FTC ANTITRUST ACTIONS IN PHARMACEUTICAL SERVICES AND PRODUCTS

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FTC ANTITRUST ACTIONS INVOLVING PHARMACEUTICAL SERVICES AND PRODUCTS [1]

I. INTRODUCTION

The Federal Trade Commission is a law enforcement agency charged by Congress with protecting the public against anticompetitive behavior and deceptive and unfair practices. The FTC's antitrust arm, the Bureau of Competition, is responsible for investigating and prosecuting "unfair methods of competition" which violate the FTC Act. The FTC shares with the Department of Justice responsibility for prosecuting violations of the Clayton Act.

When litigation becomes necessary, many of the FTC's adjudicative matters are conducted in administrative adjudication before an FTC Administrative Law Judge. This provides the opportunity for matters raising complex legal and economic issues to be heard, in the first instance, in a forum specially suited for dealing with such matters. Appeals from Commission decisions are taken directly to the federal courts of appeal. The Commission also has the authority to seek a preliminary injunction in federal district court whenever the Commission has reason to believe that a party is violating, or is about to violate, any provision of law enforced by the FTC. Such preliminary injunctions are intended to preserve the status quo, or to prevent further consumer harm, pending administrative adjudication before the Commission. Additionally, the Commission has the authority to seek a permanent injunction in federal district court in a "proper case" pursuant to section 13(b) of the FTC Act.

In the mid-1970s, the FTC formed a division within the Bureau of Competition to investigate potential antitrust violations involving health care. The Health Care Services and Products Division consists of approximately twenty-five lawyers and investigators who work exclusively on health care antitrust matters. Health Care Services and Products Division staff also work with staff in the FTC's seven regional offices on health care matters. FTC cases involving pharmaceutical services and products are summarized below.[2] Non-merger matters involving the pharmaceutical industry are investigated by the Health Care Services and Products Division staff. Mergers in the pharmaceutical industry are investigated the Mergers I Division. The Commission and its staff also have responded to numerous requests for guidance from health care industry participants through, among other things, the advisory opinion letter

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[1] This summary has been prepared by the FTC Health Care Services and Products Division staff, and has not been reviewed or approved by the Commission or the Bureau of Competition.

[2] Commission orders issued since March, 1996 are available at the FTC's World Wide Web site at http://www.ftc.gov.

process, and through the issuance of statements on enforcement policy.[3] Although the statements on enforcement policy are more specifically focused on collaborative actions by physicians and hospitals, the basic principles of these statements on enforcement policy can be instructive to the pharmaceutical industry as well.

For further information about matters handled by the FTC's Health Care Services and Products Division and Mergers I, or to lodge complaints about suspected antitrust violations, please write, call, or fax as follows:

Non-Merger Matters:

Mailing Address:	Health Care Services and Products Division Bureau of Competition Federal Trade Commission Washington, D.C. 20580
Telephone Number:	202-326-2756
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Merger Matters:

Mailing Address:	Mergers I Division Bureau of Competition Federal Trade Commission Washington, D.C. 20580
Telephone Number:	202-326-2682
Fax Number:	202-326-2655

[3] Information regarding advisory opinions is set forth in the Topic And Yearly Indices of Health Care Advisory Opinions By Commission And By Staff. These indices can be obtained from the FTC Public Reference Section. The index, and the advisory opinions issued since October, 1993, are also available at the FTC's World Wide Web site at http://www.ftc.gov.

II. CONDUCT INVOLVING PHARMACEUTICAL SERVICES AND PRODUCTS

A. Agreements on Price-Related Terms

1. **Pharmaceutical Society of the State of New York, Inc**., 113 F.T.C. 661 (1990) (consent order). The consent order settled charges that the Pharmaceutical Society of the State of New York, Inc. ("PSSNY") conspired to boycott the New York State Employees Prescription Plan in order to force an increase in reimbursement rates for plan participants who provide prescription drugs to state employees. According to the complaint, the society's actions reduced price competition, forced the state to pay substantial additional sums for prescription drugs, and coerced the state into raising the prices paid to pharmacies under the state plan. Under the consent agreement, the society agreed not to enter into any agreement between pharmacy firms to withdraw from or refuse to enter into any participation agreement. Also, for a period of ten years, the order prohibits PSSNY from continuing meetings if two persons make statements concerning their firms' intentions to join a participation agreement; and required PSSNY to refrain from communicating to any pharmacist or pharmacy firm any information regarding other pharmacy firm's intentions to enter or refuse to enter into such a participation agreement. For a period of eight years, the order prohibits PSSNY from providing comments or advice to any pharmacists or pharmacy on the desirability of participating in any existing or proposed participation agreement. *See* Chain Pharmacy Association (discussed below).[4]

2. **Alan Kadish**, 114 F.T.C. 167 (1991) (consent order). As President of PSSNY, Alan Kadish was charged with conspiracy to boycott the New York State Employees Prescription Plan along with PSSNY. A separate order similar to the PSSNY order (discussed above) was entered.

3. **Chain Pharmacy Association of New York State, Inc**., 114 F.T.C. 28 (1991) (consent order). A consent order settled charges that the Chain Pharmacy Association ("Chain") and its members conspired to boycott the New York State Employees Prescription Plan in order to force an increase in reimbursement rates for plan participants who provide prescriptions to state employees. The complaint alleged that the collective refusal to participate in the program injured consumers in New York by reducing competition among

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[4] Several affiliates of PSSNY were charged, along with PSSNY, with conspiracy to boycott the New York State Employees Prescription plan and separate orders similar to the PSSNY order were obtained against these affiliates. *See* Long Island Pharmaceutical Society, Inc., 113 F.T.C. 669 (1990) (consent order); Pharmaceutical Society of Orange County, Inc., 113 F.T.C. 645 (1990) (consent order); Westchester County Pharmaceutical Society, Inc., 113 F.T.C. 653 (1990) (consent order); Empire State Pharmaceutical Society, Inc., 114 F.T.C. 152 (1991) (consent order); Capital Area Pharmaceutical Society, 114 F.T.C. 159 (1991) (consent order).

pharmacy firms with respect to third-party prescription plans. The order prohibits Chain from organizing or entering into any agreement among pharmacy firms to withdraw from or refuse to enter into a third-party payer prescription drug plan. Also, for a period of ten years, the order prohibits Chain from communicating to any pharmacist or pharmacy firm any information regarding any other pharmacy firm's intentions to enter or refuse to enter into such a participation agreement, or from continuing meetings of pharmacy firm representatives if two persons make statements concerning their firms' intentions to join a participation agreement. For a period of eight years, the order prohibits Chain from advising another pharmacy firm on whether to enter into any payer participation agreement. See Pharmaceutical Society of the State of New York, Inc (discussed above).[5]

4. **Southeast Colorado Pharmacal Association**, 116 F.T.C. 51 (1993) (consent order). The complaint alleged that the Southeast Colorado Pharmacal Association (SCPhA) illegally conspired to boycott a prescription drug program offered through a state-retirees health plan in an attempt to force the program to increase its reimbursement rate for prescriptions filled by its pharmacy members. The order prohibits the association from entering into or threatening to enter into any agreement with pharmacies to withdraw or refuse to participate in similar reimbursement programs in the future. In addition, for five years, SCPhA is prohibited from providing comments or advice to any pharmacist or pharmacy concerning participation in any existing or proposed participation agreement, communicating the intention of other pharmacists or pharmacies to withdraw from or join a participation agreement, or soliciting other pharmacy firms' intentions about entering into a participation agreement. The association is also prohibited from continuing meetings of pharmacy representatives if members make statements concerning their firms' intentions to join a participation agreement.

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[5] Member firms of Chain Pharmacy Association were charged with conspiracy to restrain trade in their refusal to participate in the New York State Employees Prescription Plan. Separate orders similar to the Chain Pharmacy order were entered. *See* Brooks Drug, Inc., 112 F.T.C. 28 (1989) (consent order); Carl's Drug Co., Inc., 112 F.T.C. 15 (1989) (consent order); Genovese Drug Stores, Inc., 112 F.T.C. 23 (1989) (consent order); Fay's Drug Company, Inc., 114 F.T.C. 171 (1991) (consent order); Kinney Drugs, Inc., 114 F.T.C. 367 (1991) (consent order); Melville Corporation, 114 F.T.C. 171 (1991) (consent order); Rite Aid Corporation, 114 F.T.C. 182 (1991) (consent order); James E. Krahulec, 114 F.T.C. 372 (1991) (consent order) (charged as an officer of Rite Aid Corporation); Peterson Drug Company of North Chili, New York, Inc., 115 F.T.C. 492 (1992) (consent order).

5. **Baltimore Metropolitan Pharmaceutical Association, Inc. and Maryland Pharmacists Association**, 117 F.T.C. 95 (1994) (consent order). The complaint alleged that the Maryland Pharmacists Association (MPhA) and the Baltimore Metropolitan Pharmaceutical Association (BMPA), in response to cost-containment measures initiated by the Baltimore city government employees prescription-drug plan, illegally conspired to boycott the plan in order to force higher reimbursement rates for prescriptions. According to the complaint, the associations' actions increased the cost of obtaining drugs through prescription drug plans and reduced price competition between the firms providing these prescriptions. Under the consent order, MPhA and BMPA are prohibited from entering into, organizing, or encouraging any agreement between or among pharmacy firms to refuse to enter into, or to withdraw from, any participation agreement offered by a third-party payer. In addition, for five years, the associations are prohibited from providing comments or advice to any pharmacist or pharmacy concerning participation in any existing or proposed participation agreement, or the intention of other pharmacists or pharmacies to withdraw from or join a participation agreement. The associations are also prohibited from continuing meetings if two persons make statements concerning their firms' intentions to join a participation agreement.

6. **RxCare of Tennessee, Inc. et al**., 121 F.T.C. 762 (1996) (consent order). The consent order settled charges that RxCare of Tennessee, a leading provider of pharmacy network services in that state, used a "most favored nation" clause (MFN) in order to discourage pharmacies from discounting, and to limit price competition among pharmacies in their dealings with pharmacy benefits managers and third-party payers. The MFN clause at issue required that if a pharmacy in the RxCare network accepted a reimbursement rate from any other third-party payer that is lower than the RxCare rate, the pharmacy must accept that lower rate for all RxCare business in which it participates. Combined with RxCare's market power (the network includes 95% of all chain and independent pharmacies in Tennessee) the complaint alleged that the MFN clause forced some pharmacies in the network to reject lower reimbursement rates for prescriptions they fill for patients covered by other health plans.

7. **Institutional Pharmacy Network ("IPN"),** C-3822 (consent order issued August 11, 1998) (August 20, 1998). The complaint alleged that five institutional pharmacies unlawfully fixed prices and restrained competition among institutional pharmacies in Oregon, leading to higher reimbursement levels for serving Medicaid patients in Oregon long-term care institutions. The five pharmacies, Evergreen Pharmaceutical, Inc., NCS Healthcare of Oregon, Inc., NCS Healthcare of Washington, Inc., United Professional Companies, Inc., and White, Mack and Wart, Inc. (which provide institutional pharmacy services for 80% of those patients in Oregon receiving such services) compete to provide prescription drugs and services to long term care institutions. According to the complaint, the pharmacies formed IPN to offer their services collectively and maximize their leverage in bargaining over reimbursement rates, but did not share risk or provide new or efficient services. The order prohibits IPN and the institutional pharmacy respondents from entering

into similar price fixing arrangements. The order, however, allows the respondents to engage in 1) any "qualified clinically integrated joint arrangement" (with prior notice to the Commission), and 2) conduct that is reasonable necessary to operate any "qualified risk-sharing joint arrangement" as set forth in the DOJ/FTC *Statements of Antitrust Enforcement Policy in Health Care*.

8. **Asociacion de Farmacias Region de Arecibo,** C-3855 (consent order issued March 2, 1999) (March 15, 1999). The consent order prohibits an association, composed of approximately 125 pharmacies in northern Puerto Rico, from fixing the terms and conditions, including fixing prices, of dealing with third party payers, and threatening to withhold services from a government program to provide health care services for indigent patients. The association was formed in 1994 as a vehicle to negotiate with health plans. According to the complaint, in January 1995, the association refused to contract with Triple-S, the payer for the government-sponsored health reform program in northern Puerto Rico, until Triple-S raised the fees paid to the association's members. Furthermore, in March 1996, the association threatened to withhold its members' services unless Triple- S rescinded a new fee schedule calling for lower reimbursement fees for the pharmacies. Triple-S acceded to the association's demands and increased fees by 22%. The order prohibits the association from negotiating on behalf of any pharmacies with any payer or provider, jointly boycotting or refusing to deal with third party payers, restricting the ability of pharmacies to deal with payers individually, or determining the terms or conditions for dealing with third party payers.

The order does allow the association to operate any "qualified risk-sharing joint arrangement" or, upon prior notice to the Commission, any "qualified clinically integrated joint arrangement," as reflected in the 1996 FTC/DOJ *Statements of Antitrust Enforcement Policy in Health Care*.

9. **FTC v. Mylan Laboratories et. al.,** Civil Action No. 1:98CV3114 (D.D.C., filed December 22, 1998; amended complaint filed February 8, 1999). In a complaint seeking injunctive and other relief filed in U.S. District Court for the District of Columbia, the Commission charged Mylan Laboratories and three other companies, Profarmaco S.R.L., Cambrex Corporation, and Gyma Laboratories, with restraint of trade, monopolization and conspiracy to monopolize the market for two generic anti-anxiety drugs, lorazepam and chlorazepate. Thirty-four state Attorneys General filed a similar complaint in U.S. District Court, Civil Action No. 1:98CV3115 (D.D.C., filed December 22, 1998; amended complaint filed February 8, 1999).

According to the FTC's complaint, Mylan, the nation's second largest generic drug manufacturer, sought to restrain competition through exclusive licensing arrangements for the supply of the raw material necessary to produce the lorazepam and chlorazepate tablets, thereby allowing Mylan to dramatically increase the price of lorazepam and chlorazepate

tablets. The complaint seeks $120 million in disgorgement and restitution from the defendants, an estimate of the profits resulting from the alleged illegal conduct. On July 7, 1999, the court denied defendants' motions to dismiss the FTC complaint, finding that § 13(b) of the FTC Act allows the Commission to seek permanent injunctive relief for violations of "any provision of law" enforced by the FTC, and allows the Commission to seek monetary remedies such as the disgorgement of profits, which the complaint in this case seeks.

B. Agreements to Obstruct Innovative Forms of Health Care Delivery or Financing

1. **Asociacion de Farmacias Region de Arecibo**, C-3855 (consent order issued March 2, 1999) (March 15, 1999). The consent order prohibits an association, composed of approximately 125 pharmacies in northern Puerto Rico, from fixing the terms and conditions, including fixing prices, of dealing with third party payers, and threatening to withhold services from a government program to provide health care services for indigent patients. The association was formed in 1994 as a vehicle to negotiate with health plans. According to the complaint, in January 1995, the association refused to contract with Triple-S, the payer for the government-sponsored health reform program in northern Puerto Rico, until Triple-S raised the fees paid to the association's members. Furthermore, in March 1996, the association threatened to withhold its members' services unless Triple- S rescinded a new fee schedule calling for lower reimbursement fees for the pharmacies. Triple-S acceded to the association's demands and increased fees by 22%. The order prohibits the association from negotiating on behalf of any pharmacies with any payer or provider, jointly boycotting or refusing to deal with third party payers, restricting the ability of pharmacies to deal with payers individually, or determining the terms or conditions for dealing with third party payers. The order does allow the association to operate any "qualified risk-sharing joint arrangement" or, upon prior notice to the Commission, any "qualified clinically integrated joint arrangement," as reflected in the 1996 FTC/DOJ *Statements of Antitrust Enforcement Policy in Health Care.*

C. Illegal Tying and Other Arrangements

1. **Sandoz Pharmaceuticals Corporation**, 115 F.T.C. 625 (1992) (consent order). The consent order settles charges that Sandoz unlawfully required those who purchased its schizophrenia drug, clozapine (the first new drug for the treatment of schizophrenia in more than 20 years), to also purchase distribution and patient-monitoring services from Sandoz. Blood monitoring of patients taking clozapine is required to detect a serious blood disorder caused by the drug in a small percentage of patients. The complaint alleged that this illegal "tying" arrangement raised the price of clozapine treatment and prevented others -- such as private laboratories, the Veterans Administration, and state and local hospitals -- from providing the related blood tests and necessary patient monitoring. The consent order prohibits Sandoz from requiring any purchaser of clozapine, or a patient

taking clozapine, to buy other goods or services from Sandoz. The order also guards against the possibility that Sandoz might restrict other firms that want to market generic clozapine in the United States after Sandoz's exclusive selling right expires in 1994, by requiring Sandoz to provide information on reasonable terms if any company is in need of information about patients who have had adverse reactions to the drug. The order also requires Sandoz to not unreasonably withhold information from researchers studying the medical aspects of clozapine use.

2. **FTC v. Mylan Laboratories et. al.,** Civil Action No. 1:98CV3114 (D.D.C., filed December 22, 1998; amended complaint filed February 8, 1999). See description above.

III. PHARMACEUTICAL MERGERS[6]

A. Horizontal Mergers Between Direct Competitors

1. **FTC v. Cardinal Health, Inc. and FTC v. McKesson Corp., 12 F. Supp. 2d 34 (D.D.C. 1998).** 12 F. Supp. 2d 34 (D.D.C. 1998). In 1998, the FTC successfully challenged two mergers involving the nation's four largest drug wholesalers -- McKesson merging with AmeriSource and Cardinal Health with Bergen-Brunswig. If the mergers had been permitted, the two survivors would have controlled over 80% of the prescription drug wholesaling market, significantly reducing competition on price and services. The FTC filed the two actions in district court in March 1998, and the case was litigated for approximately seven weeks during June and July. Judge Sporkin enjoined both acquisitions in a 73-page opinion issued at the end of July.

2. **Roche Holding Ltd.**, C-3809 (Feb. 25, 1998) (consent order). In a 1998 case, the Commission charged that Roche Holding's proposed $11 billion acquisition of Corange Limited would harm competition in two U. S. markets, cardiac thrombolytic agents, which are drugs used to treat heart attack victims, and drug abuse testing (DAT) reagents, chemicals used to test urine samples for the presence of illegal substances.

   Thrombolytic agents are given to heart attack victims as soon as possible after the onset of symptoms in order to dissolve blood clots. There were no competitive substitutes for thrombolytic agents. Roche, through its majority ownership in Genentech, and Corange, through its Boehringer Mannheim subsidiary, produced the two safest and most effective thrombolytic agents in the U. S. There was one other thrombolytic agent approved for use in the United States, and it was significantly less effective.

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[6] For a comprehensive description of the FTC merger enforcement program in pharmaceuticals and medical devices see David A. Balto & James Mongoven, Antitrust Enforcement in Pharmaceutical Industry Mergers, 54 Food & Drug Law Journal 255 (1999).

Both companies also manufactured DAT reagents, which are chemical antibodies that detect whether an illegal substance is present in a urine sample. Workplace DAT screening is conducted at commercial laboratories with instruments designed to use only workplace DAT reagents and such drug screening is significantly different than hospital-based screening. This DAT reagent market was highly concentrated, and dominated by three of four producers, including Roche and Corange.

The complaint alleged that the acquisition, if consummated, would eliminate actual competition between Roche and Corange in the markets for the research, development, manufacture and sale of cardiac thrombolytic agents and of DAT reagents use in workplace testing. The acquisition would increase the likelihood that Roche would unilaterally exercise market power in cardiac thrombolytic agents and the likelihood of collusion or coordinated action among the remaining firms in the DAT reagents market.

The consent in the *Roche* case required, *inter alia,* Roche to divest or license all of the assets relating to Corange/Boehringer Mannheim's United States and Canadian cardiac thrombolytic agents business to a Commission-approved buyer. Roche was also required to divest, within 60 days of the final order, Corange/Boehringer Mannheim's worldwide DAT reagents business. Roche was also required to grant to the divestee an exclusive, world-wide royalty-free license for DAT reagents. Although the divestiture's took place within the required times, the Commission had included a "crown jewel" provision that would have required a larger asset divestiture had the more narrowly tailored divestiture not occurred.

3. **American Home Products Corp.**, 123 F.T.C. 1279 (May 16, 1997). In a 1997 case, the Commission alleged that the acquisition of Solvay's animal health business by American Home Products would harm competition in the U. S. market for three types of "companion animal" vaccines. The acquisition would have given American Home Products a dominant position in the markets for canine lyme vaccines, canine corona virus vaccines, and feline leukemia vaccines, enabling it to unilaterally exercise market power, as well as increasing the likelihood of collusion or coordinated action among the remaining firms.

The complaint alleged that American Home Products and Solvay were actual competitors for the three vaccines in the United States. All three markets were highly concentrated. Entry into each market was difficult and time consuming, and a number of broad patents governing the manufacture of the three products compounded the difficulty of new entry.

The consent, *inter alia,* required American Home Products to divest Solvay's U. S. and Canadian rights to the three types of vaccines to Schering-Plough no later than 10 days after the date on which the order became final. In addition, American Home Products had to provide assistance to Schering-Plough in obtaining United States Department of Agriculture certifications, and to manufacture and supply the three vaccines to Schering-

Plough for a period of 24 to 36 months or until Schering-Plough obtained the approvals. There were also provisions protecting Schering-Plough from patent infringement lawsuits relating to the three vaccines.

B. Potential Competition Mergers [7]

1. **Zeneca Group plc,** FTC File No. 991 0089 (March 25, 1999) (proposed consent order). Zeneca's proposed acquisition of Astra raised antitrust concerns based upon potential competition. Zeneca had 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 pharmaceutical products used to relieve pain during the course of surgical or other medical procedures without the use of general anesthesia. For certain procedures, long-acting local anesthetics are the only viable anesthetic. Zeneca proposed to acquire the leading supplier of long-acting local anesthetics, Astra, which was one of only two companies approved by the FDA for the manufacture and sale of these kinds of drugs in the United States. Although Zeneca did not currently participate in the market for long-acting local anesthetics, by virtue of its agreement with Chiroscience, it was an actual potential competitor. The Commission's complaint alleged that the acquisition would result in the elimination of a significant source of new competition

   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 10 business days after the date the Commission accepted the agreement for public comment. The assets to be transferred to Chiroscience consisted principally of intellectual property and know-how and included all of the applicable patents, trademarks, copyrights, technical information and market research relating to levobupivacaine. During a transitional period, Zeneca was required to continue carrying out certain ongoing activities relating to the commercialization of levobupivacaine, including manufacturing, regulatory, clinical, development and marketing activities. Zeneca was also required to divest its approximately 3 percent investment interest in Chiroscience.

2. **Hoechst AG,** 120 F.T.C. 1010 (Dec. 5, 1995). The Commission alleged that potential competition would be harmed in four separate relevant markets when Hoechst, a German pharmaceutical company, proposed acquiring Marion Merrill Dow in a $7.1 billion dollar

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[7] The Supreme Court has held that a firm that is 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). Although the Supreme Court has not ruled on the actual potential entry theory, some lower courts and the FTC have accepted or commented favorably about 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).

merger that at the time created the world's third largest pharmaceutical company. The four markets accounted for $1.4 billion in U. S. sales and affected hundreds of thousands of consumers who suffered from hypertension, angina, arteriosclerosis and tuberculosis. The largest market was the $1 billion once-a-day diltaizem market where MMD's Cardizem CD had a dominant share. Prior to the merger, Hoechst and Biovail were jointly developing Tiazac to compete against Cardizem CD. The Commission alleged that the "pendency of the merger negotiations affected Hoechst's incentives with respect to the development of Tiazac," resulting in delayed FDA approval. Before the merger agreement was finalized, Hoechst returned the rights to Tiazac to Biovail. The Commission found this fix to be inadequate since it left Tiazac as 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, 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. Hoechst marketed the only drug that was currently approved by the FDA for intermittent claudication, a painful leg cramping condition that affects over 5 million people in the U. S. 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 million people in the U. S. 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. Hoechst was required to divest one of the two drugs.

In the *Hoechst* case, potential competition was threatened in all four potential product markets. In each market, Hoechst was required to divest either the current line of business or the potential new product to a Commission-approved buyer that would develop and market it. The settlement in each market also required Hoechst to prevent the deterioration of the assets involved and maintain its research and development efforts at pre-merger planned levels pending divestiture, and to provide technical assistance and advice to the purchasers in obtaining FDA approval.

C. Innovation Market Mergers[8]

1. **Glaxo PLC**, 119 F.T.C. 815 (June 14, 1995). In *Glaxo*, the Commission alleged harm to innovation markets where the merging parties -- Glaxo and Burroughs Wellcome – were the two firms furthest along in developing an oral drug to treat migraine attacks. Current drugs existed to treat migraine, but they were available only in injectable form and were not sufficiently substitutable to be included in the relevant market. The Commission alleged that the acquisition would eliminate actual competition between the two companies in researching and developing migraine remedies. The Commission also alleged that the acquisition would reduce the number of research and development tracks for these migraine remedies and increase Glaxo's unilateral ability to reduce research and development of these drugs.

   Glaxo and Wellcome reached a consent agreement with the Commission that allowed them to proceed with their merger. The agreement required the combined firm to divest Wellcome's assets related to the research and development of the migraine remedy. Among those assets were patents, technology, manufacturing information, testing data, research materials, and customer lists. The assets also included inventory needed to complete all trials and studies required to obtain FDA approval. The Commission's purpose in requiring this divestiture was to ensure continued research and development of Wellcome's potential product in the same manner in which the product would be developed without the merger. The Commission believed the remedy would lessen the anticompetitive effects of the merger. The remedy in the Glaxo merger has been successful. Zeneca Pharmaceuticals, the Commission-approved acquirer, received FDA approval for its migraine drug, marketed under the name Zomig, within fifteen months after the Commission approved Glaxo's application to divest its migraine drug assets to Zeneca.

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[8] In several recent merger cases, the Commission 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-tech markets. Many of the Commission's pharmaceutical merger cases involve the acquisition of intellectual property 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. In industries where the main focus of competition is the development of new technologies rather than price competition, antitrust principles will apply, and that competitive rivalry must be protected. If too much of the ability to innovate in a relevant market is accumulated in one entity, and substitutes are lacking, competition may suffer. The Commission's "goal is to carefully identify those situations where a merger will reduce innovation competition." The *Merger Guidelines* recognize that a transaction may lessen competition in such nonprice attributes as "product quality, service, or innovation." *Merger Guidelines* § 0.1 n. 6. *See also*, William J. Baer and David A. Balto, "New Myths and Old Realities: Recent Developments in Antitrust Enforcement," 1999 Columbia Bus. Law Review 208 (Spring 1999).

2. **Ciba-Geigy, Ltd.**, 123 F.T.C. 842 (March 24, 1997). In March 1996, Ciba and Sandoz agreed to merge to form Novartis AG. The FTC reached a consent agreement with the parties to address the competitive impact on the innovation of gene therapies.[9] At the time of the merger, no gene therapy product was on the market, but potential treatments were in clinical trials. The complaint noted that the first products would not be available until the year 2000, but that the market could grow to $45 billion by the year 2010. 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 in order to have any hope of commercializing their own research efforts. Competition between the two firms made possible such ventures or contracts on reasonable terms. Without competition, the combined entity could appropriate much of the 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 identified five relevant product markets, all of which were located in the United States. The first relevant market encompassed the technology and research and development for gene therapy overall. The other markets each involved the research and development, manufacture, and sale of a specific type of gene therapy: cancer; graft-versus-host disease ("GVHD"); hemophilia; and chemoresistance.

In the market for overall gene therapy, the Commission alleged that Ciba and Sandoz controlled the key intellectual property rights necessary to commercialize gene therapy products. For each of the four specific gene therapy markets, the Commission asserted that the relevant market was highly concentrated and that Ciba and Sandoz were the two leading commercial developers of the gene therapy product. Moreover, entry into the gene therapy markets was difficult and time-consuming because any entrant would need patent rights, significant human and capital resources, and FDA approvals.

The remedies centered on the intellectual property rights. The new company, Novartis, was required to grant to all requesters a non-exclusive license to certain patented technologies essential for development and commercialization of gene therapy products. Depending on the patent, Novartis could receive an up-front payment of $10,000 and royalties of one to three percent of net sales. Novartis also was required to grant a non-exclusive license of certain technology and patent rights related to specific therapies for cancer, GVHD, and hemophilia to a Commission-approved licensee. Novartis could request from the licensee consideration in the form of royalties and/or an equivalent cross-license.

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[9] Two other product markets for which relief was obtained were corn herbicides, 123 F.T.C. at 847-49, and flea control products, *id.* at 849.

Further, the merged company could not acquire exclusive rights in certain intellectual property and technology related to chemoresistance gene therapy. The Commission said this would ensure that at least one other company had access to the needed gene sequences.

3. **The Upjohn, Co.**, 121 F.T.C. 44 (Feb. 8, 1996). In *Upjohn*, the Commission alleged that the acquisition of Pharmacia Aktiebolag by Upjohn would harm competition in the market for topoisomerase I inhibitors, drugs used in conjunction with surgery to treat colorectal cancer. There were no drugs available to treat this disease, but the new topoisomerase I inhibitors were expected to increase the survival rate. The merging firms were two of only a very small number of companies in the advanced stages of developing the drugs. Upjohn's CPT-11 was the most advanced product, with Pharmacia's 9-AC product a few years behind. Because it would take the other companies years to reach the advanced stage of development, the Commission alleged that it was not likely that other firms would constrain the merged firm from terminating development of one of the products or raising prices.

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 in order to have any hope of commercializing their own research efforts. Competition between the two firms made possible such ventures or contracts on reasonable terms. Without competition, the combined entity could appropriate much of the 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. In addition, the consent required the merged firm to provide technical assistance and advice to the acquirer toward continuing the research and development of 9-AC.

4. **Baxter International, Inc.**, 123 F.T.C. 904 (March 24, 1997). Baxter's acquisition of Immuno International 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 both 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 Commission alleged that competition in two plasma products would be harmed – 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. At the time of the merger, there were no current 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 entry in both product lines would be difficult and time consuming. The acquisition would allow Baxter to eliminate one of the research tracks and exercise unilateral market power.

Fibrin sealants were already widely in use at the time of the Baxter-Immuno proposed merger; according to one study, 35-40 percent of all internal surgical procedures in Europe and Asia employed fibrin sealants. Likewise, many surgeons in the U.S. mixed and applied their own fibrin sealants. However, the FDA had not approved any company for the sale of a patented fibrin sealant in the U.S. as of 1996. Therefore, 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 potential U.S. sales of $200 million.

The consent order in *Baxter* required both divestiture and licensing. In the market for Factor VIII inhibitors, the order required Baxter to divest its Autoplex product to a Commission approved buyer within four months. The product line was divested in a timely fashion to NABI of Boca Raton, Florida. The fibrin sealant market portion of the Baxter-Immuno order provides an example of a successful licensure remedy. By requiring licensure of Baxter's fibrin sealant and requiring Baxter to provide the acquirer, Haemacure, with finished product for sale, the order enabled both companies to market sealants immediately following FDA approval of Baxter's product in May of 1998. No other sealants or similar surgical adhesives/glues are expected on the market before the end of 1999. Thus, the order brought two competing products to market simultaneously. Absent the order, only one product likely would have prevailed.

D. Vertical Mergers[10]

1. **Merck/Medco,** No. C-3853 (consent order, Feb. 18, 1999). In *Merck/Medco*, the complaint alleged that Merck's ownership of Medco, a pharmacy benefits manager ("PBM"), would allow Merck to favor its own drugs on Medco's formularies. A PBM's formulary often affects drug choice and reimbursement under certain health plans. The consent agreement requires Merck/Medco to maintain an open formulary, whereby drugs are selected according to objective criteria by an independent panel of physicians, pharmacists, and others, known as a Pharmacy and Therapeutics Committee.

2. **Eli Lilly/PCS,** C-3594 (July 28, 1995). The complaint alleged that Lilly's ownership of PCS, a pharmacy benefits manager ("PBM"), would allow Lilly to favor its own drugs on PCS's formularies. A PBM's formulary often affects drug choice and reimbursement under

[10] Vertical mergers occur between firms that operate at different but complementary levels in the chain of production and/or distribution. Common examples include a merger between a manufacturer and a distributor or a merger between two manufacturers, one of which produces an end product and the other a component used to make that end product. Vertical mergers often can be efficiency-enhancing. However, vertical mergers also can have anticompetitive effects. Vertical mergers can allow competitors to raise rivals' costs, possibly by depriving them of important inputs or distribution outlets, or increasing the costs associated with obtaining access to those inputs or outlets. *See* David A. Balto, "A Whole New World?: Pharmaceutical Responses to the Managed Care Revolution," 52 Food Drug L.J. 83 (1997).

certain health plans. The consent agreement requires Lilly/PCS to maintain an open formulary, whereby drugs are selected according to objective criteria by an independent panel of physicians, pharmacists, and others, known as a Pharmacy and Therapeutics Committee. The Lilly Order was recently set aside because Lilly sold PCS to Rite Aid Corp.