FTC Continues To Target Pharmaceutical Mergers

Law360, New York (April 17, 2014, 12:41 PM ET) -- The Federal Trade Commission has often stated that merger analysis requires more than a simplistic determination that high market concentration leads to anti-competitive effects.[1] Still, the antitrust agencies have consistently considered transactions that decrease the number of market participants (particularly from three to two), to be provocative, if not problematic, even if the combined entity’s market share is relatively low.

Despite Commissioner Joshua Wright’s recent dissent in In the Matter of Fidelity National Financial Inc. and Lender Processing Services Inc., File No. 131-0159, Dec. 23, 2013, emphasizing a focus on other factors, such as coordinated interaction among market participants rather than the number of firms, the FTC continues to hew the numbers line. No place is that truer than in pharmaceutical markets.

Recently, to clear Akorn Inc.’s $640 million acquisition of fellow generic pharmaceutical manufacturer Hi-Tech Pharmacal Co. Inc., the commission unanimously required Akorn to divest five pharmaceutical products to Watson Laboratories Inc.

In its complaint, the FTC argued that in the market for two products, generic Ciloxan ophthalmic eye drops and generic EMLA cream, the proposed transaction would reduce the number of suppliers from four to three. The market shares predicted for the two products post-transaction diverged wildly: For Ciloxan, the FTC claimed that the acquisition would give the merged firm a market share of 28 percent, and for EMLA, 70 percent.

The FTC further alleged that for generic Quixin eye drops and Xylocain jelly, the deal would reduce the number of suppliers from three to two, and result in a market share of 38 percent for Quixin and 50 percent for Xylocain. Finally, the FTC alleged that Hi-Tech was poised to be the next entrant in the market for Ilotycin eye ointment, a product currently sold by three firms, with 31 percent of the current market held by Akorn.

In its analysis accompanying the consent order, the commission relied heavily on the “costly and lengthy” barriers to entry into the generic pharmaceuticals market (i.e., drug development times and regulatory requirements such as U.S. Food and Drug Administration approval) for its conclusion that proposed acquisition would reduce competition in the markets for the five products. Analysis of Agreement Containing Consent Orders to Aid Public Comment, In the Matter of Akorn Enterprises Inc. and Hi-Tech Pharmacal Co. Inc., File No. 131-0221, Docket No. C-4452 (April 14, 2014).

Moreover, according to the FTC, the specialized expertise required to develop these products results in a small number of firms in the market at the outset. In support of its conclusion that the deal would have anti-competitive effects in the market, the FTC invoked statements from customers and competitors to characterize generic pharmaceuticals markets as “commodity markets in which the number of generic suppliers has a direct impact on pricing.” Id. at 3. The FTC also cited competitors as noting that Hi-Tech’s presence in the market allowed them to negotiate lower prices from other suppliers,
including Akorn.

The Akorn-Hi-Tech acquisition shows that the FTC is unlikely to ease up soon on what has essentially become a bright-line rule in antitrust policy: Transactions resulting in three to two and sometimes even four to three reductions in the number of competitors, where there would be no timely entry, face difficult regulatory hurdles.

The FTC also has familiarity with pricing practices in the generic industry, and would like its enforcement policies to help foster lower prices through more alternatives. It is the likely rationale for the FTC’s proclivity, exemplified here, in challenging four to three transactions in the pharmaceutical industry. Nonetheless, requiring divestiture of Ciloxan (which the FTC found as the result of the deal would only hold 28 percent market share), is a particularly aggressive result.

—By Bruce Sokler and Helen Kim, Mintz Levin Cohn Ferris Glovsky and Popeo PC

Bruce Sokler is a member in Mintz Levin's Washington, D.C., office and chairman of the firm's antitrust section. Helen Kim is an associate in the firm's Washington office.

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[1] See 2010 Merger Guidelines § 4.3 (finding that market concentration is only one of several useful indicators of a merger’s likely competitive effects); Statement of the Federal Trade Commission Concerning the Proposed Merger of Office Depot, Inc. and OfficeMax, Inc., FTC File No. 131-0104 (Nov. 1, 2013) (“Analyzing the likely competitive effects of a proposed transaction is always a fact-specific exercise that must take into account the evolving nature of markets.”); Timothy J. Muris, Chairman, Federal Trade Commission, Remarks Before Workshop on Horizontal Merger Guidelines (Feb. 17, 2004) ("[C]urrent merger practice does not elevate a single fact or number to dispositive significance.").