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U.S. DISTRICT COURT
N.D. OF ALABAMA

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF ALABAMA**
**MIDDLE DIVISION**

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| **DANIEL STEWART, JR.,** | ) | |
| | ) | |
| **Plaintiff,** | ) | |
| | ) | |
| **v.** | ) | **Case No.: 4:13-CV-539-VEH** |
| | ) | |
| **SANOFI AVENTIS U.S., LLC,** | ) | |
| | ) | |
| **Defendant.** | ) | |

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## MEMORANDUM OPINION

## I. Introduction

Plaintiff Daniel Stewart, Jr. ("Mr. Stewart") initiated this products liability action in the Circuit Court of Etowah County, Alabama, on July 26, 2012. (Doc. 1 ¶ 1). Defendant Sanofi Aventis U.S., LLC ("Sanofi") removed the lawsuit to federal court on March 21, 2013, on the basis of diversity jurisdiction. (Doc. 1 at 1, 4). The case was reassigned to the undersigned on March 26, 2013. (Doc. 9). Sanofi filed an amended removal petition on April 5, 2013. (Doc. 14).

In compliance with this court's order requiring him to replead (Doc. 18),[1] Mr. Stewart filed an amended complaint (Doc. 19) on May 17, 2013. The amended

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[1] In that same order, the court explained why Indiana law applies to this dispute. (Doc. 18 at 5-7).

pleading contains one count of a product liability failure to warn asserted under the Indiana Product Liability Act ("IPLA"). (Doc. 19 at 12-13).

Pending before the court is Sanofi's Motion for Judgment on the Pleadings (Doc. 23) (the "Motion") filed on September 6, 2013.[2] Sanofi also filed copies of several persuasive case authorities in support of its Motion on September 6, 2013. (Doc. 25). Mr. Stewart opposed the Motion (Doc. 26) on September 27, 2013, and Sanofi followed with its reply (Doc. 27) on October 4, 2013.

Based upon the allegations of Mr. Stewart's amended pleading, he claims harm and injuries as a result of ingesting Zolpidem, while he was attending a business meeting in Columbus, Indiana, on October 3, 2011. (Doc. 19 ¶ 3). Zolpidem is a generic form of the more commonly know prescription sleep aid called Ambien. (*Id.* ¶ 4). Sanofi manufacturers Ambien, but not Zolpidem. *Id.* Sanofi contends that as a manufacturer of a name-brand drug, it is not liable under the IPLA for damages allegedly caused by the use of another manufacturer's generic-equivalent drug. Because the court concludes that, accepting all of Mr. Stewart's allegations as true, Indiana law would not hold Sanofi liable to Mr. Stewart on a failure to warn theory, the Motion is due to be granted.

[2] The page references to Doc. 23 correspond with the court's CM/ECF numbering system.

## II. Standard

Rule 12(c) of the Federal Rules of Civil Procedure provides that "[a]fter the pleadings are closed--but early enough not to delay trial--a party may move for judgment on the pleadings." Fed. R. Civ. P. 12(c). As the Eleventh Circuit has explained the Rule 12(c) standard:

> Judgment on the pleadings is appropriate when there are no material facts in dispute, and judgment may be rendered by considering the substance of the pleadings and any judicially noticed facts. *See Bankers Ins. Co. v. Florida Residential Property and Cas. Joint Underwriting Ass'n*, 137 F.3d 1293, 1295 (11th Cir.1998) (citing *Hebert Abstract Co. v. Touchstone Properties, Ltd.*, 914 F.2d 74, 76 (5th Cir.1990)); *see also* Rule 12(c), Fed. R. Civ. P. When we review a judgment on the pleadings, therefore, we accept the facts in the complaint as true and we view them in the light most favorable to the nonmoving party. *See Ortega*, 85 F.3d at 1524 (citing *Swerdloff v. Miami Nat'l Bank*, 584 F.2d 54, 57 (5th Cir. 1978)). The complaint may not be dismissed " 'unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.' " *Slagle*, 102 F.3d at 497 (quoting *Conley v. Gibson*, 355 U.S. 41, 45–46, 78 S. Ct. 99, 101–02, 2 L. Ed. 2d 80 (1957) & citing *Hartford Fire Ins. Co. v. California*, 509 U.S. 764, 811, 113 S. Ct. 2891, 2916–17, 125 L. Ed. 2d 612 (1993)).

*Hawthorne v. Mac Adjustment, Inc.*, 140 F.3d 1367, 1370 (11th Cir. 1998).

## III. Analysis

While the Indiana Supreme Court apparently has not yet addressed this specific issue, a plain reading of the IPLA as well as several IPLA-related opinions from other Indiana courts persuade this court that a plaintiff, such as Mr. Stewart, who allegedly

was injured by a prescription drug cannot state a claim for failure to warn under the IPLA against the manufacturer of a brand name prescription drug, such as Sanofi, when the allegations show that the plaintiff ingested solely a generic form of the drug.

### A. Plain Language of the IPLA

The plain language of the IPLA does not support Mr. Stewart's theory of liability.

> Sec. 1. Except as provided in section 3 of this chapter, a person who sells, leases, or otherwise puts into the stream of commerce any product in a defective condition unreasonably dangerous to any user or consumer or to the user's or consumer's property is subject to liability for physical harm caused by that product to the user or consumer or to the user's or consumer's property if:
>
> > (1) that user or consumer is in the class of persons that the seller should reasonably foresee as being subject to the harm caused by the defective condition;
> >
> > (2) the seller is engaged in the business of selling the product; and
> >
> > (3) the product is expected to and does reach the user or consumer without substantial alteration in the condition in which the product is sold by the person sought to be held liable under this article.

Ind. Code § 34-20-2-1.

As Sanofi correctly observes, "[t]he opening clause of Indiana Code § 34-20-2-1 requires that in order for a defendant to be held liable, it must have sold,

leased, or otherwise puts into the stream of commerce the product that caused the user or consumer's 'physical harm.'" (Doc. 23 at 12). Because Sanofi is not alleged to be responsible for manufacturing, selling, or otherwise putting Zolpidem into the stream of commerce, it cannot be held liable to Mr. Stewart under the unambiguous wording of the IPLA.

**B. Persuasive Authorities**

Sanofi has cited to several authorities in support of its Motion. The court finds the following two cases to be particularly instructive and persuasive: *Short v. Eli Lilly and Co.*, No. 49D12-0601-CT-2187 decided on March 25, 2009, by the Superior Court of Marion County, Indiana (Doc. 24-1); and the Seventh Circuit's decision in *Williams v. REP Corp.*, 302 F.3d 660 (7th Cir. 2002).

In *Short*, the court was faced with the summary judgment issue of whether the defendant could be held liable for the death of the plaintiff's husband when the evidence showed that he had only used a generic form of Prozac. (Doc. 24-1 at 14 ¶ 44). After determining that the IPLA governed plaintiff's claims, regardless of their alleged nature, the court found that the brand name manufacturer of Prozac could not be liable to the plaintiff because the statute "expressly limits liability to manufacturers or sellers of the alleged injury-causing product." (*Id.* ¶ 46).

The *Short* court further explained that innovator or original designer liability

was:

> [A] deviat[ion] from well-settled principles of Indiana law[,] . . . fundamentally inconsistent with well-settled Indiana law and the most basic tenets of products liability law[, and] . . . contrary to the overwhelming weight of authority which has unanimously rejected such an expansive theory of liability.

(Doc. 24-1 at 13 ¶ 39). This court agrees with *Short*.

*Williams* is also a summary judgment decision arising under the IPLA. 302 F.3d at 662. In affirming the district court's order granting summary judgment in favor of the defendant and rejecting an extension of products liability based upon common ownership and/or corporate affiliation, the Seventh Circuit Court of Appeals reasoned:

> Mr. Williams submits that REP Corp. is subject to liability under the Act notwithstanding the fact that it did not actually sell the machine that injured him. He offers several arguments in support of his contention. First, Mr. Williams contends that REP Corp. falls within the Act's definition of "manufacturer" and therefore may be liable under the Act. The Act defines "manufacturer" to include "a seller who: ... (D) is owned in whole or significant part by the manufacturer; or (E) owns in whole or significant part the manufacturer." Ind. Code Ann. § 33–1–1.5–2(3) (West 1996). The Act defines a "seller" in general terms as "a person engaged in the business of selling or leasing a product ...." *Id.* § 33–1–1.5–2(5). At the time the district court entered summary judgment for REP Corp., the evidence before the court indicated that "REP France" was the manufacturer of the machine and that REP Corp. was a wholly owned subsidiary of "REP France." Even if REP Corp. could be considered a "seller" under the statute's generic definition, and therefore a "manufacturer" because it is owned by "REP France," there is still no evidence that REP Corp. sold, leased or otherwise put into the

> stream of commerce the allegedly defective machine as required by Ind. Code § 33–1–1.5–3(a). It was later disclosed that REP International manufactured the machine and did not own REP Corp. This development does not change the basic analysis. REP, the parent corporation, owns REP International and REP Corp. Yet, REP Corp. still cannot be said to have sold, leased or otherwise placed the machine in the stream of commerce.

*Williams*, 302 F.3d at 663 (emphasis added).

The court acknowledges that the Supreme Court of Alabama (against the great majority of those courts which have examined the theory) has issued a decision on a certified question that has not yet been released for publication, which embraces a type of innovator liability, *see Wyeth, Inc. v. Weeks*, No. 1101397, 2013 WL 135753, (Ala. Jan. 11, 2013).[3] However, Justice Murdock issued a lengthy dissenting opinion,

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[3] As the Supreme Court of Alabama concluded its opinion in *Weeks*:

> We answer the question as follows: Under Alabama law, a brand-name drug company may be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture of a brand-name prescription drug, by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company. . . .
>
> FDA regulations provide that a generic-drug manufacturer's labeling for a prescription drug must be exactly the same as the brand-name-drug manufacturer's labeling. The Supreme Court in *PLIVA* held that it would have been impossible for the generic-drug manufacturers to change their warning labels without violating the federal requirement that the warning on a generic drug must match the warning on the brand-name version, preempting failure-to-warn claims against generic manufacturers.
>
> In the context of inadequate warnings by the brand-name manufacturer placed on a prescription drug manufactured by a generic-drug manufacturer, it is not fundamentally unfair to hold the brand-name manufacturer liable for warnings on a product it did not produce because the manufacturing process is irrelevant to

2013 WL 135753, at *20-37, on February 4, 2013, and the direct history in *Weeks* reflects that a rehearing was granted on June 13, 2013. Consequently, whether the reasoning and holding in *Weeks* will ultimately stand is debatable.

Moreover, even if *Weeks* is unchanged after reargument, the court sees nothing in Mr. Stewart's opposition to the Motion which convinces this court that the Supreme Court of Indiana will be persuaded to follow *Weeks*, especially as that opinion, consistent with Alabama law, is predominantly common-law driven in its analysis while, in sharp contrast and as illustrated above, Indiana products liability law is statutorily driven.

In sum, consistent with the plain language of the IPLA and persuasively guided by *Short, Williams*, and the plethora of other decisions cited by Sanofi, the court concludes that Mr. Stewart cannot maintain a failure to warn theory under the IPLA against Sanofi under the particular factual allegations of his case.

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> misrepresentation theories based, not on manufacturing defects in the product itself, but on information and warning deficiencies, when those alleged misrepresentations were drafted by the brand-name manufacturer and merely repeated by the generic manufacturer.

*Weeks*, 2013 WL 135753, at *19.

## IV. Conclusion

Accordingly, the Motion is due to be granted. The court will enter a separate order dismissing this action with prejudice.

**DONE** and **ORDERED** this the 10th day of April, 2014.

**VIRGINIA EMERSON HOPKINS**
United States District Judge