

Reading Between the Lines of the FTC's Interim Report on Authorized Generics

The Federal Trade Commission issued an interim report on its ongoing industry-wide study of “authorized generics” (the “Interim Report”) on June 24th.¹ The trade press focused on the Initial Report’s topline finding that the practice saved consumers money during the 180-day period of “generic exclusivity” that occurs when generic entry comes early because of a patent challenge. This is unaccustomed praise from the FTC for business practices of the brand name prescription drug industry, and readers were left to review the Interim Report and the separate statements of Chairman Leibowitz and Commissioner Rosch to understand that there was less to it than met the eye. Indeed, the point of the Interim Report was not to hail the value of authorized generics as such but to support Chairman Leibowitz’ great ambition to curtail the use of settlements of patent infringement cases between brand name and generic drug manufacturers, some of which have provisions limiting authorized generics. Moreover, especially as revealed by disagreements that spilled over onto the pages of the separate statements, there are indications that the final report will focus far more on what some see as the anticompetitive long-term effects of authorized generics, perhaps most notably in relatively low-volume markets. Still, having praised the pro-consumer benefits of authorized generics and having generally criticized agreements that prevent their entry, the Commission may be hard-pressed when the final report on authorized generics is released to justify a general policy of enforcement.

The Interim Report

The FTC’s authorized generics study was prompted by congressional requests initially made in May 2005, and resulted in demands for information sent in September 2007 to more than 100 brand name and generic drug manufacturers; pricing information was also ultimately purchased from a third-party service.² The stated goal of the study was to examine the short-term and long-term effects of authorized generic drugs on competition in the prescription drug marketplace. But, while hinting that authorized generics may deter patent challenges especially in smaller markets, the Interim Report specifically disclaims an analysis of long-term or “overall” effects of authorized generics on competition. Instead, it focuses just on effects during the 180-day generic exclusivity period.³

First, the Interim Report considers the effect of authorized generics on the prices for drugs during the 180-day generic exclusivity period, and not surprisingly concludes that consumers benefit from the practice: Pricing in wholesale and retail markets in which authorized generics competed were found to be 4.2% and 6.5% lower, respectively, than in markets in which only the exclusive generic was available. Second, the Interim Report considers the effect of an authorized generic on the revenues of exclusive generics permitted to be marketed during this period, and it finds that the revenues decline by approximately 50% — the result of a combination of lower pricing and reduced sales.

Much of the Initial Report is not even devoted to an analysis of authorized generics but instead to settlements of patent infringement litigation between brand name and generic drug manufacturers that have provisions relating to authorized generics. Thus, the Initial Report states that approximately 25% of such settlements between 2004 and 2008 contained provisions relating to authorized generics, and that approximately 25% of settlements with manufacturers of exclusive generics contain provisions in which the brand name manufacturer agrees not to launch an authorized generic. The Initial Report suggests that the chance to avoid the 50% decline in

revenues upon entry has motivated the inclusion of such provisions.

The vote to issue the Interim Report was 3-0, with Commissioner Harbour recusing herself. Chairman Leibowitz issued a statement in connection with the action, and Commissioner Rosch issued a “concurring” statement.

Discussion

Putting aside the effect, if any, that it may have on potential legislation involving patent infringement settlements between brand name and generic drug manufacturers, the Interim Report provides perhaps the best publicly-available analysis of the many and varied ways in which agreements relating to authorized generics may play a role in such settlements. Companies contemplating the use of such provisions will find the discussion informative, and perhaps useful in assessing the risks attendant to doing so.

For those who have followed the FTC’s authorized generic study, however, the real points of interest come not in the Interim Report itself but in the dueling statements issued by Chairman Leibowitz and Commissioner Rosch. These statements appear to prefigure the final report’s discussion of the question that industry observers believed the authorized generics study was commenced to address: Whether there are circumstances in which the FTC will challenge an authorized generic agreement as a violation of Section 5 of the FTC Act.

Chairman Leibowitz takes the position that the Interim Report provides “facts and analysis” that go to the two long-term questions he states the authorized generics study was intended to answer: “How much do authorized generics benefit consumers?” and “How much do they undermine the incentive for generics to seek entry prior to patent expiration?”⁴ While couched in neutral terms, it is clear that Chairman Leibowitz considers the import of the “facts and analysis” to be hardly that. He characterizes the savings to consumers documented in the Initial Report as “relatively modest,” and describes as “substantial” the effects of authorized generics on the exclusive generic.⁵ Indeed, the Initial Report itself notes that the impact of authorized generics “is likely to change the calculus of business decision-making in some circumstances for both generic and branded firms,”⁶ . . . and asserts that the “take-away” from prior studies is that authorized generics are “most likely to have a consequential impact on [patent] challenges for drugs with relatively low sales volume.”

Commissioner Rosch is not so hostile towards authorized generics, and indeed appears to believe that the demonstrated savings to consumers achieved during the generic exclusivity period is the end of the matter so far as FTC jurisdiction is concerned: “To my knowledge, no one has ever condemned price competition on the ground that it will reduce another competitor’s revenue (at least so long as the prices charged were not below the first competitor’s cost).”⁷ That the revenue in question may have been intended by Congress to encourage patent challenges is, in other words, a matter of policy and not of antitrust enforcement. Further, Commissioner Rosch sets up a bulwark against a conclusion being drawn in the final report that authorized generics injure competition because they deter patent challenges by observing that neither data collected in the authorized generic study nor any “secondary analysis” would support any such claim.⁸ He adds that any view that authorized generics “deter ANDA generics from competing . . . is purely speculative—there is no data showing that any generic drugs have not been marketed as a result of potential competition from [authorized generics].”⁹

The competing statements of Chairman Leibowitz and Commissioner Rosch may well prove to be summaries of the statements they will issue when a final report is released. Beyond this, though, there is at least the suggestion that the authorized generics study may not prove to be a call to arms for enforcement. Responding to Commissioner Rosch, Chairman Leibowitz says simply that “Congress did not ask for an antitrust analysis.”¹⁰ If so, perhaps an FTC that is inclined to believe that authorized generics are anticompetitive, even if only in smaller markets, may decline to take on what are sure to be bruising adjudications and opt instead just to push for legislative action. These obviously are difficult matters to predict in the abstract. Certainly, however, enforcement efforts will be made more difficult by the praise heaped generally on authorized generics in the Initial Report, and the suggestion that preserving them is so important that it supports legislation

against patent settlements.

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1. "Authorized Generics: An Initial Report," Federal Trade Commission (June 24, 2009). Copies of the report and of the separate statements of Chairman Leibowitz and Commissioner Rosch may be found at <http://www.ftc.gov/opa/2009/06/generics.shtm>.
 2. See Initial Report Executive Summary at 1; Initial Report at A-1 n.1. Drug companies that expended substantial resources in responding to the FTC's detailed requests for information might be chagrined to learn that *none* of that information was used by the Commission in the analysis contained in the Initial Report. Initial Report at A-1 n.1.
 3. Initial Report Executive Summary at 1.
 4. Statement of Chairman John Leibowitz on the Release of the Commission's Interim Report on Authorized Generics ("Leibowitz Statement") at 2.
 5. *Id.* at 1.
 6. Initial Report Executive Summary at 2; Initial Report at 4.
 7. Concurring Statement of Commissioner J. Thomas Rosch on the Release of Commission's Interim Report on Authorized Generics at 1.
 8. *Id.* We have previously expressed similar skepticism that evidence of the anticompetitive effects of authorized generics might be found. See [Authorized Generics: Still Legal – and Holding](#) (*Pharmaceutical Executive*, September 2006); [Permission Granted: Generics Companies Think Authorized Generics are Unfair. Does the Law Agree?](#) (*Pharmaceutical Executive*, May 2004).
 9. *Id.* at 2 n.4.
 10. Leibowitz Statement at 2.

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