UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
NORTHERN DIVISION
(at Covington)

IN RE: DARVOCET, DARVON AND PROPOXYPHENE PRODUCTS LIABILITY LITIGATION	)	Master File No. 2: 11-md-2226-DCR MDL Docket No. 2226
Boggess v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-359-DCR
Miller v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-372-DCR
Jones v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-379-DCR
Douglas v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-399-DCR
Chavez v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 12-062-DCR
Marston v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 12-066-DCR

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MEMORANDUM OPINION AND ORDER REGARDING DEFENDANT ELI LILLY AND COMPANY'S SECOND MASTER MOTION FOR JUDGMENT ON THE PLEADINGS

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This matter is before the Court for consideration of Eli Lilly and Company's (Lilly) second master motion to dismiss the claims against it in six actions in this multidistrict litigation (MDL). [MDL Record No. 1537] Lilly contends that the claims asserted against it in these cases should be dismissed pursuant to Rule 12(c) of the Federal Rules of Civil Procedure. For the reasons explained below, the motion will be granted.

I.

On March 7, 2012, this Court granted Lilly's master motion to dismiss filed in several cases. [MDL Record No. 1402] The dismissal was based on the plaintiffs' failure to properly identify Lilly as the entity that marketed, sold, or manufactured the propoxyphene products the

plaintiffs claimed to have ingested. Further, the allegations in the subject cases did not allow the Court to draw reasonable inferences that Lilly was liable for the misconduct alleged. [*Id.*, pp. 6-11] On March 26, 2012, Lilly filed its second master motion for judgment on the pleadings pursuant to Rule 12(c) of the Federal Rules of Civil Procedure. [MDL Record No. 1537]

This motion was originally filed in sixty-five cases, but Lilly later withdrew it in forty-six actions. [MDL Record Nos. 1749, 1768] After the Court granted the original motion and dismissed the claims against Lilly in seventeen cases on May 2, 2012 [MDL Record No. 1775], Lilly moved for reinstatement in the six above-captioned actions.[1] The Court reinstated the motion and ordered the plaintiffs to show cause why their claims should not be dismissed based on the Court's previous opinions regarding Lilly. [MDL Record No. 1875] The plaintiffs responded to the show-cause order on June 1, 2012. [MDL Record No. 1905]

II.

As the Court explained previously, the analysis is the same for motions brought under Rule 12(b)(6) and Rule 12(c). [MDL Record No. 1402, p. 4 (citing *Equal Emp't Opportunity Comm'n v. J.H. Routh Packing Co.*, 246 F.3d 850, 851 (6th Cir. 2001))] When evaluating a motion to dismiss under Rule 12(b)(6), the Court must determine whether the complaint alleges "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550

1 Because Lilly had inadvertently withdrawn the motion in Civil Action No. 2: 11-372, it moved to reinstate on May 3, 2012. [MDL Record No. 1779] On May 4, 2012, Lilly moved to reinstate the motion against the plaintiffs in the remaining five above-captioned cases after entry of the Agreed Order Regarding Eli Lilly and Company's Dispositive Motions in Cases in Which Plaintiffs Have Not Amended Their Pleadings. [MDL Record No. 1795; *see* Record No. 1792]

U.S. 544, 555 (2007)). The plausibility standard is met "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.* (citing *Twombly,* 550 U.S. at 556). It requires "more than a sheer possibility that a defendant has acted unlawfully." *Id.* Thus, although the complaint need not contain "detailed factual allegations" to survive a motion to dismiss, "a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (internal quotation marks and alteration omitted).

III.

In their response, the plaintiffs incorporate by reference the original opposition to Lilly's Second Master Motion for Judgment on the Pleadings. [*See* MDL Record No. 1696] These arguments were previously rejected by the Court. [MDL Record No. 1775] The plaintiffs present no new arguments in opposition to Lilly's motion with regard to *Boggess v. Eli Lilly and Company, et al.*, Civil Action No. 2: 11-359; *Miller v. Eli Lilly and Company, et al.*, Civil Action No. 2: 11-372; *Jones v. Eli Lilly and Company, et al.*, Civil Action No. 2: 11-379; or *Douglas v. Eli Lilly and Company, et al.*, Civil Action No. 2: 11-399.

The plaintiffs, however, make specific arguments concerning product identification in the remaining two matters: *Chavez v. Eli Lilly and Company, et al.*, Civil Action No. 2: 12-62; and *Marston v. Eli Lilly and Company, et al.*, Civil Action No. 2: 12-66.[2] The plaintiffs in *Chavez*

2 The *Chavez* and *Marston* amended complaints contain the following claims against the generic defendants: (1) design defect; (2) strict liability for inadequate warning; (3) negligent design; (4) negligence; (5) negligent failure to warn; (6) fraudulent nondisclosure; (7) negligent misrepresentation; (8) fraudulent misrepresentation; (9) statutory negligence; (10) breach of express warranty; and (11) breach of implied

and *Marston* filed amended complaints alleging the ingestion of products manufactured by Mylan Pharmaceuticals, Inc., but the Court ordered that those complaints be stricken on May 3, 2012, because they contained claims against generic manufacturers that had been dismissed in previous orders. [MDL Record Nos. 1781, 1782] The plaintiffs in *Chavez* and *Marston* contend that their amended complaints sufficiently stated a claim against Lilly as a generic manufacturer. They ask that the Court consider their allegations for the purposes of this motion. Therefore, the Court will review the facts asserted by the plaintiffs in their amended complaints.

Chavez alleges that he ingested a Mylan Pharmaceuticals propoxyphene product from March 16, 1998 to May 27, 2002. [MDL Record No. 1905-1 ¶ 7] Likewise, Marston alleges that from September 17, 2003 to April 7, 2004, she ingested Propoxyphene-100 APAP 650, "at least some of [which] was made by Mylan Pharmaceuticals, Inc." [MDL Record No. 1905-2 ¶ 7] The complaints also allege that Lilly's 2002 NDA-transfer agreement with NeoSan "specifically indicates that nothing therein would forbid Eli Lilly from fulfilling the requirements of a 1994 propoxyphene supply agreement that it had with Mylan and/or Mylan Pharmaceuticals." [*Id.* ¶ 148; MDL Record No. 1905-1 ¶ 113] Based on these facts, the plaintiffs assert that their claims against Lilly, in its capacity as a manufacturer of generic propoxyphene products, should not be dismissed.

The allegations in the *Chavez* and *Marston* amended complaints are sufficient to create a reasonable inference that the plaintiffs ingested propoxyphene manufactured by Lilly. In a previous order, the Court dismissed similar claims asserted against Lilly by a plaintiff who

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warranty. [*See* MDL Record Nos. 1905-1, 1905-2]

alleged the ingestion of a Mylan product. [MDL Record No. 1771] In that case, the Court concluded that "[w]ithout more facts about the terms of the 1994 agreement, it is not reasonable to infer that a product ingested in 2010 was manufactured by Lilly." [*Id.*, p. 4] The amended complaints in *Chavez* and *Marston* do not present the problem of an attenuated time line. Both plaintiffs ingested products sold by Mylan Pharmaceuticals, Inc. at a time during which it is reasonable to infer that Lilly was engaged in manufacturing generic propoxyphene for Mylan. Therefore, the allegations in these two amended complaints create more than a "sheer possibility" that at least some of the Mylan products ingested were manufactured by Lilly. *Iqbal*, 556 U.S. at 678.

Nevertheless, the complaints fail to state a claim upon which relief can be granted.[3] The claims asserted in *Marston* fail for the reasons outlined in the Court's Memorandum Opinion and Order Regarding Generic Defendants' Motions to Dismiss entered March 7, 2012. [MDL Record No. 1305] In that decision, the Court dismissed failure-to-warn claims against generic propoxyphene manufacturers, relying on the Supreme Court's decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). In *Mensing*, the Supreme Court held that state-law failure-to-warn claims against generic drug manufacturers are preempted by federal law. Because the Food, Drug and Cosmetic Act (FDCA) requires that generic drug labels match those of the corresponding brand-name products and any labeling change to satisfy state law would conflict with this "federal duty of sameness," the Court concluded that generic drug manufacturers could not simultaneously comply with both state and federal law. *Id.* at 2575 (internal quotation marks

3 The Court has previously indicated that "claims against Lilly in its capacity as a manufacturer [for generic drug companies] would likely fail." [MDL Record No. 1402, p. 15]

omitted); *see id.* at 2578. The FDCA also requires that generic drugs be identical to their brand-name counterparts "in active ingredients, safety, and efficacy." *Id.* at 2574 n.1. Therefore, this Court rejected the contention that "wrongful marketing" claims — including design defect, negligent design, negligence, and breach of warranty — should escape preemption, because they are "all based on the allegedly defective design of the drug, which the Generic Defendants . . . were powerless to change." [MDL Record No. 1305, p. 7] Finally, the Court dismissed claims of misrepresentation, fraud, statutory negligence, and breach of express warranty brought against the generic defendants, again on preemption grounds. [*Id.*, pp. 11-13]

The plaintiff in *Marston* alleges the ingestion of the Lilly/Mylan product beginning in 2003, after Lilly had divested its NDA. [*See* MDL Record No. 1905-2 ¶ 7] Therefore, her claims against Lilly are preempted under *Mensing*, because Lilly had no more power to change the label than did Mylan. The ingestion dates alleged in *Chavez*, however, coincide with Lilly's ownership of the NDA for propoxyphene. Thus, the case presents a closer question.

As explained in *Mensing*, generic drug manufacturers cannot unilaterally change the labels on their products due to FDA regulations that require that generic labels match the labels of the corresponding brand-name drugs. 131 S. Ct. at 2575. Thus, failure-to-warn claims against generic manufacturers are preempted because any state-law duty to warn consumers conflicts with their "federal duty of sameness." *Id.* (internal quotation marks omitted). In *Wyeth v. Levine*, 555 U.S. 555 (2009), on the other hand, the Supreme Court held that similar claims asserted against a brand manufacturer were not preempted because "the manufacturer bears responsibility for the content of its label at all times." *Id.* at 570-71. As a general rule, then, it

is possible for brand-name manufacturers to comply with both federal and state requirements, and therefore conflict preemption does not shield them from liability for failure to warn.[4]

The plaintiff in *Chavez* ingested a generic propoxyphene product that was allegedly manufactured by Lilly for Mylan during the time that Lilly held the NDA for the drug. By virtue of its possession of the NDA, Lilly had the power to change the brand-name label, thereby triggering a required change in the generic label. In other words, Lilly indirectly controlled the label for generic propoxyphene. Because it thus had the power to change the generic label, there is no conflict under *Mensing*. Lilly could satisfy both its state-law duty to warn and its "duty of sameness" under federal law. *Mensing*, 131 S. Ct. at 2575.

However, the allegations in the *Chavez* amended complaint are too attenuated to allow the Court to draw the reasonable inference that Lilly was liable for the misconduct alleged. *See Iqbal*, 556 U.S. at 678; *Twombly*, 550 U.S. at 556. Chavez does not allege that Lilly provided Mylan with a different, more dangerous product. Rather, the inherent argument in *Chavez* is that Lilly, as the NDA-holder for propoxyphene, owed a duty to the consumers of another company's product because it had a supply agreement with that company. In other words, Chavez seeks to hold a brand-name company responsible as a generic manufacturer based on the powers it held as a brand-name company. This convoluted theory of liability is insufficient to state a viable claim against Lilly. The claims would be dismissed under *Mensing* if they were asserted against a generic manufacturer; they would be dismissed on product identification grounds if they were

4 The Court left room for a possible exception: if the brand-name manufacturer presents "clear evidence" that the FDA would not have approved a change to the label, then conflict preemption might apply to the claims against that defendant. *Wyeth*, 555 U.S. at 571-72.

asserted against Lilly as a brand-name manufacturer. Chavez cannot create a viable claim by combining two other, untenable claims. Therefore, the claims asserted against Lilly in *Chavez* will be dismissed.

Further, the Court notes that imputing a duty to Lilly in this situation might have problematic consequences. Allowing the plaintiff in *Chavez* to assert failure-to-warn claims against Lilly would be tantamount to finding that Lilly is responsible for the labels of all generic propoxyphene, rather than only the label of the propoxyphene product it sells or manufactures. Using this reasoning, an NDA-holder could be held liable to the consumers of the corresponding generic product for failure to warn (regardless of which company manufactured the drug), simply because it had the power to change the label and chose not to do so. As the Court has repeatedly found, a "threshold requirement of any products-liability claim is that the plaintiff assert that the defendant's product caused the plaintiff's injury." *Smith v. Wyeth*, 657 F.3d 420, 423 (6th Cir. 2011). It may well be that courts in the post-*Mensing* era will decide to expand the scope of liability for brand-name manufacturers to compensate for plaintiffs' inability to recover from generic manufacturers. But it is not the place of this Court to announce a new rule of law, particularly one with such far-reaching ramifications. The plaintiffs have pointed to no case in which a brand-name drug company was held liable to a plaintiff who ingested a generic drug on the theory that the brand-name defendant has a duty to warn because it alone is responsible for the contents of the drug's label. Thus, the Court declines to extend the duty to warn to Lilly in *Chavez*.

IV.

The plaintiffs have failed to demonstrate that Lilly should be held liable as a generic manufacturer for claims that have been dismissed against other generic defendants. In its capacity as a contract manufacturer for Mylan Pharmaceuticals, Inc., Lilly had no power to change the formula or labels of the generic products it supplied. To hold it liable, the Court would have to find that Lilly owed the plaintiffs a duty to change the label as a brand-name defendant and that its failure to do so rendered it liable as a generic manufacturer. The Court refuses to adopt the line of reasoning that would render Lilly liable under these circumstances. Therefore, the claims against Lilly in its capacity as a generic manufacturer will be dismissed. Accordingly, and for the reasons outlined in the Memorandum Opinions and Orders filed on March 5 and 7, 2012 [MDL Record Nos. 1305, 1402], it is hereby

ORDERED as follows:

1. Defendant Eli Lilly and Company's Second Master Motion for Judgment on the Pleadings [MDL Record No. 1537] is **GRANTED**.

2. The claims asserted by the plaintiffs against Defendant Eli Lilly and Company in the above-captioned cases are **DISMISSED**, with prejudice.

This 31st day of July, 2012.

Signed By:
Danny C. Reeves DCR
United States District Judge