Antitrust Enforcement in Pharmaceutical Industry Mergers

DAVID A. BALTO *
JAMES F. MONGOVEN **

I. INTRODUCTION

The pharmaceutical industry is in the midst of a wave of consolidation. Some of the largest mergers in history have involved recent combinations of multinational pharmaceutical firms, such as Zeneca's acquisition of Astra, Hoechst's acquisition of Marion Merrell Dow (MMD) and the merger between Ciba-Geigy and Sandoz. It seems that each month a new "mega-merger" is announced, followed by extensive commentary on what these mergers portend for the future.

Pharmaceutical mergers, like all mergers, are subject to the antitrust laws. Mergers that are efficient and pro-competitive build stronger competitors in new markets, and benefit consumers through lower prices, a greater variety of products, and stronger incentives to innovate. A number of recent pharmaceutical and health care product mergers have had the potential for anticompetitive effects. Over the past four years, the Federal Trade Commission (FTC) has brought eleven enforcement actions challenging several of these mergers, the largest number in any single industry. This article considers these pharmaceutical and health care products enforcement actions and explains the importance of these cases for future Commission policy and for similar industries where global competition, technological change, and high regulatory barriers to entry combine to produce a background conducive to consolidations.

The article discusses the reasons for this wave of consolidation, as well as the antitrust risks involved in these mergers. It begins with some observations about the causes of the current wave of consolidation, considering factors such as global competition and increased technological competition. Part III describes the law and economic model for merger analysis, based on federal Merger Guidelines. Part IV applies the model to certain categories of pharmaceutical and health care product mergers including horizontal mergers in markets where both parties are producing in the relevant markets, mergers where one party is producing in the relevant market and the other party is a potential entrant, and innovation markets, where the merger would eliminate competition in efforts to develop future products. Finally, part V analyzes some of the remedy issues found in pharmaceutical industry mergers.

II. THE MERGER WAVE

Merger waves periodically sweep through the economy, and the United States currently is in the midst of one. The total value of acquired assets in deals announced in 1998 was 1.73 trillion dollars, which is eighty-nine percent higher than the record level recorded in 1997.[1] The total number of merger filings under the Hart-Scott-

* Mr. Balto is the Assistant Director of the Office of Policy and Evaluation, Bureau of Competition, Federal Trade Commission.

** Mr. Mongoven is an Attorney in the Office of Policy and Evaluation, Bureau of Competition, Federal Trade Commission.

This article represents the authors' own views and does not necessarily reflect the view of the Federal Trade Commission or any of its Commissioners.

[1] Judy Radler Cohen, *M&A Rings in Another Record Year*, 12 MERGERS & ACQUISITIONS REP. 1 (1999).

Rodino Act[2] in fiscal year 1998 was 4728[3] — the seventh consecutive annual increase in filings, which have more than tripled since 1991.

The current merger wave differs from the leveraged buyout or conglomerate deals predominant in past merger waves.[4] Today, mergers are more strategic, with firms trying to gain competitive advantage or respond to larger economic forces. Some firms seek to acquire market share, expand product lines, combine research and development (R&D) capabilities, gain control of key inputs, or achieve efficiencies of integration. These types of mergers have taken place in the financial services sector, electric utilities, and transportation industries. Firms in the defense and health care industries, on the other hand, have been forced into greater efficiency as a result of downsizing and rigorous cost control. Mergers increasingly are international, which raises difficult questions about competition across national borders. These consolidations are not necessarily anticompetitive, but frequently they require close review to evaluate the possibility of harm to competition when a firm acquires a competitor.

Each of these factors has contributed to tremendous increase in consolidation in the pharmaceutical industry. Several hundred pharmaceutical mergers are announced annually and the number of transactions increased by almost fifty percent from 1996 to 1997.[5] Does the sheer number of acquisitions raise concerns? As a general matter, the pharmaceutical industry remains relatively unconcentrated, with no firm comprising more than five percent of the entire market.[6] Yet there are many cases, described below in detail, involving firms that are direct or potential competitors in specific markets. It is in these cases that enforcement agencies have secured relief.

There are several reasons consolidation is increasing in the pharmaceutical industry. First, is the managed-care revolution. With rising health care costs worldwide, pharmaceutical companies are under increasing pressure from large buyers to reduce the rate of price increases. Hospitals and insurance companies have attempted to cut costs by squeezing suppliers, particularly drug companies. State and federal governments have legislated rigorous cost controls on public health care programs. These efforts make it imperative that pharmaceutical companies become more efficient and reduce costs.

A second reason is that the industry faces a record number of patent expirations. Many drugs with several billion dollars in sales will go off patent in the next five years and these companies will need to replace the blockbuster drugs they have relied on for years to maintain historic levels of profitability.[7] A third factor is the need for pharmaceutical firms to achieve economies of scale, particularly in marketing. Mergers

---

[2] 15 U.S.C. § 18a (1994). The Hart-Scott-Rodino Act establishes a premerger notification and waiting period procedure, applicable to a range of transactions defined as to nature and size, that provides the Federal Trade Commission (FTC) and the Department of Justice information about planned transactions and a prescribed time period before the transaction may be consummated, allowing the agencies an opportunity to analyze the transaction to determine whether it raises sufficient risk of an anticompetitive outcome to merit enforcement action.

[3] Federal Trade Commission and Department of Justice, 21st Annual Report to Congress Pursuant to Subsection (j) of Section 7A of the Clayton Act, Hart-Scott-Rodino Antitrust Improvements Act of 1976, at 5 (1998).

[4] *See Mergers and Corporate Consolidation in the New Economy, Before the Senate Comm. on the Judiciary,* 105th Cong., 2d Sess. 1 (1998), *available at* <www.ftc.gov/bc/testimony.htm> (statement of Robert Pitofsky, Chairman, Federal Trade Commission) (June 6, 1998) "[T]he current merger wave is significantly different from the "junk bond" fueled mergers of the 1980s . . . Today's mergers are more likely to be motivated by fundamental developments in the rapidly changing economy and reflect more traditional corporate goals of efficiency and competitiveness." *Id.*

[5] *See Pharma Industry Consolidation Accelerating*, MARKETLETTER, June 8, 1998.

[6] *See Consolidation Enters More Frantic Phase*, FIN. TIMES, Mar. 15, 1999, at 1.

[7] *See Drug Industry. European Unions*, ECONOMIST, Dec. 12, 1998, at 62 (describing reasons for Zeneca/Astra consolidation).

are one way to broaden a firm's product base and spread marketing costs over a larger number of products. In addition, mergers may increase the geographic scope of the merged firm's operations and customer base. Mergers also can reduce unit production costs and lead to the elimination of duplicative departments and systems.

An additional stimulus to industry consolidation has been the technological revolution occurring in pharmaceutical research, particularly in biotechnology. As the FTC explained to the U.S. Senate Judiciary Committee in 1998 "[E]xamination of innovation markets is another example of paying close attention to the dynamics of new competition. Research and development — innovation — is the lifeblood of our economy . . . In fact, it is a way that firms compete for future market position."[8] This revolution brings greater promises of blockbuster drugs while substantially increasing the costs of research and development. Higher costs and risks mean that fewer firms can engage in first-level research.[9] Pharmaceutical manufacturers have responded to these challenges by entering into joint ventures and other strategic alliances to combine R&D assets.[10] Several recently announced mergers in the pharmaceutical industry are motivated by the desire to increase R&D expenditures.[11] In some cases, pharmaceutical companies have tried to adjust this risk by purchasing later-stage research efforts from other industry participants; in other cases, a merger of the firms is selected as the best solution.[12]

The movement toward global markets also drives consolidation in the pharmaceutical industry. At the most basic level, companies may perceive the need for increased size to compete successfully in larger markets. More strategically, consolidations may be made to acquire direct access to foreign markets. For example, a European company with a strong drug pipeline may acquire a company with a strong marketing presence in the United States rather than develop its own marketing in a foreign culture with different business and regulatory climates. Other companies may acquire ownership of drugs that have met the regulatory requirements of a foreign country, thereby reducing the time to enter those markets.

III. MERGER LAW

Section 7 of the Clayton Act[13] is used to attack anticompetitive mergers. The Act[14] prohibits mergers and acquisitions where "the effect of such acquisition may be

---

[8] *Mergers and Corporate Consolidation, supra* note 4, at 5. A U.S. Senate report amplified a similar idea:

> Competition is as important in R&D as it is in any other commercial endeavor. Indeed, in many industries, particularly those that are based on rapidly evolving technology, competition in R&D may be crucial to success. Motivated by the benefits of getting ahead of one's competitors as well as the threat of falling behind, firms in such industries have strong incentives to be the first to develop new processes and products.

S. REP. NO. 98-427, at 202 (1984).

[9] *But see* FIN. TIMES, *supra* note 6 (suggesting that the perceived need for economies of scale in R&D is overstated).

[10] *See Drug Industry, supra* note 7, at 62; *All Quiet on the Washington Front: Fewer Blockbusters, More Mergers; Pharmaceutical Industry Forecasts for 1999,* 34 MED. MKTG & MEDIA 44 (1999); CNNfn, *Bruised Biotechs Increasingly Turn to Merger* (visited June 3, 1999) <www.cnnfn.com> (describing the need of small biotech companies to merge to continue R&D efforts).

[11] *See, e.g.*, Alan Cowell, *Zeneca Buying Astra as Europe Consolidates*, N.Y. TIMES, Dec. 9, 1998, at C1; David J. Morrow, *French Drug Makers to Combine in $10.4B Stock Deal*, N.Y. TIMES, Dec. 3, 1998, at C24.

[12] *See* Amgen, Guilford and Amgen Announce Start of Neuroimmunophilin Clinical Trials 1 (Aug. 4, 1999) (press release discussing Amgen's licensing of worldwide rights to neuroimmunophilins from Gulford), *available in* <www.amgen.com>; *Converging Biotechs*, BARON'S, Aug. 5, 1999, at 33 (noting both trends in the biotechnology sector).

[13] 15 U.S.C. § 18.

[14] Ch. 328, 38 Stat. 730 (1914) (codified as amended at 15 U.S.C. §§ 12-21 (1994)).

substantially to lessen competition, or to tend to create a monopoly."[15] The Section 7 standard invalidates mergers that are likely to have anticompetitive effects, such as higher prices, reduced output, or reduced innovation. The FTC's and the Justice Department's *Horizontal Merger Guidelines*[16] set forth the analysis used to determine if those effects are probable. The *Merger Guidelines* use a three-step analysis. First, the agencies define the relevant product and geographic markets in which the merging firms' products compete. Second, if there are overlaps in any relevant market the agencies determine the level of concentration and the likelihood of anticompetitive effects. If there are concerns over anticompetitive effects, the agencies weigh other factors that may reduce competitive concerns. Two reasons that may reduce concerns are that new entry may occur in the market or potential efficiencies from the transaction will reduce the anticompetitive effects.

Merger analysis begins by delineating the relevant geographical and product markets. The FTC and the courts attempt to define the boundaries of the relevant product market by determining the cross-elasticities of demand and supply; the FTC looks at the degree to which a change in price will cause a change in the quantity demanded and supplied of related products. Specifically, the agency asks whether a monopolist profitably cab institute a "small but significant and nontransitory" increase in price?[17] If a change in price causes insufficient reaction in substitute goods (goods thought to substitute for the product in question) to defeat the price increase, then they are deemed not to be part of the product market. Relevant facts in this determination include evidence that buyers have shifted purchases in response to price changes, evidence that sellers base business decisions on the prospect of buyer substitution in response to relative price changes, and the timing and costs of switching products.

In the pharmaceutical area, the relevant product market determination is often the single most critical issue in the decision whether to challenge a merger. Unlike many consumer products, pharmaceutical products are not substitutable for each other because of consumer preference for design, convenience, style, prestige, or any other factor short of efficacy. For instance, although a sport utility vehicle may be substitutable for a van for certain consumers, and thus may be available to defeat a price increase, a drug to aid liver function never can be a substitute for a heart drug. No matter how high prices are raised for a heart drug, drugs with other therapeutic effects cannot be substituted. The outcome of the efficacy requirement is that the relevant product market in pharmaceutical mergers usually will be limited to drugs in an individual therapeutic category. [18] The relevant product may be defined as narrowly as a specific dug compound or the manner in which that compound interacts with the body.[19] In some cases the market may be defined even more narrowly as a once-a-day use of the drug, where buyers perceive a separate market for different dosage forms. [20]

[15] 15 U.S.C. § 18. A merger also can be challenged under the Sherman Act, Ch. 647, 26 Stat. 209 (1890) (codified as amended at 15 U.S.C. §§ 1-7 (1994)), as a restraint of trade or a merger to monopoly. 15 U.S.C. §§ 1, 2. *See, e.g.*, United States v. Grinnell Corp., 384 U.S. 563 (1966); United States v. Syufy Enters., 903 F.2d 659 (9th Cir. 1990). Additionally, the FTC may add a claim under section 5 of the FTC Act, Ch. 311, 38 Stat. 717 (1914) (codified as amended 15 U.S.C. §§ 41-64 (1994)), which prohibits "unfair methods of competition." 15 U.S.C. § 45. The standards for challenging mergers under the three statutes are virtually identical. *See* United States v. Rockford Mem'l Corp., 898 F.2d 1278, 1281-82 (7th Cir.), *cert. denied*, 498 U.S. 920 (1990).

[16] U. S. DEP'T OF JUSTICE AND FEDERAL TRADE COMMISSION, HORIZONTAL MERGER GUIDELINES (Apr. 2, 1992), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,104 [hereinafter MERGER GUIDELINES].

[17] MERGER GUIDELINES, *supra* note 16, § 1.11.

[18] *See* Robert Bloch, Scott Perlman & Myles Hansen, *Product Market Definition in Pharmaceutical Mergers*, ANTITRUST REP., Sept. 1997, at 17, 19.

[19] *See* Glaxo PLC, C-3586, 119 F.T.C. 815 (June 14, 1995) (consent order).

[20] Hoechst AG, C-3629, 120 F.T.C. 1010, 1020 (Dec. 5, 1995) (consent order) (market defined as oral mesalamine, where mesalamine available in rectal form; defining once-a-day diltiazem as market, but excluding injectable form of drug); *see also Glaxo,* 119 F.T.C. at 816 (defining market of "non-injectable" anti-migraine drug).

In determining a relevant market, the Commission usually will start with a presumption that the market is limited to a specific therapeutic compound and then broaden the market as evidence is available that physicians and hospitals use other compounds as substitutes. If sufficient substitution occurs, the market may be expanded to a whole class of drugs used to treat a particular condition or illness.

In making the determination of the boundaries of the relevant product market, the FTC staff solicits the views of many industry participants, including physicians, hospitals, managed care providers, pharmaceutical manufacturers and wholesalers, and consumer representatives. Where issues of potential competition arise, staff may query FDA personnel and the research community on the new drug application pipeline.

One recurring issue is whether the brand name and generic versions of the drug are in the same relevant product market. FTC investigations typically have found that because of the significant price difference between generic and brand name versions, an increase in the price of the brand name version does not lead consumers to switch to the generic version, and vice versa. When generic versions of a drug enter the market, brand name firms typically increase prices.[21] The entry of additional generics lowers the price of other generics, but seems to have little impact on the price of the brand name version. This information leads to the conclusion that these drugs typically are not in the same product market.[22]

In defining a relevant geographic market, the FTC looks at the degree to which, in a short period of time, changes in quantities of the product demanded and supplied in one area will result from a change in price in another area. The FTC looks for a market "broad enough that buyers would be unable to switch to alternative sellers in sufficient numbers to defeat an exercise of market power by firms in the area."[23] Defining geographic markets in pharmaceutical cases is less controversial because there are few market participants abroad that do not compete in the United States. The market almost invariably is defined as the U.S. market, although in innovation market cases the market may be defined as world-wide, as will be discussed below.

After defining the relevant markets, the FTC considers the core issue of anticompetitive effects. The agencies rely on two basic models of analysis — collusion, whether express or tacit, and single firm behavior, or unilateral effects. Collusion concerns arise where, after the merger, the acquiring firm and its rivals would find it significantly easier to cooperate in reducing output and raising prices. In recent years, in conjunction with the trend toward more strategic mergers, the FTC has had more cases that raised the issue of unilateral effects where a merger results in a firm that is unilaterally able to raise prices and restrict output, or results in a firm that unilaterally can control innovation in a relevant market.[24] The agencies need not prove anticompetitive effects with certainty. As Judge Posner has observed:

---

[21] *See* ROY LEVY, THE PHARMACEUTICAL INDUSTRY: A DISCUSSION OF COMPETITIVE AND ANTITRUST ISSUES IN AN ENVIRONMENT OF CHANGE, BUREAU OF ECONOMICS STAFF REPORT, FEDERAL TRADE COMMISSION 606 (Mar. 1999); F.M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, 7 J. ECON. PERSP. 97 (1993).

[22] *But see* IVAX Corp., C-3565, 119 F.T.C. 357 (Mar. 27, 1995) (consent order) (both generic verapamil and branded version included in the same product market); Dow Chemical Co., C-3533, 118 F.T.C. 730 (consent order) (Sept. 23, 1994) (relevant market included both branded and generic dicyclomine).

[23] Hospital Corp. of Am., 106 F.T.C. 361, 466 (1985), *aff'd sub nom.* Hospital Corp. of Am. v. FTC, 807 F.2d 1381 (7th Cir. 1986), *cert. denied*, 481 U.S. 1038 (1987). Products whose value depends in large part on an intellectual property component will tend to compete in broad geographic markets because knowledge-based assets are easier to transport than physical assets. Joseph F. Brodley, *Antitrust Law and Innovation Competition*, 4 J. ECON. PERSP. 97 (1990).

[24] *See* FTC v. Staples, Inc., 970 F. Supp. 1066 (D.D.C. 1997).

> Section 7 does not require proof that a merger or other acquisition has caused higher prices in the affected market. All that is necessary is that the merger create an appreciable danger of such consequences in the future. A predictive judgment, necessarily probabilistic and judgmental rather than demonstrable . . . is called for.[25]

Because merger analysis is prospective, the probability of anticompetitive effects must be inferred from a variety of evidence, primarily the level of concentration in the relevant market and the post-merger increase in that concentration. If the post-merger concentration is high and has increased significantly, the merger is presumed to be anticompetitive. The inference is rebuttable, however, by a showing from defendants that the structural characteristics of the market make post-merger collusion unlikely, or that the ability to unilaterally wield market power unlikely. A variety of evidence is relevant to answer the ultimate question whether a merger is likely to lessen competition. Indeed, a number of market characteristics make presumption of anticompetitive effects stronger, including high barriers to entry, low level of product differentiation, relatively inelastic demand for industry output at competitive price levels, a large number of small buyers, and a high degree of transaction frequency and visibility.[26]

The absence of barriers to entry is the first industry characteristic that may rebut a presumption of anticompetitive effects. Where entry is easy, it is uncommon for post-merger firms to abuse market power, either collusively or unilaterally,[27] because such entry likely will "deter or counteract the competitive effects of concern."[28] The most reliable evidence of actual entry conditions often is the experience of recent entrants. To rebut an anticompetitive presumption, entry must be timely, likely, and sufficient.[29]

In pharmaceutical mergers, entry barriers typically are very high. Drugs must be approved by the Food and Drug Administration (FDA) and the drug approval process takes several years and millions of dollars. Thus, in its enforcement actions, the FTC has found that anticompetitive effects are unlikely to be reduced by potential entry into the pharmaceutical industry.

Another important factor in merger analysis is efficiency. As mergers can generate significant efficiencies by enabling firms to combine and better utilize assets to achieve lower costs and higher quality, the agencies will consider these efficiencies as part of their prosecutorial discretion. Efficiencies must be verifiable, quantifiable, and merger-specific, but they will "almost never justify a merger to monopoly or near-monopoly."[30]

IV. PHARMACEUTICAL MERGERS

Recent pharmaceutical merger enforcement actions can be analyzed in three categories: horizontal mergers, potential competition mergers, and innovation market mergers. First, direct horizontal mergers between rivals that compete in the same market are most likely to have anticompetitive effects. The second category of mergers occurs when one firm has a product in the market and another firm actively is engaged in a research effort to design and manufacture a competing product, whether

---

[25] Hospital Corp. of Am. v. FTC, 807 F.2d 1381, 1389 (7th Cir. 1986), *cert. denied*, 481 U.S. 1038 (1987).

[26] MERGER GUIDELINES, *supra* note 16, §§ 2,3.

[27] *Syufy Enters.*, 903 F.2d at 1395-96.

[28] MERGER GUIDELINES, *supra* note 16, § 3.

[29] *Id.* § 3.1.

[30] *Id.* § 4.

generic or not. Finally, two firms that do not have products, but are engaged in research efforts to address the same medical need may merge. Under some circumstances, this type of merger can have an anticompetitive effect on a market for innovation of new drugs.

A. *Horizontal Mergers Between Direct Competitors*

The horizontal merger model outlined above is applied where the acquisition of a direct competitor may create a firm with sufficient market share such that the merger increases the likelihood of collusion or unilateral anticompetitive effects. The fewer firms in any relevant market, the easier it is to agree on prices or other market parameters, and the more likely it is that one firm will be large enough to set such parameters unilaterally. Several recent pharmaceutical mergers fall into the category of consolidations of current competing producers. These mergers are characterized by highly concentrated markets, high entry barriers, and the ability of the surviving firm to harm competition unilaterally.

1. *Roche/Corange Merger*

In a 1998 case, the FTC alleged that Roche Holding's proposed eleven billion dollar acquisition of Corange Limited would harm competition in two U.S. markets: cardiac thrombolytic agents — drugs used to treat heart attack victims.[31] Thrombolytic agents are given to heart attack victims at the onset of symptoms to dissolve blood clots. The only other medical procedure for treating heart attacks, angioplasty (an expensive surgical procedure not available in many hospitals) is not a competitive substitute for thrombolytic agents.[32] Roche, through its majority ownership in Genentech, and Corange, through its Boehringer Mannheim subsidiary, produced the two most safe and effective thrombolytic agents in the U.S. market.[33] The only other thrombolytic agent approved for use in the United States — Streptokinase® — was significantly less effective. The U.S. market for these products is heavily concentrated, and entry barriers are high due to lengthy FDA approval requirements.

Both companies also manufactured drug abuse testing (DAT) reagents — chemical antibodies that detect whether an illegal substance is present in a urine sample. Each DAT reagent is designed specifically to detect a particular drug, and businesses typically purchase nine or ten DAT reagents from a single supplier to provide a full testing profile. Workplace DAT screening is conducted at commercial laboratories with instruments designed for workplace DAT reagents. Because hospital drug screening differs significantly from workplace screening, the latter is a relevant antitrust market. The DAT reagent market also is highly concentrated and is dominated by three of the four producers — Syva, Roche, and Boehringer Mannheim.[34] Entry is difficult because it requires producing a full panel of workplace reagents and establishing customer acceptance of the products.

The *Roche* complaint alleged that the acquisition, if consummated, would eliminate actual competition between Roche and Corange in markets for the research and development, manufacture, and sale of cardiac thrombolytic agents, as well as for DAT reagents used in workplace testing. The FTC claimed that the acquisition would

[31] Roche Holding Ltd., C-3809 (May 22, 1998) (consent order).

[32] *Roche Holding Ltd.*, C-3809, Analysis of Proposed Consent Order to Aid Public Comment, at 1.

[33] *Id.*

[34] *Id.* at 2.

increase the likelihood that Roche unilaterally would exercise market power in cardiac thrombolytic agents, as well as the likelihood of collusion or coordinated action among the remaining firms in the DAT reagents market. The case was resolved with divestiture of products in each of the markets.

2. *Sorin/COBE Merger*

In early 1999, FTC challenged the acquisition of COBE Laboratories by SNIA S.P.A. (Sorin). Both Sorin and COBE manufacture heart-lung machines that replace the function of both the heart and lungs by circulating and supplying oxygen to a patient's blood during open heart surgery. COBE is the market leader in the United States with a thirty-seven percent share of the market, while Sorin currently is ranked third with twenty-one percent.[35] The merger would have increased concentration by 1554 to a post-merger HHI level of 4638,[36] clearly a problematic increase in concentration. This increase raised concerns that the merged firm could force customers to pay higher prices.

This case posed particularly difficult issues of entry. Similar to other pharmaceutical and medical products, entry was difficult because of the time required to design and develop a new machine and to secure FDA approval. In addition, a new entrant would need to establish a nationwide service and sales network and gain customer acceptance. This is a difficult process for new entrants because manufacturers are reluctant to establish a nationwide service and sales network until they have gained consumer acceptance and have an established customer base. Likewise, customers are reluctant to purchase from a supplier unless it has an established sales and service network. Often, this results in a "Catch-22" problem.

The parties entered into a consent order requiring Sorin to divest all of COBE's heart-lung machine business to Baxter International within ten days after the Commission accepted the Agreement Containing Consent Order for public comment. Baxter was a particularly well-suited acquirer of these assets, since it sells a wide array of heart-lung machine disposables throughout the world. This divestiture enabled Baxter to offer a complete extracorporeal bypass system. The order allowed the FTC to appoint an interim trustee to oversee the divestiture process and ensure Baxter's efforts to obtain its own regulatory approvals.

3. *American Home Products/Solvay Merger*

In 1997 the FTC alleged that the acquisition of Solvay's animal health business by American Home Products would harm competition in the U.S. market for three "companion animal" vaccines.[37] The acquisition would have given American Home Products a dominant position in the market for canine lyme vaccines, canine corona virus vaccines, and feline leukemia vaccines, enabling it to exercise market power unilaterally, and increasing the likelihood of collusion or coordinated action among the remaining firms.

The complaint alleged that American Home Products and Solvay were two of only three suppliers of canine lyme vaccines, and two of only a small number of suppliers of canine corona virus vaccines. In fact, Solvay was the only supplier of

[35] SNIA S.P.A., C-3889 (Aug. 9, 1999) (consent order).

[36] SNIA S.P.A., C-3889, Complaint at 2. The antitrust agencies calculate market concentration by using the Herfindahl-Hirschman Index (HHI). The HHI is calculated by summing the squares of the individual market shares of all participants. Thus, a monopoly market would register an HHI of 10,000. An HHI above 100 is considered highly concentrated. *See* Merger Guidelines, *supra* note 16, § 1.5.

[37] American Home Prods. Corp., C-3740, 123 F.T.C. 1279 (May 16, 1997) (consent order).

canine corona virus vaccines that did not license the product from American Home Products. In addition, the merging companies were two of only three suppliers of feline leukemia vaccines in the United States; thus, all three markets were highly concentrated. Entry into each market was difficult and time consuming, requiring the expenditure of significant resources over a period of many years with no assurance that a viable commercial product would result. Broad patents governing the manufacture of the three products compounded the difficulty of new entry. Moreover, the need to obtain approval from the U.S. Department of Agriculture (USDA) to manufacture and sell animal vaccines in the United States further lengthened the time required to enter the market.

4. *Medtronic/Physio-Control Merger*

In another case, Medtronic, a manufacturer of medical devices, proposed to acquire the automated external defibrillator (AED) business of Physio-Control International.[38] AEDs are portable, automated devices used in emergency situations to diagnose and treat persons suffering from cardiac arrest. The market is highly concentrated with only three significant U.S. competitors: Physio-Control, Hewlett-Packard, and SurVivaLink. Entry is unlikely because of the time and expense required to design and develop a competitively viable product, obtain approvals from FDA, and establish a sales and distribution network. At the time of the acquisition, Medtronic did not manufacture AEDs; however, its ownership interest in SurVivaLink provides the opportunity to influence and control SurVivaLink's AED business, as well as to gain access to sensitive information. As a result of this corporate interest, Medtronic became a horizontal competitor of Physio-Control.

The FTC alleged that the acquisition would harm the market for the R&D, manufacture, and sale of AEDs, and could result in increased prices and reduced innovation. The acquisition would eliminate direct competition between SurVivaLink and Physio-Control by bringing the competitors under Medtronic's control. This would increase the likelihood of collusive behavior, reduce innovation, and ultimately, increase prices for automated external defibrillator customers.

To remedy these concerns the consent order made Medtronic a passive investor in SurVivaLink, prevented Medtronic from exercising its right to name a member of the Board of Directors, and required Medtronic to vote its shares in the same proportion as other shareholders. In addition, to alleviate concerns over access to competitively-sensitive information the consent order prevented Medtronic from exercising its rights, pursuant to its investment agreement with SurVivaLink, or under Minnesota law, to receive non-public competitively-sensitive information relating to SurVivaLink, and required Medtronic to return to SurVivaLink any documents containing trade secrets. The settlement removed Medtronic's ability to control SurVivaLink and thus would preserve the two competitors in the AED market, as well as the incentives to compete in the innovation market.

5. *Medtronic/Avecor Merger*

Medtronic's acquisition of Avecor raised concerns in the market for non-occlusive arterial pumps in the United States.[39] Medtronic manufactured a number of implantable devices, such as pacemakers and defibrillators, that regulate heart rhythm,

[38] Medtronic, Inc., C-3842 (Jan. 7, 1999) (consent order).
[39] Medtronic, Inc., C-3879 (June 10, 1999) (consent order).

tissue, mechanical heart valves, coronary stents, and perfusion devices for heart/lung machines. Medtronic's perfusion devices include non-occlusive arterial pumps and its Bio-Pump® was the leader in this market. The acquired company, Avecor, also produced perfusion devices, including, among other products, non-occlusive arterial pumps. Avecor's pump was introduced in 1997 and it was in the early stages of gaining market acceptance when Medtronic sought to acquire Avecor. The new pump offered consumers significant advantages over the Bio-Pump® and other conventional non-occlusive pumps.

The FTC found that this market was highly concentrated and entry would be difficult. In addition, there were no effective medical substitutes for non-occlusive arterial pumps. Under the proposed consent order settling the case, Avecor's non-occlusive arterial pump assets were divested to Baxter Healthcare Corporation. Medtronic also must provide substantial assistance to Baxter of the assets to enable it to obtain FDA approval to manufacture and market the Avecor pumps. In addition, Medtronic must provide additional assistance including a supply of reservoirs to use with the pump, and assistance in manufacturing both pumps and reservoirs until the buyer's manufacturing capacity is established.

6. *Johnson & Johnson/Cordis Merger*

In an earlier medical devices case, the Commission required Johnson & Johnson to restructure its acquisition of Cordis Corporation.[40] Both firms manufactured neurological shunts, medical devices used in the treatment of hydrocephalus, which is a potentially fatal condition affecting infants and children. The market was highly concentrated, with the two firms accounting for eighty-five percent of all neurological shunts sales. Entry was unlikely because of the difficulty in developing competitive neurological shunt designs, establishing manufacturing facilities, organizing a sales and service network, and obtaining FDA approval. The consent order required Johnson & Johnson to divest the Cordis Neuroscience Business to an FTC-approved buyer. Consequently, the assets were sold to a Swedish company, Elekta AB.

B. *Potential Competition Mergers*

An acquired firm's disappearance can have a negative impact on competition, regardless of whether or not it was producing in the market. The ability to wield market power also is affected by competitors not yet in the market. For example, an incumbent firm that perceives another firm as a potential entrant may refrain from charging higher prices that could induce market entry.[41] Even a firm not perceived as an entrant may be considered a potential entrant if its actions indicate that it was about to enter the market.[42] The disappearance of either of these potential competitors through merger may result in anticompetitive effects.

It is difficult at times to determine if a firm is a potential competitor in a relevant market. The pharmaceutical industry, however, is uniquely suited for potential com-

[40] Johnson & Johnson, C-3645, 121 F.T.C. 149 (Mar. 16, 1996) (consent order).

[41] The U.S. Supreme Court has held that a firm perceived to be a potential entrant may affect competition in a relevant market. *See* United States v. Marine Bancorporation, 418 U.S. 602, 639-40 (1974); United States v. Falstaff Brewing Corp., 410 U.S. 526, 533-34 (1973).

[42] Although the Supreme Court has not ruled on the actual potential entry theory, some lower courts and the FTC have accepted or commented favorably on it. *See* Roche Holding Ltd., 113 F.T.C. 1086 (1990); B.A.T. Indus., 104 F.T.C. 852 (1984); Tenneco, Inc. v. FTC, 689 F.2d 346, 352 (2d Cir. 1982).

petition analysis. Because the required FDA approval process for new drugs takes several years to complete, is transparent, and fairly predictable, the FTC often is able to determine which firms are likely to enter a relevant market during a specific time period.[43] Information about drugs under development typically is available from FDA, and often is available in the firm's Securities and Exchange Commission (SEC) filings. Although predictions about entry are not perfect, FDA's approval process provides a greater degree of certainty than usually is possible with other markets. When drugs are in the later stages of the approval process, it is relatively easy to predict whether the drugs will receive approval and enter the market. In fact, the approval process provides confidence in the ability to determine the competitive impact of the acquisition of a firm not yet in the market.

If competition from a new product can be predicted, then its competitive potential can be assessed. For instance, a merger between a firm that holds the only effective drug for a particular disease and a firm with a late-stage potential competitive drug could lead to unilateral anticompetitive effects. The existing monopolist would have no incentive to continue the research and testing procedure on the new drug because all of the sales that it may make will come at the expense of the monopolist's existing drug. In such a case, the divestiture of either the existing drug or the potential new drug may be necessary to restore the potential competition that would be lost.

1. *Zeneca/Astra Merger*

One recent pharmaceutical merger investigation that considered potential competition was the acquisition of Astra by Zeneca, which created the third largest pharmaceutical company in the world.[44] Zeneca, a drug company, entered into an agreement with Chiroscience Group PLC to market and assist in the development of levobupivacaine, a new long-acting local anesthetic being developed by Chiroscience. Long-acting local anesthetics are used to relieve pain during the course of surgical or other medical procedures by blocking pain impulses from reaching the central nervous system. Zeneca proposed to acquire Astra, the leading supplier of long-acting local anesthetics, and one of only two companies approved by FDA for the manufacture and sale of the drugs in the United States. Although Zeneca did not participate in the market for long-acting local anesthetics directly, it was a potential competitor by virtue of its agreement with Chiroscience.

The U.S. market for these drugs was heavily concentrated, with a pre-acquisition HHI of 6682.[45] Barriers to entry were high because of the need to undertake the difficult, expensive, and time-consuming process of researching and developing a new product, obtaining FDA approval, and gaining customer acceptance. The FTC al-

[43] When drug manufacturers seek approval for a drug, they file a new drug application. This begins a lengthy testing and review process that proceeds through four separate stages. The applicant must submit to FDA data demonstrating the safety and effectiveness of the drug. In addition, the applicant must provide information on any patient covering the drug for which a claim of patent infringement reasonably could be asserted against an unauthorized party. After a preclinical study (animal), the human testing procedure covers three stages: Phase I tests the safety of the drug (toxicology) in healthy persons, Phase II tests for the drug in small controlled trials in patients, and Phase III tests for efficacy through large-scale controlled trials under actual clinical conditions. *See* Jennifer Kulynuch, *Will FDA Relinquish the "Gold Standard" For New Drug Approval? Redefining "Substantial Evidence" in the FDA Modernization Act of 1997*, 54 FOOD & DRUG L.J. 127, 141 (1999); 21 U.S.C. § 355 (1994); 21 C.F.R. §§ 312, 314 (1998). Because of this drug approval process, the FTC, with the assistance of FDA, can identify firms in the drug regulatory "pipeline" that are potential entrants to the market.

[44] Zeneca Group PLC, C-3880 (June 7, 1999) (consent order).

[45] *Zeneca Group PLC*, C-3880, Complaint at 2.

leged that the acquisition would result in the elimination of a significant source of new competition. The remedy preferred by the FTC was to return the rights of development to Chiroscience. Under the terms of the order settling the case, Zeneca was required to transfer and surrender all of its rights and assets relating to levobupivacaine to Chiroscience no later than ten business days after the FTC accepted the order. The assets consisted principally of intellectual property and know-how, including patents, trademarks, copyrights, technical information, and market research relating to levobupivacaine.[46]

2. *Hoechst/Marion Merrell Dow Merger*

In a 1995 pharmaceutical merger, the FTC alleged that potential competition would be harmed in four separate, relevant product markets. Hoechst, a German pharmaceutical company, acquired MMD in a 7.1 billion dollar merger that, at the time, created the world's third-largest pharmaceutical company.[47] The four product markets accounted for 1.4 billion dollars in U.S. sales and affected hundreds of thousands of consumers who suffered from hypertension, angina, arteriosclerosis, and tuberculosis (TB).[48] The largest market was the one billion dollar once-a-day diltiazem market where MMD's Cardizem®-CD had a dominant share.[49] Prior to the merger, Hoechst and Biovail jointly developed Tiazac® to compete against Cardizem®-CD. The FTC alleged that the "pendency of the merger negotiations affected Hoechst's incentives with respect to the development of Tiazac,"[50] which resulted in delaying FDA approval. Before the merger agreement was finalized, and in an effort to resolve antitrust concerns, Hoechst relinquished the rights to Tiazac® to Biovail. The FTC found this inadequate, however, because it left Tiazac® a less-effective competitive product than it would have been absent the merger. In addition, Hoechst, as the new owner of Cardizem®-CD, also had access to sensitive information relating to Tiazac®, which was now owned by Biovail.

The other three relevant markets also featured current production by one of the merging firms and a serious, observable effort by the other to enter the market. In the second market, Hoechst marketed the only drug that at the time was approved by FDA for intermittent claudication, a painful leg cramping condition that affects over 5,000,000 people in the United States.[51] MMD had one of the few drugs in development for this condition before the merger. In the third market, MMD marketed one of two oral forms of a drug used to treat the gastrointestinal diseases of ulcerative colitis and Crohn's Disease, which affects over 1,000,000 people in the United States.[52] Hoechst was one of only a few firms developing a generic form of this drug. In the final market, MMD marketed a brand of the TB drug rifampin; Hoechst was one of only a few firms developing a generic form of rifampin. In the consent order, Hoechst was required to divest one of the two drugs in each of the markets.

The *Zeneca* and *Hoechst* cases illustrate how competition can be harmed by removing or delaying a potentially competitive product. In some industries, such as the pharmaceutical industry, firms may compete to produce a product where none currently is available because the demand for such a product is observable and quantifiable. In such cases, a merger can be anticompetitive.

[46] *Zeneca Group PLC*, C-3880, Consent Order at 3.

[47] *Hoechst AG*, C-3629, 120 F.T.C. at 1010.

[48] *Id.* at 1012-13.

[49] *Id.* at 1012.

[50] *Id.* at 1013.

[51] FTC Press Release, Hoechst Settles FTC Charges of Reducing Competition: For Four Drugs in Connection with MMD Merger, at 2 (Sept. 18, 1995).

[52] *Id.*

C. *Innovation Market Mergers*

Many of the FTC's pharmaceutical merger cases involve the acquisition of intellectual property[53] and relevant product markets defined as innovation markets. Innovation markets arise from the recognition that future competition can be harmed by a reduction in research and development.[54] In industries where the main focus of competition is the development of new technologies rather than price competition, antitrust principles will apply, and competitive rivalry must be protected. If an entity acquires the ability to innovate in a relevant market, and substitutes are lacking, competition may suffer. The FTC's "goal is to carefully identify those situations where a merger likely will reduce innovation competition."[55]

Pharmaceutical merger cases fit into the innovation market mold. Indeed, much of the rivalry in this industry is in developing new drugs. Because of the required FDA approval process, pharmaceutical firms usually are able to track the coming entry of new drugs, and know which firms are likely to become competitors and when competitors will arrive. If a firm can identify its primary future competitive threat and can determine the entry date of the next-best substitute, it may be able, through acquisition, to control a relevant market.

1. *Glaxo/Wellcome Merger*

The FTC's concern with the acquisition of competing research and development endeavors is reflected in the Commission's enforcement decisions involving mergers of pharmaceutical firms. In *Glaxo* the FTC alleged harm to innovation markets where the merging parties — Glaxo and Burroughs Wellcome — were the two firms that had progressed the farthest in developing an oral drug to treat migraine attacks.[56] At the time, drugs existed to treat migraines, but they were available only in injectable form. A noninjectable drug offered substantial benefits to consumers, and thus, the relevant market consisted of R&D for the oral form of the drug. The potential market for these drugs was substantial; for example, one study estimated that eighteen percent of women and six percent of men suffer from migraine attacks at least once a year, resulting in six billion dollars in lost productivity and physician visits.[57] Total anti-migraine drug sales in 1997 were $851,000,000.[58]

Both Glaxo and the acquired firm, Wellcome, competed to develop the new drugs, and the expectation was that the developed drugs would compete in the market. Bar-

[53] In several recent merger cases, the FTC considered the acquisitions of patents and related technology where the merging firms were either the only two, or two of only a few, firms capable of innovating in high-technology markets. In such situations, the acquisition likely would lead to anticompetitive effects. *See* PHILIP AREEDA & HERBERT HOVENKAMP, III ANTITRUST LAW ¶ 707b, at 175 (1996) ("[T]he clearest case [of exclusionary conduct] would be the acquisition of an equivalent patent covering the only known economic alternative to the monopolist's product or process. Such an acquisition forecloses potential competition by rivals who might otherwise have access to that patent. Even the acquisition of one out of several equivalent patents might have exclusionary effects.").

[54] The Merger Guidelines recognize that a transaction may lessen competition in such nonprice attributes as "product quality, service, or innovation." MERGER GUIDELINES, *supra* note 16, § 0.1 n.6.

[55] William J. Baer & David A. Balto, *New Myths and Old Realities: Recent Developments in Antitrust Enforcement*, 1999 COLUM. BUS. L. REV. 207, 222.

[56] *See Glaxo*, C-3586.

[57] Marilyn Dix Smith & William F. McGhan, *Don't Let Migraine Be a Financial Headache*, 10 BUS. & HEALTH 16, 47 (1998).

[58] Susan Riley & Kellie Rivgen, *New Product Launches Drive a Good First Half*, 10 MED. MKTG. & MEDIA 33, 62 (1998).

riers to entry, based on the need to acquire substantial specialized human capital resources, and the need to complete FDA's approval process, were high. The complaint alleged that after the merger, Glaxo unilaterally could reduce output in the relevant market by eliminating either its or Wellcome's R&D efforts to develop a noninjectable drug. The merged company would have that incentive because the remaining research effort presumably would produce a monopoly product until a "third-best" effort could receive FDA approval years later. This case was resolved with the divestiture of Wellcome's R&D assets.

2. *Ciba-Geigy/Sandoz Merger*

In *Ciba-Geigy/Sandoz*, another pharmaceutical merger case, the FTC alleged the existence of a market for the development of gene therapy products, despite the fact that no such products were licensed by FDA.[59] The complaint noted that the first products would not be available until the year 2000, but that the market could grow to forty-five billion dollars by the year 2010.[60] The FTC alleged that this merger would harm competition in a broad gene therapy R&D market.

The complaint also alleged that the merger would harm competition in the research and development, manufacture, and sale of 1) herpes simplex virus-thymidine kinase (HSV-tk) gene therapy for the treatment of cancer, 2) HSV-tk gene therapy for the treatment of graft versus host disease, 3) gene therapy for the treatment of hemophilia, and 4) chemoresistance gene therapy.[61]

The technology at issue concerned the treatment of disease through manipulation of genetic material and insertion or reinsertion into a patient's cells. Although many firms were conducting research into gene therapies, the merging firms were two of only a few entities with the intellectual property rights and other assets necessary for commercialization of such therapies. The firms' combined position in gene therapy research was so dominant that other firms doing research in this area needed to enter into joint ventures, or contract with either Ciba-Geigy or Sandoz, to have any hope of commercializing their own research efforts. In particular, they possessed an overwhelming amount of the necessary R&D resources, making it necessary for firms seeking to conduct research and development in this area to contract with one firm or the other. Competition between the two firms facilitated joint ventures and contracts on reasonable terms. Without competition, the combined entity could have appropriated most of the commercial value of other firms' research, leading to a substantial decrease in such research. In addition, there was direct competition between the two companies with respect to specific therapeutic products.

The FTC was concerned that Novartis, the newly-named surviving company, might not adequately license its gene therapy intellectual property to assure that other firms would be unable to close the R&D gap. By not licensing its intellectual property to the other research firms, Novartis could have blocked access to the broad future gene therapy market. Absent the merger, Ciba-Geigy and Sandoz could have licensed their patents either for cash or as part of competing cooperative development projects. The FTC resolved its concerns in this important innovation market through a consent order that required the licensing of certain technology and patent rights to Rhone-Poulenc Rorer.[62]

[59] Ciba-Geigy Ltd., C-3725, 123 F.T.C. 842 (Mar. 24, 1997) (consent order).

[60] *Id.* at 845 (complaint).

[61] *Id.* at 844-45.

[62] *See* Elyse Tanouye & Robert Langreth, *Genetic Giant: Cost of Drug Research is Driving Talks of Glaxo, SmithKline*, WALL ST. J., Feb. 2, 1998, at A1 (discussing Ciba-Geigy/Sandoz's licensing or gene-therapy technologies and patents); John R. Wilke, *U.S. Forces New Drug Giant to Share Genetic Research*, WALL ST. J., Dec. 18, 1996, at B4 (reporting on FTC's demand that Ciba-Geigy and Sandoz license rivals in order to preserve competition and innovation).

This licensing arrangement ensures that Rhone-Poulenc will be in a position to compete with the merged firm. According to *Business Week*, the FTC's enforcement action "shows a new savvy among trustbusters about high-tech competition."[63]

3. *Upjohn/Pharmacia Merger*

In *Upjohn*, the FTC alleged that Upjohn's 1995 acquisition of Pharmacia Aktiebolag would harm competition in the market for topoisomerase I inhibitors, which are drugs used in conjunction with surgery to treat colorectal cancer.[64] Approximately 443,000 Americans are diagnosed with the disease every year and if the cancer recurs, the survival rate is only fifteen percent.[65] Although no drugs were available to cure this disease, the topoisomerase I inhibitors were expected to increase the survival rate. The merging firms were two of only a small number of companies in the advanced stages of developing the drugs. Upjohn's CPT-11 was the most advanced product at the time, while Pharmacia's 9-AC product was a few years behind in development. Because companies require years of scientific research and significant expenditures to reach the advanced stage of development, the FTC alleged it was unlikely that other firms would constrain the merged firm from terminating development of one of the products or raising prices. This case was resolved with divestiture of Pharmacia's 9-AC R&D assets to IDEC Pharmaceuticals Company.

4. *Baxter/Immuno Merger*

Finally, a recent pharmaceutical merger illustrates the complexity of antitrust enforcement in an industry that produces hundreds of thousands of discrete products in various stages of development or marketing and where many of the products face only a few competitors. These issues arose when FTC considered the 1996 acquisition of Immuno International by Baxter.[66] This merger raised competitive problems in both a current goods market, where the two firms were horizontal competitors, and an innovation market, where neither firm produced a current product but were among the few firms with a chance to enter the market. Both firms manufactured a wide variety of biological products derived from human blood plasma. The FTC alleged that the merger would harm competition in two product markets: Factor VIII inhibitors for hemophiliacs, and fibrin sealant, a product that controls bleeding in surgical procedures. The Factor VIII inhibitor market was highly concentrated, as Baxter and Immuno were the only two companies marketing those products in the United States. In the other market, there were no producers of fibrin sealants in the United States, and Baxter and Immuno were two of only a few companies seeking FDA approval for the products. New market entry in either product line would be difficult and time consuming, and would require the expenditure of substantial resources without any assurance that a viable product would result. The acquisition would allow Baxter to eliminate one of the existing research tracks and exercise unilateral market power.

Fibrin sealants already were widely used at the time of the Baxter-Immuno proposed merger. According to one study, thirty-five to forty percent of all internal surgi-

---

[63] Naomi Freundlich et al., *A Booster Shot for Gene Therapy: FTC Trust Busters Put Conditions on a Merger Even Though the Technology is in its Infancy*, BUS. WK., Jan. 2, 1997, at 92.

[64] Upjohn Co., C-3638, 121 F.T.C. 44 (Feb. 8, 1996) (consent order).

[65] *Id.* at 45.

[66] Baxter Int'l, Inc., C-3726, 123 F.T.C. 904 (Mar. 24, 1997) (consent order).

cal procedures in Europe and Asia employed fibrin sealants.[67] Many surgeons in the United States mixed and applied their own fibrin sealants; however, FDA had not approved any company for the sale of a patented fibrin sealant in the United States as of 1996. With no other comparable products slated for launch before late 1999, Baxter and Immuno were posed to be the sole entrants in a market with estimated sales of $200,000,000.[68] The case was resolved with divestiture of Baxter's R&D assets.

Some commentators have questioned whether the FTC has intervened too readily in mergers involving R&D competition. The number of cases brought and the carefully circumscribed relief suggests, however, that the FTC is acting in a moderate fashion, and is addressing competitive concerns only where appropriate. As the director of FTC's Bureau of Competition, William J. Baer, explained "Intervention in innovation market transactions is warranted in carefully limited circumstances — namely, where few firms possess the specialized assets or characteristics needed to compete successfully in the market."[69]

V. REMEDIES

If there are probable anticompetitive effects in all or part of a merger, the Commission either must block the merger to prevent harm to consumers, or find a remedy sufficient to restore competition to where it would be before injury while allowing the rest of the transaction to proceed.

The FTC's remedies are designed to be equitable, not to punish.[70] The relief generally is prospective to stop unlawful conduct and deter future violations of the antitrust laws. One aspect of deterrence is removing any gain from illegal conduct. Generally, FTC pursues three types of remedies in competition cases: structural (divestiture and licensing); conduct (cease and desist orders); and monetary (civil penalties, disgorgement, and restitution).

The Bureau of Competition's foremost objective, when addressing the competitive problems raised by a merger, is to provide relief that will return competition to the status quo ante. Relief from a section 7 violation should be tailored to alleviate the likely anticompetitive effects in the relevant market and no broader than necessary to protect against the harm. Thus, while the FTC has "wide discretion in its choice of a remedy,"[71] the Commission seeks to ensure that its remedy is reasonably related to the unlawful practices.

Because a merger is a structural event, the remedy to cure the anticompetitive part of an acquisition, typically and preferably, is structural. If the competitive overlap constitutes most or all of the acquisition or merger in question, the FTC often will seek a preliminary injunction to halt the transaction (and the likely harm to consumers) before it happens. If the competitive overlap is a smaller part of the overall deal, however, divestiture or licensing may remedy the competitive concern, if the injunctive order can be drafted with sufficient protections.

The Commission staff recently completed a study of past divestiture efforts to determine the extent to which competition successfully was restored in these cases, a

---

[67] Mark Thill, *The Sealants are Coming! The Sealants are Coming!* REPERTOIRE (May 1998), *available in* <www.medicalmag.com/REPertoire/pastissues/mayseal.html>.

[68] Stephen Northfield, *Investment Reporter: U.S. FDA Ruling Stirs Interest in Haemacure Stock*, THE GLOBE AND MAIL, May 1998, at 6.

[69] Baer & Balto, *supra* note 56, at 222.

[70] The Commission's remedial authority is derived from the FTC Act, 15 U.S.C. §§ 41-64, and the Clayton Act, 15 U.S.C. §§ 12-21.

[71] FTC v. Rubberoid Co., 343 U.S. 470, 473 (1952).

number of which were pharmaceutical cases.[72] Staff reviewed the cases and made a number of recommendations to improve the entire merger remedial process.[73] Among the results of the study are that "the pharmaceutical divestitures established a precedent that complex technology divestitures could be acceptable remedies for large mergers. Resolution of the difficult issues concerning these orders and divestitures allowed respondents to merge without fundamentally undermining the hoped-for efficiencies."[74] Based on the study, the FTC adopted several reforms of the divestiture process including identifying buyers before the deal is cleared ("up-front buyers"), interim supply agreements, provision of technical assistance, and the use of trustees to monitor the divestiture process. These reforms are described in greater detail below.

Crafting an effective remedy depends in part on a careful analysis of market structure, especially entry barriers. It also depends on considering what kind of relief would be most effective in restoring competition. To be an acceptable alternative to litigation, a settlement must resolve the competitive concerns uncovered during the FTC's investigation. This may require the settlement to provide that the divested assets will create a viable competitor with market share that can replace the competition lost by the merger or at least facilitate entry (or expansion) of a successful competitor.

When examining a merger that has both potential efficiencies and anticompetitive effects, the FTC ordinarily will attempt to find a structural solution, such as divestiture, that will preserve the former and eliminate the latter. As the U.S. Supreme Court advised, divestiture is a "natural remedy" for a violation of section 7 and always should be "in the forefront of a court's mind when a violation . . . has been found."[75]

Sometimes divestiture and licensing may fail to restore competition completely, particularly in the pharmaceutical industry, where the products are complex and difficult to bring to market. In such a case, additional assistance from the merging parties may be necessary to help the buyer or licensee achieve timely and effective entry. In addition, some particular cases may call for special remedial action to ensure full restoration of competition. The FTC's remedial authority is sufficiently comprehensive and flexible to accomplish that goal in any competitive situation. The following discussion provides a roadmap to the remedies the FTC employs in pharmaceutical mergers.

A. *Divestiture*

Divestiture of a manufacturing plant or other physical asset is a remedy that courts often have ordered and antitrust agencies are comfortable seeking to preserve competition, particularly where the assets constitute an ongoing business.[76] If the competing assets can be sold to a third party or spun-off into a viable competitor, competition can be maintained with a one-time event. An asset divestiture is most appropriate when an acceptable buyer can be identified in advance. If that cannot be done, the Commission will try to maintain the status quo during the divestiture process by re-

---

[72] FEDERAL TRADE COMM'N, BUREAU OF COMPETITION STAFF REPORT, A STUDY OF THE COMMISSION'S DIVESTITURE PROCESS (1999).

[73] *Id.* at 31-33.

[74] *Id.* at 41.

[75] United States v. E. I. duPont de Nemours & Co., 366 U.S. 316, 331 (1960). *See* Ford Motor Co. v. United States, 405 U.S. 562, 573 (1972) (noting divestiture is "particularly appropriate" in merger cases).

[76] *See, e.g.*, OKC Corp. v. FTC, 455 F.2d 1159, 1161 (10th Cir. 1972) (ruling total divestiture of acquired assets necessary to restore "viable, independent, local competitive entity"); RSR Corp. v. FTC, 602 F.2d 1317 (9th Cir. 1979), *cert. denied*, 445 U.S. 927 (1980) (ruling partial divestiture sufficient to restore competitive entity).

quiring a tight deadline for the sale, a trustee to oversee the assets to be divested, and the use of a "crown jewel" provision, which permits a Commission-appointed trustee to divest the rights to the product, to ensure that the divestiture incentive is strong.

Pharmaceutical mergers, especially those that focus on innovation competition, may pose special challenges in designing remedies. A recent FTC staff report notes:

> The costly, risky, and time-consuming characteristics of the prescription drug R&D process may make it hard to restore innovation competition to pre-acquisition levels. . . . An initial difficulty is that any acquirer of the divested assets may otherwise lack the capability to compete with the merging parties in the innovation market at issue. Further, these divestitures may threaten any efficiencies that flow from a combination of complementary R&D assets that could characterize some mergers involving innovation markets. But when the assets required for R&D are readily identified, when the foregone scope economies in research are small relative to the benefit to consumers from protecting R&D competition, and when a strong buyer can be identified, divestitures of overlapping innovation assets can reasonably be employed to remedy potentially anticompetitive drug mergers.[77]

The FTC recognizes these challenges and has adapted remedies to meet individual circumstances. Where the merging parties are direct competitors in the production of current goods, ordinarily the FTC will require divestiture of a product or line of business of one of the two companies. The pharmaceutical cases involving direct overlap of current products that were discussed in part IV illustrate this kind of divestiture.

Although divestiture is the preferred remedy in merger cases, it requires special care as a remedy in innovation markets because the success of research and development efforts often depends on a complex array of expertise and sustained knowledge. Even in cases where divestiture is the appropriate remedy, it may be necessary at times to require ongoing obligations of the divesting party to ensure that the purchaser has some probability of successful completion of the research effort. In many pharmaceutical merger cases, the FTC has required that the surviving firm offer some form of assistance to the purchaser of the divested assets. Several examples illustrate this approach.

1. *Relief in Direct Competition Cases*

The settlement in *Roche* required the merged company to divest or license all of the assets relating to Boehringer Mannheim's U.S. and Canadian Retavase® cardiac thrombolytic agents business to Centocor or another FTC-approved buyer. If divestiture did not occur within ninety days of the final order, a "crown jewel" provision permitted a Commission-appointed trustee to divest the world-wide rights to Retavase®. In *Roche*, Centocor purchased these assets within the allotted time period. Roche also was required to divest, within sixty days of the final order, Boehringer Mannheim's worldwide DAT reagents business. According to the order, if divestiture was not completed in the time specified, the trustee could divest all of Boehringer Mannheim's CEDIA (Cloned Enzyme Donor Immuno-Assay) reagents. Roche divested the DAT business to Behring Diagnostics; Roche also was required to grant Behring an exclusive, world-wide, royalty-free license to CEDIA for DAT reagents.

---

[77] LEVY, *supra* note 21, at 132 (footnotes omitted).

To ensure that competition was fully restored, Roche had to provide substantial assistance to each of the acquirers. Roche was required to "contract manufacture" a supply of the divested products for the time period it took for each acquirer to establish its own manufacturing processes and obtain its own FDA approvals to manufacture and sell Retavase® and DAT reagents in the United States. In addition, Roche was required to provide the necessary technical assistance to the acquirers in their efforts to begin manufacturing the products. The acquirers also were allowed to hire former Boehringer Mannheim employees associated with the marketing or sales of Retavase® or DAT reagents.

The consent order settling *American Home Products* required American Home Products to divest Solvay's U.S. and Canadian rights to the three vaccines to Schering-Plough no later than ten days after the order became final.[78] In addition, American Home Products was required to assist Schering-Plough in obtaining USDA certifications, as well as in manufacturing and supplying the three vaccines to Schering-Plough for a period of twenty-four to thirty-six months, or until Schering-Plough obtained the approvals.[79] American Home Products also was prevented from suing Schering-Plough for patent infringement relating to the three vaccines. If the divestiture was not successful, the FTC could appoint a trustee to divest Solvay's three vaccine assets, as well as Solvay's manufacturing facility in Charles City, Iowa, and all equine vaccines manufactured by Solvay.

2. *Relief in Potential Competition Cases*

The FTC has followed similar divestiture requirements in mergers where potential competition has been threatened. The surviving firm has been required to divest either the current product or the product with the potential to enter the market. In *Zeneca,* the consent order required Zeneca to transfer and surrender all of its rights and assets relating to levobupivacaine to Chiroscience no later than ten business days after the date the FTC accepted the agreement for public comment.[80] The assets to be transferred to Chiroscience consisted of intellectual property and know-how, including all the applicable patents, trademarks, copyrights, technical information, and market research relating to levobupivacaine. During the transitional period, Zeneca was required to continue ongoing activities relating to the commercialization of levobupivacaine, including manufacturing, regulatory, clinical, development, and marketing activities. Zeneca also was required to divest its approximately three percent investment interest in Chiroscience.

In *Hoechst*, potential competition was threatened in all four potential product markets — hypertension, angina, arteriosclerosis, and tuberculosis. In each market, Hoechst was required to divest either the current line of business or the potential new product to an FTC-approved buyer who would develop and market it. The settlement in each market also required Hoechst to prevent the deterioration of the assets involved, to maintain its R&D efforts at planned levels pending divestiture, and to provide technical assistance and advice to the purchasers about obtaining FDA approval.

3. *Relief in Innovation Market Cases*

When the anticompetitive effects of a merger are evidenced in innovation markets, the FTC has used both divestiture and nonstructural relief. The appropriateness

[78] *American Home Products*, C-3740, 123 F.T.C. at 1288.

[79] *Id.* at 1289.

[80] *Zeneca*, C-3880, at 3.

of divestiture as a remedy and its case-by-case flexibility, are illustrated by *Glaxo*, where the merging parties were the two firms that had advanced the farthest in the development of non-injectable agonists (oral drugs used to treat migraine attacks).[81] The order required divestiture of Wellcome's non-injectable R&D assets. To restore competition fully, the order had to make certain that the buyer of the divested assets could use them effectively to mount a strong R&D effort. The assets themselves might not have been sufficient, without the "complex array of expertise and sustained knowledge" embodied in human capital, to enable an acquirer to get to market expeditiously.[82] Thus, the order also imposed significant obligations on Glaxo to assist the acquirer in its efforts to continue the research successfully. Glaxo had to provide information, technical assistance, and advice to the acquirer about its research, including consultation with and training by Glaxo employees knowledgeable about the project.[83] Additionally, under certain conditions Glaxo had to produce more of the experimental drug for the acquirer if it was unable to manufacture sufficient quantities on its own. A trustee was appointed and given the power to sell either the Wellcome or the Glaxo non-injectable assets if Glaxo had not divested the Wellcome assets within nine months.[84] The divestiture was a success because both Glaxo and the acquirer of its intellectual property have oral migraine drugs on the market. With the required assistance from Glaxo, the acquiring firm, Zeneca, received complete FDA approval in only fifteen months.

The consent order in *Upjohn* required the merged firm to divest Pharmacia's 9-AC R&D assets to an FTC-approved buyer; the National Cancer Institute, the licensor of Pharmacia's 9-AC technology, also had to approve the buyer. If the divestiture was not completed in a timely fashion, the FTC could appoint a trustee to complete the divestiture of the 9-AC assets, including an exclusive license to 9-AC in the United States as well as an exclusive or nonexclusive license to market 9-AC in the rest of the world.[85] In addition, the consent agreement required the merged firm to provide technical assistance and advice to the acquirer toward continuing the research and development of 9-AC.

The consent order in *Baxter* required both divestiture and licensing, to cure the current product overlap in Factor VIII products and the potential anticompetitive effects in the innovation market for fibrin sealants. In the market for Factor VIII inhibitors, the order required Baxter to divest its Autoplex® product. The product line was divested in a timely fashion to NABI of Boca Raton, Florida.

B. *Licensing*

Although divestiture is preferred in most cases, when the majority of a firm's value resides in its intellectual property and the ability to innovate, divestiture may be problematic. The complex interplay of human capital from which innovation springs is more fragile than typical physical assets. In addition, intellectual property often is embodied in patents, and the patent system has its own complex system of legal protections. Pharmaceutical market mergers often turn on such issues. Thus, in some

[81] *See Glaxo*, C-3586.

[82] Thomas N. Dahdouh & James F. Mongoven, *The Shape of Things to Come: Innovation Markets in Merger Cases*, 64 ANTITRUST L.J. 405, 439 (1996).

[83] *See* AREEDA & HOVENKAMP, *supra* note 54, ¶ 707i, at 184 (advocating "divestiture of sufficient assets to create viable new firms with free access to the monopolist's then-existing technology . . . where an acquisition, or a series of acquisitions, has probably made a substantial contribution to monopoly power").

[84] *Glaxo*, C-3586, 119 F.T.C. at 824.

[85] *Upjohn*, C-3638, 121 F.T.C. at 52.

cases involving pharmaceutical markets, the FTC will consider licensing as an alternative. Because the output of the innovation process can be used by more than one entity, the licensing of that output has the potential to replace lost competition without physically restructuring the merging firms. The FTC, however, always has been concerned with licensing as a remedy.[86] It is by nature more regulatory than divestiture, and may require continued oversight to ensure effectiveness.[87]

The fibrin sealant portion of the Baxter-Immuno order exemplifies the approach in using licensing. In this case, licensing was appropriate because of the advanced stage of each company's fibrin sealant project. By licensing Baxter's Tisseel® and requiring Baxter to provide the acquirer, Haemacure, with the finished product for sale, the order enabled both companies to market sealants immediately following FDA's approval of Baxter's product in May 1998. Industry reports indicate that no other sealants or similar surgical adhesives will be ready for marketing before the end of 1999.[88] Thus, the order brought two competing products to market simultaneously where only one would have prevailed due to the merger.

The remedy in *Ciba-Geigy* was intended to protect competition both in the particular products being researched, and in the broader market for gene therapy research. For the identifiable products under development, the order required the licensing of certain key intellectual property rights held by the combined firm, as well as identification of an acceptable buyer "up front." Rhone-Poulenc Rorer was identified as the licensee before the order was accepted by the FTC. For the broader gene therapy R&D market, the order required the companies to grant to all gene therapy researchers who applied, non-exclusive licenses to essential gene therapy technologies, as well as access to drug master files and safety data filed with FDA.[89] Because adequate know-how was present in the identified buyer, as well as in other companies with R&D programs in gene therapy, further technical assistance was unnecessary.

Licensing was deemed necessary to restore possibilities for partnering for other firms lost by the merger.[90] While divestiture is an easier remedy to impose and monitor, it may not always be the most effective way of restoring competition. Because licensing is flexible and can be tailored to unusual fact situations easily, it may be the preferred remedy in innovation cases where divestiture could interrupt potentially successful research efforts. In this case, a majority of the FTC commissioners determined that licensing was preferable to divestiture. The gene therapy research efforts contained a number of joint efforts with third parties, and thus, would be too difficult to disentangle from the merging firms. Divestiture would "not only . . . hamper efficiency but also could be less effective in restoring competition if it led to coordinated interaction or left the divested business at the mercy of the merged firm."[91]

---

[86] Although it may present difficulties, sometimes the divestiture of intellectual property or innovation efforts is necessary to fully restore competition. In these cases, the FTC will not hesitate to order divestiture. *See, e.g.*, discussion of *Glaxo, supra* part IV.C.1. & *Upjohn, supra* part IV.C.3.

[87] Some commentators have criticized the adequacy of licensing as an antitrust remedy. Richard T. Rapp, *The Misapplication of the Innovation Market Approach to Merger Analysis*, 64 ANTITRUST L.J. 19 (1995). For a response, see Dahdouh & Mongoven, *supra* note 82, at 438 ("Licensing is usually found to be an appropriate remedy when market participants and innovators agree that access to intellectual property is key.").

[88] The third potential competitor expects FDA approval early in 2000. *See Fusion Medical Files PMA for FloSeal Herrastatic Sealant with FDA*, BUS. WIRE, Feb. 23, 1999.

[89] *See Ciba-Geigy*, C-3725, 123 F.T.C. at 873-77.

[90] For a discussion of FTC use of licensing as a remedy, see Mary Lou Steptoe & David A. Balto, *Finding the Right Prescription: The FTC's Use of Innovative Merger Remedies*, 10 ANTITRUST 16 (1995).

[91] *Ciba-Geigy*, C-3725, 123 F.T.C. at 895 (statement of Chairman Pitofsky and Comm'rs. Steiger, Starek & Varney). Commissioner Azcuenaga dissented from the order licensing gene therapy products, noting that "the Commission has bypassed the obvious, simple and effective remedy of divestiture in favor of a complex regulatory concoction that promises to be less effective and more costly." *Id.* at 898.

Roche provides another example of licensing used in conjunction with divestiture to restore competition. In addition to divesting one of the overlapping products in the cardiac thrombolytic agent market, Roche was required to divest Boehringer Mannheim's DAT reagents and grant a non-exclusive license to all other CEDIA reagents in the United States, including, but not limited to, reagents used for therapeutic drug monitoring, thyroid analysis, testing for anemia, and hormone testing.[92] If Roche had failed to divest and license within two months of the final order, an FTC-appointed trustee could have divested all of Boehringer Mannheim's CEDIA reagents.

C. *Other Remedies*

Competition in an industry changing as rapidly as pharmaceuticals can tax all of the FTC's traditional remedies. The full reach of the Commission's remedial power, however, allows the FTC to craft specific remedies to fit individual cases.

The flexibility of the Commission's remedial powers is particularly important because of the significance of intellectual property to effective competition. The various characteristics of intellectual property — its lack of a physical nature, its ability to be used by more than one entity simultaneously, its constitutionally-recognized right to exclude — make it both a key to competition and a potential weapon in wielding market power. Therefore, the FTC occasionally utilizes nonstandard remedies to clear the way for the use of intellectual property to foster innovation and erode entrenched market power. Examples include provisions forbidding lawsuits over intellectual property rights, providing sufficient intellectual property rights to the buyer to assure commercial success, information firewalls preventing one part of a company from improperly sharing proprietary intellectual property information to another part of the company, and divesting intellectual property back to the original developer to ensure an additional competitor in the marketplace.

In *Ciba-Geigy*, for example, the complexity of the product markets and the necessity of information sharing required that licensing be supplemented in the order.[93] To minimize the financial relationships and the exchange of competitively sensitive information between the merging parties and potential competitor-licensees, the FTC appointed an independent auditor to collect and aggregate the royalty payments. In addition, the merging parties were prohibited from gaining access to confidential sales information. Each license also was required to include a binding arbitration clause to resolve disputes regarding the royalties or any other contract terms. To ensure that there was continued competition in chemoresistance gene therapy products, the order also prevented either party from acquiring exclusive rights in intellectual property and technology related to the genes.[94]

Under the consent order settling *Hoechst*, the company was required to provide Biovail with a letter of access to the toxicology data necessary to secure additional FDA approvals for Tiazac®. The order also required Hoechst to refrain from using that information, dismiss a patent infringement lawsuit filed by MMD regarding Tiazac®, withdraw a citizen petition MMD filed with FDA relating to Tiazac®, and agree not to file any subsequent litigation against Biovail regarding diltiazem.[95]

Orders preventing future litigation that could affect competition sometimes are necessary in an industry in which intellectual property and patents play an important

[92] *See Roche*, C-3809.

[93] *See Ciba-Geigy*, C-3725, 123 F.T.C. at 873-77.

[94] *Id.* at 877.

[95] *See Hoechst*, C-3629, 120 F.T.C. at 1020-21.

role in new product development. The order in *American Home Products*, for instance, requires the surviving firm to agree not to sue the firm acquiring the divested assets for infringement of vaccine patents, including patents owned by American Home Products before the merger.[96]

These additional remedial requirements demonstrate that the FTC has used and is willing to use the authority necessary to restore competition to the premerger level. The traditional remedies of divestiture and licensing are only the starting point in the effort to comply with the section 7 prohibition of mergers that substantially may lessen competition.

VI. THE PRACTICAL ROADMAP FOR PHARMACEUTICAL MERGERS

Remedies used in pharmaceutical mergers over the last four years point to continued antitrust enforcement in the industry. Although the remedies can vary widely, depending on the facts of each case, application of the *Merger Guidelines* is identical for each merger.

A. *Divestiture to an Up-Front Buyer*

The preferred remedy for an overlap of current products is divestiture of an ongoing business with customer and supplier relationships to an up-front buyer within a short period of time to complete the process. The identification of an up-front buyer by the merged parties is critical. The FTC has required an up-front buyer in every pharmaceutical merger since late 1995.

In a potential competition merger, the FTC will require divestiture of either the current product line or the product under development. In an innovation market, the FTC will use divestiture where the acquisition of selected assets by the right acquirer will result in timely, likely, and sufficient entry to compete with the retained assets. In the pharmaceutical industry, such assets may include patents, technology portfolios, and R&D assets.

B. *Timing*

Competition delayed is competition foregone; therefore, a divestiture must be accomplished as quickly as possible. The preference is for an up-front buyer, but if none is available the FTC will insist on a short time-table for divestiture. Over the last four years, that divestiture time-table has shortened, from twelve months to, in some cases, sixty to ninety days, as the cases above illustrate.

C. *Licensing*

If divestiture is inappropriate, licensing will be considered. Exclusive licenses are preferable, so that the licensee has the greatest economic stake in the technology being transferred. Licenses are more likely to be approved if they include the right to use any improvements to the technology that the licensee develops, including use in fields outside of the innovation product market.

---

[96] *See American Home Products*, C-3740, 123 F.T.C. at 1292-93.

D. *Ongoing Assistance*

In industries where innovation and technological change are crucial to competition, a divestiture package often must be supplemented by ongoing assistance. Contract manufacturing or supply agreements, access to critical personnel or facilities, and continued customer relationships may be necessary for the acquirer of the assets to enter the market and compete effectively. These factors are especially important in gaining FDA approval and in developing a customer base.

E. *Interim Trustees*

When an order requires transferring technology or an ongoing supply agreement, the FTC often requires the appointment of an auditor or trustee to ensure compliance and to assist with the USDA or FDA approval process. Additionally, the order may contain both a hold-separate and an interim maintenance requirement, to ensure that active research and development continues on schedule and that assets are not dissipated before divestiture. Auditors also may prevent any possible information-exchange problems by establishing and enforcing firewalls to prevent proprietary information from being misused.[97]

VII. CONCLUSION

The FTC's pharmaceutical and health care products enforcement actions are important for several reasons. These cases have a substantial and immediate impact on large numbers of consumers, not only by saving them from paying higher prices, but also by protecting incentives to innovate new products on a timely basis. In *Baxter International*, estimates of sales for the fibrin sealant market were over $200,000,000.[98] In *Glaxo*, anti-migraine sales in the United States for 1997 were $850,000,000.[99] Even the innovation market estimates show great potential. In *Ciba-Geigy*, estimates of the total gene therapy market in 2010 were forty-five billion dollars, although the first products are not scheduled to come on the market until 2000.[100] Competition offers the promise of lower prices and substantial savings for consumers. Indeed, effective merger enforcement can prevent the acquisition and future exclusionary use of monopoly power, which will save consumers from paying higher prices for potentially life-saving drugs in the future, as well as prevent the reduction of incentives to innovate.

Decades of merger enforcement and the *Horizontal Merger Guidelines* provide a clear roadmap for analyzing the competitive impact when two firms compete in the market. When the FTC is trying to protect future competition, however, the Commission must be able to predict the state of the market in the future. Continued monitoring of potential competition and the use of innovation markets may be necessary for effective enforcement. Both analytical constructs can enable enforcement agencies to protect innovation and future competition so that consumers receive the full benefit of protection from the antitrust laws.

---

[97] *See Ciba-Geigy*, C-3725, 123 F.T.C. at 877.

[98] *See Baxter Int'l*, C-3726, 123 F.T.C. 904.

[99] *Glaxo*, C-3586.

[100] *Ciba-Geigy*, C-3725, 123 F.T.C. at 845.