Authorized Generic Drugs:

Short-Term Effects and Long-Term Impact

Federal Trade Commission

AUTHORIZED GENERIC DRUGS:
SHORT-TERM EFFECTS AND LONG-TERM IMPACT

A REPORT OF THE
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EXECUTIVE SUMMARY

This Report analyzes the competitive effects of authorized generic drugs ("AGs").[1] AGs are pharmaceutical products that are approved as brand-name drugs but marketed as generic drugs. AGs do not bear the brand-name or trademark of the brand-name drug or manufacturer, but the brand-name and AG products are manufactured to the brand's specifications. In examining competitive effects, the Report looks both at the price and revenue effects of AG competition and at the potential long-term impacts on incentives for generics to challenge patents on brand-name drugs. The Report also assesses the competitive implications of patent litigation settlements in which brand-name companies refrain from offering an AG when the generic company agrees to defer its entry (so-called "pay-for-delay settlements"). For more than a decade, the Commission has expressed concern about brand-name companies paying generics to delay entry. As this Report observes, promises not to compete with generic entrants by marketing an AG are a common form of compensation to generics in such arrangements, and the competitive effects of such promises should therefore be analyzed in the same manner as other forms of consideration paid to generics.

Authorized generics have a unique impact during the first six months of generic competition. Under the Hatch-Waxman Amendments, when the first generic (the "first-filer") challenges the brand's patent, the FDA may not approve any additional generic competitors until 180 days after the first-filer launches its product.[2] During that period, because of the absence of competition, both the generic drug price and the first-filer's revenues are significantly higher than they would be when there are additional generic competitors. Congress created this exclusivity as an incentive for generic companies to enter as soon as possible by challenging invalid patents or patents that are not infringed.

Competition from AGs during the 180-day exclusivity period has the potential to reduce both generic drug prices and generic firm revenues. The courts have ruled that 180-day exclusivity does not preclude a brand-name company from entering with its own generic because it already has approval for its product; therefore, it can sell an AG during that exclusivity

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[1] The Federal Trade Commission conducted this study at the request of Senators Grassley, Leahy, and Rockefeller, as well as at the request of Representative Waxman, all of whom asked the Commission to examine the competitive effects of authorized generic drugs. *See* Letter from Senators Charles Grassley, Patrick Leahy, and John Rockefeller to Deborah Platt Majoras, Chairman, Fed. Trade Comm'n (May 9, 2005) (*infra* Appendix A); Letter from Hon. Henry A. Waxman, U.S. House of Representatives, to Deborah Platt Majoras, Chairman, Fed. Trade Comm'n (Sept. 13, 2005) (*infra* Appendix B). Then-Commissioner Leibowitz also requested the FTC to study "the competitive implications of authorized generics." Jon Leibowitz, Commissioner, Fed. Trade Comm'n, Health Care and the FTC: The Agency as Prosecutor and Policy Wonk, Remarks at the Antitrust in HealthCare Conference 9–10 (May 12, 2005), http://www.ftc.gov/speeches/leibowitz/050512healthcare.pdf.

[2] 21 U.S.C. § 355(j)(5)(b)(iv) (2010). Exclusivity now may be "shared" by two or more applicants filing on the same day. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(I)–(II)(bb) (2010).

period.[3] Brand-name companies now frequently launch an AG to compete with the first-filer.

AGs thus have been the subject of controversy. Brand-name companies that offer AGs contend that they are procompetitive – that they make valuable products available to consumers at lower prices than those of brand-name products and provide competition that leads to lower generic prices overall. Some in the generic drug industry, in contrast, contend that AGs harm competition by drawing revenues away from generic firms during the 180-day exclusivity period provided for first-filers that challenge a brand-name company's patents. They caution that this reduces the potential reward available to generics that challenge patents, thereby discouraging patent challenges that facilitate earlier generic competition and reduce prices for consumers. This, the AG critics argue, undermines long-run competition and the goals of the Hatch-Waxman Amendments.

As a first step toward shedding light on this controversy, the Commission in June 2009 issued an interim report that focused on the short-term effects of AGs during the 180-day exclusivity period (the "Interim Report").[4] That report presented an initial analysis suggesting that "consumers benefit and the healthcare system saves money during the 180-day exclusivity period when an AG enters the market, due to the greater discounting that accompanies the added competition provided by the AG."[5] The Interim Report, however, also found that "AG entry significantly decreases the revenues of a first-filer generic company during its 180-day exclusivity period."[6] Apart from a preliminary analysis of the use of AGs in patent litigation settlements, the Commission left most questions of long-term effects – including any possible impact of AG competition on the calculus of generic entry via patent challenges – for exploration in a final report.

This final Report refines the short-term analysis of the Interim Report and expands the analysis to consider long-term effects. It combines information obtained by compulsory process from more than 100 brand-name and generic manufacturers with price and sales data acquired from commercial sources and information gleaned from FDA databases to assess AGs' competitive effects. Moreover, it updates and extends the Interim Report's study of the use of AGs as a form of consideration in patent litigation settlement agreements.

The new analysis finds that, depending on model specifications, competition from an authorized generic during the 180-day exclusivity period is associated with retail generic prices that are 4-8 percent lower and wholesale generic prices that are 7-14 percent lower than prices without authorized generic competition. On average, the retail price of a typical generic drug during the 180-day exclusivity period is 86 percent of the pre-entry brand price without AG

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[3] *See* Teva Pharm. Indus. Ltd. v. Crawford, 410 F.3d 51, 54 (D.C. Cir. 2005).

[4] FED. TRADE COMM'N, AUTHORIZED GENERICS: AN INTERIM REPORT ("Interim Report") (2009), http://www.ftc.gov/os/2009/06/P062105authorizedgenericsreport.pdf.

[5] *Id.*, Executive Summary, at 2.

[6] *Id.*

competition and 82 percent of the pre-entry brand price when an AG competes. Similarly, the average wholesale price of a typical generic drug during exclusivity, which is 80 percent of the pre-entry brand wholesale price without an AG, falls to 70 percent of the brand price with AG competition. An analysis of authorized generic pricing over the long term provides no evidence that AG prices are higher than prices of other generics, allaying concerns that AGs might be less aggressive competitors.

The new analysis also confirms the Interim Report's finding that authorized generics have a substantial effect on the revenues of competing, generic firms during the 180-day exclusivity period; depending on how the models are specified, they estimate that the presence of authorized generic competition reduces the first-filer generic's revenues by 40 to 52 percent, on average. Moreover, the impact of AG competition on first-filer revenues persists outside of exclusivity. Revenues of the first-filer generic manufacturer in the 30 months following exclusivity are between 53 percent and 62 percent lower when facing an AG.

With regard to long-term incentive effects, the analysis concludes that the reduced revenue stemming from authorized generic competition during 180-day exclusivity has not affected the generic's incentives in a way that has measurably reduced the number of patent challenges by generic firms. Any disincentive effects would likely be experienced in small markets or in situations where the generic had little chance of winning the patent suit anyway. The Report examines a variety of evidence to reach these conclusions.

- Based on economic analysis, revenue lost from authorized generic competition would be most likely to affect decisions to challenge patents on products with small sales.
    - If a challenger anticipates a 50 percent chance of success, an expectation of AG competition could tilt the balance against bringing a patent challenge in markets with brand sales between $12 million and $27 million, a range that accounts for 13 percent of drugs, but given their low sales, approximately one percent of total prescription drug expenditures. AGs, however, are rarely introduced for these small drugs. For the drugs with higher sales that frequently do attract AG competition, AGs may conceivably deter only a narrow range of challenges that the generic believes it will rarely win, meaning that the challenges are unlikely to result in early generic entry even if pursued.[7]

[7] For instance, for a drug with brand sales of $130 million, a generic that does not anticipate AG competition will expect a patent challenge to be profitable if it has at least a 4 percent chance of winning; with AG competition, that generic would need at least a 10 percent chance of winning to expect a patent challenge to be profitable. Under this mode of analysis, the AG might discourage a challenge only if the generic thinks the chance of winning is between 4 and 10 percent, i.e., when the challenge is unlikely to be successful. For larger drugs, the presence of an AG is critical to the patent-challenge decision only when the expected likelihood of success is even less than 10 percent.

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