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The FTC Finds that Authorized Generic Drugs Yield Procompetitive Benefits

Key Points

- The FTC has found that authorized generic drugs are procompetitive because they lower prescription drug prices without deterring traditional generic drug entry.
- The FTC's report rebuts concerns raised by generic manufacturers and some in Congress over the competitive effects of authorized generics.
- *Caution*: The FTC believes that patent settlements involving authorized generic delay are similar to patent settlements involving cash payments for generic delay and may violate the antitrust laws.

The FTC on August 31, 2011 issued the results of its study on the competitive impact of authorized generics ("Authorized Generic Drugs: Short-Term Effects and Long-Term Impact," *available at* www.ftc.gov/opa/2011/08/genericdrugs.shtm). The FTC's findings provide strong support for the conclusion that entry by authorized generics is procompetitive because it lowers prescription drug prices without deterring generic entry. These findings by the FTC may well put to rest generic manufacturer lawsuits and legislative efforts to curtail entry by authorized generics.

What Led to the FTC Report

Demand for prescription drugs has shifted heavily from brand drugs to generic drugs. Innovators have responded by introducing their own generics (*i.e.*, authorized generics) to compete with the generic drugs offered by traditional generic manufacturers. This practice has drawn the ire of generic manufacturers, who have brought their complaints to the courts and to Congress. Generic manufacturers have argued that the introduction of authorized generics deflects consumer demand away from traditional generics and blunts their incentives to incur the risks and costs of challenging brand-drug patents. As a result, they argue, consumers are left with less choice and higher prices.

While this argument has not prevailed in the courts, *see, e.g.*, *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51 (D.C. Cir. 2005), it has garnered sympathy in some congressional circles. Congressional efforts to prohibit authorized generic entry have taken two routes: legislation and encouragement of agency review of authorized generic drugs. An example of the former was the Fair Prescription Drug Competition Act (a bill reintroduced this year), which would bar the introduction of authorized generics during the generic manufacturer's exclusivity period under the Hatch-Waxman Act. An example of the latter was a 2005 request by three

Senators that the FTC conduct a comprehensive study of the competitive effects of authorized generic entry. It was that congressional request that led to the recent FTC report.

The Method Behind the FTC Study

In conducting its study on the competitive effects of authorized generic entry, the FTC relied on data, including retail and wholesale pricing data, and on ordinary-course business documents (*e.g.*, planning and strategy documents) from more than 50 innovators, more than 50 generic manufacturers, commercial sources, and public sources involving more than 100 brand drugs for which authorized generics were launched over a period spanning almost ten years. The FTC concluded that both the data and the documents demonstrate that authorized generics benefit consumers.

The Tale Told by the Data

The FTC's data findings on the competitive effects of authorized generic entry are two- fold. First, authorized generic entry lowers wholesale and retail drug prices. The FTC found that authorized generic entry during the exclusivity period reduced wholesale prices by 7-14% and retail prices by 4-8%. Post-exclusivity retail prices fell 10-11% and wholesale prices fell 6-13%. Overall, the FTC found that consumers have saved hundreds of millions of dollars because of authorized generics.

Second, contrary to the claims made by traditional generic manufacturers, the FTC found that entry by authorized generics does not deter generic entry because first-filer revenue loss during the Hatch-Waxman Act exclusivity period is not meaningful enough to deter brand-drug patent challenges. In arriving at this conclusion, the FTC noted that to deter generic entry, authorized generics must diminish first-filer revenues such that generic entry costs could not be recouped. The FTC determined break-even points by employing a sliding scale that looked at pre-entry brand revenue and the likelihood of successfully challenging a brand patent. Finally, the FTC took note of the fact that in calculating first-filer profitability, post exclusivity carry-over effects (*i.e.*, maintenance of high sales post-exclusivity) must be considered.

The results reported by the FTC are dramatic. For the median-market-sized brand drug (one with $130 million in pre-entry annual revenue), the probability of success on a brand-drug patent challenge necessary to incent generic entry in the face of authorized generic entry was 10%. Entry deterrence was economically feasible only for extremely small market brand drugs where there was less than a 50% probability of a successful patent challenge. As the FTC noted, however, those markets represent a relatively trivial portion of brand drug sales. Moreover, deterrence value was diluted by the fact that authorized generic entry was unlikely for brand drugs with less than $50 million in annual revenue.

Real-world data corroborates the FTC's entry analysis. From 2003 to 2008, entry by authorized generics jumped. During this same time, increases in brand patent challenges had been equally dramatic. Moreover, brand-drug patent challenges occurred across the brand-drug revenue spectrum, from brand drugs with less than $50 million in annual sales to those with annual sales in excess of $500 million. In fact, 31% of brand-drug patent challenges occurred on brand drugs with annual revenues less than $100 million. Thus, the FTC concluded, authorized generics did not deter entry even for relatively small market drugs.

The Documents Tell a Similar Story

The ordinary-course documents the FTC highlighted mirrored the pricing and entry data. Planning and strategy documents from innovators demonstrate that decisions to launch authorized generics are driven by overall innovator revenues, not deterrence. As pre-entry brand revenues increased, so did the likelihood that innovators would introduce an authorized generic to maximize revenues. And once introduced, an authorized generic was usually priced above its initial generic competitor. As the FTC explained, this was strong evidence that innovators do not "maximize the deterrent value of [authorized generics] by acquiring market share at the expense of profitability." Finally, roughly two-thirds of authorized generics studied were not launched during or on the eve of the Hatch-Waxman Act exclusivity period. That innovators often launch authorized generics when there is no patent challenge further confirms that deterring generic entry is not a primary motivator for the introduction of authorized generics.

Similarly, planning and strategy documents from generic manufacturers show that decisions on whether to challenge brand-drug patents are primarily influenced by revenue considerations associated with the brand drug's pre-entry revenues. In fact, the FTC found no document that "expressly discusses [authorized generics] as a factor in deciding whether to file a particular patent challenge." Rather, it appears that the size of the potential market is the primary factor influencing brand-drug patent challenge. Internal documents from generic drug manufacturers highlighted this point.

Patent Challenges Make Economic Sense

"Look at the myriad of suits on the blockbusters and then say that if there were an authorized generic all of the claimants would not have filed their Paragraph IV. However is it fair that after spending millions they have an authorized generic to deal with. Yes, at least in my opinion, it is fair! Look at the price that the holder of an exclusive generic sells the product for, i.e., say 20% less than brand. A great profit. If there were [an] 'authorized' generic also, perhaps they will have to discount 30-40%—still a great profit. A profit well worth the expense of the Paragraph IV suit!" (Quote from general counsel of a generic drug manufacturer) (see Authorized Generic Drugs: Short-Term Effects and Long-Term Impact, at 89-90).

Patent Settlements Involving Authorized Generics: FTC Opposition

The FTC concluded its findings by stating its opposition to patent settlement agreements in which an innovator agrees not to launch an authorized generic during an exclusivity period in exchange for a generic manufacturer's agreement to delay generic entry.

FTC Chairman Jon Leibowitz Publicly Opposed Patent Settlements Involving Authorized Generic Delay

"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." (available at www.ftc.gov/opa/2011/08/genericdrugs.shtm).

This approach conforms to the FTC's view on reverse-payment patent settlement agreements, which the FTC has challenged on numerous occasions. The FTC's message is that deferral of an authorized generic may be treated as equivalent to a cash payment to a generic manufacturer in exchange for generic delay. The FTC believes that such arrangements may be anticompetitive and subject to challenge under the antitrust laws.

The federal courts have thus far not been receptive to the FTC's concerns about cash payment settlement agreements. Most courts have held that so long as the patent was not procured by fraud, the patent litigation is not objectively baseless (*i.e.*, a sham), and the terms of the delay do not exceed the scope of the patent holder's right to exclude, reverse-payment agreements do not violate the antitrust laws. *See, e.g.*, *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010). This reasoning strongly suggests that courts would give similar treatment to patent settlements involving the timing of an authorized generic.

The FTC has not challenged any of the numerous patent settlements involving authorized generic delay that have been filed with the FTC pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act. Whether the FTC's findings reveal a new interest in challenging patent settlements involving authorized generic delay remains to be seen. And although the FTC's views are not law, careful thought should be given to patent settlements that delay authorized generics.

Practice group contacts

If you have questions regarding the information in this legal update, please contact the Dechert attorney with whom you regularly work, or any of the attorneys listed. Visit us at www.dechert.com/antitrust.

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