Delivering expert knowledge to global counsel

International Law Office®

Product Liability - USA

Developments in federal pre-emption after *PLIVA v Mensing*

Contributed by **Arnold & Porter LLP**

August 30 2012

Authors

M Sean Laane

Kevin A Cline

Over the last eight months a number of courts have been called upon to interpret and apply the US Supreme Court's holding in *PLIVA, Inc v Mensing*(1) that federal pre-emption bars failure-to-warn claims against a generic drug manufacturer whose labelling mirrors the Food and Drug Administration (FDA) approved labelling for the brand-name counterpart of the generic product.

While the law on the scope of *Mensing* will no doubt continue to evolve, three themes have emerged in the decisions to date:

- Most courts have held that as long as the generic manufacturer scrupulously complies with its regulatory obligation to replicate the brand-name labelling, *Mensing* provides a broad shield against failure-to-warn claims and similar causes of action that are founded on an alleged deficiency in the drug's labelling.
- Any deviation from the approved brand-name labelling – including a failure to implement timely labelling updates when the brand-name label is changed – may open the door to failure-to-warn claims, provided that the plaintiff can plead and prove a causal link between the alleged deviation or delay and the injury.
- *Mensing* has created an incentive for plaintiffs who have allegedly been injured by the use of a generic drug with deficient warnings to attempt to impose liability on the manufacturer of the counterpart brand-name drug.

In *Mensing* the court consolidated two cases originating in the Fifth and Eighth Circuits against generic manufacturers of the prescription drug metoclopramide. Both circuit courts had held that federal law did not pre-empt state law failure-to-warn claims against generic drug manufacturers. In a five-to-four decision, the Supreme Court reversed, finding it "impossible" for manufacturers of generic drugs to comply with state law duties to strengthen generic drug labels without violating federal drug labelling laws.(2) These laws require generic labels to be "the same as" the labelling approved for their brand-name counterpart.(3) Thus, the court specifically rejected the plaintiffs' arguments that generic drug manufacturers could unilaterally strengthen their labelling, either through the FDA's 'changes-being-effected' process or through issuing 'Dear Doctor' letters to healthcare professionals.(4) As FDA regulations prohibit generic manufacturers from altering their product labelling except to match an updated brand-name label, the court held that federal law pre-empts state law failure-to-warn claims.(5)

Mensing's practical effect is that generic drug manufacturers which comply with the federal requirement that their labelling mirror that of the brand-name counterpart cannot be found liable under state tort law for failure to warn. Following *Mensing*, the vast majority of federal and state courts to have addressed the issue have dismissed failure-to-warn claims against generic drug companies.(6) Significantly, many of these courts have also dismissed plaintiffs' common-law claims for negligence, breach of implied and express warranty, fraud, design defect and consumer protection violations, finding the gravamen of such claims to be rooted in allegations of failure to warn.(7)

However, plaintiffs are unlikely simply to abandon product claims when they are allegedly injured by generic drugs. Indeed, they are already seeking ways to distinguish *Mensing* - with some success - based principally on two theories.

First, plaintiffs have had some success in arguing that *Mensing* does not pre-empt claims that rest on allegations that the generic manufacturer failed to update its labelling in a timely manner after new FDA-approved warnings were added to the brand-name labelling. For example, in *Fisher v Pelstring, MD* the US District Court for the District of South Carolina held that a deviation between the generic and brand-name labelling following a brand-name label revision precludes a finding of pre-emption under *Mensing*.(8) Federal district courts in Louisiana,(9) Vermont(10) and North Carolina (11) have recently reached the same conclusion, finding that such failure-to-update

claims are not pre-empted under *Mensing*.

The second pre-emption exception recognised by some courts arises where the generic company allegedly failed to issue a 'Dear Doctor' letter advising of changes to the brand-name label. For example, the US District Court for the Southern District of Alabama held in *Brasley-Thrash v Teva Pharmaceutical USA, Inc* that *Mensing* did not pre-empt claims that a generic defendant had failed to send a letter in a timely manner after FDA approved a labelling change for the brand-name equivalent.(12) Although federal law does not permit generic manufacturers to issue letters that contain additional warnings different from brand-name labelling, the *Brasley-Thrash* court found no prohibition against letters that simply reiterate warnings already contained in the approved label.(13) Therefore, the court found that *Mensing* does not pre-empt claims that a defendant failed to send a letter that was "consistent with and not contrary to" brand-name labelling.(14) Two separate Nevada state court judges,(15) as well as the state court overseeing the Reglan®/metoclopramide Pennsylvania mass tort litigation, (16) have reached the same conclusion. Thus, while *Mensing* generally provides generic manufacturers with broad protection from warnings-based claims, that protection may be lost if the manufacturer neglects to track and the brand-name manufacturer's evolving warnings and convey them in a timely manner.

However, plaintiffs must do more than identify a technical violation of the generic manufacturer's requirement to replicate the name-brand warnings. Even where a manufacturer arguably should have more promptly updated the labelling or issued a letter, the plaintiff must sufficiently plead and prove a nexus between the deficient labelling and the alleged injury – including the elements of causation and (where applicable) reliance. For example, in *Lyman v Pfizer, Inc* the court held that although *Mensing* did not pre-empt a claim that the generic defendant failed to update its label in a timely manner to match the brand-name label, the plaintiffs failed to plead sufficient facts under *Ashcroft v Iqbal* regarding the defendants' conduct.(17) Similarly, the federal multi-district litigation court overseeing *In re: Darvocet, Darvon* and *Propoxyphene* recently dismissed the plaintiffs' failure-to-update claims for failing to satisfy basic pleading requirements. Assuming that such claims were not pre-empted, the court found that the complaints did not explain, among other things, why the alleged failure to update was unreasonable or how it had injured the plaintiffs.(18) Other courts have reached similar conclusions.(19) Accordingly, even where a claim is not pre-empted by *Mensing*, defendant generic manufacturers should carefully evaluate all other potential defences, including *Iqbal*'s pleading requirements.

In addition to attempting to circumvent *Mensing* in pursuing claims against generic manufacturers, some plaintiffs also likely will seek to extend liability for alleged generic-drug-related injuries to brand-name manufacturers, invoking the 2009 California Court of Appeals decision in *Conte v Wyeth*.(20) *Conte* held a brand-name drug manufacturer liable for injuries caused by the generic equivalent because the prescribing physician purportedly relied on the brand-name product's labelling when prescribing the generic drug. Although most courts have rejected this theory as stretching the foreseeability doctrine too far,(21) two federal district courts have similarly held that a brand-name manufacturer may be liable even where the plaintiff ingested only the generic equivalent.(22) Although both cases pre-date *Mensing*, plaintiffs have a strong incentive to continue to pursue such theories in light of the 'divergent liability rules' that *Mensing* created.(23) Brand-name manufacturers will appropriately resist any such theories, which would, among other things, subvert established requirements for proving product identification and proximate causation.(24)

Ultimately, as recognised by Justice Thomas: "Congress and the FDA retain the authority to change the law and regulations if they so desire."(25) Unless and until that occurs, generic manufacturers would be wise to minimise their risk exposure by promptly updating their products' labelling following any changes to the labelling of brand-name equivalents.

For further information on this topic please contact Sean Laane or Kevin Cline at Arnold Porter LLP by telephone(+1 202 942 5000), fax (+1 202 942 5999) or email (sean.laane@aporter.com or kevin.cline@aporter.com).

Endnotes

(1) 131 S Ct 2567 (2011).

(2) *Id,* at 2578.

(3) *Id,* at 2574.

(4) *Id,* at 2575-76.

(5) *Id,* at 2575, 2581.

(6) See, for example, *In re Darvocet, Darvon and Propoxyphene Products Liability Litig*, 2012 WL 718618, at 1 (ED Ky, March 5 2011); *Bell v PLIVA, Inc*, --- F Supp 2d ---, 2012 WL 640742, at 1 (ED Ark, February 16 2012); *Kellogg v Wyeth*, 2012 WL 368658, at 1 (D

Vt, February 3 2012); *In re Pamidronate Products Liability Litig*, --- F Supp 2d ---, 2012 WL 272889, at 1 (EDNY, January 30 2012); *Coney v Mylan Pharmaceuticals Inc*, 2012 WL 170143, at 1 (SD Ga, January 19 2012); *Moore v Mylan Inc*, --- F Supp 2d ---, 2012 WL 123986, at 1 (ND Ga, January 5 2012); *Grinage v Mylan Pharmaceuticals, Inc*, --- F Supp 2d ---, 2011 WL 6951962, at 1 (D Md, December 30 2011); *Del Valle v PLIVA*, Inc, 2011 WL 7168620, at 1 (SD Tex, December 21 2011); *Fullington v PLIVA, Inc*, 2011 WL 6153608, at 1 (ED Ark, December 12 2011); *Whitener v PLIVA, Inc*, 2011 WL 6056546, at 1 (ED La, December 6 2011); *Gross v Pfizer Inc*, --- F Supp 2d ---, 2011 WL 5865267, at 1 (D Md, November 22 2011); *In re Fosamax Products Liability Litig*, 2011 WL 5903623, at 1 (DNJ, November 21 2011); *In re Accutane Products Liability Litig*, 2011 WL 6224546, at 1 (MD Fl, November 9 2011); *Guarino v Wyeth LLC*, --- F Supp 2d ---, 2011 WL 5358709, at 1 (MD Fl, November 7 2011); *Metz v Wyeth LLC*, 2011 WL 502448, at 1 (MD Fl, October 20 2011); *Morris v Wyeth, Inc*, 2011 WL 4973839, at 1 (WD La, October 19 2011); *Beck v Teva Pharmaceutical Industries Ltd*, 2011 WL 4062219, at 1 (ED La, September 13 2011); *Henderson v Sun Pharmaceuticals Industries, Ltd*, --- F Supp 2d ---, 2011 WL 4015658, at 1 (ND Ga, August 22 2011); *Huck v Trimark Physicians Group*, 2012 WL 553492, at 1 (Iowa Dist Ct, Sac Cty, January 5 2012); *Stevens v Community Health Care, Inc*, 2011 WL 6379298, at 1 (Mass Sup Ct, Essex Cty, October 5 2011).

(7) See, for example, *In re Darvocet*, 2012 WL 718618, at 3-5; *Bell*, 2012 WL 640742, at 4; *In re Pamidronate*, 2012 WL 272889, at 3-4; *Grinage*, 2011 WL 6951962, at 4-8; *Guarino*, 2011 WL 5358709, at 3; *In re Fosamax*, 2011 WL 5903623, at 5-9; *Metz*, 2011 WL 502448, at 3-4.

(8) --- F Supp 2d ---, 2011 WL 4552464, at 3 (DSC, September 30 2011).

(9) *Cooper v Wyeth, Inc*, 2012 WL 733846, at 3-4 (MD La, March 6 2012).

(10) *Lyman v Pfizer, Inc*, 2012 WL 368675, at 5-6 (D Vt, February 3 2012).

(11) *Couick v Wyeth, Inc*, 2012 WL 79670, at 4-5 (WDNC, January 11 2012).

(12) 2011 WL 4025734, at 1 (SD Ala, September 12 2011).

(13) *Id* at 2 n1.

(14) *Id* at 3; see also *Cooper*, 2012 WL 733846, at 4.

(15) *Hutchison v Endoscopy Center of Southern Nevada, LLC*, 2011 WL 6688744, at 1 (Nev Dist Ct, Clark Cty, October 5 2011) (Wiese, J); *Keck v Endoscopy Center of Southern Nevada, LLC*, 2011 WL 3921690, at 1 (Nev Dist Ct, Clark Cty, August 19 2011) (Wiese, J); *Sacks v Endoscopy Center of Southern Nevada, LLC*, 2011 WL 4915174, at 1 (Nev Dist Ct, Clark Cty, July 28 2011) (Israel, J). The Nevada court also held that *Mensing* did not pre-empt claims other than failure-to-warn, such as design defect and breach of implied warranty of fitness.

(16) *Hutchison*, 2011 WL 6688744, at 1; *Sacks*, 2011 WL 4915174, at 1.

(17) *In re Reglan/Metoclopramide Litig*, 2011 WL 6259558, at 1 (Pa Ct Comm Pls, Phil Cty, November 18 2011). *Lyman*, 2012 WL 368675, at 6.

(18) *In re Darvocet*, 2012 WL 718618, at 4.

(19) *Coney*, 2012 WL 170143, at 4-5; *Del Valle*, 2011 WL 7168620, at 7-9; *Fullington*, 2011 WL 6153608, at 6; *Metz*, 2011 WL 5024448, at 2, n3.

(20) 85 Cal Rptr 3d 299 (Cal Ct App 2009).

(21) See, for example, *Metz v Wyeth LLC*, --- F Supp 2d ---, 2011 WL 5826005, at 1 (November 18 2011); *Morris v Wyeth, Inc*, 2011 WL 4975317, at 1 (WD La, October 19 2011); *Gross v Pfizer, Inc*, 2010 WL 4485774, at 2-3 (D Md Nov 09 2010); *Finnicum v Wyeth, Inc*, 708 FSupp2d 616, 621 (ED Tex, 2010); *Fullington v Pfizer, Inc*, 2010 WL 3632747, at 2 (ED Ark, September 7 2010); *Phelps v Wyeth, Inc*, 2010 WL 2553619, at 2-3 (D Or, May 28 2010); *Moretti v Wyeth, Inc*, 2009 WL 749532, at 4 (DNev, March 20 2009); *Dietrich v Wyeth, Inc*, 2009 WL 4924722, at 1 (Fl Cir Ct, Palm Beach Cty, December 21 2009).

(22) See *Weeks v Wyeth*, 2011 WL 1216501, at 5-6 (MD Ala, March 31 2011); *Kellogg v Wyeth*, 762 F Supp 2d 694 (D Vt, 2010).

(23) *Mensing*, 131 S Ct, at 2593 (Sotomayor, J, dissenting).

(24) See, for example, *Foster v American Home Products Corp*, 29 F3d 165, 168 (4th Cir 1994) (holding that Maryland law does not permit liability against a brand-name pharmaceutical manufacturer when plaintiff only ingested generic version); *Metz*, 2011 WL 5826005, at 1 (same under Florida law); Morris, 2011 WL 4975317, at 1 (same under Louisiana law); *Finnicum*, 708 FSupp2d at 621 (same under Texas law).

(25) *Mensing*, at 2582 (Thomas, J, concurring).