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LEGAL DEVELOPMENTS

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FTC ISSUES AUTHORIZED GENERICS REPORT

On June 24, 2009, the Federal Trade Commission ("FTC") issued "Authorized Generics: An Interim Report" which presents a preliminary analysis of the short term effects of authorized generic drugs ("AGs") on competition in the prescription drug market. The study, conducted at the request of Senators Grassley, Leahy and Rockefeller and Representative Waxman, provides an analysis of the first 180 days of competition between an AG and a generic drug manufactured by an independent generic pharmaceutical company.

Under the Hatch-Waxman Act, a 180-day period of marketing exclusivity is awarded to the first generic competitor to file an abbreviated new drug application ("ANDA") challenging the brand company's patents (the "first-filer"). The FTC Interim Report suggests that when an AG enters the market during the 180-day exclusivity period, consumers benefit and the healthcare system saves money due to greater price discounts as a result of competition. The report does not support a legislative ban on marketing of AGs during the exclusivity period nor does it suggest that the presence of AGs is harmful to consumers. Given the limited scope of the preliminary analysis, however, this Interim Report does not investigate either the long term or overall effects of AGs on competition in the marketplace. A final report, which will include a more in-depth econometric analysis, will be released at a date to be determined.

For the study, the FTC acquired data from governmental and non-governmental sources, including IMS Health, Inc., the Food and Drug Administration ("FDA") and documents produced by pharmaceutical companies pursuant to compulsory information requests. The FTC received prescription sales information from more than 100 drug companies, although most of the data proved to be intractable due to accounting and reporting inconsistencies within and across firms. In the FTC's sample data set of 95 unique drugs, there were 51 drugs that were classified as ANDA-only drugs, where the independent ANDA drug was the only generic on the market, and 53 drugs classified as ANDA+AG, where the independent ANDA drug was joined only by an AG. Nine drugs show up on both lists, which can occur, for example, when an AG enters the market during the 180-day period after the independent ANDA drug.

The FTC's preliminary data analysis shows:

- Retail prices are on average 4.2% lower, relative to the pre-generic brand price, when an AG competes with one ANDA generic drug during the exclusivity period than when an AG does not enter;
- Wholesale prices are on average 6.5% lower, relative to the pre-generic brand prices, when an AG competes with one ANDA generic drug during the exclusivity period than when an AG does not enter;
- Revenues of a sole ANDA generic drug company during the 180-day exclusivity period drop substantially with AG entry, with estimates of the average decline ranging from 47% to 51%. The revenue effect for generics is so much larger than the price effect for consumers primarily because the AG represents a very close substitute for the ANDA generic and therefore typically obtains significant market share at the expense of the ANDA generic;
- To prevent this loss of revenue, a generic may be willing to delay its entry in return for a brand's agreement not to launch an authorized generic . . . during the generic's 180 days of marketing exclusivity;
- Between FY2004-FY2008, about one quarter (38 out of 152) of the final patent settlements

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reviewed by the FTC contained provisions relating to AGs;

- Between FY2004-FY2008, 76 final patent settlement agreements were with first-filer generics. About one-quarter of those patent settlements involved (1) an explicit agreement by the brand not to launch an AG to compete against the first-filer, combined with (2) an agreement by the first-filer generic to defer its entry past the settlement date by, on average, 34.7 months.

-Authorized Generics: An Interim Report, Federal Trade Commission Report, June 2009, p. 3

The FTC's initial analysis indicates that consumers benefit when an AG enters the market during the 180-day exclusivity period, as drug prices are on average lower when an AG competes against an ANDA product. According to the FTC, this short-term competition produces lower retail drugs costs, saving money for both consumers and the healthcare system. The preliminary analysis of the data found that consumers receive a 13.1% discount on an ANDA product granted exclusivity with no AG competition on average across all months of exclusivity. When a market has AG competition, consumers receive on average a 17.2% discount off of the pre-entry brand price.

The entry of an AG, however, substantially reduces the revenues of the first-filer during the exclusivity period, because the AG typically attains significant market share at the expense of the ANDA product. By promising not to launch an AG during the exclusivity period, the brand company has a considerable bargaining chip that it can use in settlement negotiations and agreements with a first-filer, which can very simply extend the brand company's monopoly and profits.

The reduction in revenue for the first-filer as a result of the AG competition is likely to change the business decisions of both independent generic pharmaceutical companies and brand pharmaceutical companies. Because a generic company can earn substantially greater revenues if it has sole access to the marketplace, a generic firm may be willing to defer entry into the market if a brand company agrees not to launch an AG to compete during the 180-day exclusivity period. The Interim Report finds that such agreements are becoming more common now than in the past.

The FTC also concludes that settlement agreements between brand companies and first-filers can harm consumers in two ways. First, the entry of a generic and the associated discounts would not be available for consumers to take advantage of as soon as would be the case under the traditional 180-day exclusivity period as the Hatch-Waxman Act intended. Prescription drug costs, and the subsequent revenues, could be significantly increased by even a few months of delayed entry by a competing generic drug. Second, consumers would lose the benefit of price discounts resulting from the competition between the AG and the first-filer generic company. When a brand company agrees not to compete against the independent ANDA product during the exclusivity period, competition in the prescription drug market would be harmed by the absence of an AG to compete with the ANDA product.

As the practice of marketing AGs during the 180-day exclusivity period has become more common, generic drug companies contend that the practice of a brand company manufacturing and selling an AG is anticompetitive and undermines the Hatch-Waxman Act, which encourages generic companies to challenge drug patents and enter the market prior to patent expiration. Brand companies maintain that the introduction of AGs into the marketplace promotes competition and is consistent with federal drug law. It is within this context that the FTC has taken on this analysis.

Chairman Jon Leibowitz said in his statement: "An American consumer should not be denied the discounts that come with generic entry – both modest discounts during the 180-day exclusivity and much more significant, 85% price reductions thereafter, when multiple generics enter – because a brand and a generic have decided they can make more money if they substantially delay the point at which they begin to compete with each other."

Commissioner J. Thomas Rosch, in his concurring statement, declares that he agrees with "the bottom-line conclusion of the Commission's Interim Report that the Report cannot properly be read to support a legislative ban on the marketing of [AGs] during the 180-day exclusivity period (or otherwise) or to suggest that AGs are harmful to consumers," before going on to "correct misimpressions that may arise from various statements and omissions in the Report." The Commission voted 3-0 to issue the report, with Commissioner Paula Jones Harbour recused.

Lawmakers in both the House of Representatives and the Senate have introduced bills that would ban brand pharmaceutical companies from introducing AGs during the 180-day exclusivity period.

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