Statement of the Federal Trade Commission
In the Matter of Teva Pharmaceuticals Industries Ltd. and Allergan plc
July 27, 2016

The Commission has accepted a proposed consent order in connection with Teva Pharmaceutical Industries Ltd.'s proposed acquisition of the generic pharmaceutical business of Allergan plc. We believe the consent order remedies the anticompetitive effects that would otherwise likely result from this transaction by requiring the divestiture of nearly 80 drug products to buyers that appear well positioned to replicate the competition that would have occurred absent the merger. The consent order includes a number of safeguards to help achieve our remedial goals.

Both Teva and Allergan are global pharmaceutical companies that are among the largest suppliers of generic pharmaceuticals in the United States. Teva is currently the largest generic drug company in the United States, with an overall generic market share of approximately 13%; Allergan is third, accounting for approximately 9% of generic sales.[1] Although this merger combines two large sellers of generic drugs, the generic pharmaceutical industry as a whole remains relatively unconcentrated. Over two hundred firms sell generic drugs in the United States and the five largest suppliers account only for about half of overall generic sales. Following this transaction, the combined firm will likely have a 22% share of industry-wide sales across all generic product markets.

Despite the industry's relatively low concentration, the Commission appreciates that the price, quality, and availability of generic pharmaceutical products have a significant impact on American consumers' daily lives and on healthcare costs nationwide. We therefore looked closely at every possible aspect of this transaction that could result in competitive harm. We examined not only particular product overlaps but also whether the combination between Teva and Allergan would result in other adverse consequences to competition. Our comprehensive investigation included the review of extensive documents from the merging parties and other industry players as well as interviews with dozens of customers and more than 50 competitors. We concluded that the substantial divestitures required by the consent order resolve the competitive concerns resulting from the transaction.

The Complaint and Remedy

As detailed in our complaint, we have reason to believe that, absent a remedy, the transaction would likely substantially reduce competition in 79 markets for pharmaceutical products, including oral contraceptives, steroidal medications, mental health drugs, and many other products. These markets include individual strengths of pharmaceutical products where

[1] This market share data is based on 2014 IMS gross sales data.

Teva and Allergan currently offer competing products as well as products where there would likely be future competition absent the merger because one or both of the parties are developing competing products.[2] To remedy the likely anticompetitive effects in each of the relevant markets, the consent order requires the divestiture of the products and related assets to specific acquirers that the Commission has closely vetted and approved. Where at least one dosage strength raised a competitive concern, we required Teva to divest all strengths. These divestitures, and the other relief contained in the proposed consent order, are designed to maintain competition in the relevant markets.

In settling this case, we rely on the Commission's extensive experience with divestitures in the pharmaceutical industry, including prior divestitures involving Teva and Allergan and have structured the divestitures in a way to minimize potential risks. This includes breaking the divested products into smaller packages to ease the load on any single buyer and requiring Teva to divest the easier-to-divest product of the overlapping products whenever possible. We also undertook an extensive review process to ensure that the divestiture buyers are acceptable and have the resources they need to compete successfully in the relevant markets. The buyers have identified third-party contract research organizations or contract manufacturers they intend to use and provided us with executed contracts. We involved interim monitors early in the divestiture negotiation process to ensure a smooth divestiture process and harmonize Teva's technological transfer plans with those of the acquirors of the divested assets. And we are requiring Teva to dedicate a full-time organization to implement the technology transfers and other measures necessary to effectuate the divestitures.

Other Potential Theories of Harm

In assessing whether the combination of the parties' generic businesses would harm competition or create a firm with a greater ability to engage in anticompetitive conduct, we evaluated three additional potential theories of harm beyond individual product overlaps.

First, we considered whether the merger would likely lead to anticompetitive effects from the bundling of generic products. Although both Teva and Allergan have broad generic drug portfolios today, the evidence did not show that the breadth of their portfolios significantly affects their ability to win business in individual drug product markets. Nor have they been able to use their portfolios to foreclose smaller competitors. Even with one of the broadest generic

[2] In addition to selling finished pharmaceutical products, Teva and Allergan also sell active pharmaceutical ingredients (API) to many third-party drug manufacturers, including parties that will now compete with the merged entity. Where the number of competitors in the finished product market is limited, the Commission determined that this vertical relationship could raise competitive concerns in markets for finished drug products by creating the incentive and ability for Teva to raise prices or withhold supply where third parties source from the merged firm. To address these concerns, the order requires Teva to provide affected customers with the option of entering into long-term API supply contracts to ensure that they have an adequate supply of API until they are able to qualify alternative suppliers.

product portfolios in the industry, Teva's overall share of U.S. generic prescriptions has steadily declined from 2010 to 2015, and the share of total prescriptions filled by the five largest generic suppliers has similarly fallen during this period. Generic sales occur at the individual product level, and customers sometimes even break up purchases by specific strengths to obtain more favorable pricing. As a result, smaller firms with much smaller portfolios compete head-to-head against larger generic firms and are the leading suppliers in the markets for many individual generic treatments. Additionally, purchasers actively seek to diversify their supplier base by sourcing from smaller suppliers. On the facts here, we concluded that anticompetitive effects arising from the merged company's portfolio of products are unlikely to occur.

Second, we examined whether the merger would likely decrease incentives to challenge the patents held by brand-name pharmaceutical companies and bring new generic drugs to market. The regulatory framework governing generic pharmaceuticals, the Hatch-Waxman Act, provides specific procedures for identifying and resolving patent disputes related to new generic drugs. Under the Hatch-Waxman Act, a company seeking to introduce a new generic drug may file what is commonly known as a "Paragraph IV challenge" to a brand-name pharmaceutical product's patent. This filing triggers a process, including potential litigation, to resolve patent issues surrounding the proposed generic product's entry into the marketplace.

We considered whether the merger would likely result in fewer or less effective Paragraph IV challenges, but the evidence did not support such a conclusion. A major incentive to file Paragraph IV challenges is the 180-day exclusivity period awarded to the first generic drug that the Food and Drug Administration approves in a market. The financial rewards associated with this "first-to-file" exclusivity period provide a strong incentive for generic drug companies of all sizes to challenge brand drug patents and litigate against brand drug companies. Indeed, first-to-file Paragraph IV challenges are not concentrated among a small group of firms. To the contrary, many firms, including small ones, have been active and successful first filers. In 2014, for example, twenty-five different companies were the first to file Paragraph IV challenges. For eight of those companies, that was their very first Paragraph IV challenge. Thus, while Teva and Allergan have actively filed Paragraph IV challenges, we found no evidence that either one has been better positioned to win the first-to-file race or that they have substantially greater incentives or ability to succeed in Paragraph IV challenges than many other generic companies. Nor did we see evidence that a merger between the two would diminish the combined firm's incentive to continue to pursue Paragraph IV challenges.

Finally, we analyzed whether the proposed transaction might dampen incentives to develop new generic products. For example, certain types of generic drugs are especially difficult to develop. For the most part, however, the parties' in-house technical capabilities to develop complex generic drugs do not overlap. And to the extent that there are complex products for which both companies have engaged in development efforts, we found that there are a number of other firms with similar capabilities such that the transaction would not substantially lessen competition. Moreover, generic firms, including the merging parties, often partner with

third parties (e.g., specialized contract development and manufacturing organizations) to obtain the technical capability to develop complex generic drugs. These types of partnership options will remain after the merger. The consent order addresses individual markets where the merger was likely to harm competition, including markets for difficult-to-develop products that are currently in the parties' pipelines.

Conclusion

We therefore concluded that the proposed merger is unlikely to produce anticompetitive effects beyond the markets discussed above. That conclusion is necessarily limited to the facts of this case. Another set of facts presented by a different transaction might lead us to find that there are competitive concerns that extend beyond markets for individual pharmaceutical products.

The extensive investigation and detailed consent order reflect the Commission's dedication to ensuring that pharmaceutical markets, including generic markets, remain competitive. We will continue to take enforcement actions, where appropriate, to ensure that any merger or acquisition complies with the antitrust laws and does not undermine competition in the pharmaceutical industry.