



# Federal Trade Commission News

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**FOR RELEASE: 8/31/2011**

## **FTC Report Examines How Authorized Generics Affect the Pharmaceutical Market *Finds Brand-Name Firms Use Leverage of Authorized Generic Entry to Delay Competition***

The [Federal Trade Commission](#) issued a final report on authorized generic drugs that concludes when pharmaceutical companies introduce an authorized generic version of their brand-name drug, it can reduce both retail and wholesale drug prices. The report also found that authorized generics have a substantial effect on the revenues of competing generic firms. Over the longer term, by lowering expected profits for generic competitors, the introduction of an authorized generic could affect a generic drug company's decision to challenge patents on branded drug products with low sales. However, the report concludes that in spite of this, patent challenges by generic competitors remain robust. Finally, the report finds that some brand companies may have used agreements not to launch an authorized generic as a way to compensate would-be generic competitors for delaying entry into the market.

The FTC has for years opposed pay-for-delay patent litigation settlements, in which a brand-name drug manufacturer compensates its generic competitor to delay entering the market and offering consumers a lower-cost alternative. With this report, the agency has found that promises by a branded firm *not* to market competing authorized generics are frequently present in pharmaceutical patent settlements.

“Today’s report finds that authorized generic competition modestly reduces drug prices during the first 180 days of generic competition, and identifies some evidence suggesting that the presence of an authorized generic could affect decisions by generic competitors to challenge patents on drugs with low revenues,” FTC Chairman Jon Leibowitz said. “But the clearest and most disturbing finding is that some brand companies may be using the threat of launching an authorized generic as a powerful inducement for generic companies to delay bringing their drugs to market. When companies employ this tactic it is a double whammy for consumers. Consumers have to pay the higher brand prices while the generic delays its entry and, once generic entry does occur, consumers pay higher prices without the benefit of competition from the authorized generic.”

An authorized generic is a lower-cost, generic-label version of a brand-name drug that is already sold by the same manufacturer. The Hatch-Waxman Act is designed to ease the introduction of generic drugs by, in certain circumstances, granting a 180-day period of marketing exclusivity to the first generic competitor of a brand-name drug, known as a “first-filer.” During that exclusivity period, no other generic company can receive FDA-approval to sell its product. However, this marketing exclusivity period does not prevent brand-name companies from introducing their own authorized generic versions.

It has become increasingly common, the FTC's report finds, for brand-name drug makers to start marketing authorized generics at the same time a generic firm is beginning its 180-day marketing exclusivity period, leading to questions about the effects of authorized generics on pharmaceutical competition.

The final report issued today, titled "Authorized Generic Drugs – Short-Term Effects and Long-Term Impact," follows up on the FTC's 2009 interim report which focused on the effects of authorized generics during the initial, 180-day period of competition by a generic drug. The Final Report looks at how competition and drug prices are affected over both the short term and the long term.

The Final Report contains four main findings:

- *Competition from authorized generics during the 180-day marketing exclusivity period has led to lower retail and wholesale drug prices.* During this time, competition by an authorized generic is associated with retail prices that are four-to-eight percent lower, and wholesale prices that are 7 to 14 percent lower, than those without an authorized generic.
- *Authorized generics have a substantial effect on the revenues of competing generic firms.* During the 180-day exclusivity period, the presence of an authorized generic competitor on average reduces the first-filing generic's revenues by 40 to 52 percent. In addition, revenues of the first-filing generic are between 53 and 62 percent lower during the first 30 months after the exclusivity period ends, if it is facing authorized generic competition. Introduction of an authorized generic can mean hundred of millions of dollars in lost revenue for the first generic competitor to enter the market.
- *Lower expected profits could affect a generic company's decision to challenge patents on products with low sales. However, the reduced revenues resulting from authorized generic competition during the 180-day exclusivity period have not substantially reduced the number of challenges to branded drug patents by generic firms.* Despite the presence of authorized generic competition, generic companies have continued to challenge patents, even on brand-name drugs in small markets.
- *There is strong evidence that agreements not to compete using authorized generics have become a way that some branded firms compensate generic firms for delaying entry to the market.* The FTC's analysis found that:
  - In FY 2010 alone, 15 drug patent settlements – involving drugs with a total market value of more than \$23 billion – combined an explicit agreement by the brand manufacturer *not* to launch an authorized generic competitor, and a commitment by the first-filing generic to defer entry.
  - Between FY 2004 and FY 2010, approximately 25 percent of patent settlements with first-filing generics involved explicit agreements by the brand not to launch an authorized generic to compete against the first-filer, combined with an agreement by the first-filer to defer entry.
  - In FY 2010, nearly 60 percent of final settlement agreements with first-filing generic firms that contained both compensation to the generic and a restriction on generic entry included explicit agreements that the brand would not market an authorized generic competitor.

- The delays in competition resulting from these agreements can be significant. In the 39 settlements between FY 2004 and FY 2010 that combined an explicit agreement by the brand not to launch an authorized generic competitor and a commitment by the first-filing generic to delay entry, generic entry was delayed by an average of 37.9 months past the settlement date.

The Commission vote to issue the Final Report was 5-0. It can be found on the FTC's website and as a link to this press release. The FTC conducted the study in response to requests from Congress. The FTC's 2009 Interim Report on authorized generic drugs can be found [here](#).

**The FTC's Bureau of Competition works with the Bureau of Economics to investigate alleged anticompetitive business practices and, when appropriate, recommends that the Commission take law enforcement action. To inform the Bureau about particular business practices, call 202-326-3300, send an e-mail to [antitrust@ftc.gov](mailto:antitrust@ftc.gov), or write to the Office of Policy and Coordination, Room 394, Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Ave, N.W., Washington, DC 20580. To learn more about the Bureau of Competition, read [Competition Counts](#). Like the FTC on [Facebook](#) and follow us on [Twitter](#).**

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(FTC File No. P062105)  
(Authorized Generics.wpd)