Client Alert

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"Brand" New Law: Illinois Court Holds Brand Manufacturers Owe Duty of Care to Generic Users

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Last week, a federal district court in Illinois held that GlaxoSmithKline (GSK), a branded drug manufacturer, owed a duty of care to a patient who took the generic version of its drug. *Dolin v. SmithKline Beecham Corp.*, No. 1:12-cv-06403, slip op. (N.D. Ill. Feb. 28, 2014). This holding is a surprising deviation from the current trend, as most courts have held that "innovator liability" does not apply where plaintiff claimed injury from taking the generic product.

BACKGROUND

The plaintiff, Wendy Dolin, is the widow of Stewart Dolin, who was an M&A partner at Reed Smith at the time of his death. Mr. Dolin was prescribed Paxil in 2010 for work-related anxiety and depression and, under Illinois' substitution law, his prescription was ultimately filled with generic paroxetine manufactured by Mylan. Six days after he began to take paroxetine, Mr. Dolin died after jumping in front of a train in Chicago.

Mrs. Dolin brought suit alleging that the paroxetine caused akathisia, a condition characterized by agitation and restlessness, and that akathisia is associated with suicidal behavior. She further alleged that GSK failed to warn that paroxetine was associated with an increased risk of suicide in adults. In fact, the complaint alleged egregious conduct—specifically, that GSK manipulated adverse event data in clinical trials. Plaintiff alleged that in comparing suicidal behavior among paroxetine, a placebo, or a comparator drug, GSK counted suicide attempts in placebo patients that occurred prior to the clinical trial.

Plaintiff brought claims for negligence and negligent misrepresentation, as well as product liability claims under theories of negligence and strict liability. The court denied GSK's motion for summary judgment on all counts except strict product liability.

THE COURT'S REASONING

The court evaluated at great length whether plaintiff's claim was common law negligence or a product liability claim as argued by GSK. The answer lay in the state's product liability law. While some states provide for exclusive remedies for injuries caused by the design or warning of a product to product liability actions against a party in the chain of distribution, Illinois law has no such limitation. The court saw "no reason why all suits brought against GSK must be brought against GSK *qua* manufacturer." Instead, GSK was responsible for the ***design and warning label*** of not just Paxil, but also paroxetine.

Concluding that the negligence claims need not be classified as product liability, the court considered whether those claims could survive summary judgment. The court's analysis focused on the duty prong of a negligence cause of action. While the majority of courts to decide this issue have found that brand manufacturers do not owe a duty of care to those who ingest a generic drug, the *Dolin* court examined the issue under Illinois law, under which the duty exists if "a plaintiff and a defendant stood in such a relationship to one another that the law imposed on the defendant an obligation of reasonable conduct for the benefit of the plaintiff." The "relationship" is determined by looking at four factors: (1) the

reasonable foreseeability of the injury; (2) the likelihood of the injury; (3) the magnitude of the burden of guarding against the injury; and (4) the consequences of placing that burden on the defendant."

Examining each of these fours factors in turn, the court first decided that Mr. Dolin's injury was reasonably foreseeable. Under Hatch-Waxman, "it was well understood that any generic manufacturer would be required by law to use GSK's design and warning label," which is similar to reasoning used by the few courts that have found brand manufacturers owe a duty to those who take generic drugs. *See*, *e.g.*, *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89 (2008); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010); *Wyeth, Inc. v. Weeks*, No. 1101397, 2013 WL 135753 (Ala. Jan. 11, 2013), reargument granted (June 13, 2013).[1] Importantly, the court also noted "that any defects later discovered could only be cured by GSK" which, though not necessarily related to foreseeability, further supports the finding that GSK owed a duty to plaintiff. For the same reasons the court found the likelihood of injury was not "so remote as to undo GSK's duty of care."

As to the third and fourth prongs, the court found that guarding against the alleged injury "could be as simple as updating the warning label," and that GSK would face no additional burden in doing so because GSK was already obligated to update the label for Paxil.

Taken together, these four factors led the court to conclude that the parties' relationship, while not "direct," was sufficient to impose a duty of care on GSK. Because plaintiff alleged that GSK breached the duty by using scientifically questionable methods, the court found there was a genuine issue of material fact as to whether GSK's negligence proximately caused Mr. Dolin's injuries.

REJECTING GSK'S COUNTER-ARGUMENTS

The court next disposed of GSK's argument that it could not be liable as a matter of law because it did not manufacture the drug that was ingested. Emphasizing that "GSK has offered no reason why it should be held liable only for those injuries caused by its negligence as a ***manufacturer***" (emphasis added), the court reiterated its finding that no legal theory barred recovery if GSK had been negligent in designing paroxetine and drafting its label.

GSK also argued that it could not be liable because under Illinois product liability law, "it is axiomatic that a plaintiff must show that the defendant's product actually caused the alleged injuries." The court rejected this argument, highlighting two flaws. First, plaintiff's claims did not need to be limited to product liability law—GSK could be found liable under common law negligence.

Second, and more interestingly, the court pointed out that the argument "conflates two facially similar, but fundamentally distinct, tort liability problems": (1) when plaintiff claims that someone other than the product manufacturer caused the injury and (2) the "indeterminate tortfeasor" problem—when plaintiff asserts that the manufacturer of the product caused the injury but plaintiff cannot identify the manufacturer because multiple companies made similar products. While Illinois courts have not allowed plaintiffs to proceed against an unidentified manufacturer in the latter situation, in the former situation (and the case at issue), the "negligence . . . is extrinsic to the [product] manufacturing process" and could proximately cause injury to any user of Paxil or paroxetine.

[1] For a discussion of *Weeks*, *see* "Weeks Defies Years of Jurisprudence, Allowing Innovator Liability for Generic Drugs," Morrison & Foerster Client Alert, Jan. 16, 2013, *available at* http://www.mofo.com/files/Uploads/Images/130116-Liability-for-Generic-Drugs.pdf.

DISTINGUISHING FOSTER

The *Dolin* court acknowledged that it was in the minority in rejecting GSK's argument. The majority of courts have followed *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994), which held that the drug manufacturer defendant could not be liable for injury caused by a product it did not make. The *Foster* court used a similar framework of analysis as the *Dolin* court but found that there was no "relationship" because the defendant did not manufacture the product.

However, the *Dolin* court criticized *Foster* for improperly "analyz[ing] the complaint as though it presented an indeterminate tortfeasor problem." The court agreed it was unfair to permit suit against ***any*** manufacturer where plaintiff simply cannot identify the ***actual*** manufacturer. But that was not the case here, where it was undisputed that Mylan manufactured Mr. Dolin's paroxetine. "[T]o suggest that the question actually raised here is simply whether GSK may be held liable for injuries caused by a product that Mylan manufactured is incomplete and misleading." Instead, the proper question is whether GSK could be liable for conduct "extrinsic to the manufacturing process and that contributed to Plaintiff's injury." Phrased this way, the court easily answered the question in the affirmative.

OTHER CLAIMS

Employing similar reasoning, the court found that plaintiff's claims for negligent misrepresentation and negligent product liability survived summary judgment. However, plaintiff could not prevail on her strict products liability claim because such strict liability required that the defendant be part of the distribution chain—which GSK was not.

IMPLICATIONS

Dolin is a setback for brand-name drug manufacturers that were enjoying a string of victories in generic pharmaceutical product liability cases. The last court to hold that brand manufacturers could be liable for injuries caused by generic drugs was the Alabama Supreme Court in *Weeks*. However, whether *Weeks*' holding will stand is uncertain, as it remains under reconsideration by the Alabama Supreme Court. As for *Dolin*, though its holding goes against the grain, it may have persuasive value if other courts begin to adopt its reasoning, which is distinct from *Foster*'s. Unless the ruling is certified for interlocutory appeal, the Seventh Circuit will not have an opportunity to address the issue until the case reaches final judgment. We will continue to monitor the "innovator liability" trend to see if this opinion influences the outcomes of similar cases and will keep you posted.

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