

# Third Circuit Splits with the Seventh Over Standing To Sue For Alleged Inefficient Design of Eye Drop Dispenser

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In a surprising decision and split with the Seventh Circuit, the Third Circuit recently held that plaintiffs have standing to sue for unfair trade practices under the theory that a manufacturer is obligated to optimize the number of eye drop doses in a container of a fixed volume, even if there is no alleged misrepresentation as to the number of doses in the product. *Cottrell v. Alcon Labs.*, 874 F.3d 154 (3d Cir. 2017). The Third Circuit suggested that claims based on such a theory may be addressed in a 12(b)(6) motion, or on preemption grounds, but that such grounds are separate from a standing analysis.

Plaintiffs in *Cottrell* alleged that defendants are manufacturers of FDA-approved eye drop medications for serious medical conditions such as glaucoma. According to the complaint, defendants deliberately designed and manufactured the tips of the droppers to dispense a dose of medication that exceeds the capacity of the eye and is expelled from the eye, thus conferring no benefit and possibly causing unwanted side effects. Plaintiffs alleged violations of consumer protection laws of New Jersey and five other states, seeking damages corresponding to the “wasted” portion of medication.

The U.S. District Court for the District of New Jersey dismissed the complaint for lack of standing under Article III of the U.S. Constitution, which the Supreme Court has held requires a plaintiff to have suffered (and at the pleading stage to have plausibly alleged) an injury in fact to a legally protected interest. The district court held that plaintiffs failed to allege such an injury because plaintiffs' pricing theory was too speculative, i.e., that it assumed (without support) that eye drop manufacturers price their medication solely based on the volume of fluid contained in the bottles, regardless of other factors. The district court also held that plaintiffs' theory of damages did not give rise to standing because consumer fraud claims under a benefit-of-the-bargain or out-of-pocket theory normally require allegations that the product at issue failed to perform as advertised or was somehow defective, which was not alleged here. The court noted that defendants' dispenser design was approved by the FDA and that defendants never promised a certain number of doses.

On appeal, a panel of the Third Circuit reversed in a 2-1 decision. The majority held that plaintiffs adequately alleged an injury in fact to a legally protected economic interest because they were allegedly forced to spend money on medication that was impossible for them to fully use due to defendants' business practices in alleged violation of state consumer protection statutes. The majority determined that the district court overcomplicated plaintiffs' pricing theory, which in the circuit court's view posited that a smaller drop size—with no other changes to the product's design or price—would provide more doses per bottle. (The dissent faulted as implausible the majority's assumption that therapies are priced by volume rather than by number of doses in light of contrary evidence).

The majority also criticized the lower court's treatment of plaintiffs' reimbursement theory as one sounding in fraud only. The majority concluded that the district court failed to appreciate that the state statutes asserted by plaintiffs provide legal protection against "unfair" business practices, not just fraudulent ones, and that plaintiffs' allegations satisfied the injury requirement. The court acknowledged that the Seventh Circuit had reached the opposite conclusion on similar allegations but opined that the Seventh Circuit improperly based its standing analysis on a finding that the complaint failed to state a cause of action on the merits, which the majority argued is a separate inquiry from whether plaintiffs claim an injury in fact to a legally protected interest.

The Third Circuit noted that the district court's reading of the asserted state consumer protection statutes could potentially provide a basis for dismissal under a 12(b)(6) motion, which the district court never reached. Nor did the trial court consider defendants' preemption arguments, having ruled on the issue of standing. It remains to be seen whether other circuits will follow the Third or Seventh Circuit's approach in subsequent cases, or whether the clear split between these Circuits will find its way to the Supreme Court. Watch this space for further developments on these issues.

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