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Lamictal and the Myth of "Generic" "Pay-for-Delay" Cases

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On April 22, 2020, the US Court of Appeals for the Third Circuit overturned a district court decision certifying a class of direct purchaser plaintiffs that purchased branded and generic versions of the pharmaceutical product Lamictal (lamotrigine), a treatment for epilepsy and bipolar disorder.[1] This decision is notable because it includes an acknowledgment that the use of average prices may be highly misleading in cases where there are individual price negotiations, widespread use of discounting, and strategic pricing by sellers in the marketplace. Importantly, this decision involves the pharmaceutical industry, where at least some of those circumstances are commonly present for direct purchasers.[2]

Case Background

This litigation focused on a so-called reverse payment (also known as a "pay-for-delay") allegation, whereby a pharmaceutical company that manufactures a branded product settles a patent dispute with a company seeking to launch the first generic version of the product, and that settlement purportedly has the effect of delaying generic entry. Specifically, GlaxoSmithKline (GSK) sold branded Lamictal tablets and it reached an allegedly anticompetitive settlement with Teva Pharmaceuticals after Teva filed an application for approval to sell generic lamotrigine tablets. In this settlement, GSK agreed to:[3]

- Delay the launch of its own authorized generic until six months after patent expiration, giving Teva generic exclusivity for six months, and
- Allow Teva to sell generic lamotrigine chewables, which are less prescribed than tablets, three years before patent expiration.

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According to the plaintiffs, but for the settlement agreement, Teva would have launched its generic lamotrigine tablets three years earlier, driving down the price of the branded product and causing GSK to respond by launching its own authorized generic to compete with Teva. In this but-for world, plaintiffs claimed that two groups of direct purchasers were harmed: companies that purchased Lamictal directly from GSK because they could have paid less for the brand or elected to switch to the generic, and companies that purchased lamotrigine directly from Teva because prices would have been lower with two generic products available instead of one. The District Court granted certification of the proposed direct purchaser class based, in part, on the testimony of plaintiffs' economic expert.

The Economics of Class Certification

In class certification matters, economists are often asked to opine on issues relating to predominance. One of the key issues that is often addressed is whether plaintiffs have put forward a common methodology capable of demonstrating that all or nearly all class members were impacted by the alleged conduct or if individual inquiry is required to assess antitrust impact. The economic framework for this analysis involves comparing the prices customers paid in the actual world to the prices they would have paid in the world absent the alleged conduct (*i.e.*, the "but-for" world).

Since we do not observe prices in the but-for world, economists typically construct a model to estimate those prices. If the price a customer paid in the actual world exceeds the price it would have paid in the but-for world, then that customer is impacted. The amount of this difference is damages. A common source of disagreement among economic experts in class certification matters is the viability of the plaintiffs' economic model in demonstrating impact. Any such model must account for supply and demand conditions and other economic factors that can affect the price paid by direct purchasers, and testing of the proposed model can shed light on whether the model is capable of demonstrating common impact to all or substantially all members of the proposed class.

Economic Arguments in the Lamictal Case

In the Lamictal case, plaintiffs' expert opined that evidence purportedly common to the propose class demonstrated that the prices paid by all or nearly all proposed class members were impacted by the allegedly illegal agreement. The "common evidence" put forward included:[4]

1. Economic literature showing that, on average, prices of generics are lower as more enter the market;
2. Teva's own general pricing forecast tending to discount a generic by 50% without competition, but by 65% when facing an additional generic competitor; and
3. Transaction-level sales data showing that the average actual price paid was consistent with Teva's predictions.

Plaintiffs' expert also proposed a model purporting to show the average price direct purchasers would have paid absent the settlement and concluded that since the average but-for price was lower than the actual average price, direct purchasers were harmed. However, the Court of Appeals found that key facts in the Lamictal case made the use of averages (among other things) problematic.

This decision is striking because the arguments advanced by the plaintiffs' expert are similar to ones seen in other "pay-for-delay" cases. In particular, it is common to see citations to inapposite economic literature; the use of averages in analyzing generic substitution for the branded product and in modeling prices; and a failure to account for differences in rebates and discounting among purchasers. In many cases, courts have concluded that these types of economic analyses were sufficient to certify a class—the Court in the Lamictal case disagreed.

Issues with a "Generic" Analysis in "Pay-for-Delay" Litigation

In its opinion, the Court of Appeals cited several key facts that it said needed to be resolved before a class could appropriately be certified. Specifically, the Court stated:

> Thus, contrary to the District Court's belief, addressing the micro-level analysis here, even though it touches on the merits, was necessary in order to determine whether the Direct Purchasers, in light of the competing expert reports and evidence, could show that common issues predominated by a preponderance of the evidence. While averages may be acceptable where they do not mask individualized injury we cannot determine whether that occurred here because of the lack of analysis.[5]

Below, we discuss three key facts cited in the Court of Appeals opinion and their implications for the economic analysis of predominance in this litigation and in other similar litigations.

First, GSK claimed that doctors "seemed more reluctant to switch patients from one epilepsy drug to another," making the launch of an authorized generic relatively less attractive and likely increasing the number of "brand stayers" who would not have switched from the branded product to any generic product.[6] This reluctance to switch patients from one product to another is not unique to treatments for epilepsy—for example, physicians are also reluctant to change patients' antipsychotic medications.[7] This prescribing behavior must be considered when assessing impact, as it affects both the incentives to launch an authorized generic and the number of potentially uninjured class members. Class members could be uninjured, for example, if they would have paid the brand price with or without the alleged conduct, as the brand price could be higher, lower, or unchanged depending on the branded seller's pricing strategy.

Second, given that launching an authorized generic was less attractive, GSK decided to implement a contracting strategy to compete with Teva's generic product by offering substantial discounts and rebates to selected pharmacies in exchange for agreeing to sell branded Lamictal instead of Teva's lamotrigine. Moreover, Teva was aware of GSK's strategic behavior and in response preemptively lowered its lamotrigine prices. Strategic contracting and pricing behaviors have important implications for assessing an economic model that purports to demonstrate common impact. As the Court of Appeals noted, to determine whether this contracting strategy raised individualized issues required a "multi-leveled microeconomic analysis of what each Defendant would or would not have possibly done in the but-for world."[8] That is, determining whether individual inquiry is necessary depends on the outcome of analyses of what GSK and Teva would have done in the but-for world and how prices to each direct purchaser would have compared to those in the actual world.

One key discussion in the Court of Appeals decision was on the use of averages: "averages may be acceptable where they do not mask individualized injury." For example, in the actual world GSK said it negotiated substantial discounts with targeted pharmacies, which may result in those pharmacies receiving much lower prices than competitors that did not receive those discounts. As a result, using an average actual price to all pharmacies may be misleading, and this may also be true in the but-for world if this contracting strategy were assumed to be implemented in both the actual and but-for worlds.

Appropriate testing can identify and demonstrate these issues with the use of averages in plaintiffs' proposed model. For example, comparing the average but-for price derived from an economic model to the individual prices realized in the actual world may show that numerous purchasers paid less than the but-for price and therefore would be uninjured. In the Lamictal case, the defendants' expert's testing showed that "the price of lamotrigine was likely *lower* for some purchasers than it would have been had GSK launched an AG"[9] and that as much as 75 percent of generic-only purchasers likely paid the same or lower prices in the actual world with the strategic pricing than they would have if GSK had launched an authorized generic.[10]

Finally, the plaintiffs' expert's use of average price effects from the economic literature rather than actual Lamictal pricing data was also found by the court to be a potential source of error because it did not account for the unique facts of the case. Notably, it is often the case that citations to economic literature on average price effects of generic entry do not necessarily speak to the effects that would occur in the matter at hand. While the ratio of the brand to generic price may, on average, depend on the number of generic entrants, there is no "rule of thumb" that can be applied in all circumstances—that is a product-specific empirical question, not a general proposition.

Similarly, the use of Teva's general pricing forecasts for its numerous products does not necessarily speak to Teva's pricing on the particular product at issue. For example, according to defendants, Teva's price for lamotrigine was set lower in response to GSK's contracting strategy. Therefore, it would not be appropriate to use general generic pricing forecasts as a proxy for what would happen in the case of lamotrigine. Moreover, this issue is not specific only to the Lamictal case, but may apply whenever there are unique, case-specific circumstances, such as strategic pricing or unique product characteristics.

Conclusions

Plaintiffs in "pay-for-delay" cases have often used company- or industry-wide benchmarks, average prices and generic substitution rates, and broad economic studies to purport to provide economic support for predominance. However, as the Lamictal case demonstrates, there is no "generic," one-size-fits-all approach to demonstrating antitrust impact in class certification. Rather, the behavior of branded and generic companies with respect to a single product requires a product-specific analysis that accounts for the facts and circumstances *in that case*. Recent decisions in cases involving Asacol and Niaspan suggest that courts may be starting to view the types of arguments proposed by plaintiffs' experts in "pay-for-delay" cases as insufficient. Indeed, as with class certification matters in other industries, analyses of product-specific pricing to individual purchasers is a predicate to demonstrating class-wide impact. Only where the appropriate rigorous testing indicates that averages "do not mask individualized injury" should the use of averages be permissible. ■

Notes

1. See *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 19-1655 (U.S. Court of Appeals for the Third Circuit, April 22, 2020) ("Remand").
2. Remand.
3. See *In re Lamictal Indirect Purchaser and Antitrust Consumer Litigation*, No. 12-cv-00995 (U.S. District Court, District of New Jersey, December 12, 2018).
4. Remand.
5. Remand, citation omitted.
6. Remand.
7. https://pubmed.ncbi.nlm.nih.gov/17650054/
8. Remand.
9. Remand
10. Remand.

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