

Competition and Antitrust Enforcement in the Changing Pharmaceutical Marketplace

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I. INTRODUCTION

Pharmaceutical markets have been an important focus of the Federal Trade Commission's (FTC's) antitrust enforcement efforts over the years, and this is especially true today. Remarkable changes are occurring in these markets: the development of new drugs and other technologies; the expiration of some major pharmaceutical patents and the rapid growth of the generic drug industry; changes in the ways pharmaceuticals are distributed and paid for, including increasing coverage of pharmaceuticals in health care benefits plans and the related development of pharmacy benefits managers (PBMs); and, partly in response to some of these factors, a variety of mergers, joint ventures, and other business arrangements.

Some of these arrangements have given rise to the need for antitrust scrutiny and occasional enforcement action. This article outlines the three areas where antitrust concerns can arise in pharmaceutical markets, and where the FTC recently has taken enforcement action or opened investigations. The first area of concern is the trend toward vertical integration in the supply and distribution of pharmaceuticals, which the FTC addressed in connection with Eli Lilly's acquisition of PCS Health Systems, Inc., the PBM subsidiary of McKesson Corp. The second area involves transactions among competitors, or horizontal mergers and joint ventures. The FTC recently has taken enforcement action in several such cases. The third and final area relates to various types of nonmerger conduct that can raise competitive concerns in pharmaceutical markets, some of which we are currently under investigation.

II. VERTICAL INTEGRATION IN PHARMACEUTICAL MARKETS

Vertical integration (the combination of various levels of production and distribution through acquisition or contractual or other relationships between firms) can be an efficient way to bring a product to market. Any time a firm produces some of its own inputs or distributes its own products, vertical integration has occurred. Ordinarily this will raise little or no antitrust concern, whether it occurs through internal expansion or by a combination of firms in a vertical relationship.

Nevertheless, under some conditions vertical acquisitions or similar arrangements can have anti-competitive effects. Numerous antitrust economists, legal scholars,¹ and

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¹ See generally ABA ANTITRUST SECTION, NON-HORIZONTAL MERGERS: LAW AND POLICY 5 (1988); Thomas G. Krattenmaker & Steven C. Salop, *Anticompetitive Exclusion: Raising Rivals' Costs to Achieve Power Over Price*, 96 YALE L.J. 209 (1986).

the 1984 merger guidelines issued by the Department of Justice (DOJ)² have recognized this problem. Although the portions of the 1984 guidelines dealing with nonhorizontal mergers were not included in the 1992 Horizontal Merger Guidelines that were issued jointly by the DOJ and the FTC,³ they continue to inform the agencies' evaluation of vertical mergers, along with analytical developments that have occurred since the 1984 guidelines were issued.⁴

Antitrust enforcement in the merger area primarily focuses on horizontal transactions, because such transactions present the greatest risk of harming the competitive process, and thereby harming consumers. This is true in the pharmaceutical industry, where most merger challenges have involved the combination of direct or potential competitors.⁵ Two developments, however, have converged to bring vertical analysis to the fore in pharmaceutical markets: the re-invigoration of vertical theories as the basis for antitrust enforcement actions⁶ and the emergence of PBMs, followed by a number of acquisitions and joint ventures through which pharmaceutical suppliers gained control of many of the major PBMs in the United States.

The FTC confronted these issues in its investigation of Eli Lilly's proposed acquisition of McKesson Corporation and its PBM business, PCS Health Systems, Inc. The investigation concluded with a proposed consent order resolving competitive concerns that included vertical foreclosure and the facilitation of coordinated interaction.⁷

Eli Lilly is one of the largest pharmaceutical manufacturers in the United States, and PCS is the largest PBM. PBMs were formed in response to a number of developments, notably the increasing inclusion of pharmacy benefits in health care packages and the demand for cost-controlling managed care principles (which are now in wide use in other health care markets) in the administration of those benefits. PBMs were unheard of five years ago, but they now administer pharmacy benefits plans for more than 120,000,000 people, a number that is expected to increase to more than 200,000,000 by the end of the decade.

PBMs serve numerous functions, including the establishment and administration of a retail pharmacy network; computerized claims processing and drug utilization review; and the establishment of formularies, which essentially are lists of Food and Drug Administration (FDA) approved drugs that are available through the PBM. The consolidation of these functions enables PBMs to play a significant role in cost containment. For example, a PBM can negotiate rebates and other discounts from drug suppliers on behalf of its customers by offering the suppliers' drugs a place on its formulary.

² 4 Trade Reg. Rep. (CCH) ¶ 13,103 (1984).

³ 4 Trade Reg. Rep. (CCH) ¶ 13,104 (1992).

⁴ See, e.g., Krattenmaker & Salop, *supra* note 1; Michael H. Riordan & Steven C. Salop, *Evaluating Vertical Mergers: A Post-Chicago Approach*, 63 ANTITRUST L.J. 945 (Spring 1995); Mary L. Steptoe, Acting Dir., Bureau of Competition, FTC, *FTC Vertical Enforcement: What's New in RPM and Vertical Mergers*, Remarks before the ABA Section of Antitrust Law (Dec. 4, 1994).

⁵ See discussion *infra* text accompanying notes 11-15. Although the 1984 Merger Guidelines evaluate mergers involving potential competitors along with vertical mergers in a single section dealing with "nonhorizontal" transactions, usually potential competition theories should be considered as part of horizontal merger analysis, since they involve similar competitive issues.

⁶ See *Tele-Communications Inc. & Liberty Media Corp.*, FTC File No. 941-0008 (Nov. 15, 1993) (consent order accepted for public comment) (Comm'rs Azcuenaga and Owen dissenting) (the agreement ultimately was withdrawn because another party prevailed in bidding for Paramount); *Martin Marietta Corp.*, Dkt. No. C-3500 (June 22, 1994) (decision and order) (Comm'r Owen dissenting); *Alliant Techsystems Inc. & Hercules Inc.*, FTC File No. 941-0123 (Nov. 15, 1994) (consent order accepted for public comment); *American Home Prods. & American Cyanamid*, FTC File No. 941-0116 (Nov. 10, 1994) (consent order accepted for public comment).

⁷ *Eli Lilly & Co.*, FTC File No. 941-0102 (consent order accepted for public comment Nov. 3, 1994).

Formularies are important devices through which PBMs bring managed care concepts to pharmaceutical markets. Like physician and hospital services that are covered by benefits packages, the supply of pharmaceuticals is governed in part by physicians' prescribing patterns that may not take fully into account cost considerations. By providing information and restricting reimbursement for certain drugs, formularies can influence the prescribing patterns of physicians and control costs, to the ultimate benefit of consumers.

PBMs initially were formed by a variety of entities, including managed care organizations, claims processors, and mail order pharmacies. Recently, a number of pharmaceutical suppliers have acquired or entered into alliances with the largest and most effective PBMs. Through these transactions, the majority of full-service PBMs capable of competing on a national scale are coming under the control of pharmaceutical suppliers. This is a trend that requires close antitrust scrutiny.

After an extensive investigation of Lilly's proposed acquisition of PCS, the FTC issued a complaint claiming that the acquisition would harm competition in several markets, including pharmaceutical markets and the national full-service PBM market. The complaint alleged that, as a result of the acquisition, products of drug manufacturers other than Lilly would likely be foreclosed from the PCS formulary. PCS would be eliminated as an independent negotiator of pharmaceutical prices with drug manufacturers. The complaint also alleged that the acquisition would facilitate collusion, through reciprocal dealing or other coordinated actions, among Lilly and other vertically-integrated pharmaceutical companies. In addition, entry into the pharmaceutical market would be made more difficult, because new companies also would be required to enter into PBM services. The complaint further alleged that the likely impact of the acquisition in the affected pharmaceutical markets would be increased prices, diminished quality, and a reduction in the incentives of other pharmaceutical manufacturers to innovate.

The proposed order in response to the complaint has two principal provisions related to Lilly's future behavior, which addresses concerns about foreclosure and the facilitation of collusion. The first provision requires Lilly to maintain an "open" drug formulary that includes all drugs selected by an independent Pharmacy and Therapeutics (P&T) committee and that does not give unwarranted preference to Lilly products. The independent P&T committee is responsible for maintaining this formulary in an objective manner. The second principal provision erects a "firewall" between Lilly and PCS, precluding communications concerning bids, proposals, prices, or certain other information related to other drug manufacturers' products.

The proposed consent order seeks to prevent potential anticompetitive foreclosure by requiring Lilly to maintain an open formulary, and by putting decisions about what drugs are allowed on that formulary in the hands of an independent P&T committee that will use only objective criteria in making its decisions. The proposed order also attempts to ensure that Lilly cannot circumvent the purposes of the order by either refusing to accept discounts or rebates on other products, thereby giving Lilly products preference on the formulary, or by making the formulary so expensive that no one will use it. The order addresses these concerns by barring Lilly from refusing to accept discounts and from inaccurately reflecting such discounts on the formulary. In addition, by placing decisions in the hands of an *independent* P&T committee, the potential for foreclosure is minimized, because the committee, not Lilly, will decide what products are included on the open formulary.

The proposed consent order still allows Lilly to operate closed formularies, to which it need not provide equal access. Although Lilly can exclude competitors from

the closed formularies, the existence of an open formulary should minimize any anticompetitive effects by providing competing suppliers with access to a formulary where their products are chosen solely on the competitive considerations of price and quality. The order permits Lilly to offer closed formularies in order to preserve the potential for cost containment. The order is carefully designed to avoid inhibiting Lilly/PCS from offering greater rebates in exchange for placement on a closed, rather than open, formulary.

Finally, by guaranteeing the existence of an objective open formulary, the order ensures that new entrants to pharmaceutical markets need not enter at both levels of the industry.

The order also protects against the potential exchange of competitively sensitive information between pharmaceutical suppliers. It requires that a firewall between Lilly and PCS be maintained with respect to information concerning other drug manufacturers' bids, proposals, contracts, prices, rebates, discounts, or other terms and conditions of sale. This will prevent the flow of competitively sensitive information between the two firms that could assist in maintaining or monitoring tacit collusion at either level of the industry, or that could allow Lilly access to information that might enable it to submit higher bids to other PBMs than it otherwise would.

The Lilly/PCS order addresses the specific competitive problems of the PCS acquisition through conduct-oriented relief. A structural approach, such as blocking the acquisition in its entirety or requiring divestiture, did not appear necessary in order to remedy these competitive concerns. As then-Chairman Janet D. Steiger and Commissioner Christine A. Varney stated, the proposed order "represents the best non-structural relief available to remedy the potential anticompetitive consequences of the transaction" while allowing potential efficiencies to be achieved.⁸

The Lilly/PCS acquisition is not the only example of vertical integration among pharmaceutical suppliers and PBMs. Several other such mergers and joint ventures have been completed or announced. As with markets that are undergoing other types of structural changes, changing conditions in pharmaceutical markets can affect the antitrust analysis of a particular transaction. Each arrangement must be viewed in the context of the current, and likely future, market structure. Then-Chairman Steiger and Commissioner Varney have said that they are "concerned about the overall competitive impact of vertical integration by drug companies into the pharmacy benefits management market."⁹ Commissioner Varney also has noted that "through monitoring [the Lilly/PCS] proposed order and through analysis of these evolving markets, the Commission can better assess all the ramifications of vertical integration in these markets."¹⁰

III. HORIZONTAL MERGERS

Accompanying the vertical transactions in the pharmaceutical marketplace are a significant number of horizontal mergers and joint ventures. The central antitrust question in such cases is whether the transaction could lead to higher prices, reduced output, or less innovation.

⁸ Statement of Janet D. Steiger, Chairman, FTC, and Christine A. Varney, Comm'r, FTC, concerning Eli Lilly & Co. (Nov. 3, 1994), as printed in 67 ANTITRUST & TRADE REG. REP., Nov. 10, 1994, at 554, 555.

⁹ *Id.*

¹⁰ Christine A. Varney, Comm'r, FTC, The Role of Competition Policy in Innovative Markets, Remarks before the 1994 Conf. on Bus. and Econ. Policies, The Mfr. Alliance 6 (Dec. 1, 1994).

Such anticompetitive effects may occur when a transaction eliminates a significant direct competitor in a relevant therapeutic category, particularly where there are few substitutes and new entry is difficult. This is often the case in many pharmaceutical markets, due to technological and regulatory impediments to entry. Acquisitions can raise antitrust issues whether they combine two producers of competing branded products, producers of branded and competing generic products, or two producers of competing generic products.

Anticompetitive effects can also arise when an acquisition eliminates competition between one or more firms that were potential entrants into a market, such as a firm that has significant research and development (R&D) efforts underway or has a product in the FDA approval pipeline. This is an area in which the FTC has taken enforcement action in several recent cases.

In September 1994, the FTC accepted a consent agreement settling charges that Marion Merrell Dow's (MMD) acquisition of Rugby-Darby would lessen substantially competition in the U.S. market for dicyclomine, a medication used in the treatment of irritable bowel syndrome.¹¹ Prior to the acquisition, MMD and Rugby-Darby were the only two FDA approved U.S. manufacturers of dicyclomine. The complaint alleged that MMD's acquisition of Rugby-Darby eliminated direct competition between the companies, creating a monopoly in the manufacture and sale of dicyclomine medications. The settlement required MMD to license its dicyclomine technology to a third party, and to contract-manufacture dicyclomine for the third party while that party awaited FDA approval to sell its own dicyclomine.

The FTC also recently challenged an aspect of Roche Holding Ltd.'s acquisition of Syntex Corp.¹² The FTC found that the merger threatened to harm competition in the market for drug abuse testing products, a market in which Roche and Syntex were substantial competitors. The situation was resolved when Roche agreed to divest Syntex's drug abuse testing business.

In another recent example, the FTC accepted a consent agreement subject to final approval relating to American Home Products' proposed acquisition of American Cyanamid.¹³ The original complaint had identified five relevant product markets in which there were anticompetitive concerns: (1) the combined tetanus and diphtheria vaccine for adults and children over age seven, (2) the combined tetanus and diphtheria vaccine for children under age seven, (3) the uncombined tetanus vaccine, (4) cytokines for white blood cell and platelet restoration, and (5) R&D for a rotavirus vaccine.

The tetanus and diphtheria vaccine product markets were alleged to be highly concentrated. The FTC determined that the proposed merger would have eliminated the direct competition between American Home Products and American Cyanamid, and made coordinated interaction among the remaining firms more likely. The FTC's consent order requires American Home Products to divest its tetanus and diphtheria vaccine business, and to enter into an interim manufacturing agreement for the acquirer to make use of while it obtains its own FDA approval.

The cytokines market involved products not yet approved by the FDA for use in the United States. Cytokines are used by cancer patients undergoing chemotherapy and radiation therapy for white blood cell and platelet restoration. Only three companies,

¹¹ Marion Merrell Dow, Dkt. No. C-3533 (Sept. 23, 1994) (decision & order).

¹² Roche Holding Ltd., Dkt. No. C-3542 (Dec. 1, 1994) (decision & order).

¹³ American Home Prods. & American Cyanamid, FTC File No. 941-0116 (consent order accepted for public comment Nov. 10, 1994).

two of which are American Home and American Cyanamid, hold patent rights for such cytokines. American Home previously had licensed its patent rights to another firm, retaining the right to receive royalty payments and information concerning sales volume on a country-by-country basis. After the acquisition, American Home would control American Cyanamid's technology and also would have access to competitively sensitive information from its licensee, which could lessen competition once the products received FDA approval. The proposed order addresses this issue by prohibiting American Home from receiving certain information from the licensee after the FDA approves the products.

In the market for the research and development of a rotavirus vaccine, the FTC focused on innovation competition. Rotavirus is a serious diarrheal disease that hospitalizes or kills thousands of children each year. There is currently no authorized rotavirus vaccine. The merging firms were two of the three firms undertaking significant development work on such a vaccine, with projects in or near the clinical trial stage.

The FTC determined that the loss of American Cyanamid would reduce the competition for the development of a rotavirus vaccine. The consent order remedies the alleged anticompetitive effects in the rotavirus research market by requiring American Home Products to license, on a non-exclusive basis, American Cyanamid's rotavirus vaccine research. This ensures that an independent competitor will continue development work on American Cyanamid's vaccine.

The approach to innovation markets taken in the American Home Products consent order is similar to that taken in the 1990 *Roche Holding Ltd.* consent order.¹⁴ When Roche acquired a controlling interest in Genentech Inc., the FTC was concerned about competition in the research and development for several pharmaceutical products. The complaint in *Roche Holding* alleged that the acquisition would eliminate potential competition and enhance the likelihood of collusion in three different pharmaceutical markets: the U.S. market for CD4-based therapeutics used in the treatment of AIDS/HIV infection, the worldwide market for vitamin C, and the U.S. market in therapeutic drugs for the treatment of human growth deficiency. In two of these markets, one of the merging firms was a current competitor, while the other was in the process of developing a competing product. In the third market, both firms were engaged in R&D but neither had a final commercial product. To preserve innovation and potential competition, the FTC's order required licensing and divestiture of patents, technology, and other assets in each market.

Another recent FTC decision involving innovation competition related to the proposed acquisition of Orthomet by Wright Medical Technologies, both of which produce orthopedic implants.¹⁵ The antitrust concerns focused on competition between Wright's current finger joint implants and potential next-generation implants, as well as competition between the two companies' R&D efforts for implants. Wright is the leading U.S. supplier of finger joint implants and, although Orthomet currently does not produce a finger implant product, the acquisition of Orthomet would have given Wright control of Orthomet's exclusive technology license agreements with the Mayo Clinic for clinical trials of next-generation finger implants. These next-generation implants are potential alternatives to Wright's current products. The acquisition would have prevented the entry of Orthomet as a competitor to Wright and reduced competition in research and

¹⁴ *Roche Holding Ltd.*, Dkt. No. C-3315 (Nov. 28, 1990) (decision & order).

¹⁵ *Wright Medical Tech., Inc.*, FTC File No. 951-0015 (consent order accepted for public comment Dec. 8, 1994).

development for next-generation implants. To resolve these antitrust concerns, the FTC accepted a proposed consent agreement providing that Wright would grant a non-exclusive license of the Orthomet/Mayo technology to Mayo, and assist Mayo in finding another licensee to develop and commercialize the implant technology.

These cases illustrate that the antitrust concerns that arise in pharmaceutical mergers are not confined to the elimination of existing competition in current markets. Concerns also can arise about the elimination of potential competition by firms poised to enter the market, and about the elimination of competition in the R&D and innovation process. Particularly in industries such as pharmaceuticals, where many markets are characterized by high rates of technological innovation but are also highly concentrated and difficult to enter, these theories of competitive harm may continue to come into play in the future.

IV. NONMERGER CONDUCT

Some antitrust issues relating to nonmerger conduct can also threaten to create or enhance a firm's power to control prices or output ("market power"). There have been a number of enforcement actions by the FTC in the past, and the Commission currently is pursuing several nonmerger investigations in pharmaceutical markets.¹⁶ Theories that may be applied to pharmaceutical markets include: tying arrangements, in which a firm with market power in one market requires buyers to purchase a product or service in another market; anticompetitive efforts to extend patent rights beyond their lawful scope, either in terms of duration or product scope; and abuse of regulatory (e.g., FDA) or judicial processes through proceedings that are designed not to achieve a legitimate outcome on the merits, but to impede competition.

V. CONCLUSION

This article has provided a brief outline of the FTC's antitrust enforcement activities in pharmaceutical markets. As these markets continue to evolve, the FTC's analysis will continue to focus on mergers and nonmerger conduct that have the potential to harm consumers, and will remain sensitive to changing market conditions that form the backdrop for the competitive analysis of particular markets.

¹⁶ See Mark D. Whitener, Dep'y Dir., Bureau of Competition, FTC, FTC Antitrust Enforcement In Pharmaceutical Markets, Remarks at the National Ass'n of Pharmaceutical Mfrs. (June 16, 1994).