Death by a Thousand Cuts

Ranbaxy Revisited: Rejecting the Performance-based Approach to No-injury Class Actions?

By Emmanuel Sanders

One of the basic principles of federal law is that under Article III, one must suffer an injury to have standing to sue. Therefore, when consumers purchase a drug, it performs as intended, and then they turn around and bring a class action against the manufacturer, "something is rotten in the state of [New Jersey]." W. Shakespeare, *Hamlet, Prince of Denmark*, act 1, scene 4, line 90. Yet "no-injury" class actions are increasingly common, and members of the plaintiffs' bar prepare to file class action lawsuits the moment that a recall of a prescription drug is announced.

A number of courts throughout the country, and especially the Third Circuit, have rejected these "no-injury" claims as an assault on Article III standing. These courts, adopting a "performance-based" theory of liability, require plaintiffs to satisfy Article III's injury-in-fact requirement by alleging either that (1) they were physically injured, or (2) the recalled drug failed to perform as intended.

Alarmingly, a recent decision in the District of New Jersey, *Fenwick v. Ranbaxy Pharmaceuticals, Inc.*, 353 F. Supp. 3d 315 (D.N.J. Nov. 13, 2018), appears to have abandoned this well-reasoned, performance-based approach. The decision has largely escaped critical review by the defense bar, because it was couched in an outward win for the defense. The U.S. District Court for the District of New Jersey denied class certification, holding that it was impossible to ascertain who would be in the class and that individualized issues predominated. *Id.* Although the denial of class certification in this case pleased defense counsel, defense attorneys cannot allow the *Ranbaxy* decision to lay the groundwork for the erosion of the performance-based approach to "no-injury" claims.

The Third Circuit has explicitly adopted a performance-based approach to "no-injury" claims. For instance, in *Koronthaly v. L'Oreal USA, Inc.*, the Third Circuit affirmed the dismissal of a consumer claim concerning lipstick purchased by a plaintiff containing trace amounts of lead. 374 F. App'x 257 (3d Cir. 2010). The Third Circuit explained that when a plaintiff alleged neither that a product failed to work for its intended purpose nor that it caused any adverse effects, the plaintiff failed to allege an injury in fact. *Id.* at 259.

Recently, in *Hubert v. Gen. Nutrition Corp.*, this performance-based approach was adopted in evaluating claims involving dietary supplements allegedly containing non-dietary ingredients; plaintiffs brought a purported class action against the manufacturer of the supplement. No. 2:15-CV-01391, 2017 WL 3971912, (W.D. Pa. Sept. 8, 2017). The court dismissed the plaintiffs' claims for lack of standing because the plaintiffs did not allege that they suffered adverse health consequences from consuming the supplements, or that the supplements failed to perform as advertised. *Id.*

While courts in the Third Circuit have not considered the performance-based approach to liability in cases involving prescription drugs, the approach was adopted in *Myers-Armstrong v. Actavis Totowa*, LLC, No. C 08-04741, 2009 WL 1082026 (N.D. Cal. Apr. 22, 2009), *aff'd*, 382 F. App'x 545 (9th Cir. 2010). In this instance, the U.S. District Court for the Northern District of California roundly rejected statutory "adulteration" as sufficient to confer Article III standing when a drug is recalled merely because of failure to comply with Current Good Manufacturing Practices (CGMP). The court explained that the fact that the medicine "was adulterated due to a lack of compliance with GMP [good manufacturing practice] requirements [was] not enough, without more, to state a claim." *Id.* at 4*. "There must be at least some physical manifestation such as physical harm," the court elaborated, "or a failure of the drug to work as intended, or a rational fear of future harm, none of which [were] alleged." *Id.*

The cases above stand for the proposition that to recover for injuries sustained in purchasing and using consumer products, such as prescription drugs, plaintiffs

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must meet a performance-based standard of liability. The product either must have (1) caused them harm or (2) failed to perform as intended. Yet in the face of the *Ranbaxy* case, the Third Circuit's approach to this issue may be in jeopardy.

In *Ranbaxy*, a manufacturer recalled multiple lots of its generic cholesterol medicine after employees noticed blue particles, glass from glass liners on machines used in the manufacturing process, in the raw material of a *different batch* of the drug. *Ranbaxy*, 353 F. Supp. 3d at 319.

The plaintiffs neither alleged physical injury nor that the drug failed to perform as intended. In fact, they did not even allege that the pills that *they* had purchased contained *any* contaminant, and even if they had, the U.S. Food and Drug Administration had advised that "the possibility of health problems related to the recalled product is *extremely low* and patients who have the recalled medicine *can continue taking it unless directed otherwise by their physician or health care provider*." *Id.* (internal citations and quotation marks omitted) (emphasis added). The court found that the named plaintiffs had suffered an injury in fact because, among other things, "batches of pills in recalled lots [] *could* have been contaminated." *Id.* at 322 (emphasis added). This is a clear retreat from the performance-based standard of liability articulated in *Koronthaly*, *Hubert,* and *Myers*, in which the courts determined that plaintiffs who suffered no physical injury and did not allege that the product that they purchased failed to perform as intended could not establish injury in fact under Article III.

Despite the fact that *Ranbaxy* is a win for the defense on the issue of class certification, defense counsel should be uncomfortable with the expansion of Article III standing that *Ranbaxy* portends. Manufacturers of drugs should not be forced to litigate with consumers who have benefitted from their products without incident, whether these claims are litigated individually or joined in a class action. Any other result is merely death by a thousand cuts.