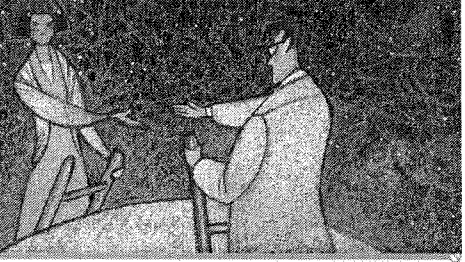
Generic Drug Strategic Alliances: Competitive Opportunities and Antitrust Risks



By David A. Balto

Generic drug firms face a myriad of competitive challenges. There are scores of strong competitors and an absence of significant entry barriers. Generic firms typically offer a significant number of products but lack the financial wherewithal, marketing depth, and financial resources of branded pharmaceutical firms. They often lack profitable proprietary drugs as well as large detail staffs and marketing forces to bring a drug to market. Generic drug firms face substantial costs to develop and market individual drugs and, like all pharmaceutical companies, confront sophisticated buyers with the power to bargain down prices. Generic drugs typically are sold, at best, at margins just slightly above cost. Thus, the generic drug market is the paradigm of a competitive market.

To better compete in this challenging environment, generic firms increasingly use strategic alliances.[1] "Strategic alliance" is an elastic term that encompasses a wide variety of arrangements. Such arrangements can range from something as formal and permanent as a merger, to more limited arrangements (e.g., joint ventures, licensing agreements, or comarketing arrangements). Strategic alliances are critical to the generic drug industry because they permit firms to harness divergent skills and resources in order to compete more effectively.

Although strategic alliances offer firms the promise of substantial efficiencies in terms of lower cost, better service, and faster introduction of generic drugs, on occasion they may raise antitrust concerns. Any agreement among competitors may lead to higher prices or less innovation or service. In fact, the Federal Trade Commission (FTC) has identified "generic-generic alliances" as a new area of antitrust concern.[2]

This article explores the reasons for generic drug strategic alliances, examines the limited situations where competitive concerns may arise, and suggests ways to structure these alliances to avoid antitrust problems.

Background

The potential efficiencies of strategic alliances cannot be understated. Strategic alliances enable firms to achieve economies of scale in product development, production, and distribution. They reduce duplication of promotion and enable participants to advertise and market their products more efficiently. Strategic alliances lead to greater product and process innovation by bringing together complementary assets, such as patents, know-how, production facilities, and even human expertise and ingenuity. Strategic alliances also enable participants to reduce the often-substantial business risks to commercially acceptable levels. Through a product distribution joint venture, firms can share the risks and expenses inherent in developing a new consumer brand.

In the generic drug marketplace, strategic alliances offer firms the opportunity to merge their efforts to achieve economies of scale and scope. For example, one generic firm may have a strong research and development program; another firm may have a large or experienced marketing staff that currently markets a drug in a similar therapeutic category. Through a comarketing agreement, these two

firms can bring a product to market faster, less expensively, and more effectively. Strategic alliances are more flexible and focused than a complete merger between two firms.

Antitrust Concerns

When strategic alliances involve current or potential competitors, these alliances may raise antitrust concerns. For example, two firms that are the only participants in a generic drug market with significant entry barriers could have the ability to raise prices if they were to merge, or divide the market by type of customer or territory. FTC Chairman Timothy Muris has observed that "[c]ollusion between the generics can thus be a means of preventing price erosion in the short term, though it may become substantially less feasible if subsequent abbreviated new drug applications (ANDAs) are approved and additional competitors enter the market."[3] The latter observation is critical: absent substantial entry barriers, one could expect new companies to enter quickly and extinguish any anticompetitive conduct.

Strategic alliances with a supplier can raise concerns where they foreclose a vital input from rivals.

In congressional testimony, the FTC suggested two potential anticompetitive scenarios. In the first, there is a single generic firm in the market. The second generic firm, rather than entering, becomes the exclusive distributor of the sole generic in the market. In effect the first generic firm is paying the second generic not to enter and they share in the higher prices that result. The second scenario would involve a market division between two firms either by geographic market or by strength of drug.[4]

Two recent FTC enforcement actions illustrate these antitrust concerns. In June 2002, Biovail and Elan entered into an FTC settlement resolving charges that they had unreasonably restrained competition in Adalat, a generic antihypertensive drug.[5] The FTC alleged a joint marketing agreement between the two firms that effectively divided the generic Adalat market. Biovail and Elan were the only two companies with Food and Drug Administration (FDA) approval to manufacture and sell 30 mg and 60 mg generic Adalat. Biovail was the first entrant in the 30 mg version, and Elan was the first entrant in the 60 mg version; both firms received FDA approval to enter into each other's market. Biovail and Elan entered a joint marketing agreement in which Elan appointed Biovail as the exclusive distributor of Elan's 30 mg and 60 mg generic Adalat products, thus enabling Biovail to profit from the sale of both products. The FTC alleged that the companies' distribution agreement substantially reduced the incentive of each firm to introduce competing 30 mg and 60 mg generic Adalat products.

The joint marketing agreement did not explicitly limit Biovail to the 60 mg market and Elan to the 30 mg market—a limitation that clearly would have been anticompetitive. In fact, the agreement specified that Biovail was supposed to use "reasonable commercial endeavors" to launch its 30 mg product "with reasonable dispatch." Instead, the agreement had a profit-sharing provision that created a strong disincentive for either Biovail or Elan to enter each other's markets. Such entry would have reduced prices, leading to less revenue under the profit-sharing agreement. As of September 2001, Biovail had paid Elan approximately $45 million for the 60 mg and 30 mg products covered by the agreement. An important factor in the FTC's analysis was the fact that, while Elan had the ability to enter into the 60 mg market, it never actively pursued opportunities to market with other generic pharmaceutical firms.

The FTC's consent order prohibited both companies from entering into anticompetitive price, output, or distribution agreements with other generic competitors. It required Elan to use its best efforts to sell, as soon as possible, its 30 mg and 60 mg generic Adalat product through a distributor other than Teva, the distributor used in the Biovail/Elan agreement. Furthermore, Biovail was required to use its best efforts to launch its 30 mg generic Adalat product as soon as possible.

More straightforward antitrust concerns are raised in merger agreements. Although the FTC has reviewed scores of generic drug mergers, they have challenged only two such mergers in the past decade. The most recent was Baxter's acquisition of certain generic drugs of Wyeth in December 2002.[6] The FTC analyzed several markets and as part of a consent agreement reached with the parties, Baxter agreed to divest assets to eliminate barriers to competition in five separate generic drug markets. In each of the markets, the FTC argued that there were four or less competitors, the merged firm would have had at least a 50% market share, and there were substantial entry barriers. One interesting aspect of the FTC's approach was that it required Baxter to end a comarketing agreement with Watson Pharmaceuticals, Inc., regarding

Watson's new injectable iron replacement therapy (NIIRT). Wyeth already was in the NIIRT market and the FTC was concerned that Baxter would have been able to inhibit Watson's post-merger ability to compete effectively after the merger.

Strategic alliances with a supplier can raise concerns where they foreclose a vital input from rivals. For example, in 1997, Mylan entered into exclusivity arrangements with the two major suppliers of the active ingredients for certain drugs—arrangements that diminished the ability of rival generics to compete and permitted Mylan to raise prices dramatically in two important drugs. These were long-term exclusivity agreements that also contained a profit-sharing mechanism so the supplier would share in the downstream profits. This arrangement significantly diminished the ability and incentives of the active ingredient suppliers to supply other generic firms. The FTC and over 30 State Attorneys General challenged these agreements, and Mylan eventually paid substantial restitution to consumers.[7]

Practical Suggestions

There are several practical suggestions to structuring strategic alliances to avoid antitrust risk. The first is to do a careful competitive analysis. Where firms are not current or potential competitors in a therapeutic category, competitive problems with an alliance are unlikely. A strategic arrangement between two firms in complementary product areas should not raise antitrust concerns. Even if the firms are competitors, there may not be competitive concerns if there are several other existing or potential competitors, or if the two firms' combined market share is not substantial (e.g., under 30%), or if there are not substantial entry barriers. In most cases, generic alliances should pass muster under these tests.

In more concentrated markets with significant entry barriers, the structure of a strategic alliance needs careful attention. Restrictions on price and output receive the most serious antitrust scrutiny—an agreement where two firms enter a market but carve out exclusive territories could raise concerns. Similarly, any agreement that restricts competition on products outside the strategic alliance could lead to an antitrust challenge.

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Generally, exclusivity provisions need the most serious consideration. Exclusivity is not illegal *per se*; rather, exclusivity poses competitive problems when it is broader than necessary to achieve the efficiency sought by the parties. Exclusivity agreements can pose less significant problems where they are narrowly structured and limited in duration. An exclusivity arrangement limited to one year and involving less than 20% of the market generally would be permissible. More extensive exclusivity arrangements may be permissible if there is a clear business justification (e.g., the need to recover investments on product promotion or the need to guarantee supply or meet special demands of customers).

Antitrust agencies and courts do not look only at the existence of *de jure* exclusivity agreements; other arrangements, such as profit-sharing provisions, can create *de facto* exclusivity arrangements, as in the *Biovail/Elan* or *Mylan* situations. Profit-sharing arrangements appear to raise a red flag for antitrust enforcers and need to be carefully scrutinized to determine that firms will have incentives to continue to compete in the market. They will raise particular concern where parties appear to have the effect of dividing markets.

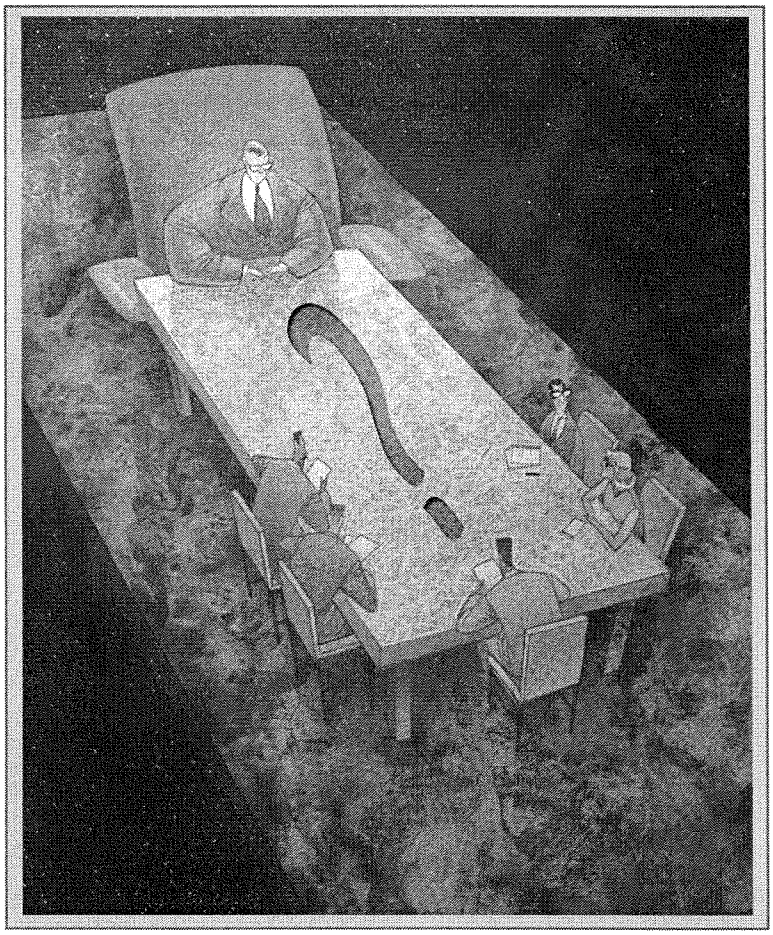
Proposed efficiencies from the strategic alliances must be carefully documented, especially before the companies enter into the arrangement. Credible evidence should demonstrate that 1) the efficiencies were taken into account during negotiations for the strategic alliance, and 2) there is a past history of achieving similar efficiencies. Significant efficiencies will be those that suggest that the strategic alliance will enable the firms to offer new products, lower prices, or provide better service.

The efficiencies of generic alliances are straightforward. An alliance may enable firms to lower production costs by exploiting economies of scale. In addition, generic alliances can improve marketing and distribution by bringing together families of products that can be marketed and distributed together. There may be substantial potential for efficiencies in research and development from generic alliances. These alliances may reduce duplicative efforts and improve the focus of those efforts.

For example, in 2001, Barr Pharmaceuticals acquired Duramed Pharmaceuticals while both firms competed in the generic oral contraceptive market.[8] Although the merger appeared to pose

potential competitive problems, the parties were able to advocate effectively that the merger would provide substantial efficiencies. Unlike Barr, Duramed had a large marketing force in female health products that could more effectively sell both firms' oral contraceptive products.

Another potential efficiency may arise where one firm possesses regulatory approval to enter a new market. For example, Andrx recently sought to enter the generic Prilosec market, the second largest drug market in the United States. Both Andrx and Schwarz challenged the Prilosec patent, but only Schwarz succeeded. Andrx, however, had the right to 180-day exclusivity. Andrx and Schwarz entered into an agreement where Andrx waived its exclusivity, permitting Schwarz to enter the market with Andrx sharing in the profits. Such an arrangement presented straightforward efficiencies—but for the agreement, there would have been no generic market entry.[9] Finally, a strong business justification for the strategic alliance is important. The parties should be able to explain to enforcement agencies why this arrangement is necessary to enhance competition and why neither party could achieve this on its own or in some less restrictive manner.



Conclusion

Now is a particularly critical time for generic drug firms to scrutinize strategic alliances to avoid antitrust risks. In addition to the FTC, which focuses 25% of its resources on the pharmaceutical industry, the state Attorneys General have formed a Pharmaceutical Task Force and brought numerous enforcement actions. Private plaintiffs are increasingly suing pharmaceutical firms for alleged anticompetitive activity—suits in which defendants can face treble damage liability.

Antitrust challenges will only increase as generic drug competition plays an even more essential role in the nation's efforts to reduce drug costs. As the FTC and other enforcers turn their attention to generic drug strategic alliances, parties considering such arrangements must carefully scrutinize the alliances for potential antitrust concerns. With thoughtful planning and analysis, "generic-generic alliances" can be structured to provide efficiencies to both parties, enhance their competitive ability, and ultimately benefit consumers.

[1] This article does not address one type of "alliance," namely patent settlements, which are discussed at length in Robert D. Paul, *Bringing Reason to Pharmaceutical Patent Settlements*, FDLI UPDATE, Sept./Oct. 2002, at 4.

[2] *Generic Pharmaceuticals: Marketplace Access and Consumer Issues: Hearings Before the Senate Comm. on Commerce, Science, and Transportation (Competition in the Pharmaceutical Industry*, prepared statement of Timothy J. Muris, Chairman, FTC, Apr. 23, 2002), *available at* http://www.ftc.gov/opa/2002/04/bioavail.htm (last visited Jan. 31, 2003).

[3] *Id.*

[4] *Id.*

[5] *In re* Biovail Corp., Dkt. No. 0110132, *available at* 2002 WL 1396710 (F.T.C. June 27, 2002).

[6] *In re* Baxter Int'l Inc., Dkt. No. C-4068, *available at* 2002 WL 31875937 (F.T.C. Dec. 20, 2002). The other generic merger challenge was Ivax Corp., 119 F.T.C. 357 (1995).

[7] FTC v. Mylan Labs., Inc., 62 F. Supp. 2d 25 (D.D.C. 1999)

[8] *Two Generic Companies Are Merging*, 20 MED. AD. NEWS (Iss. 8) (Aug. 1, 2001).

[9] Carey Krause, *Generic Prilosec Approved After Competitors Agree on Terms*, 262 CHEMICAL MARKET REP. (Iss. 17) (Nov. 11, 2002).