VIEWPOINT

Antitrust, Market Exclusivity, and Transparency in the Pharmaceutical Industry

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High prescription drug prices, which have garnered attention across the political spectrum, often make access to essential medicines quite difficult for patients. Although lowering prescription drug prices is a bipartisan objective, the role of antitrust law in restoring competition and restraining price increases is not well understood by policy makers or the public.

In this Viewpoint, we explore 3 recent legal antitrust cases in which aggrieved competitors sued rival manufacturers, alleging that the anticompetitive practices of exclusive dealing and bundling prevented their products from gaining a foothold in the pharmaceutical marketplace.

Exclusive dealing refers to arrangements by which a purchaser agrees to buy all its requirements from 1 manufacturer. These arrangements may include financial incentives, such as rebates, conditioned on exclusivity. Although rebates may result in short-term savings to third-party payers, they may also drive competitors out of the market by offering prices no rival can match. Bundling involves discounts a manufacturer offers to purchasers buying several products in its portfolio and can result in prices that competitors are not able to match.

In the first case, Sanofi-Aventis filed a lawsuit in April 2017 alleging that its competitor, Mylan, created multiple barriers (including exclusive dealing arrangements) to prevent Sanofi's epinephrine autoinjector (Auvi-Q) from obtaining market share.[1] The complaint alleged that Mylan provided "new and unprecedented rebates" to insurance companies, pharmacy benefit managers, and Medicaid on the condition that they exclude Auvi-Q from its formularies and coverage. Sanofi asserted that because of Mylan's anticompetitive behavior, Auvi-Q peaked at only 13% of the total epinephrine autoinjector market. Sanofi also pointed to a nearly 300% increase in Mylan's EpiPen wholesale acquisition cost from 2013 to 2016 (from $219 to $609), with these increases often passed on to the patient.

In a second lawsuit, filed in September 2017, Pfizer sued Johnson & Johnson and Janssen Biotech for anticompetitive conduct related to its tumor necrosis factor blocker infliximab (Remicade), which has US sales of about $5 billion per year.[2] Pfizer introduced its follow-on biologic (biosimilar) infliximab-dyyb (Inflectra) in 2016 only to be challenged with what Johnson & Johnson publicly described as its "biosimilar readiness plan." Pfizer alleged that Johnson & Johnson offered exclusionary contracts, bundled discounts, and coercive rebates to insurers aimed at preventing Inflectra from gaining market share and thwarting future biosimilars from entering the market. Pfizer asserted that 90% of accounts using infliximab did not purchase any Inflectra, which limited the product's overall market share to less than 4%. Johnson & Johnson responded to Inflectra's market launch by increasing the list price of Remicade by nearly 9%.

In a third case, filed in October 2017, Shire sued Allergan alleging that Allergan impeded marketing of Shire's dry eye disease product, lifitegrast (Xiidra).[3] Shire accused Allergan, the maker of the competitor product cyclosporine (Restasis), which has been on the market for 15 years, of entering into anticompetitive arrangements (primarily bundled discounts) with Medicare Part D prescription drug plans that essentially excluded Xiidra from that market. In its complaint, Shire emphasized the societal harms of such exclusions, asserting that Xiidra is superior to Restasis based on greater comparative efficacy for a broader population of patients. The lawsuit alleges that Allergan's bundled discounts, which included the glaucoma drugs bimatoprost (Lumigan), brimonidine (Alphagan P), and brimonidine/timolol (Combigan), were so aggressive that the Medicare Part D plans would purchase the package even if Xiidra were provided for free. Shire also pointed to Xiidra's success in the commercial insurance market (in which it has 35% of the market) as support for anticompetitive conduct resulting in Restasis controlling 90% of the Medicare Part D market.

Each of these cases in the pharmaceutical industry targets restrictive contracts that can increase the cost of drugs while reducing access to potentially better rival medications. When companies without market power engage in exclusive dealing and bundling, these actions tend not to violate antitrust law because purchasers would have other choices and the conduct could help small sellers obtain a stronger position in the market. However, antitrust concerns may arise when companies with substantial market power engage in these practices.

To determine liability for exclusive dealing, courts will consider a quantitative estimate of the extent to which the alleged conduct blocked the market, the duration of the contract, the prevalence of such conduct in the industry, the existence of entry barriers, and whether there are distribution alternatives. For bundled contracts, the Third Circuit (where the 3 cases were filed) has focused on exclusionary effects and analyzed whether the defendant's market share expanded while competitors were harmed.[4]

In contrast, the Ninth Circuit focused on the discount in another case, finding liability if the defendant's price is less than the plaintiff's cost of manufacture.[5] All 3 complaints, which are to be interpreted under Third Circuit precedent, offer allegations that could demonstrate exclusive dealing and bundling. For example, the

complaints allege barriers to entry, the plaintiffs' inability to gain market share, and harms to patients.

The Sanofi-Aventis, Pfizer, and Shire lawsuits, which are yet to be decided by the Third Circuit, offer 2 lessons. The first is that exclusive contracting by firms with substantial market power could keep viable, if not superior, competitors out of the market. This has implications for physicians and patients, especially if the contract includes provisions that restrict formularies, mandate step therapy or prior authorization, or increase consumer spending in the form of co-payments or co-insurance. A successful lawsuit, or even an out-of-court settlement, could result in an injunction that allows the aggrieved competitor to gain market share, offer more choices to consumers, and lower prices.

The second lesson is that antitrust lawsuits can reveal crucial information about pricing and the relationships among pharmaceutical manufacturers, pharmacy benefit managers, and third-party payers. As brand-name drug prices continue to increase, each of the aforementioned entities has publicly disavowed responsibility for escalating pharmaceutical costs while shifting blame to the others.

Despite the ire of Congress and the public, rebates and bundling remain obscured under confidential agreements that are not readily accessible, even to affected parties such as public payers and patients. An underappreciated benefit of the 3 new lawsuits is that this secret pricing information may be revealed during the course of litigation. Even without victories in court, greater transparency may lead to more equitable prescription drug policy via increased scrutiny of anticompetitive deals by lawmakers and the public.

The tactics used by these manufacturers join a growing array of other anticompetitive approaches used by the pharmaceutical industry during the past few years. Several prominent legal cases have alleged conspiracies among pharmaceutical manufacturers to fix prices, leading to higher drug prices and less competition. For example, a group of patients sued insulin manufacturers Sanofi, Novo Nordisk, and Eli Lilly, alleging simultaneous price hikes that increased the price of insulin products by 150% over 5 years.[6]

In a second case, 46 state attorneys general sued 18 generic drug manufacturers, alleging coordinated price fixing of 15 generic drugs.[7] Antitrust law also has been used to challenge anticompetitive conduct on the part of a single manufacturer. For instance, Turing Pharmaceuticals, the manufacturer of pyrimethamine (Daraprim)—the drug made infamous by its former CEO Martin Shkreli—has been investigated for manipulative practices aimed at preventing generic rivals from obtaining needed samples for bioequivalence testing.[8]

Each of these cases reveals the growing importance of antitrust law as a potentially positive force in the pharmaceutical marketplace. In discovering evidence about anticompetitive conduct, antitrust lawsuits can finally provide insight into the details of drug pricing and discounting among pharmaceutical manufacturers, intermediaries, and third-party payers that affect the cost of drugs for patients and the health care system. Antitrust investigations and litigation have the potential to open markets, foster competition, and provide patients with greater access to more affordable prescription drugs.

ARTICLE INFORMATION

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