Generic Drug Mergers: Overcoming the Antitrust Hurdles

by David A. Balto

As in many other markets, there has been considerable consolidation involving generic pharmaceutical manufacturers. Novartis Inc.'s $1.7 billion acquisition of Eon Labs Inc.[1] and Teva Pharmaceuticals USA's proposed $7 billion acquisition of Ivax Corporation[2] are just two recent examples.

The vast majority of generic drug mergers are procompetitive, or are at least competitively neutral. Generic drug mergers can be procompetitive by combining marketing and manufacturing expertise to enable the generic drug firms to reduce costs and to provide lower-cost products to consumers. Generic drug markets are highly competitive where prices are slightly above marginal cost at best. Moreover, generic drug firms face substantial costs when developing new drugs. Perhaps the greatest hurdle faced by generic drug companies, however, is marketing. An individual generic drug company has a limited family of drugs to market—the greater the range of drugs, the more effectively a generic drug manufacturer can market its drugs to the thousands of physicians, insurers, and pharmacy benefit management companies (PBMs).

It is not surprising then that there has been a significant trend towards consolidation in the generic drug market. As in any market, mergers and acquisitions are reviewed by the antitrust enforcement agencies: the Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice. The FTC reviews all pharmaceutical mergers. Generic drug mergers are receiving increasing attention by the antitrust enforcement officials. In some respects, that may seem surprising, in other respects not. Although generic drugs are low priced and significantly less expensive than their branded rivals, empirical evidence and economic studies show that the number of competitors in the generic drug market has a significant impact on price competition in those markets. In 2002, FTC economists found that the entry of the fifth, sixth, and seventh generic firms into a drug market had a significant impact on prices.[3] Therefore, mergers that reduce the number of competitors in a drug market could raise significant competitive concerns.

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The Merger Review Process

Before considering the details of generic pharmaceutical mergers, it is important to understand the antitrust agencies' review process. Under the Hart-Scott-Rodino Act,[4] the agencies must be notified by the merging parties of the vast majority of mergers and provided with general information about the merging parties' sales and assets. Following notification, the antitrust agencies have 30 days to decide whether to conduct a more extensive investigation (a "second request"). The parties cannot merge until the antitrust agencies complete their investigation. Most mergers are resolved during this initial 30-day period. Because the majority of investigations move so quickly, companies that have concerns about a proposed merger should contact the agencies' staffs at an early stage in the investigation.

In pharmaceutical mergers, the FTC begins by identifying all of the product overlaps between the two merging companies and then asks the merging parties for a list of all of the drugs manufactured or marketed, product brochures, business plans, and industry studies. In addition, because products in development are an important part of the agency's analysis, an entire list of research and development (R&D) projects will be requested. The FTC also will request a list of joint ventures

and strategic alliances in order to identify the various alliances that may be impacted by the merger. Finally, the FTC will ask about any intellectual property rights litigation because it may suggest where entry barriers into certain markets exist.

During the initial 30-day period, the FTC staff also solicits information from a variety of other sources (i.e., major competing buyers such as PBMs, insurers, and other major pharmaceutical purchasers, and "key opinion leaders" such as physicians and scientists conducting R&D in individual therapeutic areas). Because so many investigations are concluded within this period, it is important that parties that have an interest in the merger act as proactively as possible during this time. At this stage, competitors and customers have a valuable opportunity to educate the FTC staff on any concerns that the merger may raise for them.

If the FTC believes potential competitive concerns from the merger exist in any therapeutic area, the agency may ask for a second request investigation, which typically delays an acquisition by an additional six to nine months. In a second request, the FTC has full reign to secure a wide variety of documents with information regarding the competitive impact of the merger and may depose the merging parties' competitors and customers to determine the competitive impact of the merger.

Following the FTC's investigation, the agency may challenge the merger in court, permit the merger to occur, or require the merger to be restructured in order to resolve competitive concerns. A majority of second request investigations result in a consent decree in which the merging parties restructure the transaction in order to satisfy competitive concerns raised by the FTC.

In all markets, the FTC conducts the following five-step merger analysis:

(1) define the relevant product market;
(2) define the relevant geographic market;
(3) determine the likely competitive effects of the merger;
(4) determine whether the anticompetitive effects will be overcome by the new entry; and
(5) determine whether the anticompetitive effects will be overcome by the potential efficiencies resulting from the merger.

In pharmaceutical mergers, the analysis typically focuses on defining the product market, determining the competitive effects of the merger, and identifying any barriers to market entry.

Merger Analysis

The product market inquiry attempts to define which products effectively compete with each other. The FTC identifies product markets by therapeutic category—the disease state that a given pharmaceutical attempts to treat. Product markets are defined from the perspective of customers; but there is no clear answer as to who the actual customers are in the pharmaceutical market. Patients are the "customers" but they have little choice over the product; prescribing physicians are gatekeepers to the product selected; and third-party payers ultimately pay for the products but have little control over what the physician prescribes. Depending on the nature of the market in question, the FTC may focus on any of these customer sets. The agency will then ask whether any set or subset of customers view the merging parties' products as competing.

For branded pharmaceuticals, the FTC typically will attempt to define the relevant product market by talking to the payers (i.e., the PBMs and insurance companies that ultimately pay for the product). The agency also will rely heavily on any information provided by key opinion leaders. For generic pharmaceuticals, the FTC typically will talk to wholesalers and pharmacy chains about the competitive alternatives.

One controversial issue in relevant product analysis of pharmaceutical mergers is whether branded and generic products should properly be considered in the same market. In some nonmerger enforcement actions, the FTC has included branded and generic firms in the same market. In pharmaceutical mergers, however, the FTC rarely will include those drugs in the same market because competition between generic drugs rarely impacts the price of branded pharmaceuticals.

The centerpiece of merger analysis is on the competitive effects—how the elimination of one of the merged firms will impact competition in the marketplace. Typically, if there are a large number of competitors—at least four remaining after the merger—there should be few competitive concerns. Although recent FTC studies show that prices fall as the number of competitors increases,[5] the FTC is not willing to bring an enforcement action simply because the number of competitors in a market is reduced. Rather, the FTC staff will focus on those mergers where it can tell a "story" that the merger has some special potential to decrease output or increase prices.

The final issue scrutinized by the FTC is the ability of other firms to enter the market effectively. Absent significant barriers to entry, anticompetitive effects from a merger are not

likely. The most important factor in the FTC's analysis is the history of entry. If firms have not entered the market in the past, it is unlikely that they will do so after the merger. In most cases, however, the barriers to generic entry should not be substantial—typically there are no intellectual property rights, production manufacturing, or supply barriers to limit entry. In some cases, on the other hand, there may be significant barriers to entry, including production complications, restrictions on the availability of active ingredients, or the small size and maturity of the market (i.e., suggesting little profit opportunities from market entry). Oftentimes, the FTC will rely on the views of competitors, customers, and other market participants to provide the agency staff with the information of what actually is needed to enter a market.

Recent FTC Enforcement Actions

The FTC has brought enforcement actions in only limited circumstances in mergers involving generic drugs. In 2002, Baxter Healthcare Corporation acquired substantially all of the assets related to Wyeth's ESI Lederle generic injectable pharmaceutical business for a total of $316 million dollars.[6] The FTC brought an enforcement action requiring a divestiture in five markets: 1) propofol, 2) pancuronium, 3) vecuronium, 4) metoclopramide, and 5) new injectable iron replacement therapies (NIIRTs).[7] Propofol is a preferred anesthetic agent for out patient surgery with annual sales of between $375 and $400 million dollars. Baxter manufactured the only generic propofol and Wyeth was a potential entrant—Wyeth's entry would have registered a significant deconcentration of the market and lower prices. Propofol is manufactured in an extremely complex process and requires the use of a patent-protected preservative. Any potential entrant would have to develop a propofol product using a different preservative that did not infringe existing patents. The Consent Decree required Wyeth to divest its propofol assets to Faulding Pharmaceutical Company.[8]

Pancuronium is a rapid onset long-acting neuromuscular blocking agent used to temporarily freeze muscles during surgery and other procedures. It is an extremely small market with sales of approximately two million dollars. The merger would have reduced the number of competitors from three to two. In this case, the entry barrier was maturity and size of the market—with only a two million dollar market it was highly unlikely that other firms would attempt to effectively enter the market. Baxter marketed pancuronium pursuant to an exclusive agreement with GensiaSicor; in order to resolve the competitive concerns, Baxter had to terminate all of its rights and interests in GensiaSicor pancuronium product and divest all of its assets to GensiaSicor.

Vecuronium is an intermediate acting neuromuscular blocking agent with sales in the United States of $21 million. This market was less concentrated than other markets and would have reduced the number of competitors from five to four. In this case, the entry barrier again was the relatively small size of the product and the difficulty of manufacture. Companies were unlikely to devote resources to enter this market because the existing suppliers had become entrenched and vecuronium also was a complicated drug to manufacture.

Metoclopramide is an anti-antiemetic used for the prevention and treatment of nausea for patients undergoing chemotherapy. It is an older drug with sales of only $13 million. The merger would have reduced the number of competitors from four to three and new entry was unlikely because of the small size of the market.

The case of NIIRTS helps illustrate the agencies' concerns in preserving market arrangements that help bring generic products to the market. NIIRTS are used to treat iron deficiency in patients undergoing hemodialysis. The approximate market was $225 million. The two major competitors in this market were Watson and American Regent. Competitive concerns arose because Watson was in a co-promotional agreement with Baxter in order to eliminate the potential anticompetitive effects. Entry into the market was difficult and time consuming because of Food and Drug Administration (FDA)-imposed new chemical entity exclusivity and a lack of raw material suppliers. In order to resolve the competitive concerns from the merger, Watson was required to terminate its co-marketing agreement with Baxter. If a third party is forced to abandon its relationship with one of the merging parties as part of a divestiture package, the FTC staff will work hard to ensure that the third party receives the resources it needs to compete in the post-merger world. Experienced antitrust counsel can help guide companies through this process by educating the FTC staff of what those companies need to compete.

More significant competitive concerns were raised by Novartis' acquisition of Eon Labs. Although there were overlaps in over 10 generic pharmaceutical markets, the merger was approved through the divestiture of three overlapping drugs (orphenad-

rine citrate, desipramine hydrochloride tablets, and rifampin) to Amide Pharmaceutical, Inc. In each of these markets, the number of competitors was reduced to less than four. The only other competitor in the desipramine hydrochloride market was Watson Pharmaceuticals, which manufactured three of the six strengths of the drug and accounted for only a minuscule share of the market. Similarly, Impax Laboratories and Versapharm were the only other rivals in the orphenadrine citrate and rifampin markets and when combined accounted for more than 70% of the market.

In each market, the most significant entry barrier was the maturity and small size of the markets ($6 million for desipramine hydrochloride, $10 million for orphenadrine citrate muscle relaxant, and $14 million for rifampin drug use in the treatment of tuberculosis). The FTC disregarded the impact of branded pharmaceuticals because they were priced significantly higher than the generic pharmaceutical companies.

Remedy

An interesting issue in any pharmaceutical merger is how to remedy the potential anticompetitive effects of the merger. The FTC's objective is to create firms that have the incentive and ability to compete aggressively after the merger. If the agency identifies a competitive problem, it has a broad range of powers to require the merging parties to divest sufficient assets so that a new firm can effectively enter the market and replace competition. Divestitures typically include all of the assets in the business (e.g., intellectual property, trade names, other information).

The remedy required in the Novartis/Eon merger illustrates the FTC's broad remedial powers. Novartis must provide various transitional services to enable Amide to compete against Novartis immediately following the divestiture. Specifically, Novartis is obligated to divest all inventory of the three divested products and to supply Amide with the two products that Amide currently does not manufacture while Amide attempts to obtain FDA approval to manufacture the drug. In addition, Novaratis must supply Amide with sufficient product for a two-year period of time and potentially additional periods until Amide receives FDA approval. Finally, Novartis is required to provide technology transfer assistance to enable Amide to obtain the necessary FDA approval.

Other enforcement actions demonstrate the steps the FTC will take to preserve the competitiveness of the abandoned partner. The FTC has required merging companies to provide the "personnel, assistance, and training," necessary to ensure that the acquiring firm can use the acquired assets successfully.[9] In some instances, this may mean that the merging party must provide incentives for its employees to join the acquiring company.[10] In addition, the FTC, at times, has prohibited the merging party from using its customer contacts to sell its products to the acquiring party's customers for a period of time after the merger.[11]

Conclusion

The recent merger wave, combined with the ever-present drive to contain healthcare costs, will place generic pharmaceutical mergers prominently on the FTC's radar screen in coming years. The agency's reaction to the issues that these mergers raise certainly will shape the competitive landscape for years to come. For this reason, the FTC will be especially attentive to the observations and concerns of parties that are affected by these mergers. It is prudent, therefore, for companies with such concerns to be proactive in contacting the agency and assisting the FTC in addressing competitive issues.

1 Press Release, Novartis, Novartis Completes Acquisition of 98% of Eon Labs, Substantially Strengthening the Leading Position of its Sandoz Generics Unit (July 21, 2005), *available at* http://dominoext.novartis.com/NC/NCPRRE01.nsf/44aff02a639be034c1256b4b007b5f4d/1ef8b6279ecb7f16c1257045002fe251?OpenDocument (last visited Aug. 10, 2005).

2 Press Release, Teva Pharmaceuticals Industries Ltd., Teva to Acquire Ivax for $7.4 Billion (July 25, 2005), *available at* http://www.tevapharm.com/pr/2005/pr_536.asp (last visited Aug. 10, 2005).

3 U.S. Fed. Trade Comm'n (FTC), Generic Drug Entry Prior To Patent Expiration: An FTC Study, (July 2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf (last visited Aug. 10, 2005) [hereinafter FTC Study].

4 Hart-Scott-Rodino Antitrust Improvements Act of 1976, Pub. L. No. 94-435, 90 Stat. 1383-97 (codified as amended in scattered sections of 15, 18, and 28 U.S.C).

5 FTC Study, *supra* note 3.

6 Press Release, Baxter, Baxter Completes its Acquisition of ESI Lederle (Dec. 20, 2002), *available at* http://www.baxter.com/about_baxter/news_room/news_releases/2002/12-20-02esi.html (last visited Aug. 10, 2005).

7 In the Matter of Baxter Int'l and Wyeth, FTC File No. 021-0171, Docket No. C-4068 (Feb. 3, 2003), *available at* http://www.ftc.gov/opa/2003/02/baxter-wyethdo.htm (last visited Aug. 10, 2005).

8 *Analysis of Agreement Containing Consent Orders to Aid Public Comment*, In the Matter of Baxter Int'l and Wyeth, FTC File No. 021-0171, Docket No. C-4068 (Feb. 3, 2003), *available at* http://www.ftc.gov/os/2002/12/baxter_wyethanalysis.htm (last visited Aug. 10, 2005).

9 In the Matter of Sanofi-Synthelabo and Aventis, FTC File No. 041-0031, Docket No. C-4123, at 24-5 (Sept. 20, 2004), *available at* http://www.ftc.gov/os/caselist/0410031/040924do0410031.pdf (last visited Aug. 10, 2005).

10 In the Matter of Precision Castparts Corp. and Wyman-Gordon Co, FTC File No. 991-0240, File No. C-3904 (Dec. 17, 1999), *available at* http://www.ftc.gov/os/1999/12/precision.do.htm (last visited Aug. 10, 2005).

11 In the Matter of CIBA-Geigy Ltd., CIBA-Geigy Corp., Chiron Corp., Sandoz Ltd., Sandoz Corp., and Novartis AG, FTC No. 961 0055, Docket No. C-3725, at 18 (Mar. 24, 1997), *available at* http://www.ftc.gov/os/1997/04/c3725.do.pdf (last visited Aug. 10, 2005).