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# *In re Lamictal*: Squeezing the Balloon in Antitrust Class Actions

by Kevin McDonald

The Third Circuit's recent decision in *In re Lamictal*[1] brought to mind Oliver Wendell Holmes, Jr. and Dizzy Dean at the same time. Perhaps I should explain.

The genius of law in courts—what we call litigation—is that it operates as a system. It is a legal system, to be sure, but it does more than declare or explain a rule of law. It *applies* the law to an actual, living dispute involving real people facing real consequences. To do so, the system operates with multiple moving parts that are separate from, but connected to, the legal proposition central to the result. "Of course, the legal rule is X," the system tells us, "but are these the right parties to invoke the rule? Is this the right time and place to apply it? Is the proffered evidence reliable enough to support the rule? Is the remedy sought the apt way to vindicate it?" The interconnections of a system's parts are important, as shown by the brief but sparkling baseball career of Dizzy Dean. When he insisted on pitching too soon after a foot injury, he threw his arm out.[2]

The ultimate goal of the system is to resolve disputes, within the limits of human fallibility, sensibly and fairly—to do justice. But justice is produced by the system itself, not by those who operate it case-by-case: "That is not my job," replied Justice Holmes when urged to "Do Justice!" "My job is to play the game according to the rules."[3] Few agree on the definition of justice, and opposing litigants never do, so we do not want the internal operation of the system to depend on someone's personal view of justice. Besides, I would argue, the litigation process has its own method of adjusting to keep its results sensible and fair. When one part of the paradigm functions poorly, other parts can (and do) modulate—as a balloon when squeezed at one point pops out at another—under pressure to keep the system balanced.

I think this balloon effect may help explain the *Lamictal* court's refusal to certify a class of direct purchasers in an antitrust suit alleging that the defendants had delayed the introduction of a generic version of the anti-epilepsy drug, Lamictal. This is one of a series of antitrust cases based on the settlement of prior litigation, in which a branded drug company (here, GSK) had claimed that a generic company (here, Teva) was infringing its patent. The antitrust claim is that the patent settlement was a "pay off" to induce the generic to delay its entry from the earlier time that (according to plaintiffs) it would have entered the market otherwise. The obvious difficulty with these claims, since all settlements involve exchanges of value (*i.e.*, payment), is that the patent by its terms would

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[1] *In re Lamictal Direct Purchaser Antitrust Litigation*, No. 19-1655, 2020 WL 1933260 (3d. Cir. Apr. 22, 2020) ("*Lamictal*").
[2] *Total Baseball* (John Thorn & Pete Palmer, eds.) at 330 (Warner Books 1989).
[3] Quoted in Michael Herz, *"Do Justice!": Variations of a Thrice-Told Tale,* 82 Virginia L. Rev. 111 (1996).

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have kept the generic out if the brand had won the infringement case, so as Judge Posner once said, "competition would be prevented to the same extent."[4] In 2013, however, the Supreme Court's *Actavis* decision held that such settlements "might" be illegal under antitrust's rule-of-reason test, which purports to consider all relevant competitive circumstances. In order to leave undisturbed some two hundred years of "traditional" patent settlements, *Actavis* declared that the settlement must include a "large and unexplained reverse payment" to qualify for scrutiny. The Court also said it would "normally not [be] necessary to litigate patent validity to answer the antitrust question."[5] Since 2013, the lower courts have struggled with what *Actavis* might mean, regarding the definition of reverse payments and otherwise, and the majority has been gently mocked for its conclusion that the patent merits might not matter. (One court of appeals noted that the obvious need to consider the patent merits in the case before it "appears to vindicate the [*Actavis* dissent's] analysis."[6]).

After *Actavis*, antitrust class actions based on reverse payments mushroomed, led by the classes of "direct" drug purchasers, composed mostly of wholesalers who buy the vast majority of branded drugs. Federal antitrust law limits damages claims to those who buy from defendants directly, and for decades the understanding of bench and bar was that direct purchaser classes were sure to be certified, whereupon the pressure to settle would ordinarily be too much to resist. That is changing. As class action complaints have become more frequent, so have the decisions denying class certification, even some involving direct purchasers. This is partly due to the complex web of healthcare pricing and reimbursement in the drug industry, and partly due to Supreme Court decisions read to require that all members within a defined class be injured. In cases involving drug wholesalers, reasons have included (1) numerosity (a class must be too numerous to proceed individually; as to many drugs, the three largest wholesalers can account for 95% or more of sales), and (2) predominance of common issues (all essential elements, including injury, must be subject to common proof).

In *Lamictal*, predominance was the issue because the class definition potentially included uninjured members. One reason that direct-purchaser classes were routinely certified before was that they were defined simply as those who purchased the *branded* drug between two dates: the date that generic entry should have occurred and the date that generic entry did occur. The injury was the inability to purchase a lower-priced generic, so once generic entry occurred, the damages period was over. *Lamictal* was more complicated, however, because of the theory of liability. Recall that *Actavis* required a "reverse payment" as a prerequisite to an anticompetitive effect. In *Lamictal*, the reverse payment was alleged to be the clause in the settlement by which the brand (GSK) agreed not to launch its own "authorized generic" for six months after Teva entered under the settlement. This "No-AG" clause is a common way for a patentholder to guarantee an exclusive licensee that it will allow no other generic entry, even by itself. Because such exclusivity obviously conveys value to the generic, the Third Circuit held that it meets the *Actavis* test of a "reverse payment." The *Lamictal* plaintiffs argued that, when the generic actually did enter, there should have been three drugs (GSK's branded drug, Teva's generic, and GSK's authorized generic), and even lower prices than with a single generic. The class thus included more than just those who bought the branded drug before generic entry, but also direct purchasers of *generic* Lamictal after Teva launched.

But that was a problem because discovery showed that GSK had planned to compete very aggressively on price with its *branded* product after generic entry (because doctors don't like to change epilepsy drugs during treatment), and that Teva planned to drop its own price severely in

[4] *Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003).
[5] *FTC v. Actavis, Inc.*, 570 U.S. 136, 133 S. Ct. 2223 at 2236 (2013) ("*Actavis*").
[6] *In re Wellbutrin XL Antitrust Litigation*, 868 F.3d 132, 167 n.58 (3d Cir. 2017) (Jordan, J.).

 

anticipation. Compared to the plaintiff's "but for" world with a high-priced brand and two slightly lower-priced generics, the actual prices resulting from the settlement could have been lower still, and those who paid them thus uninjured. Rather than sort that out, the District Court certified the class based on plaintiffs' expert's use of an aggregate average price that "masked" the individual negotiations, charge-backs, discounts, and other factors determining the real prices paid. The appeals court reversed and remanded with instructions to perform the "rigorous" analysis necessary under Rule 23 to ensure that all class members were injured.

One might read *Lamictal* as a pedestrian example of the trend toward greater scrutiny during class certification. And some may say such setbacks will not stop claims by drug wholesalers, which are often large enough to pursue in individual suits. But consider this: Why did these direct purchasers include the post-entry period and attempt to tie overcharges to generic purchases as well as brand purchases? Were they just greedy?

The answer may lie in the concept of "antitrust injury," the most important instance of the balloon effect in antitrust history. From the 1940s to the 1970s, the antitrust laws were applied so expansively that defendants were repeatedly found liable in cases where no anticompetitive effect had occurred. Numerous common business practices (such as tying, exclusive territories for distributors, etc.) were declared *per se* illegal, and mergers were illegal solely due to their potential ("incipient") effects. Private suits seeking damages for these "violations" soared. In 1977, the Supreme Court's *Brunswick*[7] decision dramatically curtailed these suits not by fixing some of the bad liability theories (that would take decades), but by inventing "antitrust injury." There, a merger declared illegal solely because Brunswick had "deep pockets" (honestly) had the incidental effect of causing some bowling alleys to survive that would have failed. The plaintiff, a rival to Brunswick, claimed injury because it lost profits from having to compete with the surviving lanes. No, said the Court, an "antitrust injury" must flow from a competition-*reducing* aspect of the violation. This injury flows from an aspect of the merger that *increased* competition. After *Brunswick*, antitrust courts ask *why* the conduct hurt consumers, and insist that plaintiff's injury "flow" from the same answer.

Antitrust injury is now a central, omnipresent issue in every private antitrust suit. In *Lamictal*, the Third Circuit said that plaintiffs' burden on class certification was to show through common proof "facts supporting an antitrust injury."[8] The *Lamictal* class went awry by attempting to tie their own injury to the only alleged source of competitive harm, the No-AG clause. Recall again that, to preserve traditional patent settlements, *Actavis* had to find the anticompetitive evil in the reverse payment itself. *Actavis* means that, without a reverse payment, there is no competitive harm, and in *Lamictal*, without a No-AG clause, there is no reverse payment. Plaintiffs may have been loath to admit that the only relevance of the No-AG clause was that it had "value" and helped cause the settlement to occur. That exposes the fallacy in *Actavis*, because all settlements convey value to the generic. Instead, plaintiffs attempted to tie a separate injury to the No-AG clause itself, based on GSK's failure to launch its own generic. That gave them not only a theory of causation hard to prove (brands can and do launch authorized generics, but not often, as there are many good business reasons not to), but a class definition with uninjured members that could not be certified.

And so we see how the pieces fit. In *Lamictal*, the bad liability theory of *Actavis* leads to a bad antitrust injury theory, which leads to a bad class definition, which cannot be certified. These portions of the balloon, I predict, will keep bulging out until *Actavis*, or something else, goes pop.

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[7] *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977).

[8] *Lamictal*, *supra* n.1, Slip Op. at 14.

 