designed and manufactured, but which becomes defective because of the failure to warn of dangers which may be present when the product is used in a particular manner." <u>Ilosky v. Michelin Tire Corp.</u>, 307 S.E.2d 603, 609 (W. Va. 1983).

(<u>Id.</u> ¶¶ 9-10).

On October 26, 2010, Caraco removed. On January 17, 2011, Trivillian's moved to dismiss. Both defendants allege Trivillian's is not a proper party. Caraco frames its assertion as a fraudulent joinder challenge justifying the exercise of diversity jurisdiction. Trivillian's relies upon Rule 12(b)(6), apparently presupposing the exercise of diversity jurisdiction is appropriate. The defendants' substantive arguments, however, overlap entirely.

In sum, Caraco and Trivillian's contend that West Virginia Code section 30-5-12(a) and the learned intermediary doctrine independently operate to exonerate Trivillian's from liability for either Counts One or Two. Section 30-5-12(a) provides as follows:

All persons, whether licensed pharmacists or not, shall be responsible for the quality of all drugs, chemicals and medicines they may sell or dispense, with the exception of those sold in or dispensed unchanged from the original retail package of the manufacturer, in which event the manufacturer shall be responsible.

W. Va. Code § 30-5-12(a). Both defendants assert that the "majority of courts" addressing the issue have concluded that section 30-5-12(a) shields pharmacists from liability on failure to warn claims. (E.g., Trivillian's Memo. in Supp. at 4).

II.

A. Fraudulent Joinder Standard

The fraudulent joinder standard is well settled. Our court of appeals lays a "heavy burden" upon a defendant removing a case on such grounds:

"In order to establish that a nondiverse defendant has been fraudulently joined, the removing party must establish either: [t]hat there is <u>no possibility</u> that the plaintiff would be able to establish a cause of action against the in-state defendant in state court; or [t]hat there has been outright fraud in the plaintiff's pleading of jurisdictional facts."

<u>Mayes v. Rapoport</u>, 198 F.3d 457, 464 (4th Cir. 1999) (emphasis added) (quoting <u>Marshall v. Manville Sales Corp.</u>, 6 F.3d 229, 232 (4th Cir. 1993)). The applicable standard "is even more favorable to the plaintiff than the standard for ruling on a motion to dismiss[.]" <u>Hartley v. CSX Transp., Inc.</u>, 187 F.3d 422, 424 (4th Cir. 1999).

As the decision in <u>Hartley</u> illustrates, fraudulent joinder claims are subject to a rather black-and-white analysis

in this circuit. Any shades of gray are resolved in favor of remand. At bottom, a plaintiff need only demonstrate a "glimmer of hope" in order to have his claims remanded:

CSX contests these points and we are unable to resolve them with the snap of a finger at this stage of the litigation. Indeed, these are questions of fact that are ordinarily left to the state court jury.

In all events, a jurisdictional inquiry is not the appropriate stage of litigation to resolve . . . various uncertain questions of law and fact. Allowing joinder of the public defendants is proper . . . because courts should minimize threshold litigation over jurisdiction. Jurisdictional rules direct judicial traffic. They function to steer litigation to the proper forum with a minimum of preliminary fuss. The best way to advance this objective is to accept the parties [as] joined . . . unless joinder is clearly improper. To permit extensive litigation of the merits of a case while determining jurisdiction thwarts the purpose of jurisdictional rules.

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We cannot predict with certainty how a state court and state jury would resolve the legal issues and weigh the factual evidence in this case. <u>Hartley's claims may</u> not succeed ultimately, but ultimate success is not required . . . Rather, there need be only a slight possibility of a right to relief. Once the court identifies this glimmer of hope for the plaintiff, the jurisdictional inquiry ends.

Id. at 425-26 (emphasis added).

B. Section 30-5-12(a)

A number of judicial decisions have considered the extent to which section 30-5-12(a) immunizes local pharmacies from product liability claims. Representative of the majority position is <u>Vagenos v. Alza Corp.</u>, No. 1:09-1523, 2010 WL 2944683 (S.D. W. Va. Jul. 23, 2010). In <u>Vagenos</u>, a local pharmacy was joined in an action alleging injuries arising out of the decedent's use of a fentanyl patch. The pharmacy was alleged to have committed negligence and engaged in negligent misrepresentations which were "limited to claims for the failure to provide adequate warnings regarding the Patch." <u>Id.</u> at *2. Noting that the "majority of courts to consider the issue have concluded that § 30-5-12 shields pharmacists from liability on failure to warn claims," the district court concluded the pharmacy was fraudulently joined. <u>Id.</u>

The minority approach with respect to failure to warn claims is illustrated by <u>Ashworth v. Albers Medical, Inc.</u>, 395 F. Supp.2d 395 (S.D. W. Va. 2005), a decision that reiterated an earlier interpretation of section 30-5-12(a) stated in <u>Walker v.</u> <u>Rite Aid of West Virginia, Inc.</u>, No.: 2:02- 1208, 2003 WL 24215831 (S.D. W. Va. Oct. 14, 2003). In <u>Ashworth</u>, plaintiff unwittingly purchased, and a local pharmacy innocently sold,

counterfeit Lipitor. She alleged, <u>inter alia</u>, that the pharmacy failed to provide adequate warnings about the spurious pharmaceutical. One defendant removed, asserting fraudulent joinder based upon section 30-5-12(a). The court first observed "that § 30-5-12(a) immunizes Rite Aid from all claims <u>based upon</u> <u>the quality of the drug</u>." <u>Id.</u> at 405-06 (emphasis added).

Respecting Rite Aid's liability on the failure to warn claim, however, the court noted its earlier decision in Walker. In that case plaintiff purchased an over-the-counter pain medicine at a local pharmacy. He alleged negligent design and manufacture by the entity that produced the drug and a failure to warn theory against the producer and the pharmacy. The court in Walker concluded that section 30-5-12(a) expressly abrogated liability for product defect claims. It additionally observed, however, that section 30-5-12(a) was silent respecting warning labels placed on drug packaging. Inasmuch as the Legislature could have specified that a pharmacy was relieved from all forms of product liability, including failure to warn or "use defectiveness" theories, as opposed to relief only from liability as to the quality of the drugs sold, the court concluded that section 30-5-12(a) did not immunize pharmacies from failure to warn claims in the sale of non-prescription drugs.

B. The Learned Intermediary Doctrine

The learned intermediary doctrine is a shorthand form for the principle that a drug manufacturer's duty to warn is owed to the prescribing physician and not the patient. Some courts have extended this manufacturer protection to pharmacies dispensing prescription drugs. Despite the ruling in <u>Walker</u> that would have allowed imposition of liability upon Rite Aid for a failure to warn claim despite section 30-5-12(a), the court in <u>Ashworth</u> nevertheless found fraudulent joinder based upon the learned intermediary doctrine:

The court finds that the learned intermediary doctrine applies to discharge any duty of the pharmacy to warn its customer of counterfeit drugs where as here the drugs are dispensed unaltered from the purported manufacturer and absent the allegation that the pharmacy had knowledge of either the counterfeit scheme or the existence of such counterfeit drugs in the distribution system at the time of the purchase.

Ashworth, 395 F. Supp.2d at 407-08.

But Hartman cites the more recent decision by the West Virginia Supreme Court of Appeals in <u>State ex rel. Johnson &</u> <u>Johnson Corp. v. Karl</u>, 220 W. Va. 463, 647 S.E.2d 899 (2007). She believes <u>Karl</u> worked a sea-change in the jurisprudence governing the learned intermediary doctrine. In <u>Karl</u>, the supreme court of appeals confronted a pharmaceutical

manufacturer's request for adoption of the learned intermediary doctrine to protect it from a failure to warn claim brought by a consumer.

The supreme court of appeals mentioned and parted company with the substantial majority of other state courts that had addressed the issue as well as with <u>Ashworth</u> and other decisions predicting West Virginia would adopt the learned intermediary doctrine generally. <u>See Vitatoe v. Mylan</u> <u>Pharmaceuticals, Inc.</u>, 696 F. Supp.2d 599, 609 (N.D. W. Va. 2010) ("Prior to <u>Karl</u>, federal district courts in West Virginia had speculated, albeit incorrectly, that West Virginia would likely adopt the learned intermediary doctrine."). The precise holding in the <u>Karl</u> case is as follows: "[U]nder West Virginia products liability law, manufacturers of prescription drugs are subject to the same duty to warn consumers about the risks of their products as other manufacturers." <u>Id.</u> at 478, 647 S.E.2d at 914.

It is true that the <u>Karl</u> decision did not involve a pharmacy. The case dealt only with a physician and manufacturer as defendants. Additionally, the majority opinion appears to have been influenced heavily by the "current state of the prescription drug industry and physician/patient relationships" impacted by direct marketing of drugs to consumers through mass media advertising. Id. at 465, 647 S.E.2d at 901.

However, in applying the fraudulent joinder standard, one might possibly conclude that <u>Karl</u> has a more expansive reach. The decision could be read as a wholesale rejection of the learned intermediary doctrine in all of its applications, including its potential to exonerate pharmacies. For example, the majority opinion cites the <u>Ashworth</u> decision, dealing with pharmacies, as one of the "federal court[decisions] . . . [to] have . . . speculated that West Virginia would adopt <u>the</u> <u>doctrine</u>." <u>Id.</u> at 477, 647 S.E.2d at 913 (emphasis added). The observation is immediately followed by this reservation: "While federal court opinions applying West Virginia law are often viewed persuasively, we are not bound by those opinions." <u>Id.</u>

C. Analysis

Hartman contends that Trivillian's did not provide her a patient information leaflet about Zolpidem. She also asserts that discovery may demonstrate that Trivillian's failed in other respects to warn her of the compound's adverse effects. Trivillian's will doubtless interpose one or more defenses to these allegations.

The fraudulent joinder standard resolves such factual disputes in favor of the party seeking remand. The disputed legal issues are dealt with similarly. Respecting the application of section 30-5-12(a), <u>Vagenos</u> and other cases read the statute to immunize pharmacies from failure to warn claims. The decisions in <u>Ashworth</u> and <u>Walker</u>, however, conclude that failure to warn claims are actionable under a use-defectiveness theory irrespective of section 30-5-12(a). There is likewise uncertainty concerning the learned intermediary doctrine. In sum, the <u>Karl</u> decision may be read as allowing affixation of liability upon pharmacies when failure to warn claims are alleged against them. This incertitude respecting both legal issues dooms defendants' fraudulent joinder challenge.

Simply put, "The party alleging fraudulent joinder . . . must show that the plaintiff cannot establish a claim even after resolving all issues of law and fact in the plaintiff's favor." <u>Hartley</u>, 187 F.3d at 424. Given the uncertainties here in both the factual and legal landscape, Caraco and Trivillian's cannot satisfy their heavy burden. The court, accordingly, concludes that Trivillian's is not fraudulently joined.

Based upon the foregoing discussion, it is ORDERED as follows:

- 1. That plaintiff's motion to remand be, and it hereby is, granted; and
- 2. That this action be, and it hereby is, remanded for all further proceedings to the Circuit Court of Kanawha County.

The Clerk is requested to transmit this written opinion and order to all counsel of record and to any unrepresented parties.

DATED: April 29, 2011

John T. Copenhaver, Jr. -62

United States District Judge