UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

JAMES DAVID BECK	**CIVIL ACTION**
VERSUS	**NO. 10-1901**
TEVA PHARMACEUTICAL INDUSTRIES LIMITED, ET AL.	**SECTION I**

ORDER AND REASONS

Before the Court is a motion to dismiss filed by defendants, Teva Pharmaceutical Industries Limited ("Teva Israel") and Teva Pharmaceuticals USA, Inc. ("Teva USA" or collectively "Defendants").[1] Plaintiff, James David Beck, opposes the motion.[2] For the following reasons, defendants' motion to dismiss is **GRANTED** and the above-captioned case is **DISMISSED WITH PREJUDICE**.

BACKGROUND

According to the amended complaint, Beck sustained debilitating neurological damage from taking methotrexate to treat a bad case of psoriasis.[3] Beck filled his prescription for methotrexate 2.5 mg, prescription number 6903440, at a Wal-Mart SuperCenter Pharmacy.[4] He became gravely ill after taking the medication and experienced "an absence of oxygen to his brain."[5] As a result, Beck sustained severe damage of the myelin sheath of nerve cells in his brain stem.[6] He is now unable to walk or take care of himself without constant supervision.[7]

[1] R. Doc. No. 18.
[2] R. Doc. No. 21.
[3] R. Doc. No. 9, pg. 2.
[4] R. Doc. No. 9, pg. 2.
[5] R. Doc. No. 9, pg. 2.
[6] R. Doc. No. 9, pg. 3.
[7] R. Doc. No. 9, pg. 3.

Beck alleges that defendants Teva Israel and Teva USA manufactured, produced, and marketed the drug that caused Beck's injuries.[8] Beck claims the medication was unreasonably dangerous for its anticipated use on the ground that the manufacturers failed to provide an adequate warning for their product, as required by the Louisiana Products Liability Act (LPLA), La. Rev. Stat. Ann. §§ 9:2800.51, et seq.[9] Beck argues in his opposition to the motion to dismiss that the drug was unreasonably dangerous because "[a] warning label should have been placed on the drug, methotrexate, in that it is so strong it should be used by physicians whose knowledge and experience include the use of antimetabolic therapy because of the possibility of serious toxic reactions which can be fatal."[10]

Teva USA and Teva Israel filed a motion to dismiss Beck's complaint for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6).[11] Relying on the Supreme Court's recent decision in *PLIVA, Inc. v. Mensing*, 564 U.S. ___, 131 S. Ct. 2567 (2011) (slip opinion), defendants argue that Beck's state-law duty to warn claims are preempted by federal drug regulations applicable to generic drug manufacturers. In addition, Teva Israel seeks dismissal under Federal Rules of Civil Procedure 12(b)(2) and 12(b)(4) for lack of personal jurisdiction and improper service of process with respect to the Israeli corporation. Because the Court finds

[8] R. Doc. No. 9, pg. 2-3. Plaintiff served defendant Teva USA with a summons and a copy of the complaint on July 11, 2011. R. Doc. No. 17. As for Teva Israel, plaintiff claims he has attempted to effect service through registered mail sent to the company's headquarters in Petach Tikva, Israel, as ordered by the Court during a prior hearing. R. Doc. No. 21, pg. 5-6.

[9] R. Doc. No. 9, pg. 3. The complaint alleges that defendants are "are liable within the meaning of the Louisiana Products Liability Act, La. Rev. Stat. Ann. § 9:2800.51, et seq., for manufacturing, developing, producing and marketing the defective drug, methotrexate, in that the drug was unreasonably dangerous for its reasonably anticipated use." The complaint only states that "[t]he drug, methotrexate, is so strong that it should be used by physicians whose knowledge and experience include the use of antimetabolic therapy because of the possibility of serious toxic reactions which can be fatal, and it has been reported to cause fetal death and/or congenital anomalies. (As noted in www.drugs.com)." Plaintiff's counsel agreed orally before the Court on September 9, 2011 that his only allegation under the LPLA is directed to a failure to warn.

[10] R. Doc. No. 21, pg. 2.

[11] In their motion to dismiss, defendants noted they do not concede that plaintiff ingested any product manufactured or marketed by Teva Israel or Teva USA. R. Doc. No. 18-1, n.2.

that Beck failed to state a claim upon which relief may be granted, the Court declines to address Teva Israel's arguments under Rules 12(b)(2) and 12(b)(4).

LAW

A district court may dismiss a complaint, or any part of it, for failure to state a claim upon which relief can be granted if the plaintiff has not set forth a factual allegation in support of his claim that would entitle him to relief. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955, 1964-65, 167 L. Ed. 2d 929 (2007); *Cuvillier v. Taylor*, 503 F.3d 397, 401 (5th Cir. 2007). As the Fifth Circuit explained in *Gonzalez v. Kay:*

> "Factual allegations must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). The Supreme Court recently expounded upon the *Twombly* standard, explaining that "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, ---U.S. ----, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009) (quoting *Twombly*, 550 U.S. at 570, 127 S.Ct. 1955, 167 L.Ed.2d 929). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* It follows that "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged-but it has not 'show[n]'-'that the pleader is entitled to relief.'" *Id.* at 1950 (quoting Fed.R.Civ.P. 8(a)(2)).

577 F.3d 600, 603 (5th Cir. 2009).

This Court will not look beyond the factual allegations in the pleadings to determine whether relief should be granted. *See Spivey v. Robertson*, 197 F.3d 772, 774 (5th Cir. 1999); *Baker v. Putnal*, 75 F.3d 190, 196 (5th Cir. 1996). In assessing the complaint, a court must accept all well-pleaded facts as true and liberally construe all factual allegations in the light most favorable to the plaintiff. *Spivey*, 197 F.3d at 774; *Lowrey v. Tex. A & M Univ. Sys.*, 117 F.3d 242, 247 (5th Cir. 1997). "Dismissal is appropriate when the complaint 'on its face show[s] a bar

to relief.'" *Cutrer v. McMillan*, 308 Fed. Appx. 819, 820 (5th Cir. 2009) (quoting *Clark v. Amoco Prod. Co.*, 794 F.2d 967, 970 (5th Cir. 1986)).

DISCUSSION

Defendants argue that the complaint fails to state a claim because federal drug regulations applicable to generic drug manufacturers preempt state-law duty to warn claims such as the one asserted in this matter. The Supremacy Clause provides that federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Federal law expressly preempts state law when Congress "indicate[s] pre-emptive intent through a statute's express language." *Altria Group, Inc. v. Good*, 555 U.S. 70, 76-77, 129 S. Ct. 538, 543, 172 L. Ed. 2d 398 (2008). Implied preemption occurs when Congress intends for federal law to exclusively occupy an entire field of regulation, or when federal law conflicts with state law. *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287, 115 S. Ct. 1483, 1487, 131 L. Ed. 2d 385 (1995). In cases where it appears "impossible for a private party to comply with both state and federal requirements," *id.*, preemption applies when "federal law blocks a private party from independently accomplishing what state law requires." *Mensing*, 131 S. Ct. at 2580.

In support of their position that impossibility preemption bars plaintiff's state-law duty to warn claims, defendants rely on the Supreme Court's decision in *PLIVA , Inc. v. Mensing*, 564 U.S. ___, 131 S. Ct. 2567 (2011) (slip opinion). In that case, the plaintiffs claimed that generic drug manufacturers of metoclopramide did not adequately warn of the risks associated with long-term use of the medication. However, the Court explained that generic drug manufacturers obtain FDA approval by showing, among other things, "that the [safety and efficacy] labeling proposed . . . is the same as the labeling approved for the [brand-name] drug." The ongoing duty of

sameness prevented the manufactures from unilaterally strengthening the warnings by using the FDA's "changes-being-effected" (CBE) process, or by using "Dear Doctor" letters to send additional warnings to physicians. Although the manufacturers could have asked the FDA to strengthen the labeling warnings for both brand-name and generic drug manufacturers, the Court explained that "[s]tate law demanded a safer label; it did not instruct the Manufacturers to communicate with the FDA about the possibility of a safer label." As a result, it would have been impossible for the generic drug manufacturers to comply with federal regulations, and at the same time, "independently satisfy" the state labeling requirements. Accordingly, the federal drug regulations preempted the plaintiffs' state-law duty to warn claims.

In his opposition, Beck relies almost entirely on unattributed quotes taken from *Gaeta v. Perrigo Pharmaceuticals Co.*, 630 F.3d 1225 (9th Cir. 2011). In that case, decided six-months before the Supreme Court's decision in *Mensing*, the Ninth Circuit held that impossibility preemption does not bar state-law duty to warn claims against generic drug manufacturers. In doing so, the Ninth Circuit joined the reasoning of the Fifth Circuit decision that was subsequently reversed by the Supreme Court in *Mensing*. By continuing to rely on these precedents, plaintiff argues— in direct contradiction with the Supreme Court's decision in *Mensing*— that generic manufacturers can discharge their state-law duties to warn of additional risks by using the CBE process, the "prior approval process," or by asking the FDA to send "Dear Doctor" warning letters to physicians.

Plaintiff's reliance on *Gaeta* is misplaced. As defendants observe, these arguments are not viable in light of the Supreme Court's decision in *Mensing.* The Supreme Court expressly rejected the argument that generic manufacturers could discharge their state-law duties without violating federal law by using the CBE process or by using "Dear Doctor" letters. Nor would

defendants be able to satisfy their state-law duties by asking the FDA to modify the labeling requirement for both brand-name and generic drug manufacturers. *See Mensing*, 131 S. Ct. at 2580-81 (explaining that state law "demanded a safer label; it did not instruct the Manufacturers to communicate with the FDA about the possibility of a safer label.").[12] As the Supreme Court held in *Mensing*, the duty for generic producers to comply with federal labeling regulations preempts the state-law duty to provide adequate labels under the LPLA. To the extent plaintiff alleges only that he ingested methotrexate 2.5 mg, as opposed to a name-brand form of the medication, the Court finds that he failed to show he is entitled to relief.[13]

Accordingly, defendants' motion to dismiss is **GRANTED** and the above-captioned case is **DISMISSED WITH PREJUDICE**.

New Orleans, Louisiana, September 12, 2011.

LANCE M. AFRICK
UNITED STATES DISTRICT JUDGE

[12] The Louisiana plaintiffs' claims in *Mensing* arose from the same provision in the LPLA authorizing Beck's duty to warn claims. La. Rev. Stat. Ann. § 9:2800.57 (A) provides, "A product is unreasonably dangerous because an adequate warning about the product has not been provided if, at the time the product left its manufacturer's control, the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product."

[13] Plaintiff's counsel agreed orally before the Court on September 9, 2011 that plaintiff does not allege he ingested a name-brand form of methotrexate.