WSGR ALERT

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FTC ISSUES FINAL AUTHORIZED GENERIC REPORT

On August 31, the Federal Trade Commission (FTC) issued its final report on the effect of authorized generic drugs (AGs) on competition in the prescription drug market.[1] The August 2011 final report followed 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 FTC undertook these analyses at the request of Senators Chuck Grassley, Patrick Leahy, and John Rockefeller, as well as Representative Henry Waxman, who asked the commission to examine the competitive impact of authorized generics in the pharmaceutical industry over both the short term and the long term. FTC Chairman Jon Leibowitz (then a commissioner) also was an early proponent of the FTC examining the competitive effects of AGs.[2]

Report's Key Findings

The FTC's final report contained four key findings:

1. Competition from authorized generics during the 180-day marketing exclusivity period has led to lower retail and wholesale drug prices

2. Authorized generics have a substantial impact on the revenues of competing generic firms

3. Lower expected profits could, in theory, affect a generic company's decision to challenge patents on products with low sales, but competition from authorized generics has not substantially reduced the number of patent challenges

4. Agreements not to compete using authorized generics have continued to serve as a vehicle for branded firms to compensate generic firms for delayed market entry

First, the final report reiterates the findings of the interim report that competition from an authorized generic during the 180-day exclusivity period is associated with retail generic prices that are 4 to 8 percent lower and wholesale generic prices that are 7 to14 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 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, addressing concerns that AGs might be less aggressive competitors.

Second, the new analysis also restates the interim report's finding that authorized generics have a substantial impact on the revenues of competing generic firms during the 180-day exclusivity period. Indeed, the FTC estimates that, on average, the presence of authorized generic competition reduces the first-filer generic's revenues by 40 to 52 percent. Moreover, the impact of AG competition on first-filer revenues persists outside of the 180-day exclusivity period, as revenues of the first-filer generic manufacturer in the 30 months following exclusivity are between 53 and 62 percent lower when facing an AG.

Third, with regard to long-term incentive effects, the FTC concludes that the reduced revenue stemming from authorized generic competition during the 180-day exclusivity period has not reduced the number of patent challenges by generic firms. Generic companies have continued to challenge patents, as the number of drugs receiving their first Paragraph IV certification approximately doubled between 2003 and 2008.

While the FTC concludes that the presence of competition by AGs has not substantially deterred generic challenges, some generic companies' internal documents do reflect concerns that AG competition could impact the profitability of patent challenges or require generic firms to better manage their product selection and litigation processes. In

[1] See the FTC's August 2011 report entitled, "Authorized Generic Drugs: Short-Term Effects and Long-Term Impact," available at http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf.

[2] See remarks by Jon Leibowitz entitled, "Health Care and the FTC: The Agency as Prosecutor and Policy Wonk," American Bar Association's Antitrust in Healthcare Conference, Washington, D.C., May 12, 2005, available at http://www.ftc.gov/speeches/leibowitz/050512healthcare.pdf.

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particular, some of the financial forecasts produced by generic companies support assertions that the expectation of AG competition has tipped the balance *against* proceeding with a Paragraph IV challenge for certain small-market drugs.

Finally, the FTC concludes that there is strong evidence that agreements not to compete with an authorized generic have become a way for brand-name companies to compensate generic competitors for delayed market entry. Such agreements, which the FTC has termed as "pay-for-delay" patent settlements, long have concerned the commission. Between 2004 and 2010, 39 of 157 patent settlements with first-filer generics (approximately 25 percent) contained such provisions. The average generic entry delay for the 39 agreements was 37.9 months, and the total market for the drugs involved in these settlements exceeded $23 billion. The length of time during which the brand agreed not to launch or sponsor an AG ranged from 10 days to 45.5 months, with the average length of the restriction being 9.6 months and the median restriction being 6 months.

Observations on the Report

As an initial matter, the FTC's 270-page report, which includes data from 59 brand-name companies and 59 generic companies (including all of the major firms involved in marketing AG products), provides a wealth of information to industry participants and practitioners alike. Without naming sources for any particular data, the report provides substantial detail on the extensive data mined from the key players in the pharmaceutical industry.

Based on this report, the FTC appears to take a fairly favorable view of the competitive impact of authorized generic drugs on the prescription drug marketplace. First, the FTC finds that competition from authorized generics leads to lower retail and wholesale drug prices. Second, while authorized generics do substantially impact the revenues of competing generic firms, particularly the first-filer, the FTC did not find evidence that the presence of authorized generics has substantially reduced the number of patent challenges by generic firms.

The FTC does, however, appear to take strong exception to the competitive impact of authorized generics in one circumstance: "pay-for-delay" settlements. For over a decade, the FTC has vigorously opposed pay-for-delay settlements in the pharmaceutical industry. The FTC's focus on this issue has become more intense since Chairman Leibowitz took the helm of the commission in early 2009, as he has pressed the commission's view on pay-for-delay settlements in the courts, Congress, and now in this report. According to the report, there is an uptick in the use of promises by branded firms not to compete with an AG as a way of compensating generic firms for accepting a delayed entry date under the patent settlement. While the FTC has not yet challenged a pay-for-delay settlement based on a "no-AG" theory, the FTC's continued public pronouncements regarding its concern over these types of agreements demonstrates that the agency remains committed to deterring and perhaps challenging these agreements in the future.[3] As a result, pharmaceutical companies should be cognizant of the antitrust risk resulting from such agreements.

For additional information regarding the FTC's report, or for any related questions, please contact Seth Silber or Jonathan Lutinski in Wilson Sonsini Goodrich & Rosati's antitrust practice.

[3] Indeed, the FTC consistently has reiterated its position that "no-AG" agreements can serve as compensation for delayed generic entry in patent litigation settlements agreements in speeches by Chairman Leibowitz (see, e.g., footnote 2), as well as in the FTC's 2009 interim report concerning the effect of authorized generic drugs on competition in the prescription drug market.

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