

Publications

Pharma Giants in Antitrust Pricing Lawsuit over Biosimilars

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Pfizer sued Johnson & Johnson (J&J) in federal court in Pennsylvania last week, alleging anticompetitive discounts and other actions to prevent competition with J&J's biologic Remicade. The complaint illustrates the hurdles to successfully bringing a biosimilar to market, despite the Biologics Price Competition and Innovation Act (BPCIA). The case also will provide another opportunity for courts to evaluate the antitrust implications of loyalty discounts and bundling.

In 2014, Remicade ranked as the third highest-selling drug in the world with more than \$10 billion in sales. A dose of Remicade can cost from \$1,300 to \$2,500. In 2010, Congress enacted the BPCIA to provide a pathway for approval of biosimilars, which are biologic drugs designed to have active properties similar to one that has been previously approved. To obtain approval, a biosimilar applicant must demonstrate high similarity between the biosimilar and the reference biologic. The BPCIA also provides a process to allow a biosimilar applicant to challenge patents that purportedly cover the reference biologic.

According to the complaint, J&J's Remicade was protected by patents until 2016 and became J&J's best-selling drug. Pfizer received permission from the U.S. Food and Drug Administration (FDA) to market its competing biosimilar, Inflectra, in April 2016 and began selling it in November. At that point, J&J allegedly implemented its "Biosimilar Readiness Plan" to fend off Remicade competitors. According to the complaint, J&J used rebates to effectively induce major insurers representing 70 percent of the patients covered by commercial health insurance plans to use Remicade exclusively for both existing and new patients. J&J also allegedly conditions rebates to insurers on other J&J products on Remicade exclusivity. According to the complaint, J&J similarly offers discounts to hospitals and other health care providers based on purchases of Remicade equal to levels when Remicade faced no competition. As a result, Pfizer alleges that it is foreclosed from 70 percent of the market for its biosimilar.

For most of its claims, Pfizer will have to show that J&J has power in an appropriately defined market. Such market power is usually shown through a high percentage share of sales in that market. Here, Pfizer has alleged a market defined as infusion-administered drugs where approved FDA labeling encompasses certain medical indications without certain restrictions. J&J allegedly has 60% of such a market, which is at the lower end of the levels usually needed to show market power.

Pfizer will also need to show that J&J's actions harmed competition in the market. The U.S. Supreme Court has not provided a test to determine when so-called loyalty discounts are anti-competitive. As a result, lower courts have chosen between the defendant-friendly price-cost test, which condemns the discounts only if the discounted price is below the defendant's variable costs, and the more plaintiff-friendly foreclosure test, which condemns the discounts if the pricing prevents competitors from competing for a large percentage of available customers.

As we have detailed in prior alerts, the U.S. Court of Appeals for the Third Circuit has considerable experience in evaluating such discounts. According to those older cases, courts in the circuit will apply the price-cost test only if the plaintiff alleges harm *solely* from low prices on a single product; on the other hand, where the defendant has "bundled" low prices on both contestable and non-contestable products, courts in the Third Circuit have used the foreclosure test. Here, Pfizer alleges that J&J has bundled the low prices for the allegedly incontestable demand of current Remicade patients with the contestable demand of the drug for new patients.

Pfizer also alleges that J&J has bundled exclusive or near-exclusive purchases of Remicade with purchases of other popular J&J products. The courts have developed different tests to determine when such multi-product discounting is anti-competitive when competitors do not sell the same range of products. The Third Circuit's precedent here is particularly plaintiff-friendly but has been heavily criticized by other circuits, commentators, and even some later Third Circuit judges. Finally, Pfizer alleges that J&J's Remicade prices, even after discounts, have continued to increase even after Inflectra's introduction, showing harm to competition and ultimate consumers. J&J executives have disputed that final assertion when discussing the complaint, although they have not yet filed a formal answer.

Bringing a biosimilar to market is expensive, even with the BPCIA. This case shows that the costs can go beyond product development and patent disputes to include fights over marketing schemes. Given the huge amounts of money at stake for both companies in this dispute, the case is likely to provide at least one judicial precedent on when discounting and exclusive dealing arrangements violate antitrust laws. Thus, the case is well worth watching by those both inside and outside the pharmaceutical industry.

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