A Novel Theory for Innovator Liability

Kimberly Bessiere Martin and *Jennifer J McGahey* examine whether California's decision in *Conte v Wyeth* – where the innovator is liable for injuries caused by another company's generic version – may be applied in other jurisdictions.

While the courts of California have a history of creating new theories of liability that are then adopted by other jurisdictions in the US[1], attempts to extend a novel theory of liability that came out of the state's Court of Appeals decision in *Conte v Wyeth*[2,3] have failed to date.

California's liability theories have a history of being adopted by other US jurisdictions

Under this theory, termed innovator liability, plaintiffs argue that brand name manufacturers of pharmaceuticals owe a duty to convey accurate prescribing information about a pharmaceutical's risk and benefits to patients who only ingested a generic version of the medication. Prior to *Conte*, this argument had been made in other cases, but the majority of courts considering the issue had rejected it. The California court's November 2008 ruling, however, gained enough support to allow the case to proceed to a jury. By recognising the innovator liability theory, the *Conte* decision was thought to signal a potential shift in the legal landscape. This article reviews the *Conte* decision and whether it has the potential to extend the innovator liability theory to other jurisdictions in the future.

Generic labelling

To understand the *Conte* decision, it is important to understand the regulatory scheme applicable to generic labelling. Though the branded pharmaceutical manufacturer must submit to the Food and Drug Administration a new drug application that must be supported by extensive studies of the drug's safety and effectiveness, a generic manufacturer's abbreviated new drug application only requires a certification that the generic product is a bioequivalent of the brand name drug and that the labelling and warnings for the generic drug are identical to those for the approved brand name medication. Thus, generic pharmaceutical labelling is identical in most respects to the branded labelling. (In fact, when product liability claims are made against a generic manufacturer, it often asserts that its labelling must be identical to a branded manufacturer's labelling, and as a result, it cannot be liable for claims relating to it[4].)

Under the innovator liability theory, brand name companies are liable for injuries allegedly caused by a generic

As a result, under the innovator liability theory, plaintiffs have argued that brand name manufacturers are liable for injuries allegedly caused by a generic pharmaceutical because it is foreseeable to a branded manufacturer that its prescribing information may be relied upon in prescribing generic medication, particularly when many states have statutes that authorise pharmacists to fill prescriptions for brand name drugs with their generic equivalents. The majority of courts considering this argument prior to *Conte*, however, held that imposing such a duty on branded manufacturers was a stretch of existing products liability law and rejected the theory[5].

The pre-*Conte* days

In rejecting the innovator liability theory, most courts have held that such claims were an attempt to circumvent the traditional principles of product liability law, which require an injury by a product manufactured or placed in the stream of commerce by the defendant. To the extent that plaintiffs attempted to couch their claims under a theory of negligent misrepresentation, pre-*Conte* courts found that imposing liability under such a scenario stretched the traditional negligence concept of foreseeability too far.

Before the Conte decision, this theory was rejected by the courts

Most courts dismissing this theory pre-*Conte* followed the opinion of the US Court of Appeals for the Fourth Circuit in *Foster v American Home Products*, which is viewed as the seminal case rejecting innovator liability. In *Foster*, the plaintiffs' infant daughter was prescribed Phenergan (promethazine), which was manufactured by Wyeth. The pharmacy, however, substituted a generic equivalent. The plaintiffs alleged that their daughter died as a result of consuming the generic medicine. The plaintiffs argued that "because generic drugs are required by federal law to be equivalent to their name brand counterparts", Wyeth was ultimately responsible for representations or omissions on the generic manufacturer's label.

The court rejected the argument that a generic manufacturer is not responsible for misrepresentations on its own labelling since it merely copies the brand name manufacturer's labelling. "[A]s an expert, a manufacturer of generic products is responsible for the accuracy of labels placed on its products." In reaching this conclusion, the court deemed significant the generic manufacturer's ability to alter its own labelling. Furthermore, the court found no legal authority for holding one manufacturer liable for injuries arising out of the use of another manufacturer's product.

Kimberly Bessiere Martin and **Jennifer J McGahey** are partners at US law firm Bradley Arant Boult Cummings, based in the Huntsville, Alabama, and Birmingham, Alabama, offices, respectively. Contact email: kmartin@babc.com.

The plaintiffs argued that a duty existed because it was foreseeable to Wyeth that misrepresentations concerning Phenergan could result in personal injury to users of a generic equivalent. The court disagreed: "We think to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far." This analysis of the theory of innovator liability was followed by the majority of courts until the decision of the California Court of Appeals in *Conte*.

The *Conte* decision

In Conte, the plaintiff sued Wyeth and the generics manufacturers after taking the generic version of Reglan

In *Conte*, the plaintiff sued Wyeth, the brand name manufacturer and innovator of Reglan (metoclopramide), as well as manufacturers of the generic version for injuries she suffered after taking the generic version. It was undisputed that Ms Conte ingested the generic version only. She claimed that the manufacturers disseminated false, misleading and/or incomplete warnings about the medication's side effects. The trial court dismissed the claims against Wyeth on the grounds that neither the plaintiff nor her doctor relied on the drug information disseminated by Wyeth and that Wyeth owed no duty of care to the users of generic versions of Reglan. Ms Conte appealed.

The appellate court examined the trial court's decision as to Wyeth. First, the appellate court found that although Wyeth contended that Ms Conte's physician did not rely on information disseminated by it, there was sufficient evidence for a jury to consider whether Wyeth's prescribing labelling was a causal factor in the physician's decision to prescribe metoclopramide. The court then held[6]: "Wyeth's duty of care in disseminating product information extends to those patients who are injured by generic metoclopramide as a result of prescriptions written in reliance on Wyeth's product information for Reglan."

The court acknowledged that its position was contrary to the majority of courts that had been presented with this issue, but based its decision in large part on its finding that it was foreseeable that people taking generic metoclopramide could be injured by their reliance on Wyeth's product information: "The fact that Wyeth did not manufacture or sell the metoclopramide *Conte* ingested does not relieve Wyeth from its general duty to use due care in disseminating product information to those it knows or should know are likely to be harmed as a result of their physician's reliance on that information." The California Supreme Court declined to hear Wyeth's case.

The California court did not view itself as marking out new territory

In reaching this decision, the California court did not view itself as "marking out new territory" by recognising this duty on the part of branded manufacturers and stated that where a manufacturer "authors and disseminates information about a product manufactured and sold by another, it may be liable for negligent misrepresentation where the [manufacturer] should reasonably expect others to rely on that information and the product causes injury."

Extending *Conte* to other jurisdictions

When the California Supreme Court declined to review the *Conte* decision, it was anticipated that the innovator liability theory might gain acceptance in more jurisdictions. Indeed, *Conte* certainly emboldened the plaintiffs' bar as pharmaceutical products liability lawyers increasingly asserted the innovator liability theory of recovery.

Thus far, however, the reported rulings indicate that all attempts to extend the theory beyond California have failed. Courts confronting the innovator liability argument since the *Conte* ruling have found *Conte* to be anomalous – a non-binding, rogue decision that is contrary to the laws of their respective states[7]. The post-*Conte* opinions rejecting the innovator liability theory include the US Court of Appeals for the Eighth Circuit, which held "[w]hatever the merits of *Conte* under California law", it was inapplicable under Minnesota law[8]. While the decisions of California courts often result in the expansion of legal theories in other jurisdictions, the innovator liability theory does not appear to be one of those areas. While not specifically discussing the Conte decision, other courts continue to reject the innovator liability theory. As such, this theory, for now, appears to have limited applicability in the courts of California only[9].

All attempts to extend the theory beyond California have failed

References

1. See, eg, *Greenman v Yuba Power Products, Inc.*, 377 P.2d 897 (Cal. 1963)
2. 168 Cal. App. 4th 89 (Cal. Ct. App. 7 Nov 2008)
3. US ruling means originator drug companies may be liable for damages caused by generics, *RAJ Pharma* online, 16 April 2009
4. See, eg, *Mensing v Wyeth*, 588 F.3d 603 (8th Cir. 2009)
5. See, eg, *Foster v Am. Home Prods. Corp.*, 29 F.3d 165 (4th Cir. 1994) (applying Maryland law)
6. *Conte*, 168 Cal. App. 4th at 107
7. See, eg, *Mensing v Wyeth, Inc.*, 588 F.3d 603, 613-14 (8th Cir. 2009); *Finnicum v Wyeth, Inc.*, --- F.Supp. 2d ----, 2010 WL 1718204 (E.D.Tex. 28 April 2010); *Hardy v Wyeth, Inc.*, No 9:09-cv-152, 2010 WL 1049588, at *2-*5 (E.D.Tex. 8 March 2010) (report and recommendation); *Howe v Wyeth, Inc.*, No 8:09-cv-610, 2010 WL 1708857, at *3 (M.D.Fla. 26 April 2010)
8. *Mensing*, 588 F.3d at 613-4
9. See, eg, *Couick v Wyeth, Inc.*, --- F.Supp. 2d ----, 2010 WL 785952, at *2-*3 (W.D.N.C. 8 March 2010)

