# *Mensing* and *Demahy* and a dilemma for the US Supreme Court

By *Kimberly Martin* and *Lindsey Boney*

Pharmaceutical companies are waiting on pins and needles to see whether the US Supreme Court will deliver yet another blockbuster decision on pre-emption after it hears the consolidated cases of *Mensing* and *Demahy*[1].

Of all the topics that the court has considered in recent years, none has been more intriguing and difficult to predict than pre-emption and whether or not federal regulations shield drug makers from state law claims. In each of its past three terms, the court has released at least one landmark decision on the matter.

In *Mensing* and *Demahy*, the court will decide whether states can hold generics manufacturers liable for failing to provide warnings not required of their branded counterparts by the Food and Drug Administration. Its ruling could have far-reaching implications for the way in which pharmaceutical manufacturers – whether they are generics or branded firms – conduct their business. Arguments are expected to be heard on 30 March.

Both *Mensing* and *Demahy* involve failure-to-warn claims asserted against drug manufacturers over injuries allegedly caused by the heartburn drug Reglan and its generic equivalent, metoclopramide. Both the Fifth and Eighth Circuit Courts of Appeals concluded that the state-law claims against the generics manufacturers were not pre-empted by federal law because the generics firms could have at least proposed label changes to the FDA[2].

It is intriguing that the Supreme Court decided to hear these consolidated cases at all. *Mensing* and *Demahy* are the only circuit court-level decisions on the question. Both decisions reached the same conclusion, and US district courts have consistently followed their reasoning. Moreover, the Supreme Court decided to hear *Mensing* and *Demahy* against the recommendation of the Solicitor General, who argued that generics manufacturers are obligated to provide the FDA with new information about labelling concerns.

In *Mensing* and *Demahy*, two of the petitioners, generics manufacturers Actavis Inc and Actavis Elizabeth LLC, have filed their brief and are arguing to the Supreme Court that the circuit courts misread federal regulations to reach a logically flawed conclusion about the duty of generics manufacturers. These regulations, they say, make it impossible for generic drug manufacturers to comply with state-law duties to warn and the requirements of the Hatch-Waxman Act. They argue that Hatch-Waxman, which provides a streamlined approval process for generic drugs once the brand patents have expired, only applies if the "product is a copy of the brand in every significant respect, including its labeling"[3]. This requirement means that generics must have the same labelling as their branded equivalent at all times[4]. And if generics must always have the same label as their branded equivalent, generics manufacturers are unable to comply with different warning standards under state law.

The conclusion of the circuit courts – that generics have the authority (and a duty) to at least suggest label changes – need not be true, the generics manufacturers say, because although they do have a duty to comply with FDA labelling regulations, that duty is cabined. Only labelling changes that conform a generic's label to its brand equivalent are permissible and, in fact, if the generic product deviates from its branded counterpart in any way, including in its labelling, the FDA has the power to withdraw approval.

The Supreme Court faces a dilemma in *Mensing* and *Demahy*. If it accepts generic pre-emption, branded manufacturers will likely see a rise in the theory of innovator liability – ie where the innovator is liable for injuries caused by another company's generic version[5]. To date, courts have soundly rejected the innovator liability theory; *Conte v Wyeth* stands alone against 52 decisions in 22 states that have rejected the theory[6].

In *Demahy*, the Fifth Circuit reasoned that if it applied generic pre-emption, then it must conclude that[7]: "Congress intended the name brand drug manufacturer to bear the sole burden of coping with incipient risks… and… that Congress intended either that the name brand manufacturer be liable for all failure-to-warn claims – even those arising out of the use of generic substitutes – or, that the injured plaintiff be left with no remedy." Faced with the alternative of providing plaintiffs no avenue of relief, courts may hold innovators liable for all pharmaceutical injuries, a development that could stunt the development of new drugs. Branded manufacturers would potentially face open-ended liability for as long as any generic version of its original product was manufactured.

Alternatively, if the Supreme Court rejects the generic pre-emption argument, generics manufacturers will be required to conduct appropriate pharmacovigilance to ensure their labels are "revised… as soon as there is reasonable evidence of an association of a serious hazard with a drug"[8]. It is unclear what scope of pharmacovigilance would be required. Both the Fifth and Eighth Circuits have said generics manufacturers are not required to conduct post-market clinical trials to justify label changes, but those courts suggest that the burden would at least include sending "Dear Doctor" letters in the event new problems arise[9]. To date, generics manufacturers have argued that performing this post-marketing pharmacovigilance will create an undue burden and drive up the ultimate cost of generic drugs for consumers.

However, the news would not be all bad for generics firms if the court rejects the petitioners' argument in *Mensing* and *Demahy*. A recent decision from the Seventh Circuit Court of Appeals suggests that, under the Supreme Court's decision in *Wyeth v Levine*, which rejected pre-emption for drug manufacturers, the FDA's failure to accept a warning suggested by a manufacturer would shield that manufacturer from state-law failure-to-warn claims[10].

In all, it would be surprising if the Supreme Court were to decide to reverse all existing circuit court precedent and the views of the Solicitor General by accepting generic pre-emption. Given the vagaries of the court's implied pre-emption jurisprudence, however, no decision can be too surprising. One thing is certain: *Mensing* and *Demahy* look set to have profound effects on the pharmaceutical industry.

**References**


1. *US Supreme Court, Writ of Certiorari for Pliva v Mensing, Actavis Elizabeth v Mensing and Actavis v Demahy, 10 December 2010, www.supremecourt.gov/orders/courtorders/121010zr.pdf*
2. *Demahy v Actavis Inc, 593 F.3d 428, 446-48 (5th Cir 2010); Mensing v Wyeth Inc, 588 F.3d 603, 608 (8th Cir 2009)*
3. *Brief of petitioner at 6*
4. *21 USC § 355(j)(2)(A)(v); 21 CFR § 314.94(a)(8)(iii)*
5. *Martin KB and McGahey JJ, A Novel Theory for Innovator Liability, Regulatory Affairs Pharma, 20 December 2010*
6. *Conte v Wyeth, Inc, 85 Cal Rptr 3d 299 (Cal Ct App 2008); Kellogg v Wyeth, No 2:07-cv-82 (D Vt Oct 20, 2010); Scorecard: Non-Manufacturer, Name-Brand Defendants In Generic Drug Cases, Drug and Device Law Blog, http://druganddevicelaw.blogspot.com/search/label/Scorecards*
7. *Demahy, 593 F.3d at 447*
8. *Ibid at 437 (quoting 21 CFR § 201.80(e))*
9. *Demahy, 593 F.3d at 448; Mensing, 588 F.3d at 611*
10. *Robinson v McNeil Consumer Healthcare, 615 F.3d 861 (7th Cir 2010)*


**Kimberly Martin** is a partner at US law firm Bradley Arant Boult Cummings, based in Huntsville, Alabama. **Lindsey C Boney IV** is an associate based at the firm's Birmingham office.